Innovation in European healthcare – what can Sweden learn?

An analysis of the systems for innovation in five European countries supported by

LIF - the research-based pharmaceutical industry

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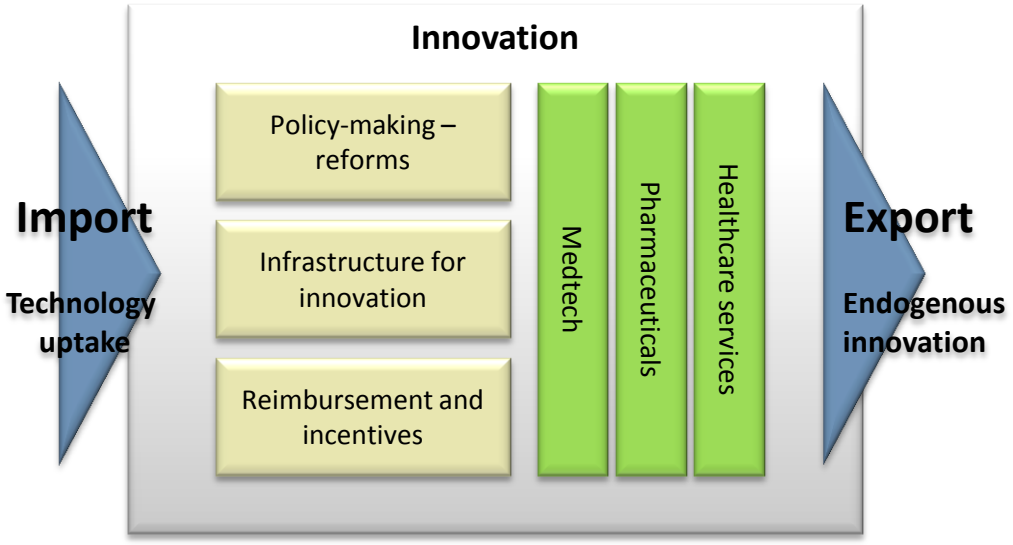
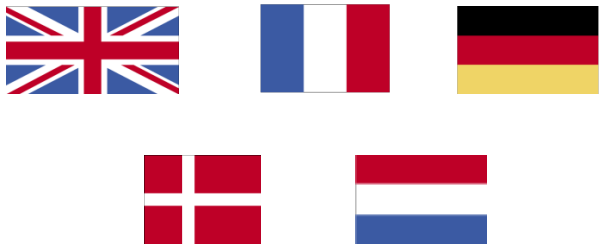
Introduction

If it was up to the NIH to cure polio through a centrally directed program. . .
You'd have the best iron lung in the world but not a polio vaccine

Samuel Broder - former director of the National Cancer Institute

Purpose and scope - what Sweden can learn from the efforts to improve innovation that have been made in other countries?





The systems for innovation in five European countries are analysed: Denmark, Germany, France, the Netherlands, the UK

The analysis focuses on three areas:

- **Policy-making and reforms**: what is the political system doing to support innovation? (specifically in healthcare, not general measures like tax exemptions, labour laws etc)
- **Infrastructure for innovation**: are there technology transfer offices, academic health science centres, clusters etc? Focus on infrastructure specific for healthcare, rather than general policies and measures of innovation.
- **Reimbursement and financial incentives**: are there channels into the healthcare system for innovative products and services?

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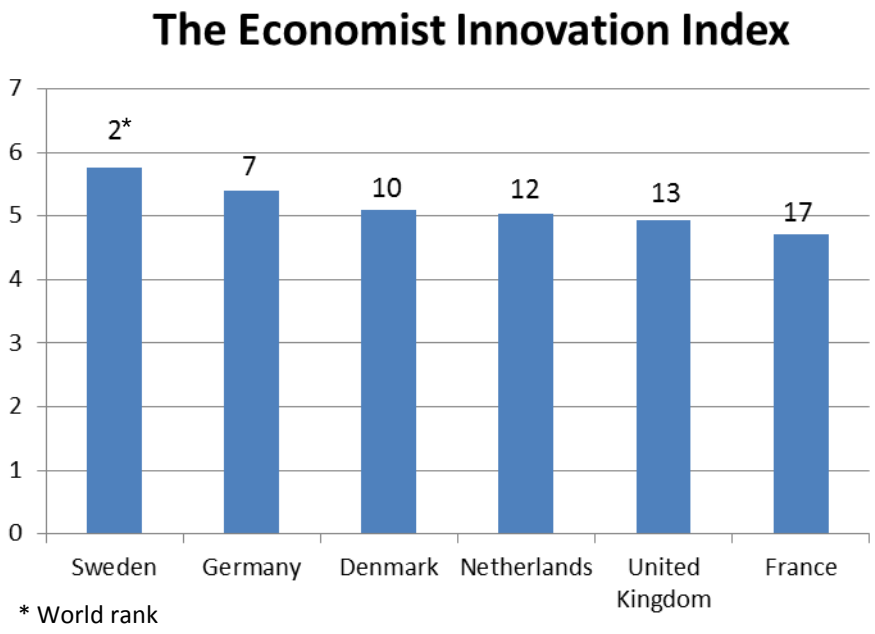
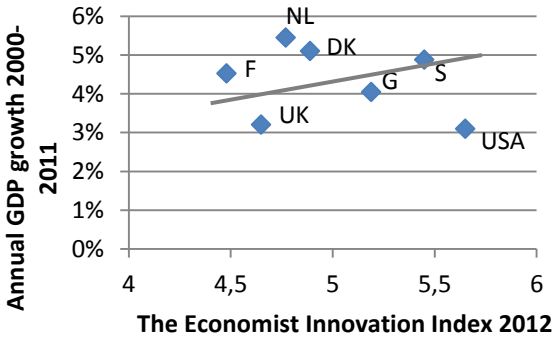
Sweden scores high on The Economist Innovation Index

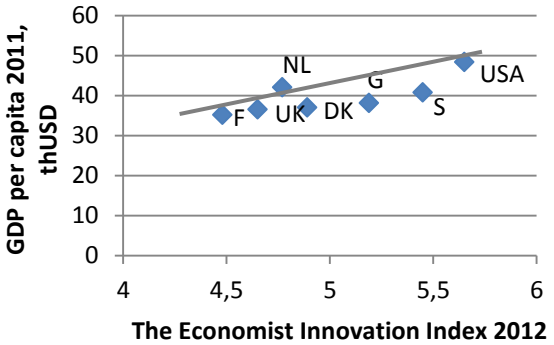


Sweden is highly competitive in the area of innovation. However, for many companies in the healthcare and life science sectors it is **crucial to have a strong domestic market**.

Quantitatively, Sweden is too small a market to allow healthcare companies to grow to any significant size. It is therefore **vital that the Swedish healthcare market is qualitatively superior** to its global competitors.

Innovation matters – in terms of growth and size of the economy. Innovation creates the wealth that may support welfare.





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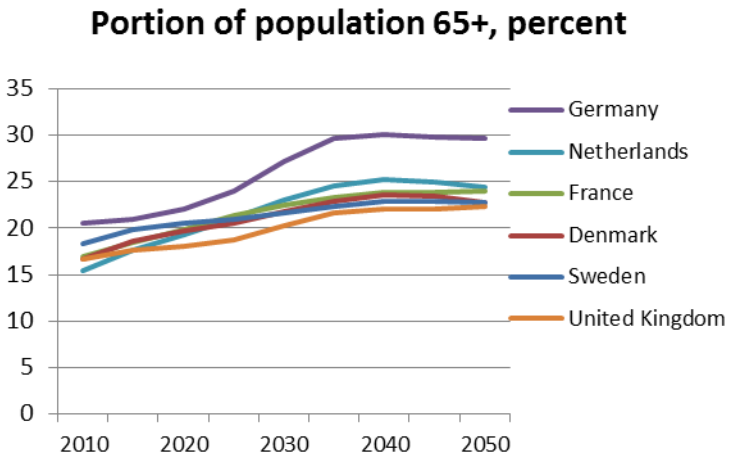
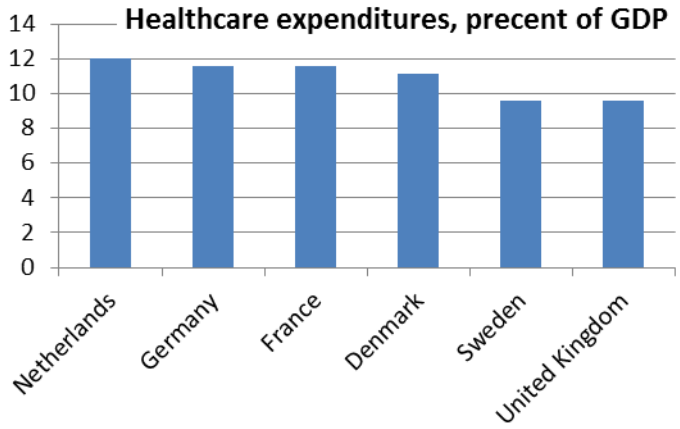
Demography and technology drive the need for increased productivity – but innovation today is productivity tomorrow





The stakeholders perceive that innovation and productivity are opposing forces in the Swedish healthcare system

Productivity **Innovation**

However, the stakeholders´ view is that productivity and innovation may work in synergy. In fact, many express that innovation is ***future productivity***.

Productivity

Innovation

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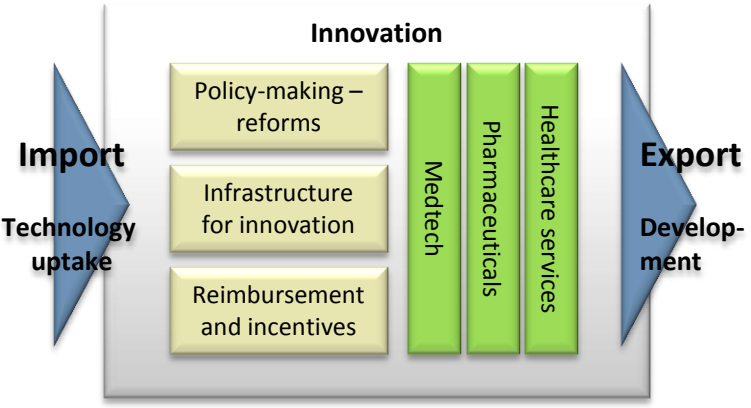
The criteria for a good innovation climate differ for medtech, pharmaceutical and healthcare service companies



Innovation is largely about new ideas being generated in Sweden – turned into solutions and hopefully developed to commercially available products and services that may contribute to our healthcare, but also to our future exports.

Innovation is also about patients in Sweden benefiting from new ideas generated in other parts of the world – about clinical trials, new therapies, partnerships with global pharmaceutical and medtech companies.

Medtech

Medtech companies have a business model different to that of pharma. They have physical products that require global distribution and continuous feedback from users.

Innovation requires a close partnership with healthcare service providers.

Medtech SMEs need a domestic market and their first paying (local) customers when launching new products.

Pharmaceuticals

The needs of pharmaceutical companies differ depending on whether they are big Pharma or biotech SMEs.

Big Pharma's main concern in Sweden is the technology uptake. In order to innovate they need a healthcare system willing to participate in clinical trials and to continuously replace old therapies with innovative solutions.

Biotech SMEs are selling information, rather than products. Their customers are a limited number of global pharmaceutical companies and offering consists of projects, IP, documentation, competence etc.

Innovation requires partnership with healthcare providers, but more importantly, with academic research and the research infrastructure.

Healthcare services

Healthcare providers, whether private or public, are an integrated part of the healthcare system - it's guidelines, reimbursement, regulations and policies.

Innovation of healthcare services is often complex, since it requires change of an intricate system and its stakeholders – and sometimes includes political risk. It may be in the form of new patient pathways, introduction of new technologies, process efficiency, integrated care etc.

Innovation requires flexibility of the healthcare system: decentralised decision-making; predictable reimbursement systems, rather than static long-term contracts; ways to introduce new technologies and to cross interfaces in the system.

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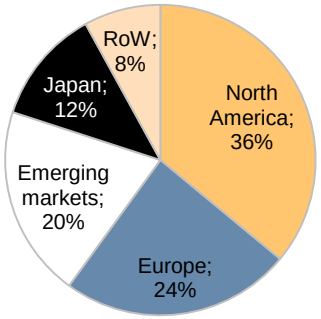
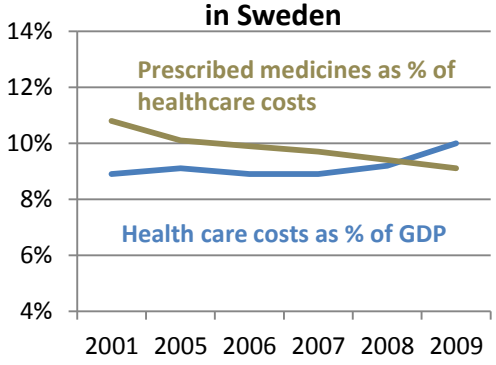
The patent cliff is being replaced with an inflow of novel drugs over the next few years – how will Sweden respond?

- The pharmaceutical industry faces a “patent cliff” which has pushed companies to adopt widely diverging strategies with licensing deals and acquisitions
- The two main issues facing the global pharmaceutical industry are:
  - Decreasing health budgets (pharmaceutical expenditures in Sweden fell 1.2 billion SEK in 2102)
  - Unproductive R&D spending
- This is not new, but the industry’s response may not necessarily benefit the mature markets in Europe - like the push into emerging markets which is now starting to produce results.
- R&D is a difficult issue to address, but things are improving:
  - The past two years has seen the highest number of drug approvals in the US since 2004
  - European pharma companies have nearly 60 drugs in the launch pipeline from 2013 to 2015, with peak sales potential of $64bn, outweighing the estimated $27bn of patent expiry revenue losses those companies face in that period.
- Consequently, a new wave of innovative drugs can be expected. Should the healthcare systems respond to these by applying strict cost containment measures, or find methods to balance cost, medical benefits and innovation?

Global pharmaceutical market, 2011, %



Drug expenditures are falling in Sweden



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Venture capital flight away from life sciences – difficulty to find capital is a growing issue

- The costs, time and uncertainty when developing new pharmaceuticals continue to grow – causing venture capitalists to flee investments in life science
- This is a global trend: only 20 American life science companies received start-up funding in the first quarter of 2013, the lowest number since 1995
- There are many explanations for the decline in life-size investments: the time and money required to develop new drugs or devices; stricter government regulations and the trials needed for approval.
- The market for initial public offerings in biotech has dried up
- ”*Today, we can invest in a couple of graduates holed up in a coffee shop building a social media app on their laptops – a small investment with a higher expected return”,* senior partner at a leading US life science VC firm

Innovation in Swedish healthcare

The issues as perceived by various stakeholders

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Is clinical research part of the overall objectives of the counties?

- *”Clinical research could be said to be part of our objectives, but it isn’t really part of our assignment. This is due to the financial situation, but also to the ‘de-academisation’ of the hospitals*”, specialist at a University hospital in Stockholm
- ”*The quest for increased productivity in healthcare goes on all over the world, and it is a necessary effort, given the technological and demographic development that we are facing. However, it is clear that it has led to that the room for clinical research in Sweden has shrunk.*” CEO global pharma Company
- ”*We are increasingly focused on productivity, which may be necessary, but the resources or even acceptance for clinical research are no longer available*”, specialist at a University hospital in Region Skåne
- ”*In all honesty, we are talking about innovation and translational/clinical research, but on the political level, we are not really enforcing it. Production of healthcare has been at the heart of our efforts. By necessity, but still*”, Senior policy maker SKL
- ”*Leading University hospitals in the US are better at differentiating between management of healthcare services and academic excellence than Swedish counties are. The production of healthcare is carried out under the requirements of productivity, whereas clinical research is evaluated according to academic standards.*” CEO global pharmaceutical company

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Sweden is described as an attractive place to carry out clinical trials – though the healthcare system is said to be reluctant

- Representatives of the global pharmaceutical companies all say that Sweden is 'overrepresented' in terms of clinical trials in relation to the size of the Swedish market – and that Sweden is perceived to be an attractive place to carry out clinical trials by their global organisations. The cost is higher than at emerging markets, but the quality and level of predictability is also higher.
- However, the voice from the medical industry is unanimous: the healthcare system is focused solely on increased productivity, which has led to a growing resistance to participate in clinical trials
- *"It is increasingly difficult to engage the clinics and the people who carry out the tests, not because they are not interested in participating, but because they feel that the clinical trials is perceived to be something that the cat dragged in by the counties and the hospital administrations"*, medical director global pharma company
- *"We are paying for these trials, fairly generously, still they are not seen as a source of additional resources by the hospital and counties – but as a burden*", CEO global pharma company
- *"If it works, we would prefer to have a single point of contact for the clinical trials. I would like to point out Västra Götaland as a county that has managed to do this quite well*", medical director global pharma company

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The barriers between industry and healthcare are too high – claim both sides of the fence

- "*We may have taken the rules on communication a bit too far. Innovation requires a dialogue*" Senior policy maker SKL, (Swedish Association of Local Authorities and Regions)
- "*The drugs that are now being developed are complex, often aimed at patients receiving specialist treatment at large hospitals. How can we possibly support the healthcare with information and education if we are only allowed to speak with the doctors once or twice per year?",* Medical director global pharmaceutical company
- "*The patients and the hospitals would only gain from improved collaboration. The level of complexity has increased, treatments are carried out in integrated processes and the clinics would be better off talking with the vendors. They should formulate their needs and objectives, rather than technical specifications – and they should do so in dialogue with industry*", CEO large Swedish medtech company
- "*The communication is too restricted, at all levels. We should probably find ways to improve the communication between Academy, healthcare and the industry*", senior official SKL
- "*Of course there are also cultural barriers, but my impression is that these have decreased between academy and industry, but grown between industry and the healthcare system. There is a growing acceptance for commercialisation of scientific results at the medical schools and universities, but little interest in translational research in the healthcare system*.", Regional innovation officer
- "*I can understand the reluctance to meet with pharma reps that existed before, when the market was flooded with people claiming that 'my powder washes whiter than yours'. However, time is no longer the issue, but attitudes. The pendulum has swung too far in the opposite direction.*", CEO global pharmaceutical company

Sweden has established an infrastructure for innovation similar to that of other European countries – and the stakeholders are cautiously optimistic

- "*There is a large number of agencies and departments for innovation being set up. It's still early days, why it's not clear what all this will lead to, but I am satisfied with the efforts so far*", CEO small biotech company
- "*Everybody is working on innovation in healthcare today, the government, the regions and counties etc. My only concern is that it may develop into something overly complex*.", CEO medium-sized medtech company
- "*An area where we really do need support are the EU applications. We are not big enough to be able to apply for EU grants, since these are complex and exhaustive. We need to rely on the institutions that we collaborate with in order to submit an application*.", CEO large Swedish medtech company
- *"There is absolutely nothing wrong with what can be found in the Government Bill on research and innovation. It's what cannot be found that's the problem: commercialisation of research on how the medical industry can be supported*", CEO pharmaceutical company
- "*Life science and healthcare is pointed out by the government as focus areas, but in reality very little is happening. The way that the hospitals are managed, there is little room to test new technologies. The innovation infrastructure should also contain a long-term strategy for investments in innovation and new technologies. The political attention and interest in long-term strategies appear to be low, since the effects can only be observed long after this political term",* Regional innovation officer, Sweden

There is no well-defined structure to get reimbursed for innovative products – and national recommendations are filtered through layers of decision-makers

- All the stakeholders suggest that there are no structured financial incentives or methods for reimbursement of innovative products – and that it is vital for small companies to find their first customers
- ”*It is vital for medtech companies to find its first customers. Unfortunately, there are no such early customers in the Swedish healthcare system*”, regional innovation officer
- ”*We will soon launch our first product, but not in Sweden. We have selected Germany as our first target market, since there is reimbursement for our products*.”, CEO small medtech company
- ”*The lack of reimbursement for innovation is a major problem. Take for example our monoclonal antibody: you go through all the hurdles with an HTA and the assessment by TLV to reach a national recommendation. TLV does an excellent job, but then the recommendation is filtered through multiple layers, from NLT to the counters, the hospitals, the clinics and individual doctors. National recommendations should be binding, a right of the patient. Or at least, vetos on national recommendations at the local level should give the benefit of the doubt to innovation.*”, CEO global pharmaceutical company
- ”*It is of paramount importance for our portfolio companies to find our first paying customers. In particular for companies with physical products, where user feedback and partnership with the clinical reality is necessary. Today, there is no structured reimbursement method for innovative products.*” Head of life science investments, Industrifonden

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Issues in Sweden: access to capital

Access to capital is always an issue, but the need for capital is considered a bigger challenge in Sweden than in the analysed countries

Early stages – development and commercialisation

Market entry, product launch, international business development

0,1-20MSEK

>50MSEK

"Access to capital is typically not the major issue for SMEs. The biggest hurdle is the uptake of innovation and new technologies within the NHS"

Director of innovation, Department of Health, the UK

"There is a lack of capital in the early stages, in biotech as always, but now increasingly also in medtech. The ROI is too low, the investors are hesitating. My impression is that capital is still available in Stockholm, but not in other parts of the country"

Regional innovation officer, Sweden

"When we have reached our objectives, we will be too big for any Swedish buyer. I expect that we will have foreign owners a few years from now"

CEO Swedish pharmaceutical SME

"We have the capital for significant investments in life science and medtech, but the number of potential investments is limited – few companies grow to a position where they become visible on our radar.

There are no Swedish investors that are bridging the gap between actors like Karolinska Innovation/Karolinska Development and us"

Head of Life Science investments, Industrifonden

"There is capital available, the problem for a small company is more the complex structure of public bodies. We are not always sure where to turn."

CEO, French life science company

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Summary - the innovation challenges in Sweden as perceived by stakeholders in the healthcare system

- The overall concern is that the pursuit of productivity has shrunk the room available for innovation.
- Particularly, these areas of concern are mentioned :
  - The lack of reimbursement for innovative products
  - Lack of interest, or emphasis of clinical research in the Swedish healthcare
  - Healthcare providers' reluctance to participate in clinical trials
  - The barriers between industry and healthcare
  - Limited opportunities for financing of start-ups and SME:s
- The stakeholders are cautiously optimistic regarding the Swedish infrastructure for innovation. Many initiatives have been taken only recently and the outcome remains to be seen.
- Industry - academy barriers are perceived to be lower than a few years ago — collaborations and knowledge transfer are easier today

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Two innovative companies

Elekta and IndexPharmaceuticals

InDex Pharmaceuticals

InDex Pharmaceuticals is a biopharmaceutical company located at the Karolinska Institutet Science Park

The company is developing a novel treatment of severe Ulcerative Colitis, where other medical treatments have failed and the only option is surgical removal of the colon.

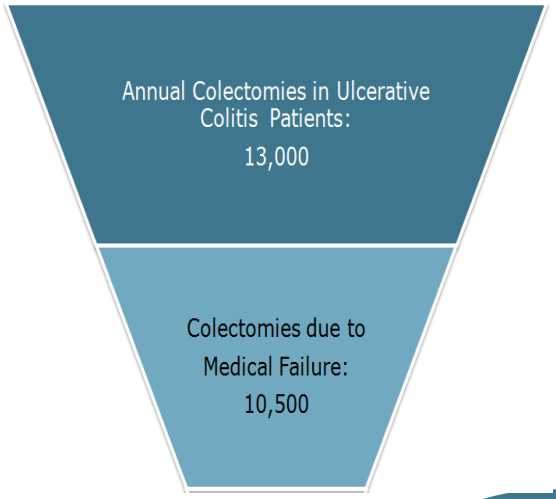
InDex Pharmaceuticals: Kappaproct - a new treatment for severe ulcerative colitis patients

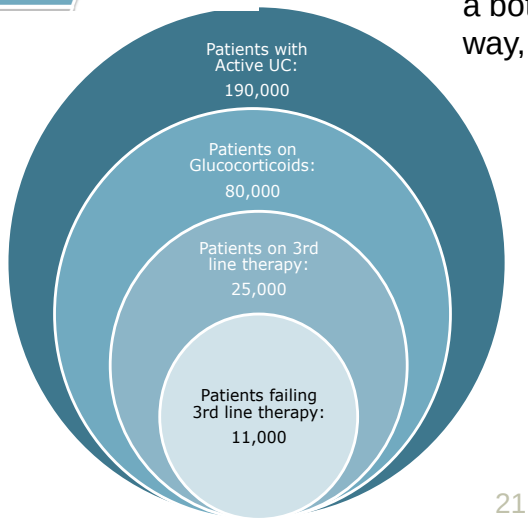
Kappaproct®

- Kappaproct is a novel treatment in Phase III clinical development that presents an effective pharmaceutical treatment option to severe, Ulcerative Colitis patients, whose only current option is surgical removal of the colon (colectomy)
- Pre-clinical and clinical documentation suggest a compelling and differentiated product profile
  - Previous clinical studies show efficacy in severe Ulcerative Colitis patients
  - Excellent safety profile
- Orphan Drug Designation in EU allows short path to market
  - Possible approval 2015
- Niche buster opportunity with global annual revenues projected between 1 and 2 billion USD
- Patent protection beyond 2030 in EU, US and Japan
- Data from the ongoing Phase III trial are expected in H1, 2014
  - Out-licensing H2 2014/2015
  - Companion diagnostics opportunity
  - Platform technology

Addressable Patient Population in EU of 10,500 Patients Annually

Kappaproct®





The addressable target population in the countries within the EU is approximately 10,500 per year.

The target population in the United States is at least as large as the EU population.

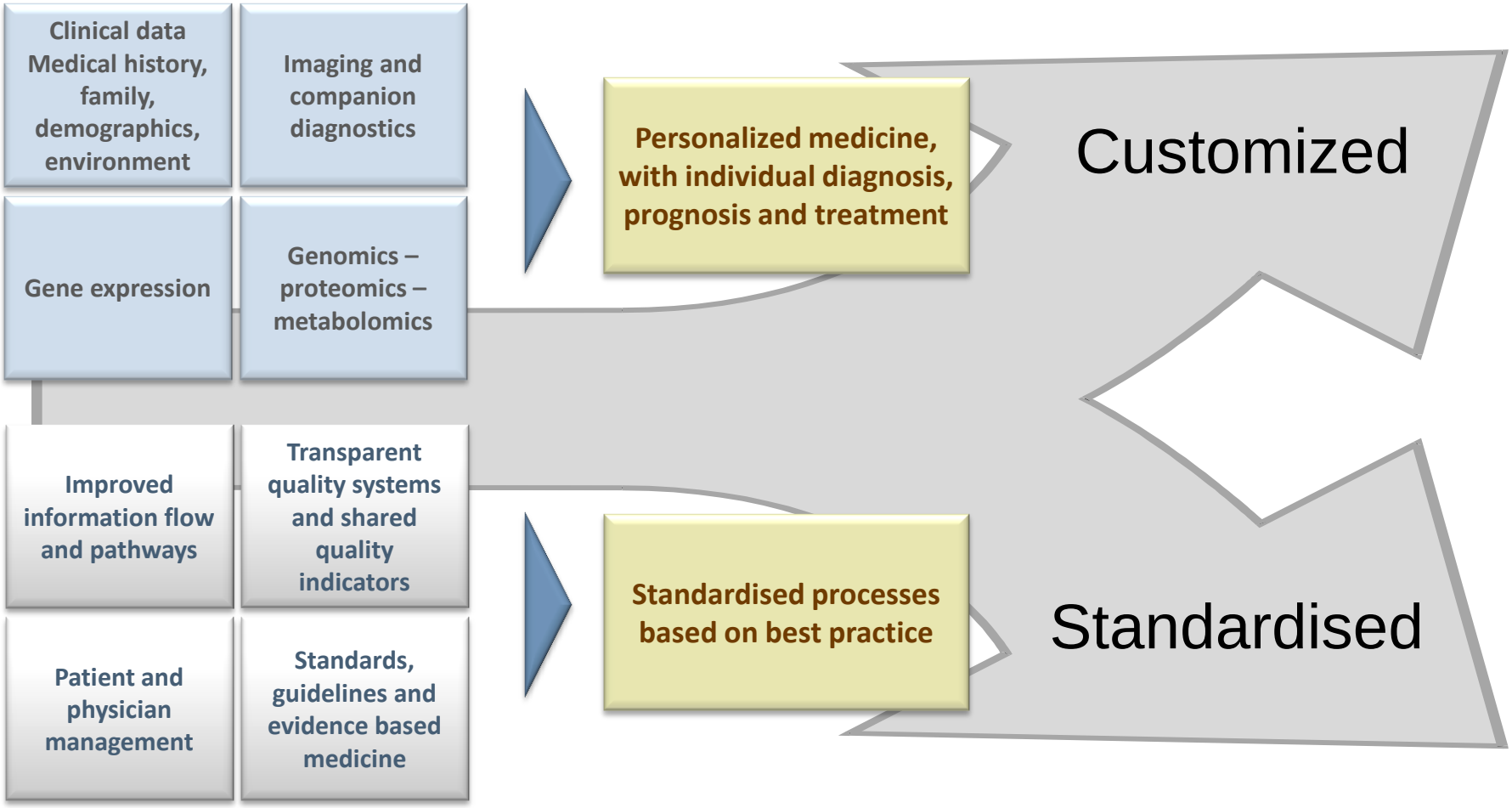
There are two ways to determine the addressable population for Kappaproct. First, the total annual colectomies performed in UC patients in the EU is 13,000. Of these, 10,500 are elective colectomies due to medical failure, as opposed to acute medical conditions such as colon perforation or fulminant infection.

Secondly, one can follow the current treatment paradigm to arrive at a bottom-up estimate of medical failures. Doing the analysis this way, one arrives at a very similar number of patients.

"With a companion diagnostic we would be able to address a much bigger portion of the patient population, not only those failing third line therapy. We are a niche company with an orphan drug, which makes it possible for us to take a drug all the way to market, but the exhaustive clinical trials required for a treatment and its associated companion diagnostic are very expensive. We would certainly benefit if the collaboration with healthcare, the reimbursement etc could be improved."

Jesper Wiklund, CEO, InDex Pharmaceuticals

Healthcare will become polarised – both standardized and customized



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What conclusions can be drawn from InDex Pharmaceuticals?

- It is within reach for a small biotech company to bring a niche-buster to the market
- Companion diagnostics is a growing field, supporting personalised medicine and customised treatments
- Sweden cannot be best at everything – but there is a long tradition of developing diagnostic products and technical products with a biomedical content
- Sweden could aim at becoming the best environment to develop and test drugs that have an associated companion diagnostic – both for small local companies that are developing a product and global pharma companies carrying out clinical trials
- This would require supporting clinical trials as well as establishing reimbursement models for treatments and companion diagnostics
- **Sweden has the opportunity to be positioned as a global leader in a growing and exciting area**

Elekta is a research driven company focused on neuroscience and oncology

Elekta develops solutions for treating cancer and brain disorders – state-of-the-art tools and treatment planning systems for radiation therapy, radiosurgery and brachytherapy, as well as workflow enhancing software systems.

Elekta solutions in oncology and neurosurgery are used in over 6,000 hospitals worldwide.

The company has 3,400 employees globally. The corporate headquarters is located in Stockholm.

Net sales in 2011/12 was 9,048 MSEK

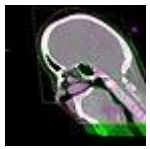
The impact that research has on improving cancer care is reflected in growing R&D investment which amounted to 778 MSEK, or 9% of sales in 2011/12.

Research is performed in collaboration with users at leading universities and hospitals.

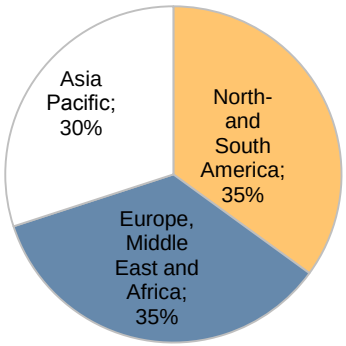
Asia is a growing market for Elekta; the company has been particularly successful in China where a tender was won in August 2012 with the Health Department of the People's Liberation Army. Elekta will deliver a range of clinical solutions, including the Gamma Knife, linear accelerators and associated software. The total value of the contract amounts to some USD 35 million, Elekta's largest deal ever in China.

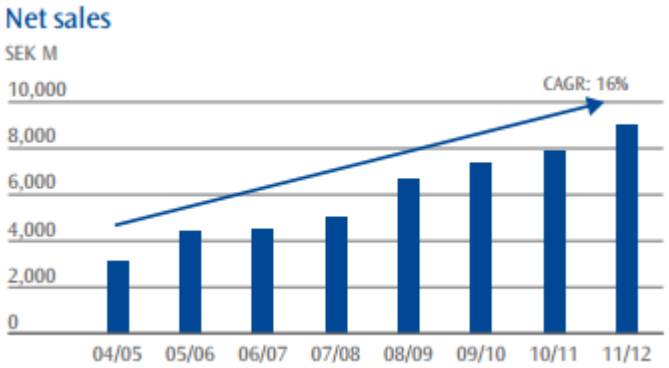
Neuroscience

Oncology



Net sales by geographic market





By 2014/15 Asia's share of sales is estimated to increase from the current 30% to 40%

Elekta has established a model for integrated product development in collaboration with the customer from the early stages – though not in Sweden

”We have grown to a global position where we don’t really need Sweden, but we are a Swedish company and we would like to have a strong foothold in Sweden as our domestic market.”

Tomas Puusepp, CEO Elekta

”We partner with leading oncology clinics and work close together with them in the product development – from the early stages, to commercialisation and onwards.”

Måns Barsne Vice President R&D, Elekta

”Most of the great Swedish medtech innovations were developed more than 30 years ago. The counties are focused on production of healthcare, as they should, but the efforts on clinical research is insufficient. They don’t see the need for continuous clinical improvements.

You can compare this with the Princess Margaret Hospital in Toronto, which is building up a cluster around our partnership and is embracing the idea that new companies will be formed to support translational research and commercialisation for the benefit of the patient”

Tomas Puusepp, CEO Elekta

”Given the infrastructure and availability of qualified personnel, Stockholm is an excellent site for our product development. We would invest a bigger portion of our 100 MEUR research budget if the Swedish healthcare system was more interested in collaboration”

Måns Barsne Vice President R&D, Elekta

What conclusions can be drawn from Elekta?

- Medtech companies and biotech companies with a physical product need a domestic market, since they need to interact with their customers already in the early stages of product development
- Sweden is not perceived to be a fertile ground for establishing partnerships – due to a strong focus on productivity, but also a general lack of interest in clinical development in the counties
- The experience from Elekta show that mutually beneficial partnerships are possible, leading to:
  - Improved product quality, in medical outcome, ease-of-use and patient safety
  - Faster and more cost efficient product development
  - Increase in academic activities, like publishing and graduation of Ph.D. students
  - Improved translational clinical research
- **A partnership model like the one established by Elekta could be implemented in Sweden**

The five European countries

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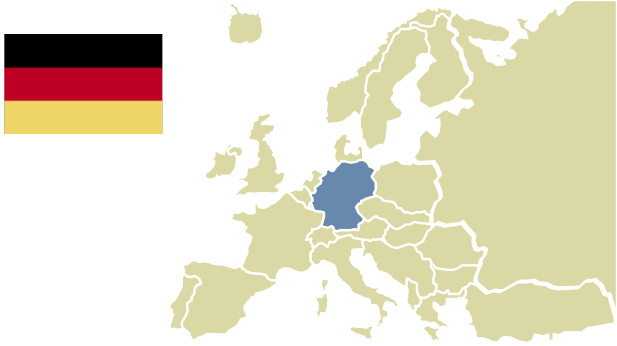
Germany

Germany is mainly going through change in reimbursements and financing

New rules for innovations in health care are partly already introduced, others are discussed



German healthcare system

- Germany has a highly fragmented healthcare system – both among providers and the financing bodies
- From a financing point of view, there are two patient segments – those belonging to the Statutory Health Insurance (90% of population) and those who are privately insured (remaining)
- Around 287,3 bn € in annual healthcare expenditures (2010)
- There are both public and private providers – for profit and not for profit
- The number of hospitals is decreasing slightly – private increasing, public decreasing
- Healthcare is paid by contributions from employers and employees (50/50) – 15,5% of salaries in total
- Only a limited portion (8%) of healthcare expenditures comes from taxation – though this will increase to around 11% over the next few years

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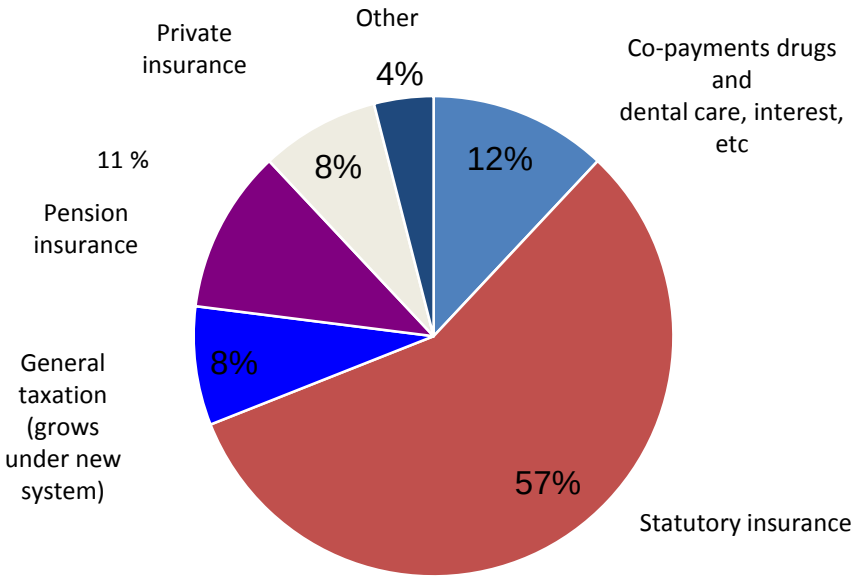
The German health care system is based on an embracing social health insurance system

- A social health insurance system, based on solidarity
- Administered through 144 statutory health insurance funds (used to be 300 a few years ago - rapidly decreasing through mergers)
- Compulsory affiliation up to a certain income break-point (in 2012, € 4237,50)
  - ~89 % of the population belong
  - Individuals above break-point may bail out
- A multitude of providers - private and public
- Slowly growing importance of private health insurance as well as the fully private market
  - 8,95 mill people (10,95% of the population) is fully privately insured (2011)



Total expenditure on health as % of GDP	11,6 %
Public expenditure on health as % of total	76,9 %
Private expenditure on health as % of total	23,1 %

Role of important Government and Official Bodies in the German Healthcare System I

Deutscher Bundestag (German parliament)

- Central law making authority in the German system

Bundesrat

- The body through which the Länder participate in the legislation and administration of the Federation
- Is also involved in the legislative process in concurrent legislation, especially in health legislation

German Ministry of Health

- Central body for strategic development of the health system
- Drafts for new or changed laws
- Negotiates central health policy issues with the parliamentary parties

Parliament

- Counterpart of the ministry of health in legislative processes

Role of important Government and Official Bodies in the German Healthcare System II

Länder (federal states)

- Have direct responsibility for public health, certification of health professionals, hospital planning and hospital investment
- Individual federal state governments participate directly in the decisions of the national state or Federation. This is done through the Bundesrat

Länder Health Ministries (combined with social policy and labour)

  - Hospital planning and financing
  - Supervision of regional sickness funds
  - Public health services
  - Supervision of health professionals and their professional institutions

Role of important Government and Official Bodies in the German Healthcare System III

Gemeinsamer Bundesausschuss (G-BA / Federal Joint Committee)

- G-BA is the main decision-making body within the SHI under the level of the ministry of health and the parliament - formulating and implementing which services will be provided and under which conditions
- G-BA has wide-ranging regulatory powers
  - Assessment of new methods of medical diagnosis and treatment
  - Decision, if and what added benefit a new innovative drug has to offer and under what circumstances it may be prescribed for reimbursement by the statutory health insurance funds
  - Issues the directives that are necessary for safeguarding medical service provision
  - Recommendations on requirements regarding the content of disease management programs
  - Issues directives governing quality assurance in the ambulatory, inpatient and inter-sectoral spheres
- Since 2004 national groups representing patients were given the right to file applications and to participate in the consultations of the G-BA

Self-governing bodies of service providers and health insurance funds

- The following three organizations form the Federal Joint Committee:
  - National association of outpatient doctors (Kassenärztliche Bundesvereinigung) and dentists (Kassenzahnärztliche Bundesvereinigung)
  - The German Hospital Federation (Deutsche Krankenhausgesellschaft) and
  - The federal association of health insurance funds (GKV-Spitzenverband)
- Besides their role in the G-BA self-governing bodies have an important role in contracting in inpatient and outpatient sector of healthcare
- In many fields contracts of the self-governing bodies are binding for all SHI-members, all SHI outpatient doctors and all hospitals, which are part of the hospital plans of the Länder
- In the field of medical aids the federal association of health insurance funds has several duties: setting up and updating a list of all accepted medical aids, setting upper fixed price for certain groups of medical aids, giving advices to the SHI about medical aids contracts

Germany needs more healthcare for the same money and has taken a few strategic actions to achieve this

- New SHI financing system / more competition
- DRG to optimize inpatient processes
- New mechanism for acceptance and price setting for innovative drugs
- New forms of contracting in outpatient sector
- Integrated care contracts to improve inpatient-outpatient processes
- Financing of capital investments in hospitals remains to be solved

- New financing system of SHI started January 2009
- Competition increasingly a central steering instrument
- Outpatient sector:
  - statutory health insurance companies can select groups of doctors for contracting
  - Hospitals has entered into the outpatient market, often by setting up MVZs
  - The new centres show some resemblance with polyclinics in England
- Inpatient sector:
  - DRG introduction led to rapid changes
  - Fast growing private hospital groups
- "Dividing line" between in- and outpatient sector begins to disappear through Integrated Care
- Treatment quality and quality transparency have become important issues
- Supply with pharmaceuticals: G-BA now controls if drugs are really innovative; if a drug is accepted as innovative, GKV-Spitzenverband and pharmaceutical company have to agree on the price

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The key players all face challenges in the current health care system

The federal state

The federal state must contain the expenditure of the SHI:s and therefore the ancillary wage costs

Through the different legislations this was achieved: In the end of 2012 the GKV and the Gesundheitsfonds together had financial reserves of around 23,5 bn €

The federal state must contain the possibility to get care in all parts of Germany, also in rarely populated areas (inpatient and outpatient care)

Implementation of innovations into the health care sector is an on-going discussion topic

SHI (Die Krankenkassen)

From 2009 and onward the central government has set the contribution %age nationwide (15,5%) - contributions then have to be paid into a new health funds, and SHI will get money through the health funds leading to mergers between SHI funds. (First examples: merger between TK und IKK direkt; KKH and Allianz BKK -> seen for the first time in Germany)

The new additional contributions directly from the insurees, if an SHI-fund does not get enough money from the health funds, lead to massive loss of insurees (example DAK), because insured persons have the right to change SHI funds, when additional contributions apply; this has led to a very cautious, risk-avoiding financial policy of all SHI funds

The Health Care Providers

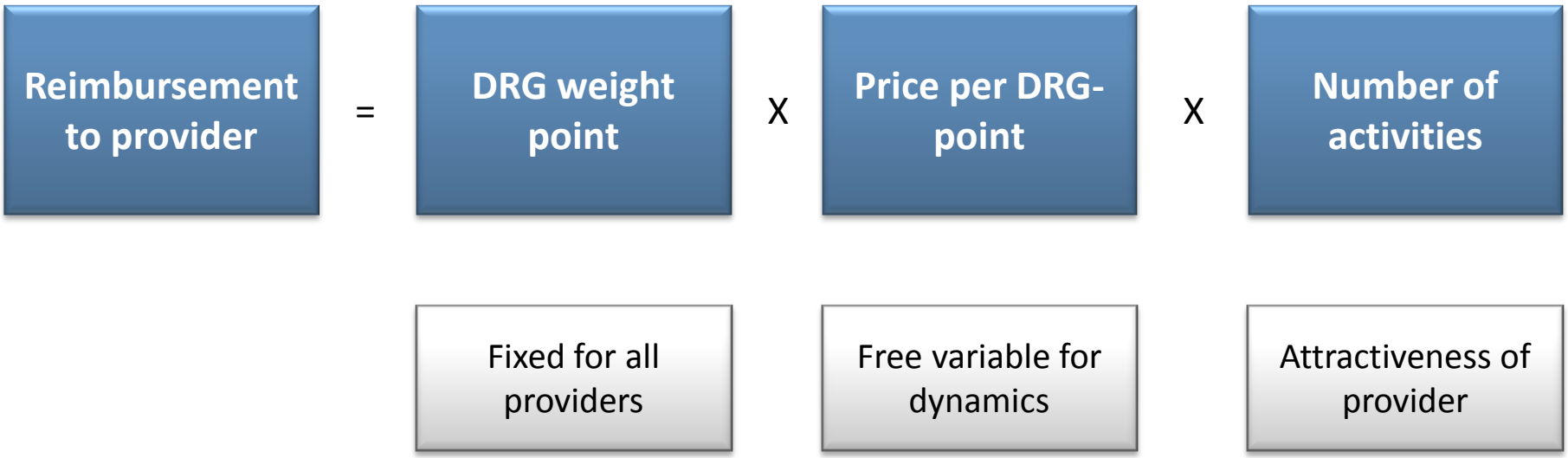
It is crucial for the hospitals to adapt to the DRG system in a profitable way

Price and cost development do not match – costs are growing faster than the prices

Pharmaceutical companies have to adopt their business strategy to new rules for innovative drugs

MedTech companies complain about the time gap before an innovation is properly paid within the SHI

DRG was developed in the US in the 80's as a way to manage healthcare, distribute resources and control cost



DRG reimbursement is always all-inclusive: It covers a process rather than an activity. The treatment, consumables, drugs, medical devices, hospital stay are all included.

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In order to create cost containment the DRG-system has been introduced into the German Health Care system

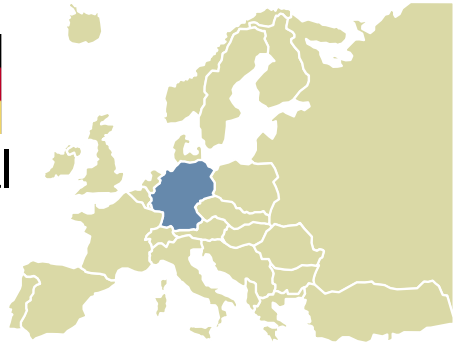
The DRG system was implemented in order to create:

- Greater transparency and efficiency in the hospital sector
- Improved performance of the reimbursement system
- A better reallocation of financial resources
- An optimization of the operational and organizational structures
- A reduction of the rate of expenditure in the future
- The overall aim is to create health care to a greater extent without increasing prices

So far, the implementation has led to:

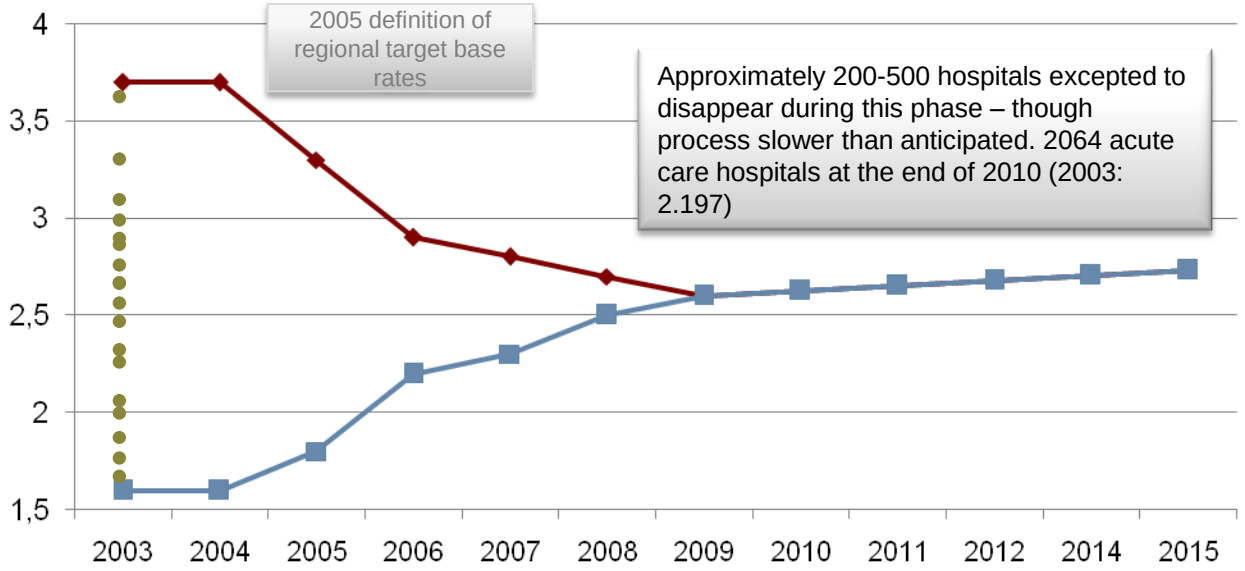
- A decrease in the average length of stay (from 8.5 to ~7 days)
- A lowered number of beds
- Reductions of nursing staff
- A strengthened out-patient sector (this sector has potential to become even stronger through development of medical innovation treatments)
- Improvement of the cooperation between management and medical professionals
- Improvement of cooperation between inpatient and outpatient sector (Integrierte Versorgung (IV), Medizinische Versorgungszentren (MVZ))
- Increasing number of inpatient cases as a result of (too) low increase of prices (base rates)

The base rate varied during the convergence phase - regional base rates where established in 2009 – followed by convergence on the national level



Introduction phase | State convergence phase

Base rate



Approximately 200-500 hospitals excepted to disappear during this phase – though process slower than anticipated. 2064 acute care hospitals at the end of 2010 (2003: 2.197)

"Losers"

These hospitals disappear through closing down or merger if they do not improve – they need strong management in order to do this

"Winners"

These hospitals increase their revenues and will be able to develop

During the budget neutral phase 2003/04, the base rates were set individually for each hospital to match previous budgets

From 2005, the individual base rate converged - having a direct effect on the individual hospital budgets.

In addition, hospitals and health insurances contract the number of cases treated in the individual hospital

Starting from 2010 the regional base rates develop within a corridor of -1.5 to +2,5% around the theoretical German base rate.

The theoretical German base rate in 2012 was ~2,992 Euro.

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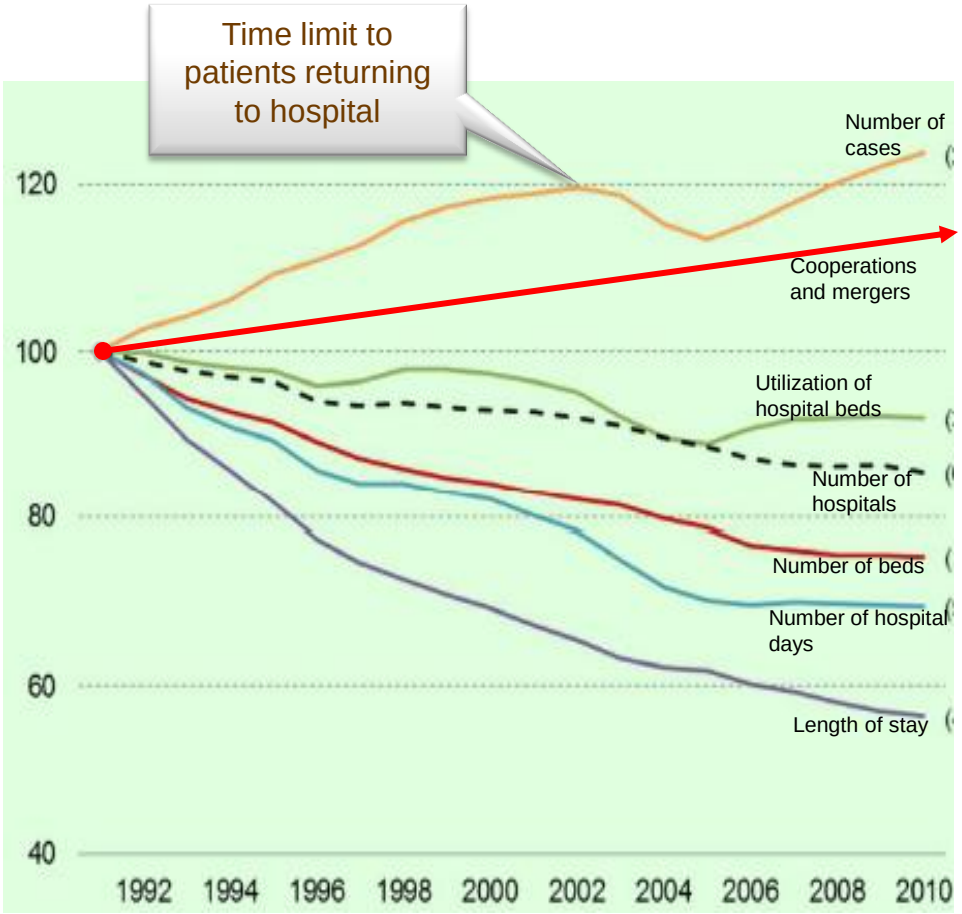
General trends in Germany hospital sector

- In Germany, the regulations do not allow establishment of new hospitals for treatment of SHI patients. A new provider cannot set up provision of healthcare without being part of the hospital plan of the Länder. However, when being part of the plan the provider is free to work under the national reimbursement system and attract SHI patients.
- Therefore, entry into the German SHI inpatient segment needs to be based on an acquisition – also for regulatory reasons.
- Growing market volume; 2010: 74,3 billion Euros
- Number of hospitals is decreasing (2003: 2.197; 2010: 2.064)
- Number of hospital beds is decreasing (2003: 541.901; 2010: 502.700)
- Length of stay in hospitals is decreasing
- Number of public hospitals is decreasing
- Number of private hospitals is increasing (private hospital groups are fastest growing part of the market)



There are public, private for profit and private not-for-profit hospitals in the German healthcare system

Public institutions

- The public hospitals provide 48,4% of the total number of hospital bed. These hospitals are run mostly by communities; university hospitals by the *Länder*
- This part of the market is steadily decreasing, due to inefficient management

Decreasing in number

Private for profit institutions

- There is an increasing part of profit-making private hospitals – 17,3% of the total number of hospital beds
- One university hospital (Giessen-Marburg) has been privatized
- This part of the market is steadily increasing, due to efficient management and ability to respond to change

Growing in number

Private Not-for-profit institutions

- These institutions belong to religious organizations and other charities
- Provide over 34,3% of the total number of beds
- This part of the market is slowly decreasing, due to difficulties to attract capital and less efficient management

Decreasing somewhat in number

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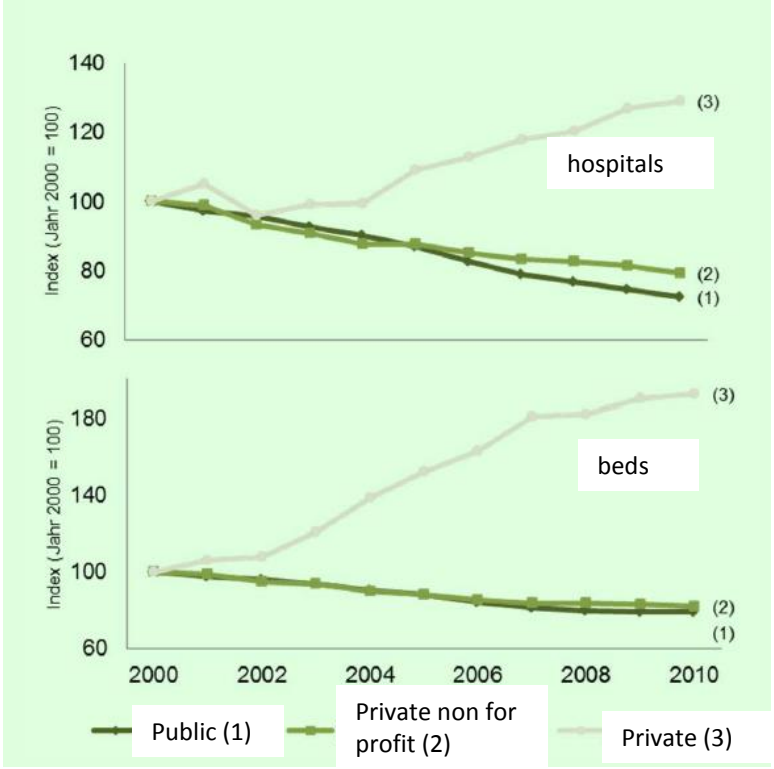
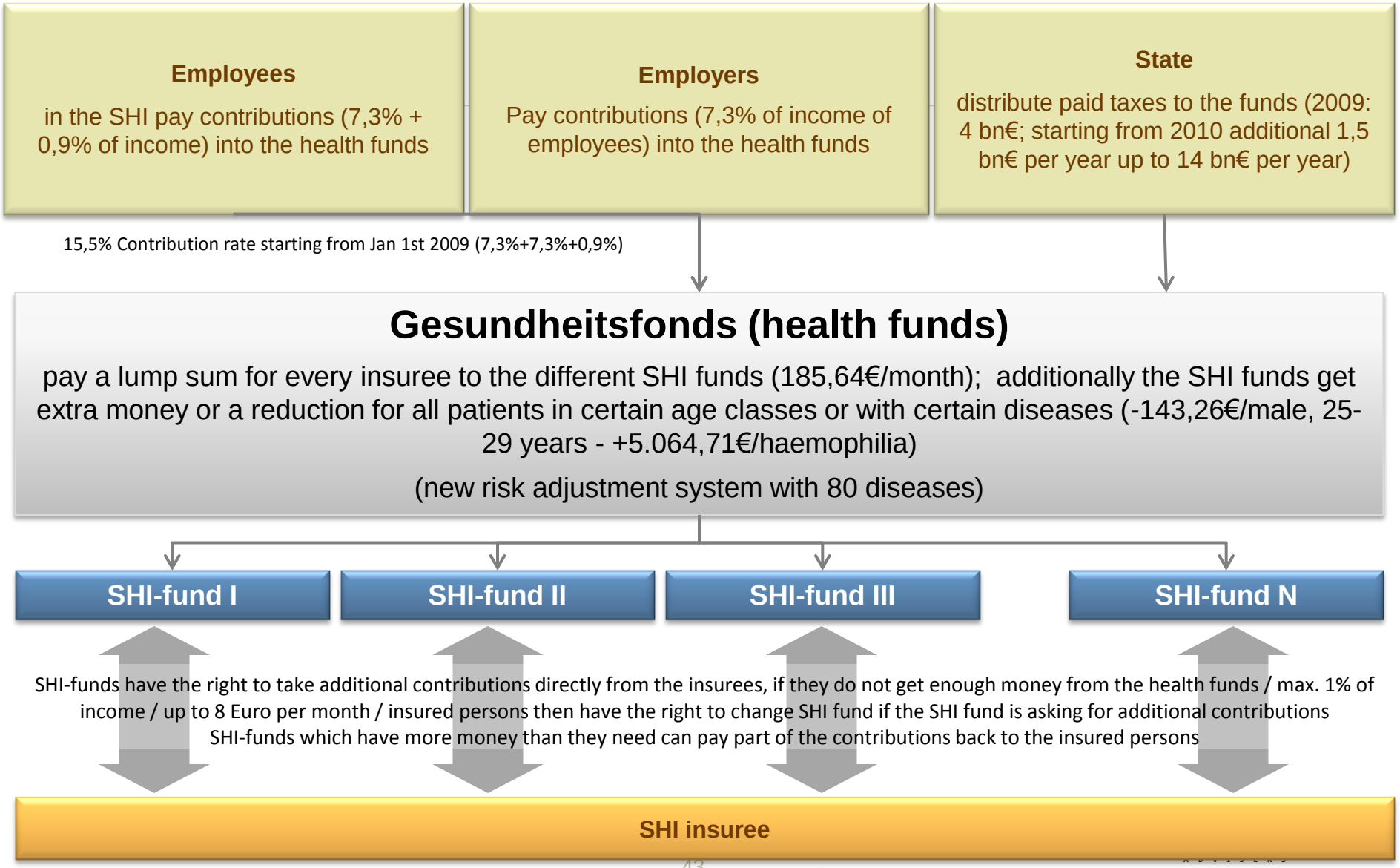
Increasing number of mergers and acquisitions and beginning Internationalization

- An increasing number of privatizations of community hospitals during the last 10 years
- Growing number of mergers also in the private not for profit sector
- First acquisitions of big private hospital groups by international companies (Fresenius AG bought Helios Kliniken GmbH in 2005; Helios bought Humaine Kliniken GmbH in 2006 and Damp Holding in 2012)
- First German university hospital (Giessen-Marburg) was bought by Rhön Klinikum AG in the beginning of 2006
- Only few international hospital groups entered the German market:
  - Ameos AG (Switzerland; since 2003)
  - Capio (Sweden; since 2006)



Financing System of the German SHI system (from 2009)



Employers pay the Contributions to SHI funds, who transfer them to the National Health Fund / SHI funds get paid, risk adjusted, from the National Health Fund

Central Changes in the German healthcare System 2011/12

- Health care reform of 2010 (**Act for Sustainable and Socially Balanced Financing of Statutory Health Insurance**) was particularly dedicated to reorganise the financing of the health system
  - From January 2011 onwards, the income-related contribution rate is fixed at 15.5% by law
  - Future over-proportional expenditure rises will be financed through premiums (Zusatzbeiträge)
  - The premium is not income-related and has to be imposed by the respective Statutory health insurance funds (SHI-funds), which are not able to cover their costs through the funds allocated by the health care fund system (income-related contributions and subsidies by state)
  - The basic idea of financing future health expenditure increases through premiums is such to foster competition among SHI-funds
- The Act on the Reform of the Market for Medicinal Products (**Gesetz zur Neuordnung des Arzneimittelmarktes – AMNOG**)
  - Starting 2011, manufacturers are required to submit evidence of the added benefit for patients as soon as they bring a product with new active ingredients to market
  - The Joint Federal Committee decides if and what added benefit a new medicinal product has to offer and under what circumstances it may be prescribed for reimbursement by the statutory health insurance funds
  - A maximum reimbursement rate will be fixed for medicinal products without an added benefit
  - If this is not possible owing to a lack of other products with comparable pharmacological and therapeutical properties, the manufacturer will agree on a reimbursement price with the statutory health insurance that may not exceed the costs of the comparable therapy
  - In the case of drugs that do have an added benefit, the GKV-Spitzenverband and the specific pharmaceutical company then negotiates the reimbursement price

Central Changes in the German healthcare System 2011/12 II

- The law on the reform of the SHI care structure (**GKV-Versorgungsstrukturgesetz**) became effective in the beginning of 2012
- Most important new regulations:
  - Insuring outpatient physician care in densely populated regions by better reimbursement and better working conditions
  - Regionalization of the planning process for SHI doctors
  - Regional associations of SHI doctors (Kassenärztliche Vereinigungen) get the right to decide about the distribution of SHI reimbursement between the SHI doctors in the region
  - Only SHI outpatient physicians and hospitals have the right to found and run Medical Treatment Centers (Medizinische Versorgungszentren MVZ)
  - Highly specialized outpatient care (e.g. outpatient cancer treatment) can be carried out by specialized outpatient physicians and hospitals with specialized departments
  - Minor reform of the Federal Joint Committee (Gemeinsamer Bundesausschuss G-BA)
  - The Federal Joint Committee has now the possibility of testing examination and treatment methods whose benefit has not yet been sufficiently proved, but which show potential as a treatment alternative. A request can be submitted by
    - the manufacturer of a medical product whose use significantly depends on the application of a new examination or treatment method
    - Companies that are not providers of a new method, but that have an economic interest in its provision by the statutory health insurance providers

Central Changes in the German healthcare System 2012/13

- The **Pflegeneuausrichtungsgesetz** (PNG - reform of the long term care insurance) becomes effective in the beginning of 2013
  - Most important new regulation:
    - Brings more financial benefits especially for dementia people in outpatient long term care
    - Higher contributions to the statutory long term nursing care insurance (+0,1%; new contribution: 2,05%)
    - Better possibilities for long term nursing care homes to contract outpatient physicians and dentists
- The **PsychEntgeltgesetz** (law on new reimbursement system for psychiatric care) becomes effective in the beginning of 2013
  - Most important new regulation:
    - DRG like reimbursement for psychiatric inpatient care
    - The reimbursement is not oriented on a DRG group for a case; it is based on a payment per day per indication
    - The new reimbursement system starts in the beginning of 2013 with a implementation phase of 9 years (4 years budget neutral, 5 years convergence phase)

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Innovations in the German Health Care System

- Different rules and laws apply for the introduction and reimbursement of innovations in the different sectors of the German healt care system
- Therefore a discussion of innovations hase to take in account the different forms of innovations and the different sectors of the German health care system:
  - Inpatient care
  - Outpatient care
  - Integrated care and special outpatient contracts

Sectors	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	Use: open Reimbursement: NUB	Use: open Reimbursement: NUB	Legislative Framework
Outpatient Care	G-BA	G-BA	Legislative Framework
Integrated Care / special outpatient contracts	-	-	Rules of SGB V

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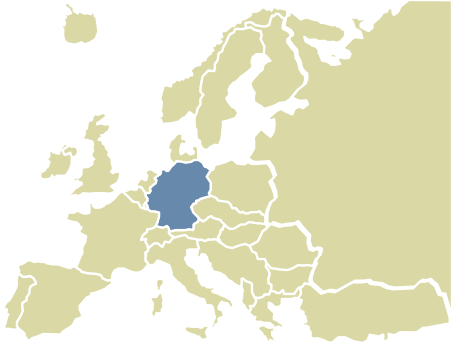
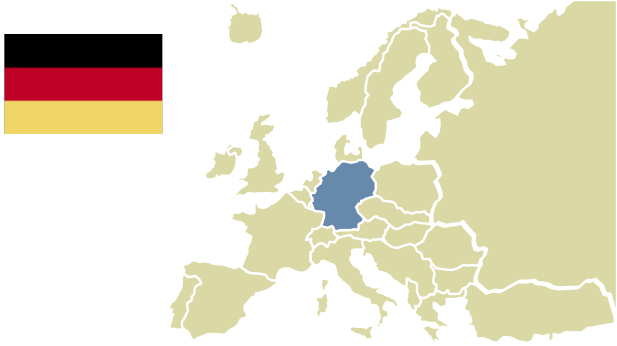
Inpatient Sector: NUB Process
(NUB = New Diagnostic and Treatment Methods)

Sectors	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	**Use: open** **Reimbursement: NUB**	**Use: open** **Reimbursement: NUB**	Legislative Framework
Outpatient Care	G-BA	G-BA	Legislative Framework
Integrated Care / special outpatient contracts	-	-	Rules of SGB V



Cost of Pharmaceuticals and Medical Devices in the German DRG System

- In DRG systems, costs for pharmaceuticals and medical devices are included in DRG classification and therefore in reimbursement rates
- Problem: time lag between the data collection and time when hospitals are paid on the basis of this data
- Together with the German DRG System (G-DRG) a special process for new technology (pharmaceuticals, MedTech innovations and new treatment processes) used in hospitals was introduced: The NUB pathway (NUB = new Diagnostic and Treatment Methods)
- The update of the G-DRG by InEK is done yearly based on the data from the previous 2 years
- Hospitals can apply individually for using innovative drugs, innovative medical technology and/or new procedures under the NUB process



Cost of Medical Devices in the German DRG System

- Every hospital will need to apply separately (electronic application at InEK) and the “on-top” payment (if the application is approved) will be available only to the hospitals that applied for it - and not automatically to every hospital in Germany
- The adequate uptake and correct coding of a new technology by the hospitals that participate in InEK’s calculation system is surveyed by InEK
- The reimbursement for NUBs, which are accepted by InEK, but has no fixed additional payment (Zusatzentgelt ZE), has to be negotiated with the SHI
- If a NUB has got a fixed reimbursement, no negotiation with SHI is neccessary
- Should the new technology be adequately used, correctly coded and exhibit a cost profile of sufficient difference, the InEK may integrate it permanently to the G-DRG
- The NUB pathway has the potential to accelerate market access for new technologies but requires significant effort from its users

Three steps for Integration of New Technologies in the German DRG System

1. Acceptance of the application by the InEK [NUB Status 1]
2. Agreement with the sickness funds about an additional payment/ an innovation case fee including the uncertainty of negotiations with sickness fund
3. Integration of the procedure into the regular case fee catalogue to lower transaction costs for negotiations and uncertainty for the hospitals
    1. Negotiable supplementary payment (ZE)
    2. Fixed supplementary payment (ZE)
    3. Specific DRG

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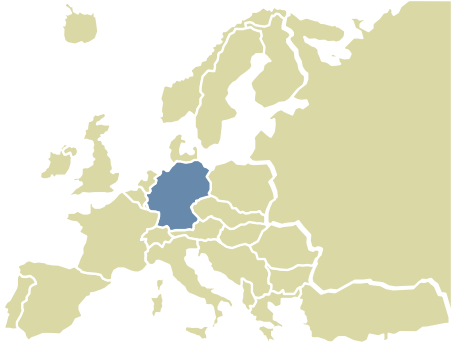
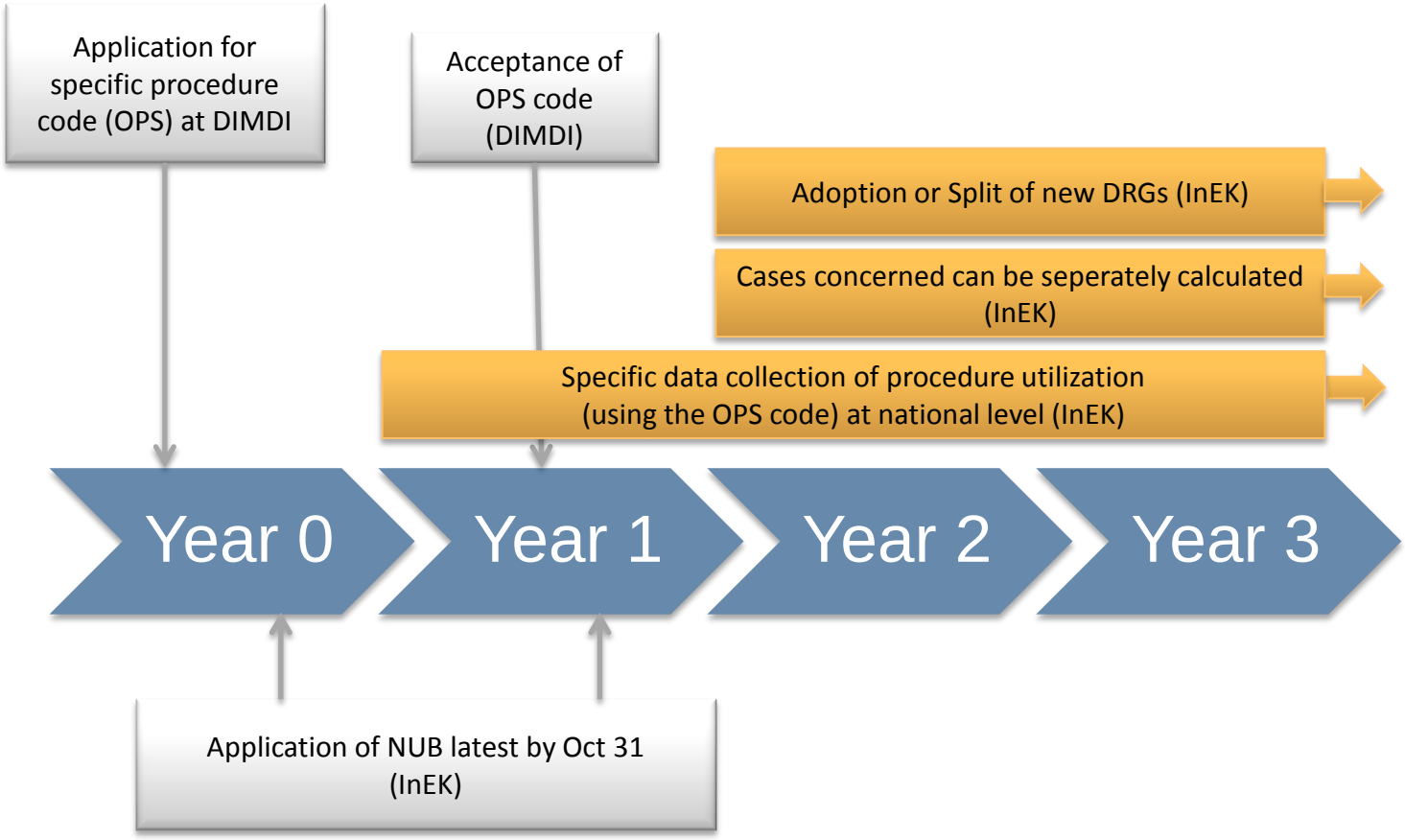
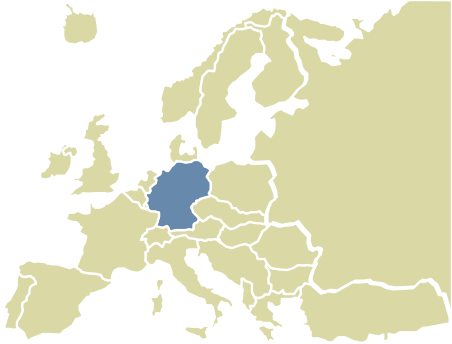
NUB Process in the German DRG System (System Level)





NUB Process in the German DRG System (Hospital Level)



Individual (re)application of the hospital for an NUB

Decision of InEK about status of NUB application

If status 1 , but no fixed reimbursement: Negotiation of NUB reimbursement between single hospital and SHI funds
(No reimbursement guarantee, as long as the additional reimbursement is not fixed by InEK)

If status 1 with fixed reimbursement: reimbursement guarantee for NUB

October 31 year 1

January 31 (for year 1)

Status of submitted NUB applications (InEK -> hospitals)

If status 1: Inclusion for the next version of the DRG catalogue possible
(Otherwise re-application as NUB possible)

After inclusion in the next version of the DRG catalogue: Reimbursement through new or splitted DRG / no NUB application neccessary

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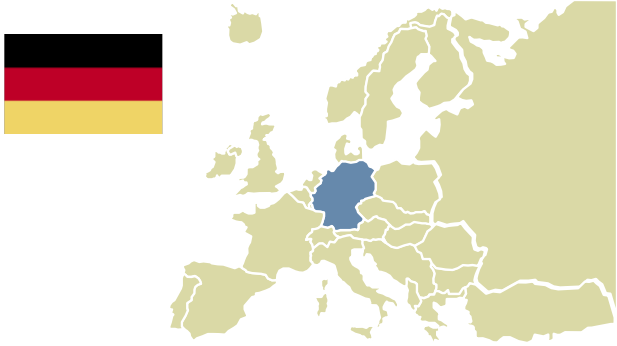
Overview: Different Situations within the NUB Process



		Extrabudgetary payments	Additional payments		Unique DRG
		Local negotiations between single hospital and SHI funds		Pre-determined reimbursement / same throughout Germany	
		NUB regulations	Included in regular system of G-DRG reimbursement		
With OPS code	Sufficiant number of patients and minimal variations in calculated costs			Fixed supplementary payment (Zusatzentgelt ZE)	Unique DRG
	Number of patients treated with the new technology is too low or variations in calculated costs are too high	Accepted NUB application (with OPS)	Negotiable supplementary payment (Zusatzentgelt ZE)		
Without OPS code		Accepted NUB application (without OPS)			

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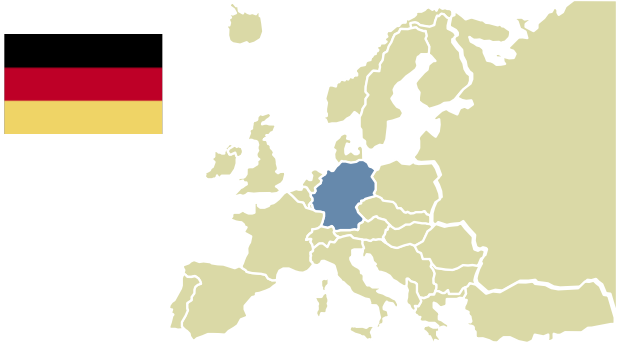
Innovative drugs in the outpatient sector

Sectors	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	Use: open Reimbursement: NUB	Use: open Reimbursement: NUB	Legislative Framework
Outpatient Care	**G-BA**	G-BA	Legislative Framework
Integrated Care / special outpatient contracts	-	-	Rules of SGB V

Implementation and use of innovative drugs in the outpatient sector

The Act on the Reform of the Market for Medicinal Products (Gesetz zur Neuordnung des Arzneimittelmarktes – AMNOG)

- Came into force on January 1st 2011
- The Federal Joint Committee is given a pivotal assignment along with the Institute for Quality and Efficiency in Health Care: assessing the benefits of recently authorised pharmaceuticals pursuant to § 35a SGB V
- Their findings form the basis for taking the decision on what price a pharmaceutical company may offer its recently authorised pharmaceutical in Germany
- The law obliges pharmaceutical companies to submit a dossier on the benefit assessment when a new product accesses the market in Germany or when new therapeutic indications are authorised



Implementation and use of innovative drugs in the outpatient sector: AMNOG

- Federal Joint Committee assesses within three months after a new pharmaceutical accessed the market if claimed additional benefit in relation to the appropriate comparator is proven
- The companies submit a dossier to the FJC based on the authorisation documents and all studies carried out on these pharmaceuticals
- They have to prove the pharmaceutical´s additional benefit in comparison to a specific appropriate comparator set forth by the FJC
- The FJC can commission the Institute for Quality and Efficiency in Health Care or third parties to assess the benefits
- The findings of the assessment our published and pharmaceutical companies, associations and experts are given the opportunity to comment on the findings
- After another three months, the FJC passes a resolution based on the benefit assessment and the round of consultation, the extent of the additional benefit and the costs of the therapy
- After publication the FJC takes a decision on the further procedure for establishing a price for the pharmaceutical
- The GKV-Spitzenverband and the specific pharmaceutical company then negotiates the reimbursement price for pharmaceuticals that have proven additional benefit as a discount on the original selling price within six months
- If negotiations do not achieve an agreement, an arbitration commission defines the reimbursement price using the European price level as a standard
- If the new pharmaceutical does not have any additional benefit compared to the appropriate comparator, it will be included in the reference price system six months after market launch
- If a pharmaceutical without additional benefit cannot be assigned to any reference price group, a reimbursement price will also be agreed where the annual therapeutic expenses are not any higher than of the appropriate comparator.

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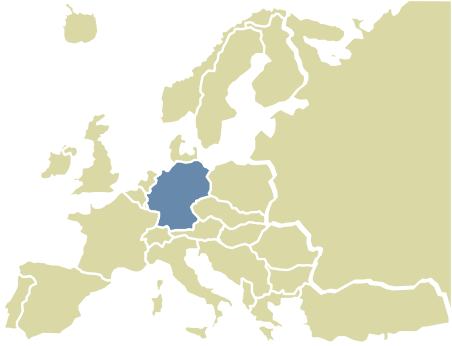
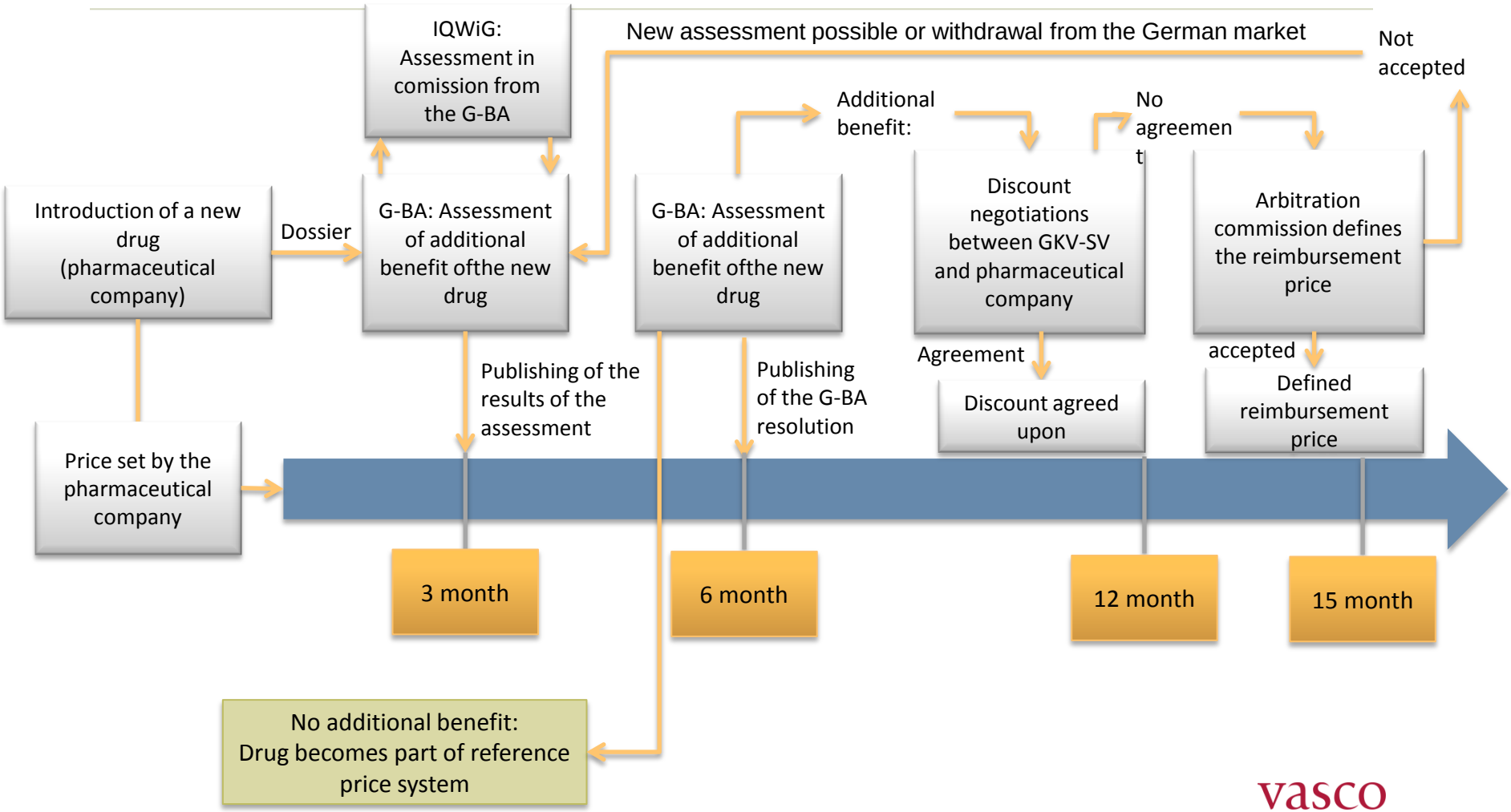
Implementation and use of innovatis drugs in the outpatient sector: AMNOG





Innovations in the outpatient sector

Sector	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	Use: open Reimbursement: NUB	Use: open Reimbursement: NUB	Legislative Framework
Outpatient Care	G-BA	**G-BA**	Legislative Framework
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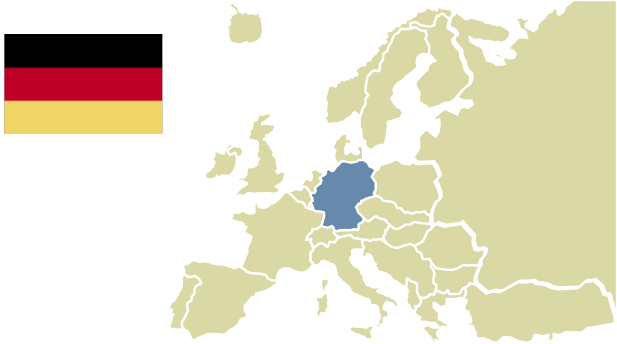


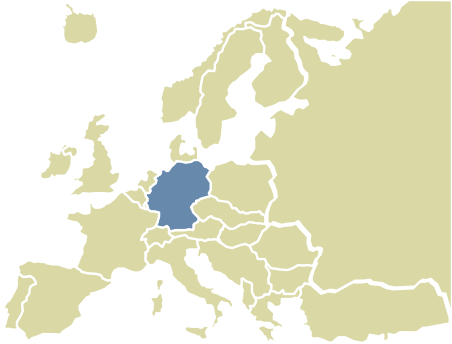
Implementation and use of innovations in the outpatient sector (SHI)

Principles for implementation or reimbursement of innovations

- Outpatient care:
  - Positive evidence based assessment as a condition to implement a new method for diagnosis or treatment
  - Methods are not reimbursed by SHI, as long as the G-BA has not yet decided about a positive benefit of the treatment („Erlaubnisvorbehalt“)
- Inpatient care:
  - „Negative“ evidence based assessment as a condition to exclude (new) methods
  - Methods are reimbursed by SHI, as long as the G-BA has not yet decided about the „negative“ benefit of the treatment („Verbotsvorbehalt“)

Methods which are to be approved for statutory medical care must be examined by the G-BA, if they are

  - not yet listed as claimable services in the standard schedules of fees (EBM and BEMA)
  - contained in the corresponding schedule of fees, but the indication or type of service provision has been considerably changed or extended
- If it is unclear whether this is a “new method” in this sense, relevant information can be sought from
  - the evaluation committees responsible for this area of service provision,
  - from the National Association of Statutory Health Insurance Physicians (KBV) for ambulatory medical care provision
- **Important:** A positive decision of the G-BA on the introduction of a new service in statutory medical care is the precondition for service definition and payment agreement
  - Responsible for a payment agreement is the committee for rating office-based doctors’ services, consisting of the National Association of Statutory Health Insurance Physicians (KBV) and the health insurance funds
- Without a payment agreement, a service in statutory medical care cannot be billed



Implementation and use of innovations in the outpatient sector (SHI)

Who is entitled to make an application?

- The initial condition for the initiation of a discussion procedure is the corresponding application from bodies entitled by law to submit an application
- These are normally
  - the responsible national confederations of regional associations of service providers,
  - the GKV national confederations of regional associations of health insurance funds
  - the organisations recognised in the Ordinance on Patient Participation or the neutral members of the G-BA

What must an application for examining a method contain?

- A complete application to examine the criteria of benefit, medical necessity and cost-effectiveness for an diagnostic and therapeutic method must contain:
  - A description of the diagnostic or therapeutic method to be examined,
  - The indications and objectives to be examined,
  - A detailed justification, based on information for the relevant indication, on the benefit, medical necessity and cost-effectiveness, each supported by scientific literature and in comparison to methods already provided,
  - Information on the relevance of the method,
  - Information on the urgency of the evaluation

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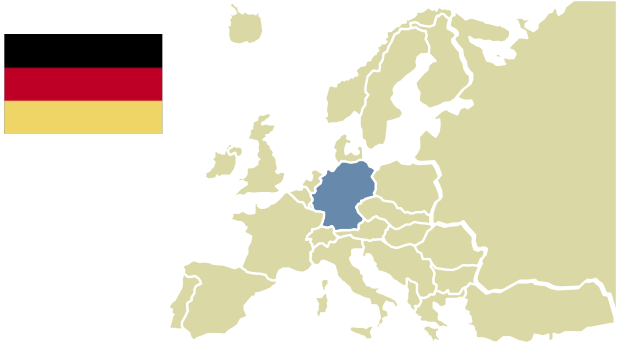
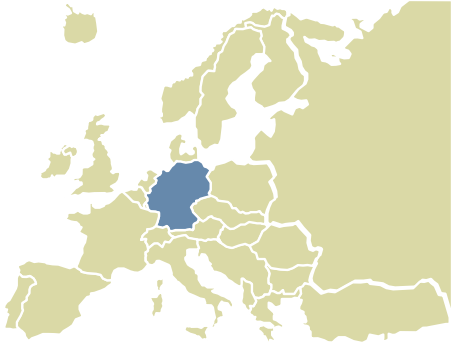


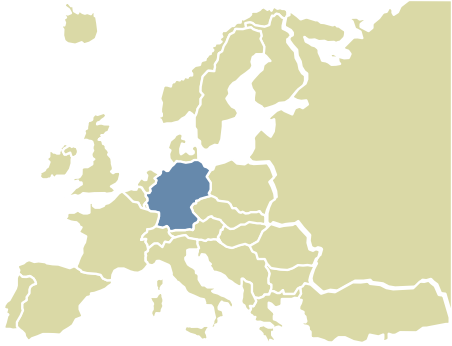
Implementation and use of innovations in the outpatient sector (SHI)

- **How can the benefit of a method be demonstrated?**
  - The G-BA employs the methods of evidence-based medicine when evaluating evidence from studies
  - This is linked to a outcome-orientated analysis of study results:
    - the valid demonstration of (additional) benefit is demanded
    - the evaluation incorporates the study type, internal validity and quality of the studies, consistency of the study results, as well as aspects of the transferability into real provision of health care.
  - For new diagnostic and therapeutic methods of fundamental importance for health care the G-BA normally commissions the Institute for Quality and Efficiency in Health Care (IQWiG) with the evaluation of the benefit
- IQWiG employs scientific methods they have developed themselves and which specify the evaluation process and the persons to be involved



Implementation and use of innovations in the outpatient sector (SHI)

- **Evaluation of diagnostic testing methods**
  - A special point here is ->
    - to list the consequences for the patients of the use of the test in comparison, or in addition to, the established standard
  - Matters relevant to the patient include, for example, demonstrable therapeutic or prognostically relevant changes in disease stages as a consequence of the new diagnostic testing method, which can lead to a change in the therapeutic procedure and thus to a change in the morbidity or mortality
  - This normally requires studies extending beyond diagnostic accuracy (sensitivity and specificity)
  - Patient-relevant outcomes accepted by the Code of the Procedure (Verfahrensordnung – VerfO) of the G-BA include mortality, morbidity, quality of life, as well as physical and psychological function. Surrogate (intermediate) outcomes should be causally related to patient-relevant outcomes.



Implementation and use of innovations in the outpatient sector (SHI)

- **Demonstration of the benefit of a method**
  - Benefit of a method must be demonstrated in comparison to an established standard
  - Superiority in comparison to the standard is also referred to as additional benefit
  - Randomised controlled trials (RCTs) are generally the best method to demonstrate additional benefit
  - With a randomised controlled trial, the conclusion that additional benefit for a method can be assumed is regarded as highly reliable
  - If there are no qualitatively appropriate documents of this degree of reliability (for example, because of the rarity of a disease, the lack of a therapeutic alternative, or for ethical reasons) studies of a lower level of evidence may be accepted
  - In the evaluation of the cost-effectiveness, the decision is influenced by the additional costs in comparison to the standard, relative to the difference in benefit.

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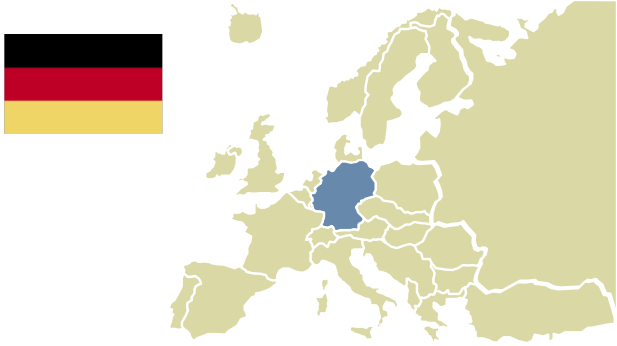

Implementation and use of innovations in the outpatient sector (SHI)

- **Internal evidence - statements**
  - Together with the publication of the discussion theme, professional societies, experts, patient representatives, associations, manufacturers and the interested public are called on to make statements
  - These statements represent the practical experience of physicians and other users (“internal evidence”) and are an important complement to the evidence provided by studies
  - All statements are systematically evaluated and documented
  - The IQWiG too has established a statement procedure in the context of benefit evaluation
  - Aside from the benefit and the risk-benefit evaluation, the necessity and cost-effectiveness are important in reaching a decision
  - Benefit and medical necessity are evaluated across all sectors
  - Sector-specific necessity and cost-effectiveness are examined in the health care context
  - Assessment of the necessity includes the relevance of the medical problems, the spontaneous course of the disease and the availability of diagnostic and therapeutic alternatives.

Decision-making of the Federal Joint Committee (Gemeinsamer Bundesausschuss - G-BA)

Application – from the sessions organisations, sickness funds or patient associations

Announcement of assessment procedure and possibility to participate via comments

Systematic search of literature, assessment of benefit and harm, performed either by IQWIG or by G-BA working groups

Appraisal – assessment of benefit, necessity and cost/benefit relation

Decision of the G-BA board

Possible conclusions after benefit assessment

Permission or confirmation as service for the SHI care

Exclusion as service for the SHI care

Suspension of assessment until new evidence is provided

New possibility of testing potentially beneficial examination and treatment methods by the G-BA

- The Federal Joint Committee has got the right to pass guidelines for testing examination and treatment methods whose benefit has not yet been sufficiently proved, but which show potential as a treatment alternative.
- This possibility is anchored in the SHI care structure law (GKV-Versorgungsstrukturgesetz, abbreviated VStG) in the new section 137e of the German Social Code, Book Five (SGB V).
- A request can be submitted by
  - the manufacturer of a medical product whose use significantly depends on the application of a new examination or treatment method
  - Companies that are not providers of a new method, but that have an economic interest in its provision by the statutory health insurance providers
- This new testing possibility starts, when the new guideline of the G-BA has been approved by the German health ministry (probably during January/February 2013)

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Structural Innovations in the Inpatient Care System

Sectors	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	Use: open Reimbursement: NUB	Use: open Reimbursement: NUB	**Legislative Framework**
Outpatient Care	G-BA	G-BA	Legislative Framework
Integrated Care / special outpatient contracts	Rules of SGB V	Rules of SGB V	Rules of SGB V

Structural Innovations in the Inpatient Care System

- Structure and financing of inpatient care in Germany is intensively regulated by law
- A hospital which will treat SHI patients (and will get reimbursement from the SHI) has to be a part of the hospital plans of the respective state (Bundesland), in which it is situated
- In most of the German states the hospital plan (which has to be passed by the state parliament) contains also the different departments of every hospital, which is part of the hospital plan, and the numer of beds for every hospital department
- In some of the German states the hospital plan contains also regulations about the minimum personell of hospital departments
- Changes in the inner structure of a hospital (for example closing down a department, changing the number of beds in a department or opening a new department), which is part of the hospital plan of a state, have to be discussed with the hospital planning authority of the respective state
- Also cooperations between hospitals need an agreement with the planning authority
- Thus, innovations in the structure of hospitals (e.g. implementation of a joint emergency department) often need an agreement with the planning authority of the state

Structural Innovations in the Outpatient Care System

Sectors	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	Use: open Reimbursement: NUB	Use: open Reimbursement: NUB	Legislative Framework
Outpatient Care	G-BA	G-BA	**Legislative Framework**
Integrated Care / special outpatient contracts	-	-	Rules of SGB V

Structural Innovations in the Outpatient Care System

- Structure and financing of outpatient care in Germany is also intensively regulated by law
- The regulation also defines the organisational and company form in which physicians can work in the outpatient sector
  - The Social Law Book V (SGB V) allows 4 different forms of outpatient doctor‘s practices:
    - Doctor‘s practice with a single physician (Einzelpraxis)
    - Doctor‘s practice with several physicians (Berufsausübungsgemeinschaft)
    - Side practice (subsidiary) of a doctor‘s practice (Filiale or Zweigpraxis)
    - Medical treatment center (Medizinisches Versorgungszentrum - MVZ)
- The doctor‘s practice always has to work in the juridical form of a self-employed physician
- The MVZ is the only form which also allows other juridical forms (e.g. GmbH or GbR, but since 2012 not AG) and can be founded and owned by others than physicians (today mainly hospitals)
- The medical head of an MVZ has to work in the MVZ
- Thus, structural innovations in the outpatient sector in principal are very difficult to realize without change of the social law book V

Structural Innovations: Integrated Care and Special outpatient contracts

Sectors	Pharmaceutical Innovations	MedTech Innovations	Structural Innovations
Inpatient Care	Use: open Reimbursement: NUB	Use: open Reimbursement: NUB	Legislative Framework
Outpatient Care	G-BA	G-BA	Legislative Framework
Integrated Care / special outpatient contracts	-	-	**Rules of SGB V**

During the last ten years two central structrural innovations were introduced into the German health care system: Integrated Care and Special outpatient contracts

Integrated Care Contracts:

- New provisions for so-called integrated care (paragraphs 140 a–h, Social Code Book V) were introduced as part of the Reform Act of SHI 2000
- The aim of these provisions was to improve cooperation between ambulatory physicians and hospitals on the basis of contracts between sickness funds and individual providers or groups of providers belonging to different sectors
- With the SHI Modernization Act, in force from 2004, sickness funds got the right to deduct 1% of the resources for ambulatory physicians and hospital care once integrated care contracts have been concluded
- Integrated care contracts have to involve care givers from different sectors or at least different categories of providers within a sector
- Integrated care requires that sickness funds negotiate selective contracts with single providers or a network of providers, i.e. physicians, hospitals, rehabilitative institutions
- The separation of additional money for integrated care ended with the introduction of the new health fund and the new risk adjustment system on January 1st 2009
- At that time in Germany existed about 6.200 integrated care contracts with more tghat 4 Mill. insured people within the SHI with a financial volume of about 800 Mill. Euro (no newer statistic available)

Special outpatient contracts:

- Since 2004 the social law (§73c SGB V) contains the possibility for the SHI for special outpatient contracts outside the normal contracts which always contains all outpatient physicians and all SHI companies
- In addition every SHI has to signe selective contracts with General Practitioners
- These selective contracts are used especially for the realization of innovative care models
- Used by the AOK Baden-Württemberg
  - The AOK Baden-Württemberg has 4 such selective contracts (Cardiology, Gastroenterology, Psychiatry/Neurology and Psychotherapy, Intravitreal operative Drugapplication – IVOM)
  - In addition AOK Baden-Württemberg signed the first selective contract with GPs
- The participation in these selective contracts is not compelling: physicians and patients have the right to participate, but also the right to deny.
- These selective contracts also give the possibility to depart from many of the rules of the social law book V; e.g. the partners can contract special reimbursement rules, but also special quality requests

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What can Sweden learn from Germany?

- Germany has a healthcare system with diversity and a multitude of providers – both private and public
- The country introduced an all embracing DRG system a few years ago. The objective with the reform was to meet the demographic and technological challenge to allow the healthcare consumption to increase, while keeping the expenditures constant in portion of GDP.
- Already when the system was designed, it was understood that emphasis on productivity would reduce the room for innovation. Therefore, entry points into the healthcare system for innovative solutions were created – in the form of special reimbursement structures in the inpatient as well as outpatient sector.
- The most important lesson that Sweden can learn from Germany is that there are ”good” and ”bad” costs in healthcare – and that the management of these can be incorporated into the reimbursement system.
- Sweden should consider establishing a national **reimbursement method for innovative solutions** – preferably incorporated into the DRG system
- The German **integrated care contracts** are useful for innovative healthcare services or technologies that are integrated with services. They can be used to establish new pathways, treatment of chronic patients etc, in situations where innovation needs to cross barriers in the healthcare system.

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France

The healthcare system in France has been harmonised

Financing of the French health care system

Who pays?

Taxation

- The 'general social contribution' (CSG), 5.25% of gross salary accounts for a third of the health insurance funds' revenues
- Taxes paid by pharmaceutical firms (based on sales and promotional expenditure)
- Specific taxes on tobacco, alcohol. These taxes are allocated to the main health insurance fund (the general scheme covering 84% of the population) and account for 3.4% of its revenue
- The CSG is proportional to income, but the lower rate applied to benefits makes it progressive.

Social health insurance contributions

- Contributions are regressive for self-employed people and farmers, but proportional for salaried workers
- Rates are set by parliament through the annual Financing of Social Security Act.
- Non-contributing people are funded from the global pool of social health insurance revenues.

Voluntary health insurance

- Rates depending on the type of insurer (commercial insurers, non-profit mutual associations or non-profit provident institutions) and type of policy
- Salaried workers purchase VHI through their employers (55% of policies) or they may be purchased on an individual basis.

Co-payments

- May be significant
- Relief by exemptions or insurance
- Upfront payment

Out of pocket payments

Who collects the money?

Taxes

- Taxes to fund health care are national. There is no funding of health care by local taxes.
- Tax rates are set by parliament in the annual Financing of Social Security Act.
- Taxes are earmarked

Social health insurance contributions

- The three main health insurance schemes cover 96% of the population
- General scheme covers salaried employees in commerce and industry and their families (84% of the population) and CMU beneficiaries
- Agricultural scheme covers farmers and employees (7%)
- The scheme for non-agricultural self-employed people (5%)
- Small schemes for certain categories (for example, miners, seamen)
- The population has no choice of insurer. All residents are automatically affiliated to a health
- Insurance scheme on the basis of their professional status and place of residence.

Co-payments

- Outpatient care is paid upfront and then partially reimbursed

How is the money spent?

Expenditures

- Total HC expenditure EUR 220 billion or 11.8% of GDP:
  - Public health insurance: EUR 167.1 billion
    - Inpatient: 46.3%
    - Outpatient: 43.6%
    - Medical-social: 9.5%
- Public expenditure accounts for 7.7 % of GDP and private expenditure for 2.3%.
- Increase in the health insurance schemes' expenditure defined every year.
- This target (the Objectif national des dépenses d'assurance maladie; ONDAM) is split into four sub-budgets (public hospitals, private for-profit hospitals, ambulatory care and institutions/services for the elderly and the disabled)

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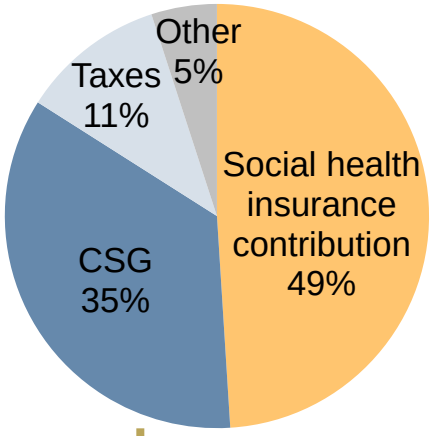
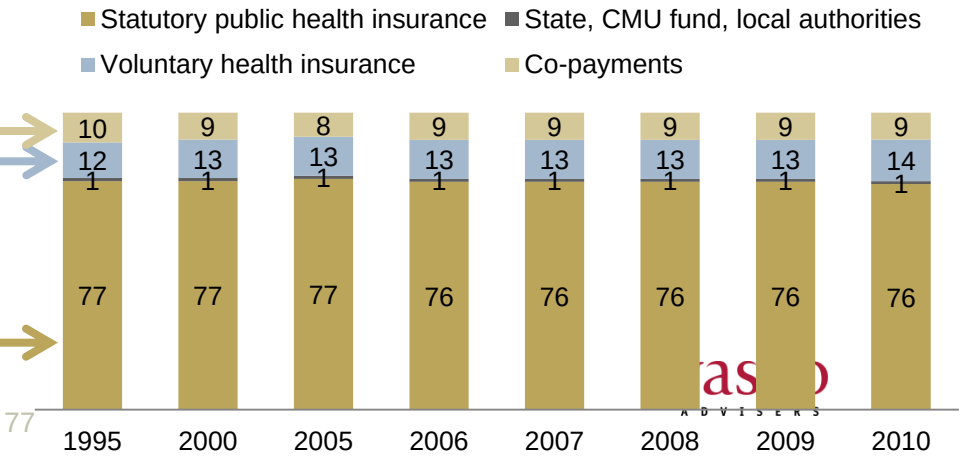
Out of pocket payments

2010 Health insurance funds' revenues



Evolution of the financing structure of health expenditures in percentage

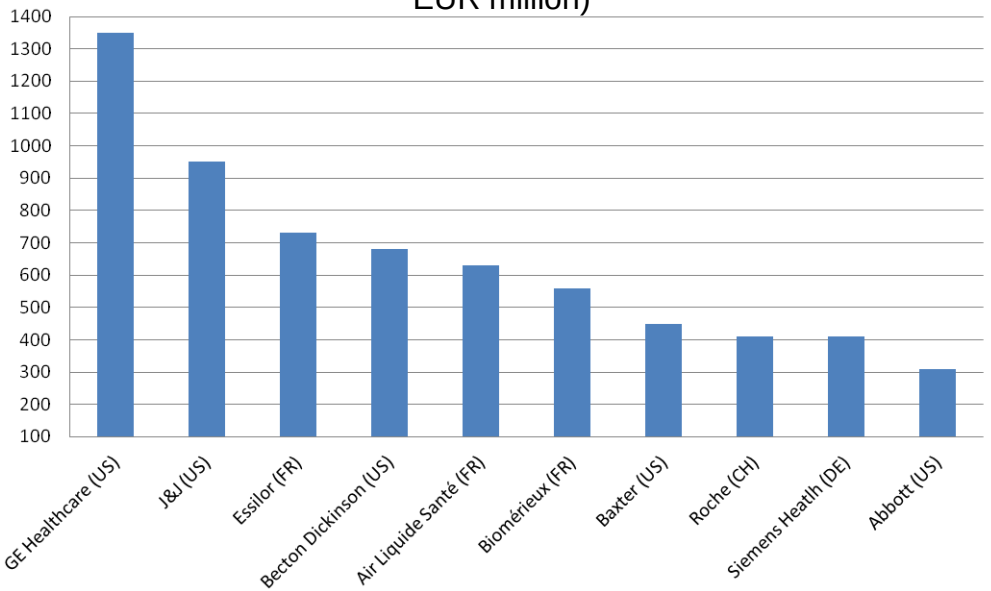


1. Medical Devices

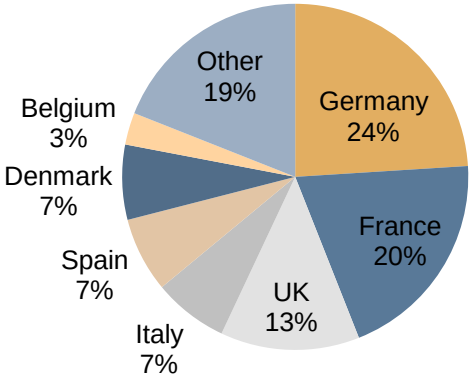
The French medical device industry lacks large exporting French firms 94% of the sector is made of SMEs and start-ups

- The European market represents 30% of the global market with a growth of 5% per year
- The French market represents EUR 19 billion in 2009. It is the 4th biggest market after the USA, Germany and Japan.
- France's trade balance in deficit in the medical device sector represents EUR 700 million
- The reimbursed medical devices represent 43% of the French market

Biggest providers of medicaldevices in France (revenues in EUR million)



The European medical device market (2009)



Hospitals' combined purchasing strategies make it difficult for SMEs to access the French devices' market

- No specific problems for SMEs to access the outpatient market
  - 80% of the 20,000 pharmacies' supplying in medical devices shared by 7 wholesalers
- The inpatient market, however, is difficult to access by SMEs
  - Concentration strategy to increase bargaining powers
    - Example: In the Ile-de-France region, 2 central purchasing agencies manage more than EUR 450 million of medical devices / Objective 2013: 600 million
  - Hospitals' call for tenders concern important volumes of devices only
- The European Commission recommends to use the "pre-commercial public procurement" procedure (already used in the UK)
  - Public purchasing of innovative medical devices not yet available on the market
  - The public purchaser has the right to exploit the results commercially and benefit from discounted purchasing costs once the product is on the market.

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The French Medical Devices Market: high innovation potential but declining sector

- Innovative SMEs
- High-level scientific research
- Products with strong added-value
- Historic technological breakthroughs:
  - Recent successes : CoreValve, Stentys, Mauna Kea, SuperSonic Imagine, Spinext, Ipsogen

- Concern regarding the lack of French global medtech companies that may support and providea harbour for SMEs:
  - Foreign multinationals acquire French innovative SMEs and start-ups
  - Strong resentment against American companies among interviewees:

Stronger sentiment than in other European countries

« Technology watch becoming industrial espionage » A renowned surgeon/researcher

« Rogue behaviours » A SME's CEO

  - On a long-term basis: risk of decreasing scientific and industrial know-how in the French sector

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The reimbursement process: a variety of public actors

- The **National committee for the evaluation of medical devices and health technologies (CNEDiMTS)**, the specialist committee of the French National Authority of Health (HAS), gives a guidance on the requests for inclusion or renewal of inclusion of devices on the LPPR (List of products and services qualified for reimbursement)
  - Inclusion on the list is for a maximum duration of 5 years in a specific indication.
  - For a new device, the guidance of CNEDiMTS is based on assessment of medical benefit and, if the latter is sufficient, on the assessment of added clinical value (ACV).
  - Assessment:
    - of the risk/benefit ratio
    - of the role of the device within therapeutic strategy
    - of its benefit to public health

- The reimbursement tariff is then negotiated between the **economic committee on healthcare products (CEPS)** and the manufacturer. The CEPS is an inter-ministerial committee (Ministry of Health/Research/Industry) that sets prices for drugs and devices, taking into consideration the medical-economic evaluation of the CNEDiMTS.

- The **Committee for the evaluation of medical procedures (CEAP)** assesses the medical procedure associated with a new device in order to include a mew medical act on the Joint classification of medical procedures (CCAM). The CEAP generally assesses requests for the inclusion that are made by external bodies like the national Association of Health Insurance Funds (UNCAM), the learned societies etc.

The average time necessary to get a device reimbursed is long: 2-5 years

HTA
Evaluation of the medical benefit by the CNEDiMTS (HAS)

→ Recommendation

If the added medical benefit is sufficient, theCEPS decides the reimbursement tariff based on the recommendation

The new device is added to the List of reimbursed devices

LPPR

•*Outpatient:* the new device is reimbursed directly to patients

• *Inpatient*:
- The device is included in the GHS
- Expensive devices are excluded from the GHS payment system and reimbursed additionally based on hospitals' real costs

There are 2 options to get an innovative devices reimbursed: either to get the device itself reimbursed (LPPR list), or to get the associated medical act reimbursed (CCAM list)

HTA of a Non-Existing Act Manufacturer and learned society request evaluation from the CEAP (HAS)
→Recommendation

The UNCAM decides the reimbursement tariff based on recommendation

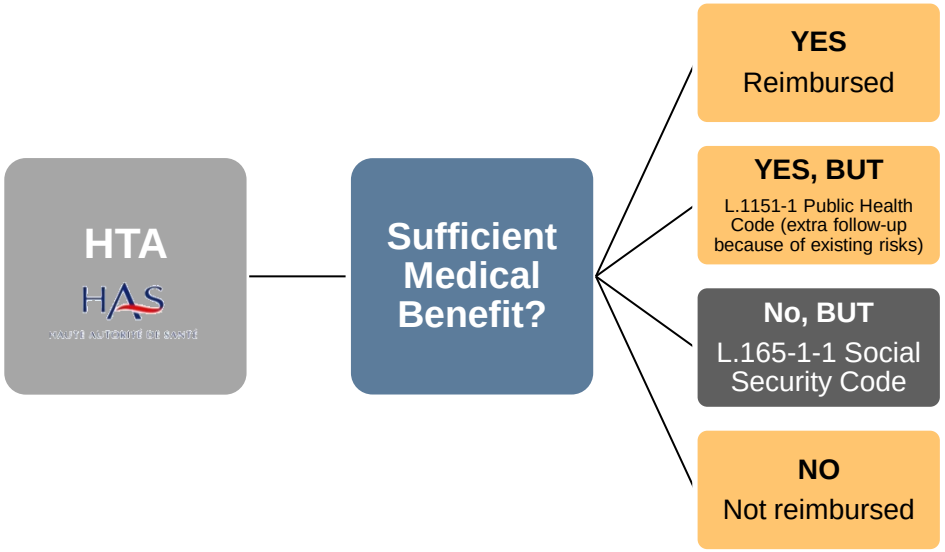
The new Medical Act is addedon the Reimbursed Acts List

CCAM

T2A: the procedure is included in the GHS reimbursement

Shortening the reimbursement process of innovative products/devices/procedures: the “fast-track” procedure of the Article 165-1-1 of the Social Security Code

- In 2009 a new procedure was created to accelerate the reimbursement process of innovative products, difficult to evaluate in terms of « expected medical service »
- Temporary and limited reimbursement while waiting for completementary results to evaluate the innovative product, procedure or device.
  - Recommendation of the HAS
  - Decision of the Ministry of Health
- 3 innovative technologies were selected by the Ministry of Health through this procedure in December 2011: 2 medical devices and one therapeutic procedure. One year later, protocols are currently under review by the Ministry.
- Only for exceptionnally innovative products. It does not solve the general problem of the long and unpredictable reimbursement procedures mostly due to the lack of clear and product-specific guidelines of the HAS.



« The medical device industry warmly welcomed the implementation of this fast track procedure, which is more in line with the industrial cycles of development ’
A representative of the association of the medical device industries

Shortening the reimbursement process of innovative devices/drugs: the “fast-track” procedure of the Article 165-1-1 of the Social Security Code

Definition of the research question according to the missing data
Identification of innovative techniques which can be eligible to the Article 165-1-1 procedure

Prioritisation and pre-selection of innovative techniques
Taking into consideration the research question, the expected public health innovation and the relevance of the study

Industry and / or learned societies

Proposition of a protocol established with a scientific committee
Length of the study, targeted population, participating medical centres, practical considerations regarding the use of the technique, costs identification…

Protocol Validation
Feasibility study

Reimbursement conditions
- Tariff setting
- Definition of payment structures to medical centres
- Création of a GHS/specific coding for the realisation of the study

Final agreement between the industry/learned societies and the Ministry of Health on the research protocol and the reimbursement conditions

Medical Devices: the long and costly process of medical trials

- According to the report (Oct 2012) of the Centre d'Analyse Stratégique (public think tank), the main issue for SMEs and start-ups is the lack of clear guidelines regarding the clinical trials and the lack of dialogue possible between SMEs/start-ups and the competent authorities (HAS)

> *"The lack of product-specific guidelines regarding clinical trials remains the main issue for SMEs specialised in the medical device sector today. The HAS does not have clear guidelines like the FDA in the US"*
> Representative of the association of the medical device industry

- Example: The APHP medical devices committee (CODIMS), which assesses the therapeutic relevance of innovated medical device for the French AP-HP hospitals' group (Ile-de-France), deplores the poor clinical relevance of files provided to assess medical devices (wrong comparator, inappropriate ends-points, insufficient follow-up to assess long-term security, small population studied).

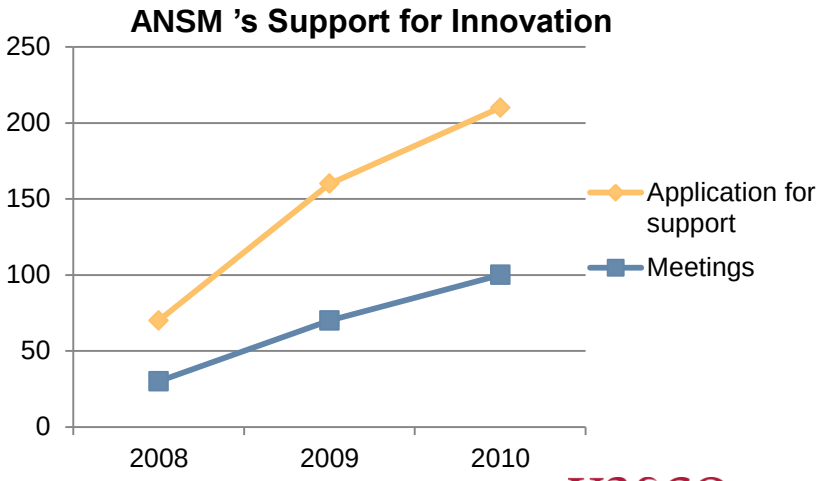
CE Class	Class I	Class IIa or IIb non implantable	Class IIb implantable	Class III
Average cost of clinical trials	N/A	< 1 million €	1-3 millions €	> 3 millions €
Average length of clinical trials	N/A	6 months	1 year	> 1 year

A successful solution to provide administrative, methodological and technical support to promoters of innovative products: ANSM's Support for Innovation

- The ANSM (former AFSSAPS) is the national body in charge of delivering the Market Authorisation (AMM) and of market surveillance for the products already on the market.
- Since 2007, it provides scientific or regulatory support for SMEs/start-ups/academics/hospitals, from the innovative concept to clinical trials.
- Meetings with project leaders, whether academic or manufacturer, at different stages of the development process. In 2010, 97 meetings were organised at the request of developers and 55 national scientific opinions were rendered.
- Special methodological support for clinical trials
  - Pre-submission procedures for clinical trial requests. Sponsors can solicit the ANSM's opinion when preparing their clinical trials, and therefore submit better-quality dossiers.
  - Manage and evaluate the quality of clinical trials

Objectives:

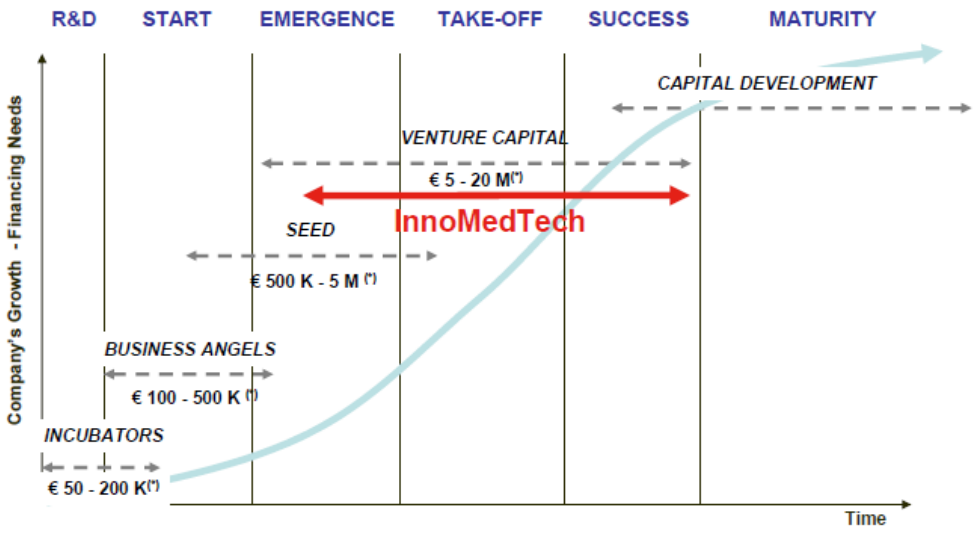
- Anticipate the new risks associated with therapeutic or technological innovation (clinical trials)
- Ensure early market authorisation for new treatments that respond to public health needs
- Support manufacturers in their approaches to innovation by providing them with perspectives from both a medical and a regulatory standpoint



Financing the development of innovative devices: failed attempt to create a public/private fund to finance sector-specific R&D: InnoMedTech

- Replicate the existing InnoBio venture fund specialised in the development of innovative drugs
- Created in 2009, EUR 139 million
  - 37% public money
  - 63% from the pharmaceutical industry

- InnoMedTech. Created in 2012, the fund did not succeed in attracting private contributers (medtech).
- Reasons for failure
  - Lack of large national players, specialised in medical devices, willing to contribute
  - Minimum required contribution to the funds were too high
  - Lack of general interests: freeriding issues. Manufacturers already have in-house R&D



2. Pharmaceuticals

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The French Sécurité Sociale controls the price of innovative drugs

- France defines the price of innovative drugs according to the medical benefit provided by the innovative drugs.
- The interministerial committee, the CEPS, negotiates the price with the pharmaceutical companies according to the calculated level of improved medical service.
- If it is high, the price reference is the one suggested by the phamaceuticals, taking into consideration the price in Germany/UK/Netherlands.
- Tendency towards a better harmonisation of the European prices, with increasing pressures from the European Commission.

« The French regulated price system for drugs remains a major limitation to the uptake and diffusion of the most innovative – and thefore the most expensive – treatments. »

Former R&D director who worked in the pharmaceutical industry for 12 years

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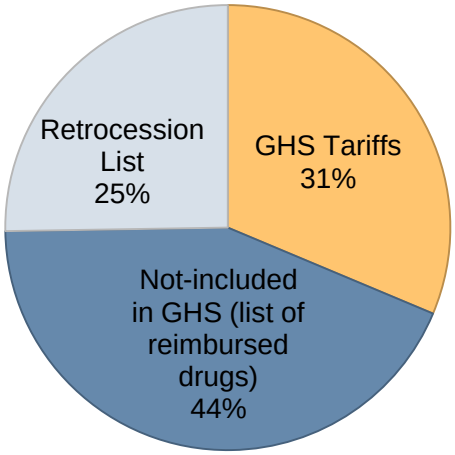
Hospitals carry out more and more outpatient activities which increase the inpatient drug market for outpatients

- Inpatient market represents an increasing share of the total market
- 8% growth of the inpatient market since 1999
- In 2009, it represents 20% of the total French pharmaceutical market. This share doubled in 20 years.

The 3 segments of the inpatient drugs' market
Total: EUR 5.75 billion



The inpatient market is divided into 3 segments:

- Drugs included in the different GHS tariffs
  - High competition, mostly among generics
  - Stable expenditures
- Expensive drugs excluded from GHS (real-cost payments). On the list of Reimbursed Drugs:
  - Mostly innovative drugs
  - Increasing share of total drugs expenditures
- Drugs that hospitals can provide to outpatients : on the “retrocession” list
  - Mostly innovative drugs, no competition with generics
  - Prices fixed by national authorities
  - The 2005 reform stopped the rapid growth of expenditures: drugs made available in private pharmacies

Improved access to innovative drugs: from hospitals' to private pharmacies

- Innovative medications which are exclusively reserved for in-hospital use have become more accessible to outpatients
  - Development of home hospitalisation to cut hospitals' costs
  - Financial agreement between the hospital's pharmacy and pharmaceutical companies: order drugs at discounted price
- Hospitals' pharmacies can order specific innovative drugs for outpatients if no alternative treatments are available
- Some drugs are still available only in hospitals's pharmacies (anti-cancer treatments, immunosuppressive agents) because of special storage conditions
  - Geographic inequalities
  - But becoming increasingly accessible in private local pharmacies since 2005

ATU System: Off label use
Exemptions of market authorisation to place innovative medicinal products placed on the market

- A major challenge for regulatory agencies is balancing the need for rapid access to drugs for new indications against the limited information on their benefit–risk ratio for those uses.

- Temporary Authorizations for Use (ATU) are issued under the following conditions:
  - Innovative products intended to treat, prevent or diagnose serious or rare diseases.
  - There is no appropriate alternative treatment
  - Their effectiveness and security are alleged by existing scientific knowledge

  Objective is to treat, not to investigate (it is not a clinical trial)

- 2 types of temporary authorization: nominative ATU (for one patient) and cohort ATU (for a group of patients).
  - Since 1994, thousands of patients with serious disease conditions benefited from innovative treatments which received their market authorisation months after.

- Availability 10-12 months on average before MA
- In 2010, more than 240 drugs have been made available by the ANSM through this procedure and about 15,000 patients were treated under nominative ATU.

- In 2011, the ANSM delivered more than 25,000 nominative ATU for 18,000 patients (30% children). 460 refusals.
- In 2011, 15 of the available drugs in ATU obtained the market authorisation.
- In 2011, 18 cohort ATU were submitted: major therapeutic innovations have been made available months before receiving the market authorisation (tritherapy of hepatitis C, targeted therapy of the metastatic melanoma.)

- Cancer :
  - In 2011, 31 products were authorised for 3000 patients with nominative ATU
- Rare diseases :
  - 70% of the authorised products were available through ATU beforehand
- It was the case for all new AIDS medicines

Temporary Recommendations for Use (RTU)
Off label prescribing

- Since May 2012, the ANSM has the ability to **regulate the prescription of drugs** not authorised on the market. Only if:
  - there is no appropriate alternative treatment with an market authorisation or a cohort ATU for this specific indication
  - the risk / benefit ratio of the drug is deemed favorable, especially regarding published scientific evidence on efficacy and safety.
  - RTU is a regulatory process for temporarily supervising the prescribing of drugs for indications for which they are not yet licensed. This is a temporary measure not exceeding 3 years.
  - Follow up of patients, data collection and reporting to ANSM

3. Financial incentives and reimbursement systems

A long way to go from innovation to reimbursement. The difference between medical devices and drugs

Medical Devices	Drugs	Medical Acts
CLINICAL TRIALS		
Industry	Industry	Teaching hospitals and health professionals
MARKET AUTORISATION		
CE Marking AFSSAPS→ANSM Market surveillance	EMA Efficacy and Security AFSSAPS→ANSM Delivers Market Autorisation AMM	
HTA / EVALUATION OF THE MEDICAL BENEFIT		
HAS HAUTE AUTORITÉ DE SANTÉ CNEDiMTS	HAS HAUTE AUTORITÉ DE SANTÉ Transparency Commission	HAS HAUTE AUTORITÉ DE SANTÉ CEAP
COVERAGE DECISION : PRICING		
CEPS after negotiations with manufacturers	CEPS after negotiations with the pharmaceutical company UNCAM Reimbursement Rate	UNCAM Tariff and Reimbursement Rate for Medical Acts
REIMBURSEMENT BY THE STATUTORY PUBLIC HEALTH INSURANCE		
Ministry of Health List of reimbursed medical devices	Ministry of Health List of reimbursed drugs LPPR	UNCAM List of reimbursed acts

The evaluation of new products by the HAS: the 2 types of Added Clinical Value

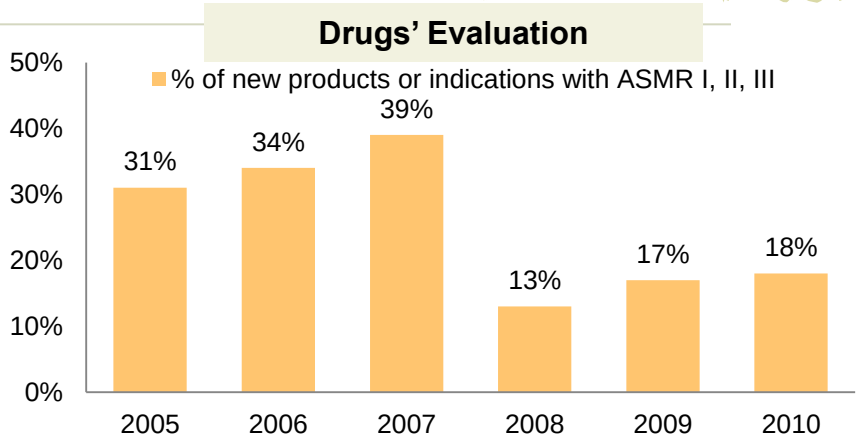
- SMR: Non-comparative approach. The impacts of the innovative product on the pathology.
  - Is it in the public interest to reimburse this product?
  - Advantages provided by the new product to the patient: risk/benefit, efficiency…
- ASMR : Comparative approach.
  - Advantages of the product compared to alternative treatments
  - Quantify the improvement of the medical service
- This medical-economic evaluation will affect the reimbursement tariffs
- Most drugs are covered at a rate of 65%, but this varies from 100% for non-substitutable or expensive drugs to 15% for drugs judged to have a low medical benefit.
- Taking into account the respective weight of the different types of eligible drug consumed and the proportion of expenditure fully reimbursed (that is, without any contribution from the patient), the average rate of reimbursement for drugs is estimated to be 73%.

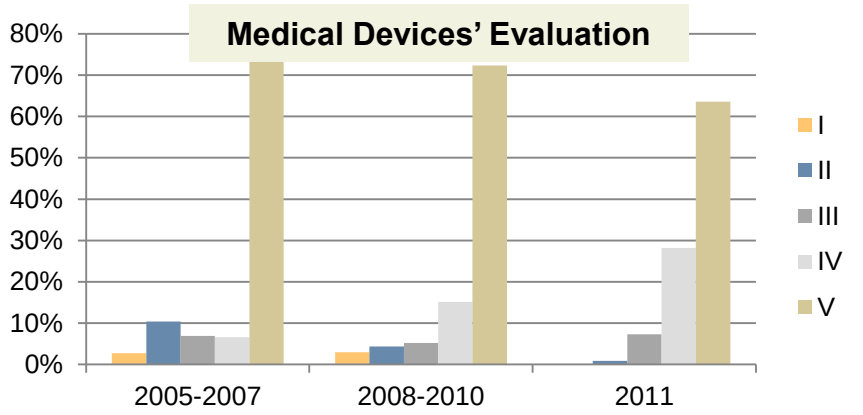
Drugs' Added Clinical Value	Reimbursement Tariffs
Irreplaceable drugs	100%
Drugs with major medical benefit	65%
Drugs with moderated medical benefit	30%
Drugs with insufficient medical benefit	15%

Devices' added clinical value	
I	Major innovation
II	Important innovation
III	Moderated innovation
IV	Minor innovation
V	No innovation

The evaluation of new products by the HAS. Evolution of calculated medical benefit

- The vast majority of drugs are covered at a 65% rate. In 2009, among the 109 new drugs reviewed by the Transparency Commission, the vast majority of new drugs were evaluated with major or considerable therapeutic value (90) while only 10 were deemed insufficient
  - SMR judged sufficient in more than 90% cases
  - BUT No clinical added value for more than 60% of new drugs/new indications: decreased proportion of drugs with “significant” added value (ASMR: moderate to major, I to III)
- Following the creation in 2010 of the 15% rate of coverage for drugs with low SMR, the reimbursement rate of 171 additional drugs has been lowered from 35% to 15%.
- HAS: 84 days was the average time for issuing guidance in 2011





Some particularly expensive drugs and medical devices are excluded from the GHS payment system and reimbursed additionally based on hospitals' real costs

- **Additional reimbursement based on the price the hospital pays only if three criteria are fulfilled:**
  - high cost and non-generalized use
  - thus introducing heterogeneity within the GHM costs
  - inscription on a list published by the Ministry of Health

Objectives:

➔ prevent patients or treatments selection based on financial criteria instead of medical ones

➔ guarantee an equal access for all patients to the most innovative care according to their needs

Reminder:

➔ drugs + medical devices are included within the GHS tariffs in principle

➔ are thus introduced in the GHS tariffs when they don't fulfill anymore the criteria above

The impact of T2A on innovation

Activity-based financing

TARIFFS
PER HOSPITAL STAY
(GHS and supplements)

Common or equipment-related devices are included in GHS
OR the associated medical act included on CCAM list

TARIFFS
PER MEDICAL PROCEDURE
(ambulatory, outpatient, emergencies, organ retrievals)

REAL COSTS PAYMENT
(expensive drugs, innovative medical devices)

Other kinds of financing (lump sum)

ENVELOPE FOR PUBLIC INTEREST MISSIONS AND CONTRACTING PROMOTION

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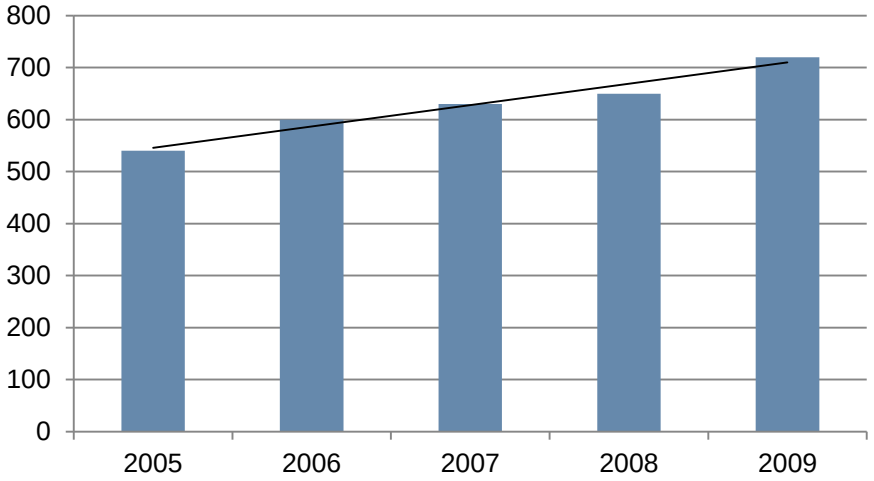
In hospitals, expensive and innovative drugs that are paid in addition to the DRG tariffs are listed on special lists

In public and private hospitals, expenditures related to implantable devices – the most innovative ones, 100% reimbursed - have risen sharply due to the recent technological improvements and the aging of the population, after the increase due to the convergence of the public list and the not-for-profit private hospitals' list of reimbursed devices

Evolution of innovative devices' expenditures (not included in GHS) in public hospitals (EUR Million)



REAL COSTS PAYMENT
(expensive drugs, innovative medical devices)

The list of medical devices to be reimbursed additionally to the GHS tariffs is constantly being reviewed in order to meet the reform's objectives

- Recent attempts at controlling the growth of medical devices' expenditures:
  - Decreasing reimbursement tariffs
  - Negotiations price/volume with companies, price regulations
- But difficult to control, evaluate and rationalise very heterogenous devices
- Difficult to distinguish truly innovative products and simple « marketing improvement »
- Difficult to integrate implantable devices in GHS (Ministry of Health's objective)

REAL COSTS PAYMENT
(expensive drugs, innovative medical devices)

The impact of T2A on innovation

Activity-based financing

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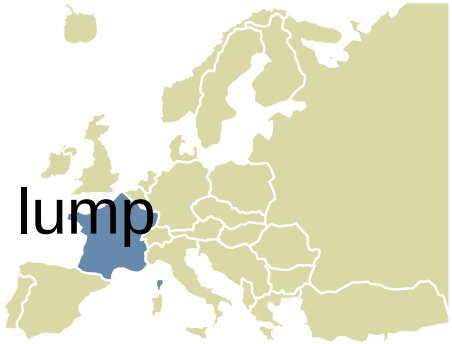


Public support to innovation is financed by the lump sum envelope for public interest missions

Hospital Clinical Research Programme (PHRC)

Annual national and regional thematic call for tender to bid for public grants (Ministry of Health)
Select and finance projects according to national or regional research priorities
Facilitate the transfer of fundamental research to clinical research

ENVELOPE FOR PUBLIC INTEREST MISSIONS AND CONTRACTING PROMOTION

Teaching, Research, Recourse and Innovation lump sums

Support for Innovative and Costly Techniques (STIC)

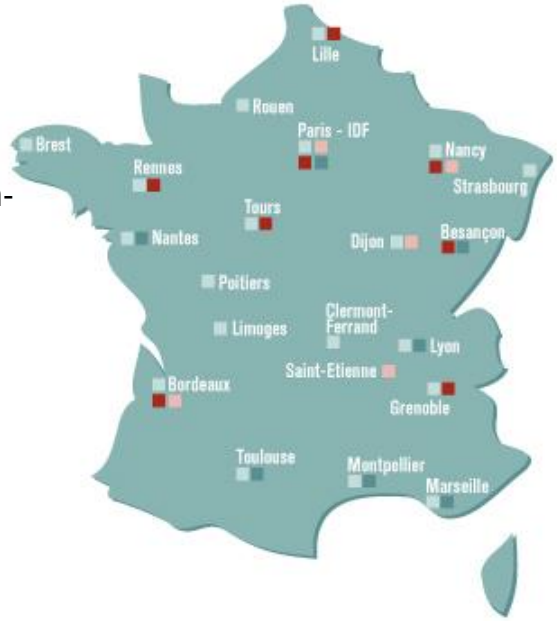
Annual call for tender to bid for public grants (Ministry of Health)
Exclusively concerned with (non-drug) innovations validated by an earlier clinical research phase
Partnership between sponsors and hospitals (only hospitals are eligible). The manufacturers provide devices to hospitals (CE-marking obtained)

The Support for Innovative and Costly Techniques (STIC): a public support programme which contributes to the uptake and the diffusion of innovative devices

- Created in 2000, the STIC finances medical-economic evaluation projects in hospitals.
- Faster uptake of innovative techniques in hospitals and faster reimbursement process.
- Organised by the Ministry of Health (for the non-cancer stream) and by the National Institute of Cancer
- 2010: EUR 11 million of public grants, 95 projects between 2005 and 2011

The STIC programmes facilitate the transfer of new technologies:

- Uptake of innovative products
  - Defribrillator, negative pressure wound therapy…
- Improvement of technical evaluation
- Information sharing between professionals
- Geographical diffusion through the associated medical centre procedure
  - A STIC programme includes partnerships between a leading specialised hospital and associated hospitals willing to develop new techniques



24 CIC-P Plurithématique
11 CIC-BT Intégré en biothérapie
9 CIC-EC Epidémiologie clinique/ essais cliniques
8 CIC-IT Innovation technologi

Financing innovation through the Public Investment Bank : public subsidies, co-financing, loans without collaterals

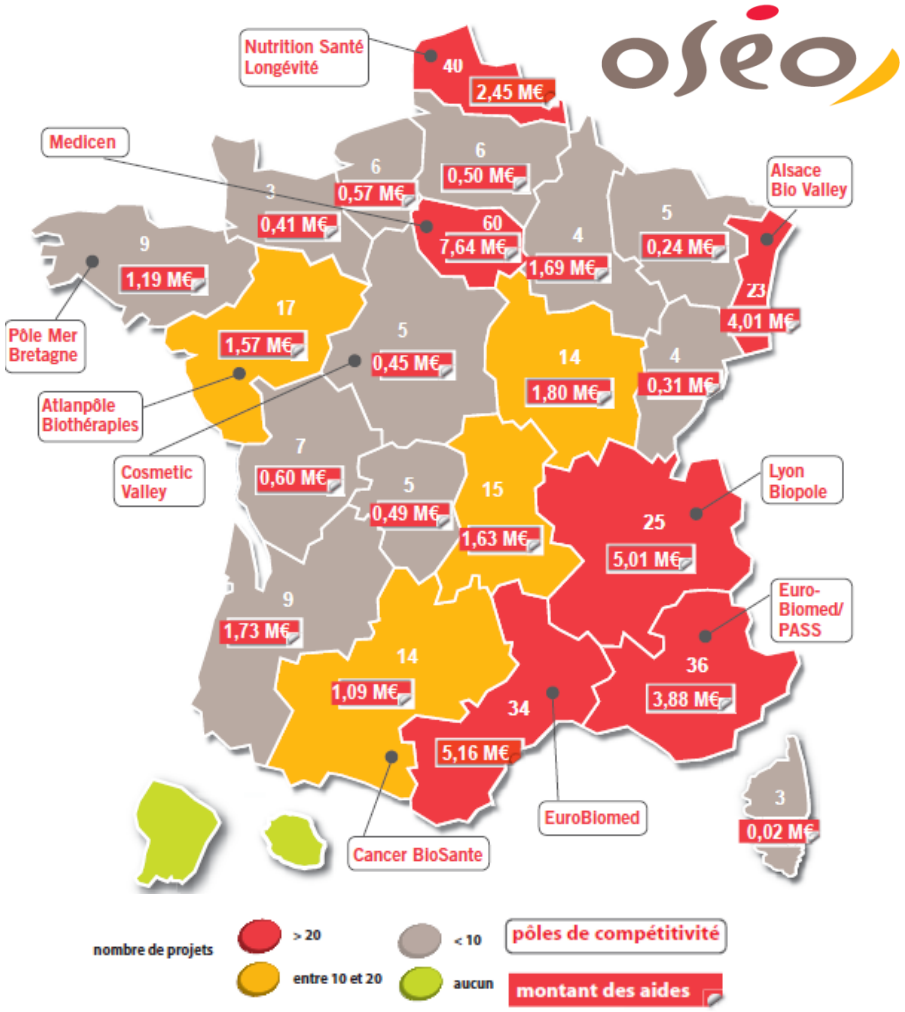
Pharmaceuticals

- 344 projects
- EUR 42.07 million invested
- Average amount per project : EUR 122,000

Pharma-biotech projects are particularly innovative:

56 % of projets and 2/3 of invested funds concerned technological breakthroughs.

58 % of the companies have less than 10 years and 64% have less than 50 employees.



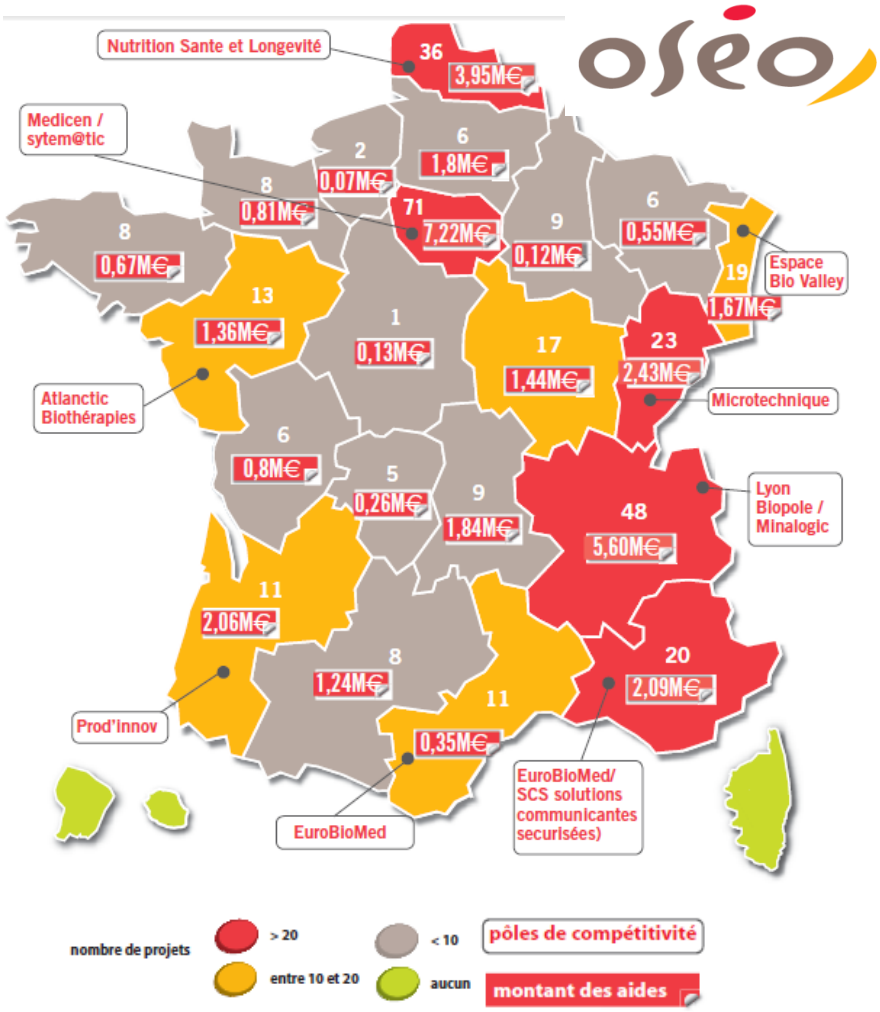
Financing innovation through the Public Investment Bank : public subsidies, co-financing, loans without collaterals

Medical Devices

- 337 projects
- EUR 36.46 million invested
- Average amount invested per project: EUR 108,000

2/3 of the companies have less than 10 years and ¾ have less than 50 employees.

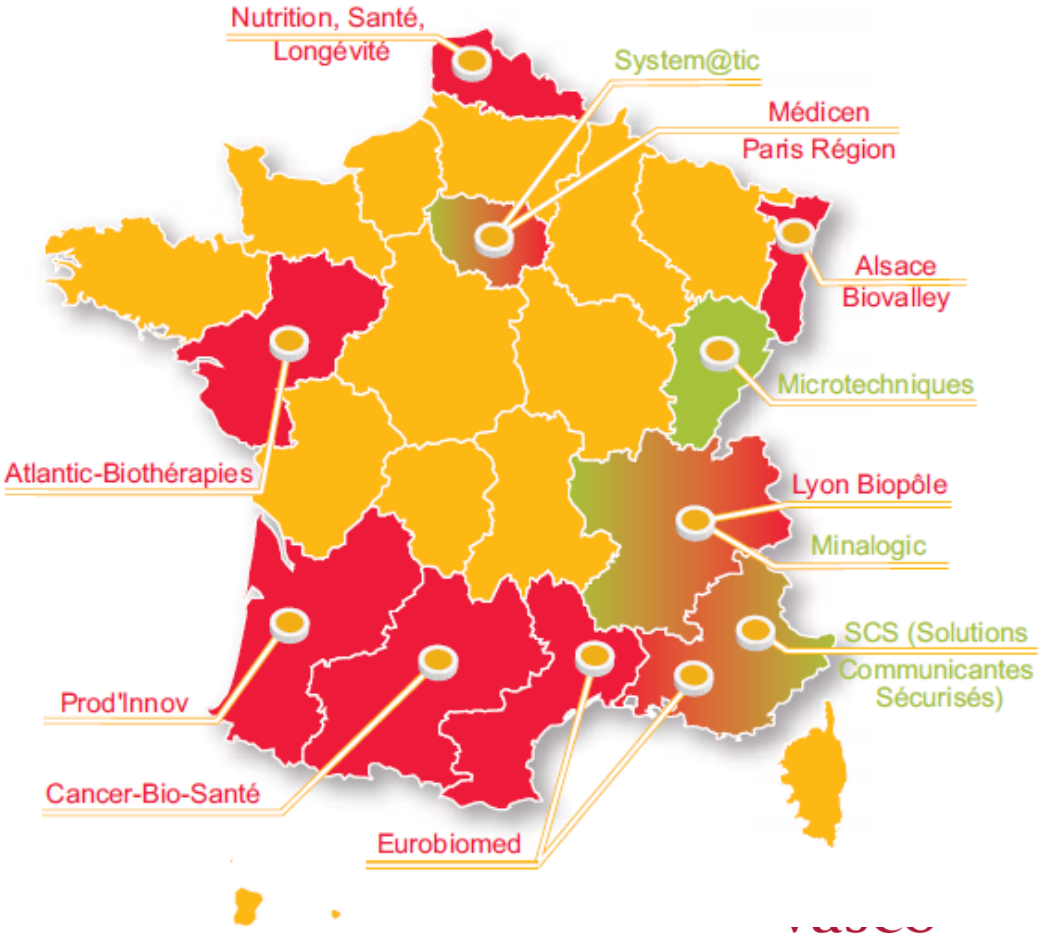
Less projects presenting a real technological breakthrough (23% VS 40% in 2009) but increasing projects presenting incremental innovation.



4. Infrastructures for innovation

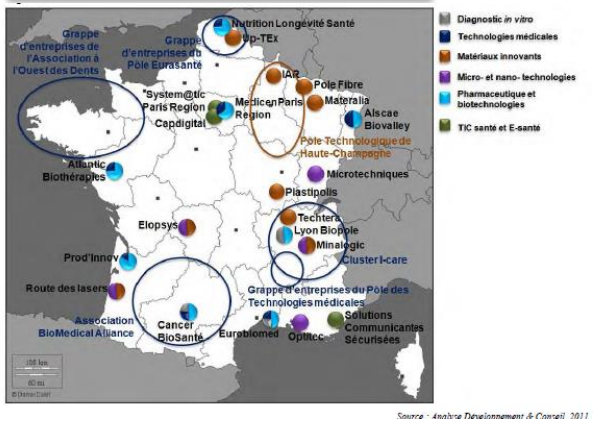
8 clusters specialised in the health sector

- 8 health-specialised cluster (in red)
- Interdisciplinary clusters (in green) contribute more and more to the medical R&D



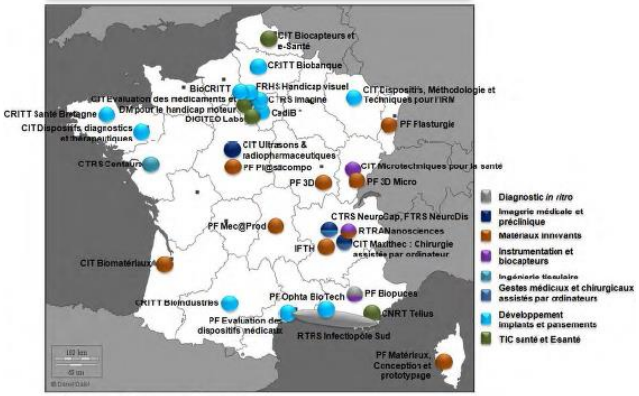
Clusters, technology transfer offices and Clinical Research Centres for clinical trials (medical devices)

Clusters contributing to the R&D specialised in medical devices



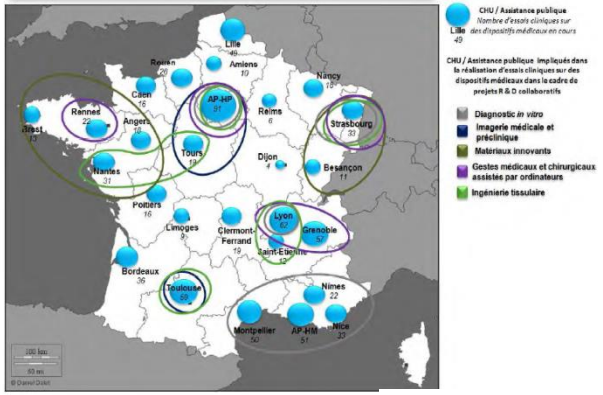
Source : Analyse Développement & Conseil, 2011

Technology Transfer Centres to support public and private research actors (medical devices)



*: Centre de développement et d'innovation en Bioengineering Paris Val-de-Marne

Clinical Research Centres for clinical trials (medical devices)



"There is still no interdisciplinary research centres to test innovative surgery procedures on animals with advanced technology material , which makes clinical trials in surgery difficult to organise. France needs centres such as the CIMIT (Center for Integration of Medicine and Innovative Technology) in the US, a public-private structure including multidisciplinary teams"

A renowned surgeon and researcher

"There is a lack of research centres offering advanced technology material – such as MRI scanners - for research purpose. The waiting queues are long, which makes the clinical trials even longer"

A start-up CEO

Medical Devices' Patenting: less dynamic in France in the last 10 years than in other European countries

Studies by the French government show that France is falling behind in patent applications in the medical device sector.

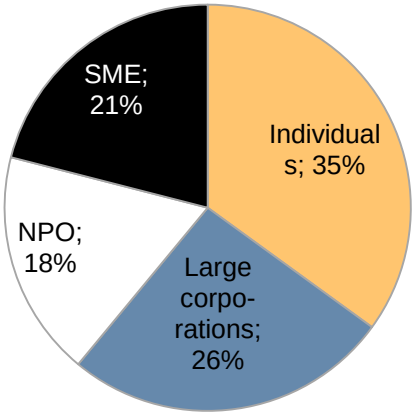
Japan, Germany and Great Britain are all far ahead France in number of patent applications for medical devices.

This is explained by the small number of large, global French medtech companies.

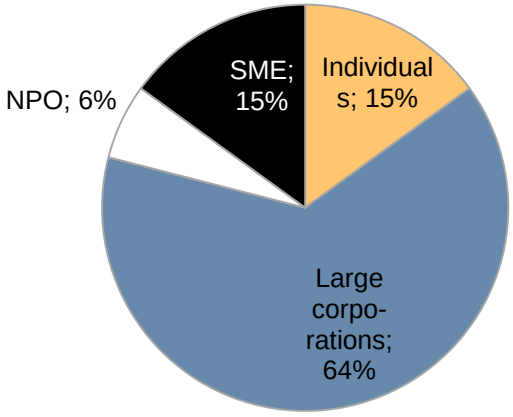
Start-ups creation by public research centres

2010	CNRS	CEA	AP-HP	INSERM	IGR	Institut Pasteur	Institut Curie
Start-ups created per year	27	7	5	4	5	4	1
In the medical sector only	NS	4	20	NS	NS	NS	NS

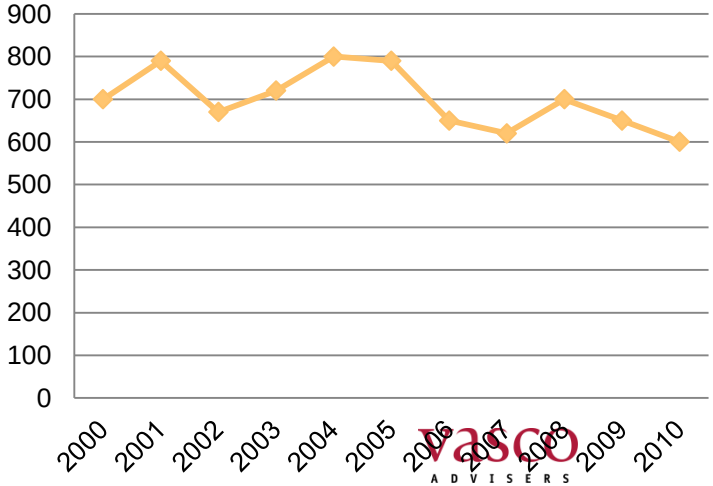
Patent applications medical devices



Patent applications total



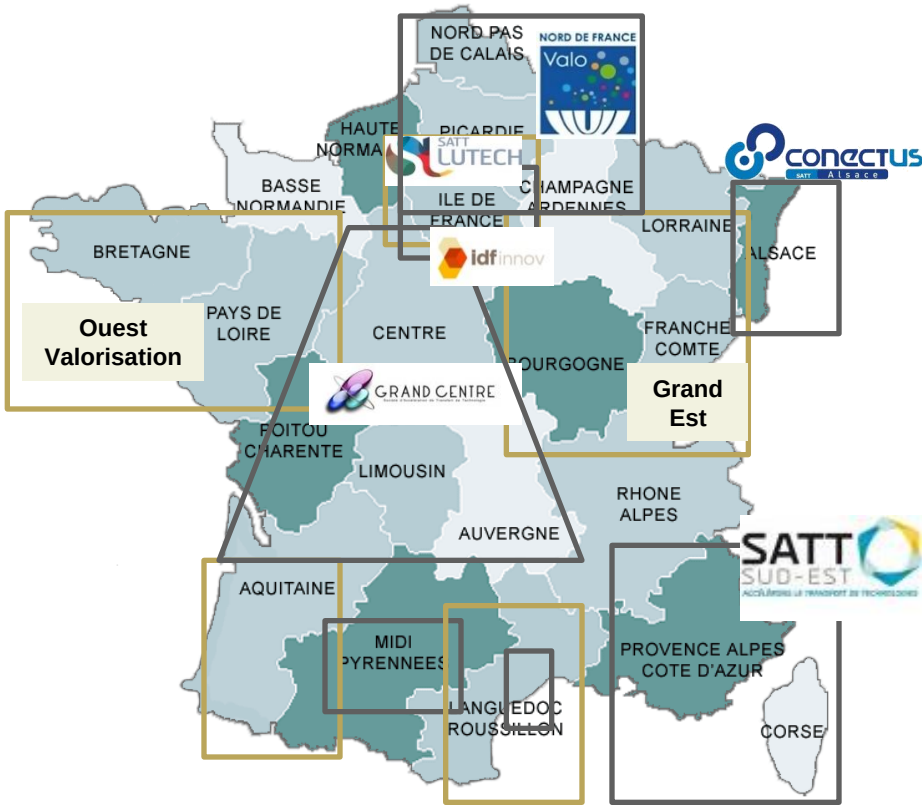
New patents in the medical device sector (except in vitro diagnostic) 2000-2010



New infrastructures for innovation to cope with the fragmentation of public medical research structures: SAAT

- SATT (Accelerating Technological Transfer Structures) are financed by the « Investissements d'avenir » (part of the national stimulus package): EUR 900 million national grants
- **Accelerating research studies and the transfer to industry** (cf. next slide)
- **National public support to finance phases of maturation of inventions and the establishment of proof of concept.**
  - Identified problem: the innovative products developed by the public research centres are not mature enough to be integrated into SMEs. No prototype to demonstrate the added value of the product
  - SATT role: financing projects, so the innovative products reach a sufficient level of development to be able to be integrated in SMEs.
  - Better risk-sharing structure: once the proof of concept is financed, it is easier to raise funds

2011: Creation of the SATT
12 existing SATT today, created in 2011-12



The example of the SAAT Conectus Alsace

- 2006: creation of Conectus, a network including all the research centres (CNRS…), universities, engineering schools and teaching hospitals of the Alsace Region.
- 1er January 2012: Conectus became a SATT
- Since 2006, 12 start-ups have been created, 5 projects were financed (EUR 5.3 million) and 1,100 companies contacted the SATT.
- Stakeholders:
  - Public research centres: 67%
  - National Government: 33%

- Before the creation of the SATT, there were 6 services of *valorisation de la recherche* (research commercialisation) in the Alsace Region. Identified as a limitation to the rapid transfer of research to industry.
- Different stakeholders delegated the management of intellectual property to the SATT (research centres, teaching hospitals, universities etc
- Today: single point of contact, the Conectus Alsace SATT, which has the full competency to manage patents, licenses and industrial contracts. Elsewhere, universities still manage industrial contracts.
- Length of negotiations to define license agreements fell from 9-12 months to 2-3 months: accelerating the transfer of research to industry

conectus SATT Alsace

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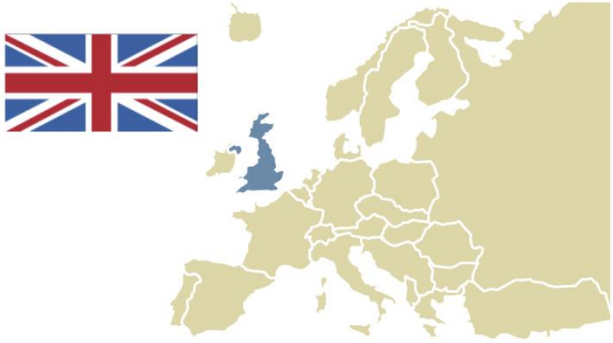
What can Sweden learn from France?

- France has a healthcare system with diversity and a multitude of providers – both private and public
- There is a national reimbursement system, which has been harmonised during the last couple of years to cover all providers, private as well as public
- National recommendations on innovative products are incorporated into the reimbursement system
- However, the average time to get approval for reimbursement is long, compared with Germany or Sweden.
- France has also introduced the Article 165-1-1 of the Social Security Code – a “fast track” for innovations that are difficult to evaluate in terms of expected medical outcome.
- In conclusion: like Germany, France shows that **specific and predictable reimbursement for innovative products** is important, but in terms of implementation we have more to learn from Germany.
- The French experience emphasises a lesson Sweden has already learnt: the importance of having headquarters of global companies in the country. The stakeholders in France point out the lack of global French medtech companies as a main reason for the sector’s decline.

The UK

The healthcare in the UK is going through profound change



The National Health Service (NHS) is the publicly funded healthcare system in the UK

- Established in 1948, the NHS provides preventive medicine, primary care and hospital services to all those “ordinarily resident” in England.
- Health **services in England are largely free at the point of use**.
- Responsibility for publicly funded health care rests with the Secretary of State for Health.
- The Department of Health is the central government body responsible for setting policy on the NHS, public health, adult social care and other related areas.
- **Responsibility for commissioning health services at the local level lies with 151 primary care organizations**, mainly primary care trusts (PCTs), each covering a geographically defined population of, on average, just over 340 000 people.
- In the health care sector, most regulatory activity is independent (self-) regulation through a range of bodies. NHS hospitals are in the process of attaining greater autonomy from the Department of Health.
- Health care professionals have retained a significant degree of autonomy in regulating their practice through their professional associations, although there have been significant changes in recent years to strengthen oversight.

NHS

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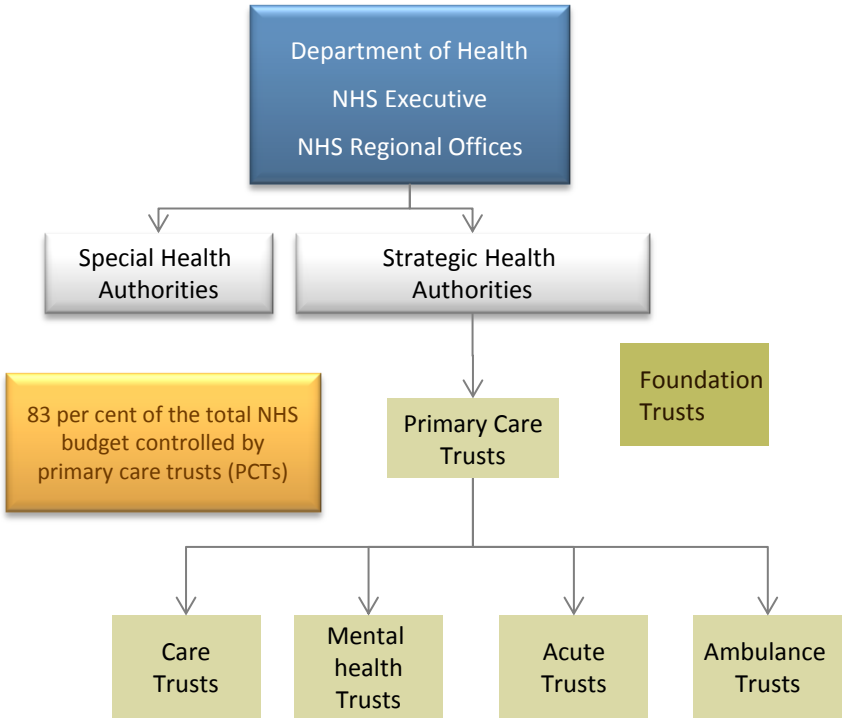
The NHS is underpinned by a set of principles, the core of which is that access to high-quality healthcare must be based on clinical need and not the ability to pay

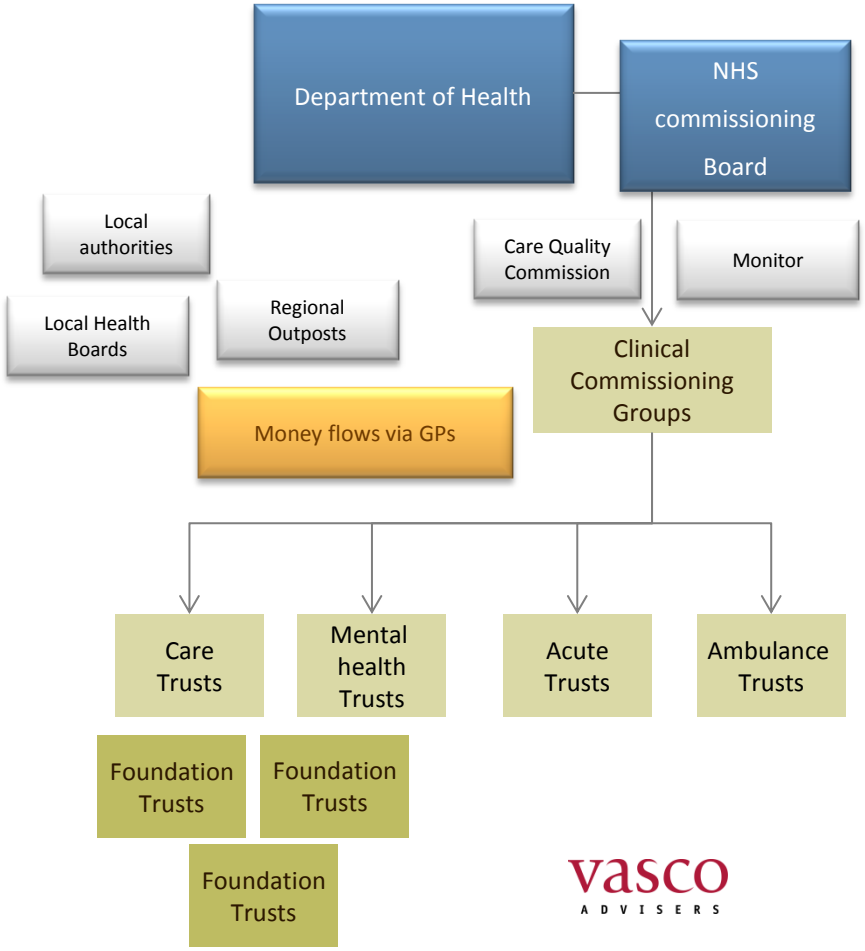
- The NHS is a Single-payer healthcare system, funded through general taxation and free at point of service for consumers
- The NHS in England is the largest of the UK healthcare system by far, employing more than 80% of the labour force (1.4 million people) and delivering healthcare services to a population of 52 million people.
- The NHS in England treats about 3 million people on a weekly basis. There is no geographical discrimination of service delivery for residents of and within the UK.
- In the 2010 Spending Review the Coalition Government gave the NHS relative protection with a 0.1% real-terms annual increase; however this settlement has resulted in extremely demanding productivity targets- namely the 'Nicholson challenge' to generate £20 billion in efficiency savings by 2015.
- The NHS annual 2011/12 budget was of £106 billion. More than 80% of the NHS funding is allocated to the 152 Primary Care Trusts who have thus far acted as the commissioners buying healthcare services from providers and ensuring access to patient care.
- The current legislation underpinning the NHS is the *National Health Service Act of 2006*, but the changes proposed of the *Health and Social Care Bill of 2012*, are already being implemented and transforming the NHS.

Health services in England are mainly financed through taxes

- Primarily **funded by general taxation and National Insurance** contributions.
- **Some care is funded privately** through private medical insurances (PMI), – some user charges, cost sharing and direct payments for health care delivered by NHS and private providers.
- Health **expenditure** in the United Kingdom **has risen significantly in recent years**, with total spending on health care as a proportion of gross domestic product (GDP) increasing from 5.6% in 1980 to 8.7% in 2008.
- Each year, the Department of Health allocates around 80% of the total NHS budget to PCTs using a weighted capitation formula.
- Since 1999, there have been **significant changes to the way in which PCTs pay for health services**, particularly in the hospital sector, with the introduction in 2003–2004 of activity- based funding – developed in England as a system known as Payment by Result (PbR).
- The NHS spends about £1,980 for every man, woman and child in the UK per year
- In 2009–2010, of estimated total NHS current expenditure of £99.8 billion, £88.5 billion (88.7%) was expenditure on NHS bodies (e.g. NHS trusts, GPs, dentists), £9.7 billion (9.7%) was on centrally-managed budgets (e.g. Connecting for Health), and £1.5 billion was on funding personal social services (1.5%); in addition the NHS had a capital budget of £5.5 billion.
- In terms of out-of-pocket payments, while most NHS health care is free at the point of use, some services are either not covered by the NHS and patients must, therefore, pay themselves (direct payments) or are covered by the NHS but are subject to cost sharing, usually in the form of co-payments.
- Most out-of-pocket payments by individuals are direct, with some 41% devoted to over-the-counter medicines, while user charges for NHS services are the largest part of co-payments, accounting for 13% of the total.

Today the PCTs are the main purchaser of healthcare in the UK – tomorrow it will be the GPs - Clinical Commissioning Groups





PCTs reduced from 300 a few years ago, 150 recently, 50 today

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The money flows via the General Practitioners – the objective is increased efficiency and free choice for the patient

Patient

Primary care | **Secondary care** | **Tertiary care**

Clinical Commissioning Groups (GPs)

NHS healthcare providers

Independent sector providers (private for profit and NPO)

NHS spending on outsourced care increases

NHS reforms aim at the private sector playing a bigger role in providing state-funded care

Total NHS spending on the independent sector was estimated at £5.9bn in 2011-12.

6,5% of the £91bn healthcare spending by primary care trusts

Money flow - purchase of healthcare

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Prior to the *Health and Social Care 2012* reforms, the NHS structure consisted of the following major bodies

- **Department of Health:** The Department of Health (DH) is led by the Secretary of State of Health and is directly accountable to Parliament. As the prime health-policy maker, the DH sets the national standards for the NHS in securing care quality and access to healthcare for the nation.
- **Strategic Health Authorities (SHAs):** 10 SHAs have operated at a regional level, providing strategic leadership in planning and delivery of health services, managing capacity and integrating national priorities.
- **Primary Care Trusts (PCTs):** 152 PCTs have been accountable to SHAs and played the critical role of commissioning primary and secondary services from NHS Trusts. PCTs have set their own budget within the overarching budgets of SHAs.
  - Each PCT has overseen an average population of under 330,000.
  - They have been central to the NHS by having control of more than 80% of the healthcare budget.
- **Foundation Trusts (FTs):** FTs are unlike ordinary NHS Trusts, in that they have greater managerial and financial freedoms. They also have the status of being legal, independent, self-governing entities. FTs can raise capital in both public and private sectors within their borrowing limits.
  - FTs are marked by a record of strong governance and financial probity.
  - The Coalition Government has prioritised **the transformation of all NHS Trusts to achieve FT status by 2013/14.**
- **Arm's Length Bodies (ALBs):** Operating at a national level, ALBs are Special Health Authorities meant to support other NHS Trusts. Examples include: NHS Information Centre for Health and Social Care, National Patient Safety Agency, and National Institute of Health and Clinical Excellence (NICE)

The **Health and Social Care Act 2012** will radically overhaul the current NHS structure, realigning accountabilities, organisational boundaries, funding pathways, and incentives in the NHS

- The White Paper '*Equity and Excellence: Liberating the NHS'* published in July 2010, set out its strategy for radically revolutionizing the NHS
- Presented to Parliament in January of 2011, the healthcare bill underwent significant scrutiny and opposition from several professional bodies from the medical community. This led to the government's "listening exercise" in April 2011, which briefly halted the Bill's legislative progress for a month.
- The Bill gained Royal Assent on March 27th 2012, as the Health and Social Care Act 2012, and its revisions are readily being implemented.
- **Clinical motivations** behind the reforms:
  - To increase the autonomy and decision-making powers of the doctors and nurses who, as providers, are closest to comprehend the needs of their patients and their locality.
  - Shifting population demographics towards an ageing population pool, increasingly affected by long-term diseases requiring chronic care;
  - A shift towards a more patient-centred heatlhcare system that enables freedom of choice for the patient and boosts competition among providers.
- **Political and Economical motivations** behind the reforms:
  - As a means to reduce administration and management costs, and its related bureaucratic costs, **the reforms will eliminate two layers of management, namely the PCTs and the SHAs**. This is expected to generating savings of £4.5 billion which would be reinvested in healthcare.
  - The need to find significant efficiency savings as a result of the Nicholson challenge to maintain the sustainability of the NHS.
  - A stronger priority towards innovation to maintain the UK healthcare market's global position in the life sciences industry and provide value for money in healthcare.

Primary Care Trusts (PCTs) have played the critical role of commissioning primary and secondary services for providers in the NHS

- PCTs have set their own budgets and priorities within the overarching budgets and priorities of the SHAs.
- Prior to the reforms, a total of 152 PCTs existed throughout England, each overseeing an average population of 330,000.
- PCTs have thus far controlled 80% of the healthcare budget.
- The Department of Health allocates revenue for NHS services to its PCTs based on:
  - A weighted capitation formula – taking into account population characteristics (ie: size, age, deprivation levels) and unavoidable market forces accounting of variations in costs.
  - Recurrent allocations – previous financial year's allocations adjusted, for example, for any newly devolved central budgets and transfer of responsibilities and their associated budgets between PCTs.
- Its total revenue allocations in 2011-12 were £89 billion.
- The revenue allocations for 2012-2013 were announced to be £91.6 billion, an increase of £2.5 billion, or 2.8%.
  - The weighted capitation formula was not applied for 2012-2013 revenue allocations as all PCTs received a uniform uplift so as to maintain financial stability within the NHS at a time of significant transition.
- This is the last round of allocations made to PCTs as from 2013 onwards, the NHS Commissioning Board would be responsible for the commissioning of resources to Clinical Commissioning Groups (CCGs) while the Department of Health will make grants to Local Authorities for public health needs.
- **The Health and Social Care Act 2012, is calling for all PCTs to be abolished by April 1, 2013.**

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Clinical Commissioning Groups are groups of GPs who, from April 2013, will design and commission healthcare services at a local level

- The NHS is moving from a PCT based model to a CCG based model. A total of 212 CCGs will be established by April 2013, commissioning services for NHS trusts.
- The NHS Commissioning Board will authorise the CCGs in four waves. The first wave consisting of a total of 35 CCGs have already been authorised.

Resource Allocation:

- The NHS Commissioning Board and the DH are working with an independent panel of experts – the Advisory Committee of Resource Allocation, ACRA – to develop a Fair Shares formula on which to base the funding allocations for CCGs.
- The NHS Commissioning Board has devised that the fair shares formula will be based on the number of patients registered to each CCG. It will use patients' diagnosed conditions to assess overall level of need.
  - Birth rates, levels of mental health service use, local market forces raising costs in some areas will be taken into account.
- The NHS Commissioning Board has conceded that it will not be able to allocate funding for CCGs based on a fair shares formula for 2013/14 period.
- Instead, it is currently finalising CCG allocations based on estimates derived from the analysis of 2010-11 PCT baseline spending estimates uplifted to 2013/14 values.

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The new national level bodies overseeing healthcare commissioning and quality are the NHS Commissioning Board, Monitor, and Care Quality Commission

- **NHS Commissioning Board (NHS CB)** will act as the performance manager of the CCGs starting April 2013
- Formally established in October 1, 2012, the NHS CB is a new Special Health Authority operating at a national level. It will allocate resources to CCGs, be the contract holder for primary care, and act as commissioner for specialised services.
- The purpose of the NHS CB will be to effectively utilise an £80 billion commissioning budget to improve patient outcomes. Currently its main priority is the authorisation of CCGs. It will take up its full statutory responsibilities in 1 April, 2013.
- The NHS CB will also take up many of the functions of the PCTs with regards to direct commissioning of primary care health services.
- **Monitor** will act as the independent **economic sector regulator** for the NHS Foundation Trust.
- It will work together with the NHS Commissioning board to **regulate prices** and develop national tariff structures.
- Monitor will **also license providers** of NHS services in England, giving it powers to enforce behaviour such as making trusts and commissioners provide high quality data on pricing and costs of services, **discourage** anti-competitive behaviour, enable integrated care, and support patient choice, and service continuity.
- **Care Quality Commission (CQC)** will regulate and inspect the care quality of NHS trusts. The Act sets out the CQC's functions in assuring safety and quality, and assessing the performance of commissioners and providers.
- All NHS Trusts will have to **register with the CQC** and demonstrate a standard of quality in provision of healthcare services.

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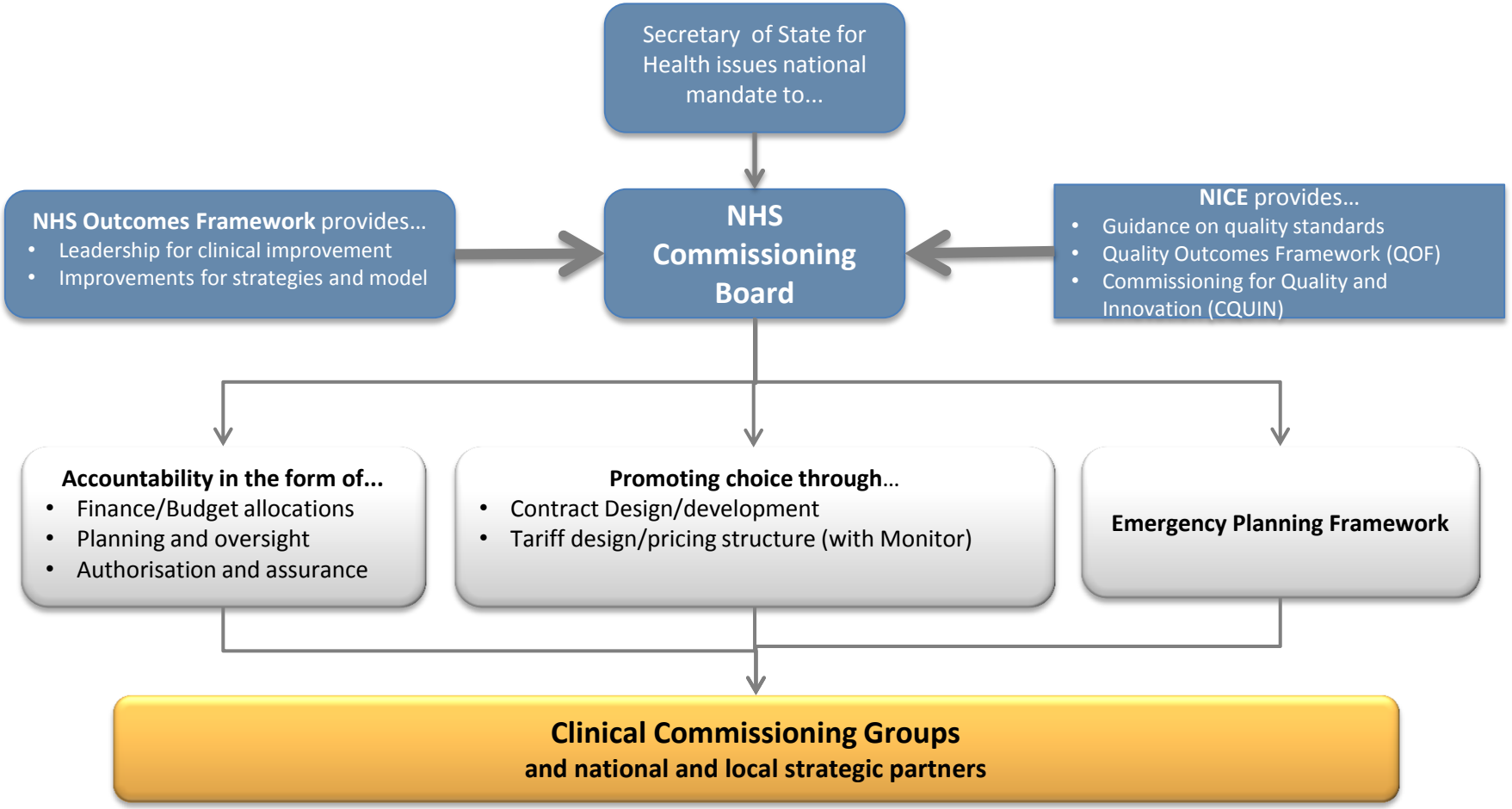
The **NHS Commissioning Board (NHS CB)** will act as the performance manager of the CCGs starting April 2013



The NHS, must deliver **efficiency savings of up to £20 billion by 2015** in order to remain economically sustainable

- These savings have to be delivered through the NHS quality and efficiency improvement work, known as the **Quality, Innovation, Productivity and Prevention (QIPP) challenge,** or the **Nicholson Challenge**
- In order to support the Nicholson challenge, the DH has worked with SHAs to develop savings plans at a regional level. It has also used national policy tools such as a two year pay freeze for NHS staff and the reduction in hospital tariffs.
  - At a local level, providers and commissioners are encouraged to work together to increase productivity and reduce input costs by redesigning services to achieve the same or better outcomes, or by securing the same services for a lower cost.

Concerns about the Nicholson Challenge

- In the financial year 2011/12, the first year of efficiency savings, ministers have claimed that the NHS in England has achieved productivity gains of £5.8 billion, including from freezing staff pay and cutting back fees that hospitals receive.
- However, the National Audit Office (NAO) who monitors public spending, has recently raised doubts about these claims, indicating that it can only verify £3.4 billion of the £5.8 billion supposedly achieved.
- The King's Fund concludes that the **NHS is unlikely to meet the Nicholson Challenge** after surveying 45 NHS finance directors about the performance of their organisations.
- Regardless of the current year's achievements the major savings were achieved through the easiest means of reducing hospital tariffs and freezing pay. It is next year (2013-2014) that is of concern.
- The two year pay freeze will end in April 2013, and an average increase of 1% in staff pay is expected, adding 400-500 million in NHS expenditure.

NHS hospitals are reimbursed for services through a scheme known as **Payment by Results' (PbR)**

- Payment by Results (PbR) is the national tariff system by which hospitals and providers are reimbursed for their activity.
- The main currency of healthcare activity linked to PbR is the **Healthcare Resource Group (HRG).**
- An HRG is essentially a case-mix grouping of different patient diagnosis and treatment procedures clustered because they are known to consume similar types of resources.
- Medical intervention and patient diagnoses are classified based on the OPCS-4 and ICD-10 classification systems. The data is grouped and coded into Health Resource Groups (HRGs).
- These resources also factor in non-clinical costs such as food, cleaning, and estate costs, all of which may be utilised between a patient's period of admission to discharge.
- The price for standard clinical procedures is known as the 'reference costs', which are national average costs throughout the NHS. Tariffs are adjusted for long/short hospital stays, clinical best practices, specialised care, and market forces for geographical variation.
- PbR has continued to expand in scope since its establishment. At its start it only covered about £100 million of activity, mainly in elective procedures, with plans to cover as much secondary care expenditure as possible –about £60 billion. Primary care expenditure for GPs, dentists, opticians, and prescribing (about £20 billion) have thus far been covered by national contracting and funding arrangements.
- PbR can be flexible and allow for deviation from tariff rules. For example, 'innovation payments' give commissioners flexibility in paying for a new drug or device which gives better care than in the tariff.

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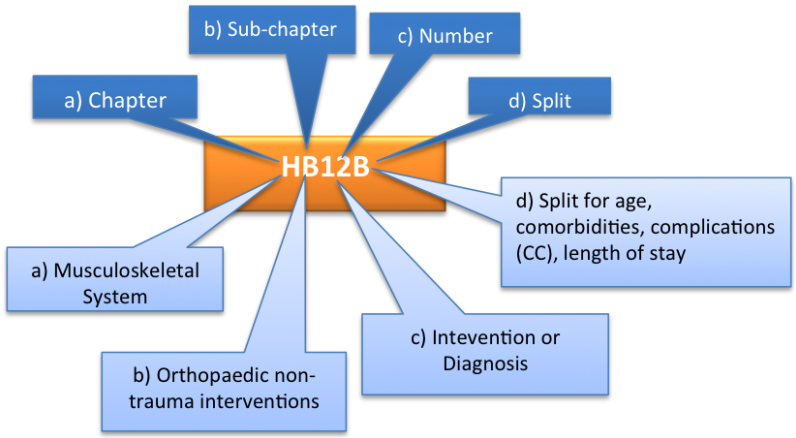
PbR was first introduced in 2005/06 and covered about £100 million of activity for mainly a small number of elective procedures

- Over time, the proportion of activity incorporated into the PbR system has gradually risen. It now incorporates about 60% of an average hospital's activity, and accounts for around one-third of total PCT spending.
- The PbR system is based on a simple principle of 'equal pay for equal work'; The more patients that a hospital treats, the more money it can receive.
- Such a system incentivises providers to treat more patients, particularly for elective services. This has supported waiting time policies by reducing waiting times.
- However a challenge with the PbR system has been that it has not facilitated large scale shifts from hospital activity to other care settings such as community care.
- Hospitals arguably have very strong incentives to treat more patients.

Concerns about PbR

- It is therefore not comprehensive and has proven to be slow in incorporating activity pertaining to mental health and community care services.
- This can present a significant challenge to fulfilling policy ambitions to reduce costs and find efficiency gains.
- Furthermore, Payment by Results up to now have essentially been 'payment by activity', with the results not factoring in the actual level or quality of care.
- It is arguable that GP-Consortia (CCGs) are not likely to resist the incentives for hospitals have more activity. Therefore it may be up to national level bodies such as Monitor and the NHS Commissioning Board might need to play a stronger role in setting prices and monitoring hospital activity.

The currency of healthcare activity linked to PbR is the case-mix coding system referred to as the **Healthcare Resource Group (HRG)**



- HRGs were introduced in 1991 in the UK as the NHS equivalent of diagnosis related groups (DRGs) pioneered in the USA and adapted to reflect UK medical practice.
- HRGs are coding classifications for acute healthcare in England, translated from the two clinical classifications systems: OPCS-4 (interventions) and ICD-10 (diagnoses).
- The HRG coding system has undergone revisions every 3 to 5 years, expanding in scope and complexity. The most updated system was introduced in 2006 as the **HRG4.**
- HRG4 extends the number of groupings from 650 under HRGv3.5 to over 1500, arranged in 21 chapters, each covering a human body system.
- HRG4 is the first major revision to inform tariff payments since 2009—10 although they have always been used to inform reference costs.

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The design of HRG4 reflects a significant improvement from its predecessors in that it improves the PbR system by permitting more flexible arrangements

- HRG4 is more detailed, and more capable of differentiating routine and complex treatments with more splits for comorbidities, complications, age, and length of stay.
- **Unbundling:** HRG4 is unique by introducing **unbundled HRGs**, which allow separate reporting, costing, and reimbursing, of different components within a care pathway.
- **HRG4 is setting independent.** Unbundling makes it possible to move parts of a care pathway (ie: diagnostic imaging, rehabilitation) away from the hospital setting and can encourage more outpatient services.
- However, a distinction exists between current funding structure and funding policy, which indicates that unbundling will not necessarily attract a tariff.
  - For example, if diagnostic imaging is unbundled from its core HRG, it will only act as a marker that the activity has taken place. It will be rebundled to factor in its costs
- Unbundling is useful when changes in the care pathway can be expected. Unbundled HRGs have been introduced for the following:
  - Chemotherapy
  - Diagnostic imaging
  - Critical Care
  - High cost Drugs
  - Radio Therapy
  - Rehabilitation
  - Renal Dialysis
  - Specialist Palliative Care
- **Pathway tariffs:** In contrast pathway tariffs are useful when paying for all patient encounters for a given condition.
- Pathway tariffs are appropriate for provision of maternity services – which include booking in, assessment, antenatal care, the birth itself, and postnatal care.

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PbR is being incrementally reformed to incentivise quality care through **Best Practice Tariffs (BPTs)**

- Although tariffs are based on national average costs, they are not exactly reflective of them. The DH reinforces the cost-reducing incentive of a tariff fixed at average cost by annually reducing all tariffs to encourage efficient use of NHS resources.
- PbR system does not contain any safeguards to balance the risk of losing clinical quality when cost-cutting is prioritised.
- **Best Practice Tariffs (BPTs)** were introduced in 2010/11 to incentivise reimbursement based on clinical quality and shift away from costing mechanisms based on average costs.
- BPTs have been introduced where the costs are below the national average costs for a given procedure, or where there is significant unexplained variation in current practice, or where the evidence base defining good practice is strong.
- BPTs have their scope expanded on an annual basis. The revisions are prioritising an initiative to shift hospital activity and its costs to other care settings. It will expand the number of procedures covered by the BPTs and aim to incentivise day case and outpatient activity
- Similarly, a 'pay for performance' component is introduced in the form of the **Commissioning for Quality and Innovation (CQUIN)** payment framework.
- CQUIN was first introduced in 2009/10. It acts as a further incentive for providers by allowing them to potentially earn an additional 2.5% of their income depending on how well they meet specific standards of quality improvement.

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PbR is being incrementally reformed to incentivise quality care through **Best Practice Tariffs**

The first Best Practice Tariffs were released in 2010/11 for two elective and two non-elective high-volume service areas, with characteristics of unexplained variation in practice and clear consensus of what clinical best practice was:

(a) Cataracts – **aimed to reduce the number of times patients are assessed before and after surgery,** by setting a price for the whole pathway rather than pricing each spell of activity

(b) Cholecystectomy (gall bladder removal) – aims **to encourage** keyhole surgery in **a day case setting** where clinically appropriate

(c) Fragility hip fracture – an additional payment for rapid surgery and orthogeriatric care

(d) Stroke – additional payments for urgent brain imaging and care in an acute stroke unit

The second wave of best practice tariffs in 2011-12 included:

(a) **day case procedures** – encourages providers to increase day case rates in several surgical procedures including hernia repair and prostate resection

(b) interventional radiology – **incentivises use of minimally invasive techniques** to substitute open surgery where clinically appropriate

(c) paediatric diabetes – a non-mandatory payment to encourage the running of high quality paediatric diabetes clinics

(d) primary total hip and knee replacements – **encourages best clinical management of patients and minimal lengths of stay**

(e) transient ischaemic attack (or mini-stroke) – a tariff for timely and effective outpatient systems for treating patients with TIA to complement the acute stroke best practice tariff

In 2012-13, we introduced best practice tariffs for:

(a) **same day emergency care** – promotes management of 12 clinical scenarios on a same day basis in an ambulatory emergency care manner

(b) procedures in outpatients – encourages three more procedures to be performed in an outpatient setting

(c) **day cases – two further procedures** added to the list introduced in 2011-12 to incentivise day case activity

(d) paediatric diabetes – applies to providers who provide services in accordance with the best practice specification

(e) interventional radiology – list of procedures covered by the interventional radiology best practice programme has been expanded to include a further five

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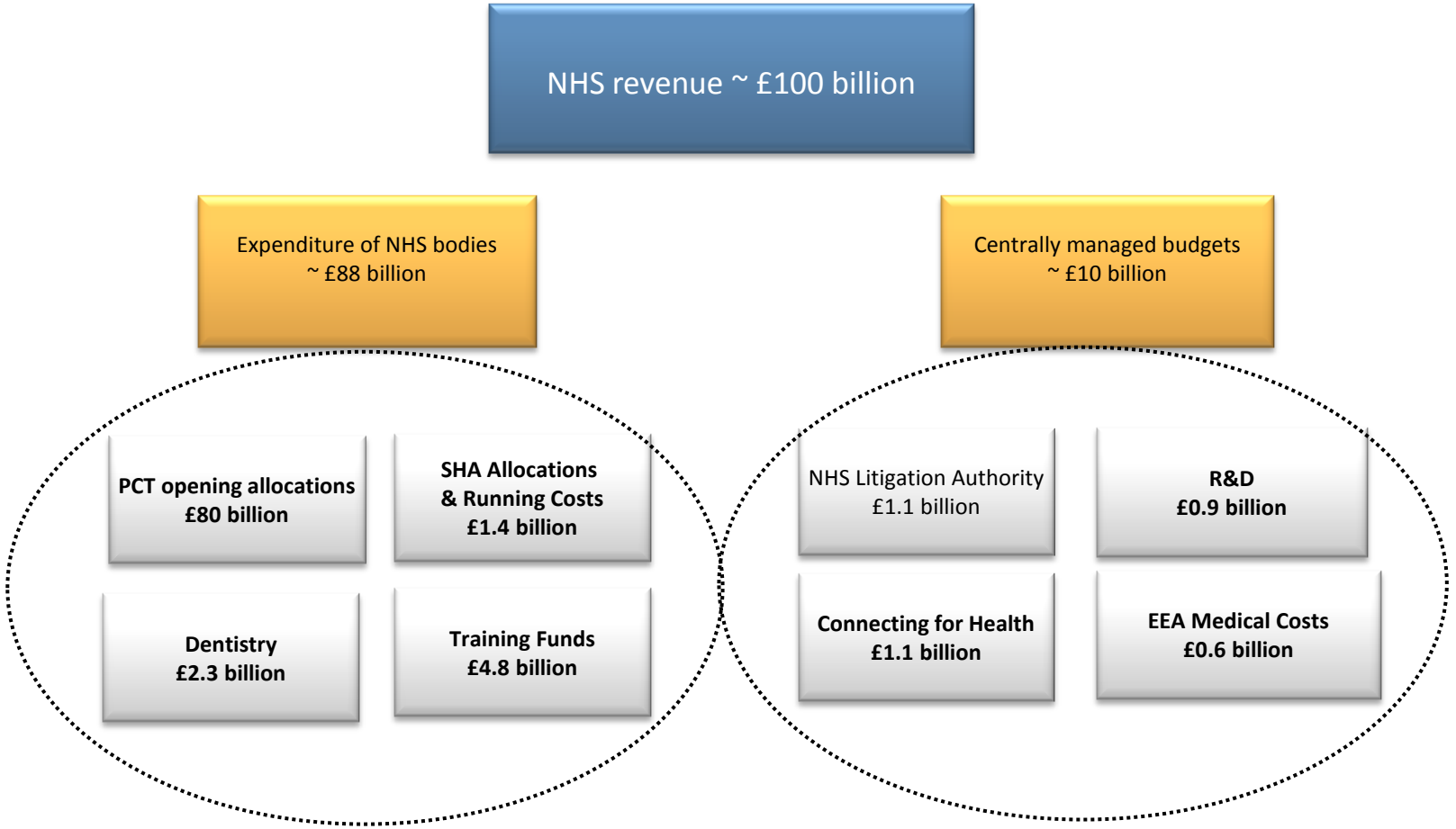
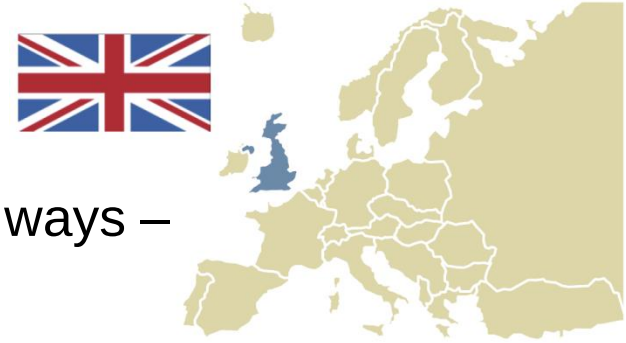
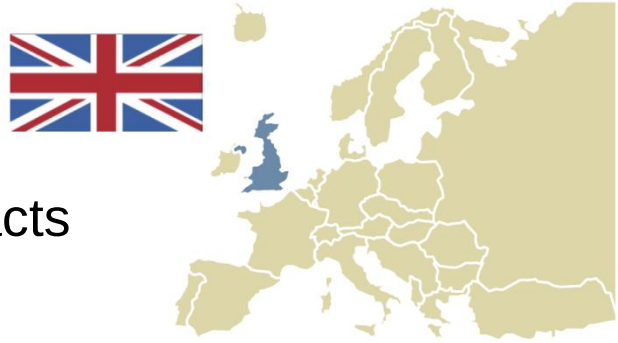
How the annual NHS budget is spend





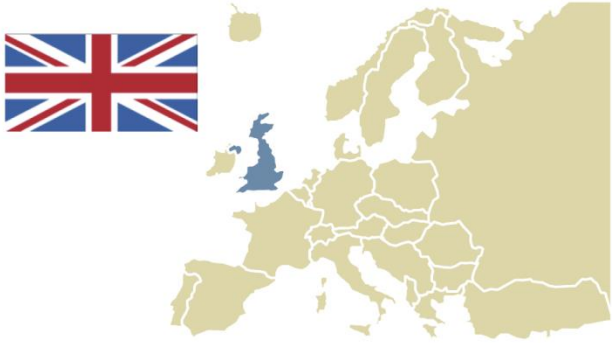
NHS-funded primary care is provided in various ways – with GP's as the primary point of contact

- The **first point of contact** for general medical needs is usually **self-employed GPs** and their practices, typically entering into contractual engagements with PCTs, although GPs may also be employed directly by alternative providers (e.g. commercial sector).
- Community health services, NHS Direct, NHS walk-in centres, dentists, opticians and pharmacists are part of NHS primary care services. The primary care system also plays a gatekeeping role in determining access to more specialized, often hospital-based, acute health care services.
- **A small private sector exists alongside the NHS**, funded through private insurance, direct payments from patients, or publicly funded payments by PCT.
- In addition to secondary care, a **range of more specialized tertiary services** are also provided by NHS trusts and deal with more complex or rare conditions.
- Social care is the statutory responsibility of 152 councils with adult social services responsibilities (known as CASSRs).
- The mental health care system is a mix of primary care and community-based services supported by specialist inpatient care.



Payment for services changed from block contracts to a performance based system

- Before 2003, hospitals were mainly paid using a system of annual block contracts, with an agreed sum of money for a given amount of activity.
- Thus there was **no direct relation between activity, case mix and payment**.
- Instead of block contracts for activity (which are insensitive to the volume and nature of activity), from 2002/03 **hospitals were to be paid for the activity they undertook**, so called Quality Outcomes Framework (QOF).
- The government argued that this would **introduce stronger incentives to ensure improved performance**.
- The QOF gives an indication of the overall achievement of a practice through a points system.
- The QOF is almost the only area where they can make a difference to their income.
- Most practices got, and still get, a significant proportion of their income through the QOF.



The Quality of Outcomes Framework (QOF) is based on four components

Clinical standards

86 indicators covering 20 clinical areas, including:

- coronary heart disease, stroke or transient ischaemic attacks, hypertension,
- diabetes, chronic obstructive pulmonary disease

Organizational standards

36 indicators covering records and information:

- about patients, information for patients, education and training, practice
- management and medicines management

QOF

Experience of patients:

three indicators covering:

- the services provided,
- how they are provided and patient involvement in service development
- plans

Additional services

- nine indicators covering four service areas including
- cervical screening, child health, maternity and contraceptive services

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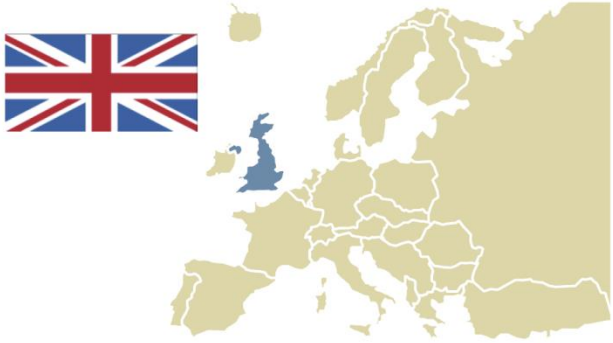

Providers of NHS services are mainly regulated by four central bodies

Care Quality Commission (CQC)

- Responsible for regulation and inspection of all health care providers (NHS, private sector and voluntary sector)
- Responsible for licensing, monitoring and inspection of all health and adult social care, and has enforcement powers

Audit Commission

- Is concerned with the financial health and probity of NHS bodies
- Ensures that essential standards of quality and safety are being met where care is provided
- Has a wide range of enforcement powers to take action on behalf of people who use services if services are unacceptably poor

National Institute for Health and Clinical Excellence (NICE)

- Develops guidelines in the areas of health:

1. Health technologies: guidance on the use of new and existing medicines, treatments and procedures within the NHS
2. Clinical practice: guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS; and
3. Public health: for those working in the NHS, local authorities and the wider public and voluntary sector, guidance on the promotion of good health and the prevention of ill health

Strategic Health Authority (SHA)

- Is key link between the Department of Health and the NHS, responsible for developing plans for improving health services in their local area
- Ensures local health services are of a high quality and are performing well
- Aims to increase the capacity of local health services so they can provide more services

The Health and Social Care Act (2012) by the Conservative Liberal Democrat Coalition government implies major changes to the NHS

- Although the eventual **impact of this reform is difficult to assess** and a great deal of the detail remains to be worked out, the reform is the single most fundamental reform to health system among Western European countries.
- Changes being gradually introduced include a **fundamental change to the structure** of health care commissioning, with the abolition of PCTs and their replacement by a system of GP consortia that will commission and contract for services and the abolition of the regional tier of NHS governance (SHAs).
- The principal purpose of the reforms, as stated by the government, is to **extend choice and competition**.
- Another major principle introduced by this reform will allows NHS-services to be offered by **"any willing provider"**. In effect this means that the private sector, including commercial companies, will be able to compete against the NHS and its partners to provide services.
- The Confederation of the British **Industry supports the bill**, declaring that "Allowing the best provider to deliver healthcare services, whether they are a private company or a charity, will spur innovation and choice."

The reform is controversial – private healthcare providers in the public system are not accepted in the same way as in Germany or France

- The government aims to strengthen the voice of patients through the setting up of a new national body, **HealthWatch**, and local HealthWatch organisations.
- A new body, **Public Health England**, will lead on public health at the national level, and local authorities will do so at a local level
- **Key regulators** – CQC and NICE– will be retained, though it remains to be seen how their roles may change.
- A **new regulator**, Monitor, will be established to regulate providers of NHS services in the interests of patients and prevent anticompetitive behaviour
- In addition, it is already clear that the new government intends to **restrict NHS expenditure** compared with previous regimes. This is almost certain to have an impact on the delivery of NHS services.
- According to many commentators, the recent Spending Review plans for the NHS (October 2011) amount to **a de facto cut in NHS spending** in real terms.
- For example the British Medical Association remains in “outright opposition” to the reform.
- One of the most persistent criticisms of the reforms has been that this could amount to partial privatisation of the NHS. Critics fear a “rush to the bottom”, as providers may slash costs to win contracts, driving down quality of treatment for patients.
- Another major concern is about fragmentation of the NHS and a loss of coordination and planning as a result of the abolishment of PCT’s.
- The Lancet predicted an "unprecedented chaos" as a result of the reforms, with a leaked draft risk-assessment showing that emergencies would be less well managed and the increased use of the private sector would drive up costs.
- The health think tank “The King's Fund” state that private sector organisations have always played an important role in the NHS and that "the NHS will remain a publicly funded system under the proposals, and at least for the foreseeable future the majority of services are likely to be provided by NHS organisations".

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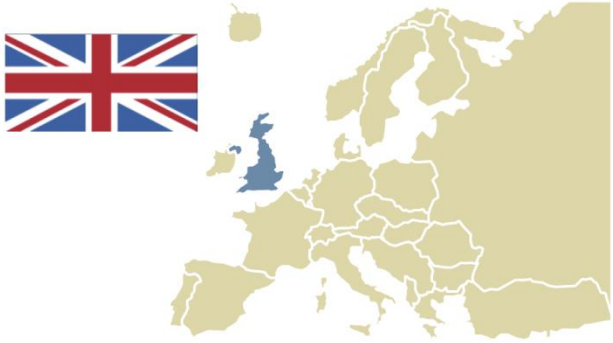
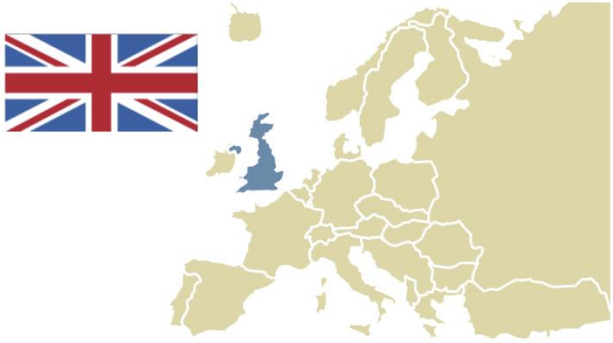


The United Kingdom is a major producer of pharmaceuticals

- **UK ranks fourth in the world in 2007 in terms of value of exports**, behind Germany, Switzerland and the United States.
- At the same time, pharmaceutical care is a major component of expenditure on health care in the United Kingdom, both within the NHS, where it accounts for a total of £10.8 billion.
- The **UK healthcare industry** (pharma, medical biotechnology and medical technology sectors) **employs over 100,000 people**, largely in highly skilled jobs, in companies ranging from large multi-nationals to SMEs.
- The industry invested over £4.4 billion in R&D in the UK in 2009, over 28 per cent of all business R&D. It also generated over £10 billion in value added in 2009, representing over 7 per cent of total manufacturing.
- It is also a **major exporter**, with 2009 exports of pharmaceuticals and medical technologies accounting for over £24 billion.
- The UK has 64 companies whose primary business activity is to develop biotechnologies that can be applied to industrial uses. These companies together generate sales of £230m per year based on the latest financial data and employ 1,600 people.



Overview of the UK medical industry

Medtech

- Total of 3,113 companies.
- Combined in-scope turnover of £15bn.
- Total number of employees is 64,000.
- 99% of companies have less than 250 employees.
- 87.5% have turnovers in the range of £100k to £5m per annum.
- The UK is home to 466 companies with turnovers in excess of £5m per annum.
- 52% of all companies are over 10 years old.
- Exports for the first ten months of 2011 are down 11%.

Top 3 segments in the sector		
By turnover	**By employment**	**By no. of companies**
Single use technology	Professional services	Professional services
Wound care	In vitro diagnostic technology	Assistive technology
Orthopaedic devices	Single use technology	Single use technology

Biotech

- Total of 945 companies, of which 325 or 34% are directly involved in therapeutic development and manufacture.
- These companies have a combined turnover of £3.4 billion.
- Total number of employees close to 23,000.
- 98% of companies have less than 250 employees.
- 5.3% of therapeutic companies are focused on oncology or infection.

Top 3 segments in the sector		
By turnover	**By employment**	**By no. of companies**
Specialist services	Specialist services	Specialist services
Small molecules	Small molecules	Small molecules
Antibodies	Antibodies	Therapeutic proteins

Pharmaceuticals

- Total of 365 companies with a combined turnover of £31.8bn.
- Total number of employees 77,795 in 388 sites.
- Of the Top 50 global companies 37 have sites in the UK.
- 19% of companies have more than 250 employees and employ
- 89% of the total workforce.
- Small molecules is the major product/service type followed by specialist suppliers to the sector and vaccines.
- 52% of companies have turnovers of £5m or more per annum.
- 67% of all companies are over 10 years old.
- Geographical R&D and manufacturing employment is centred in the South East and East of England, the North West, Scotland and the North East.

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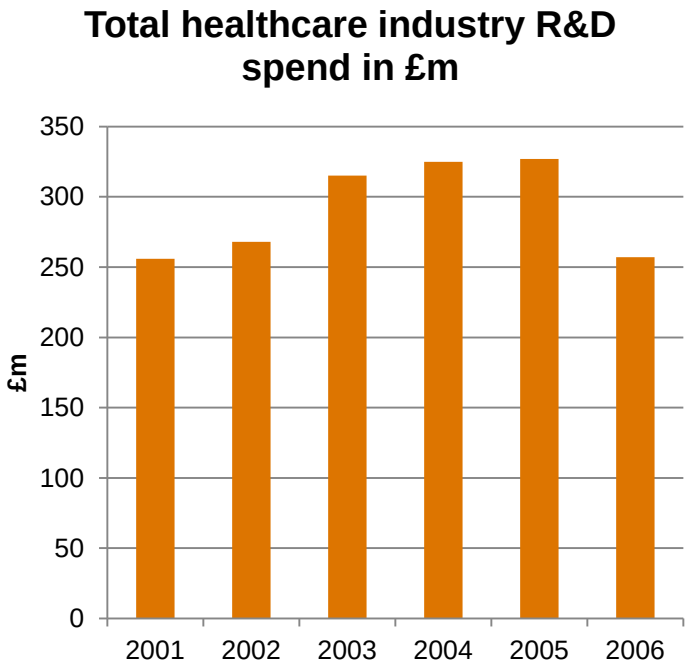
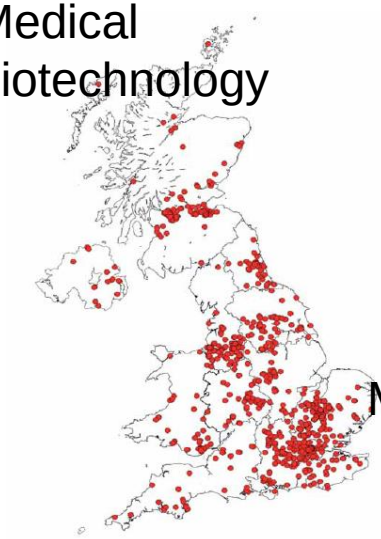
Healthcare industries are clustered mainly around the greater London area and the Northwest

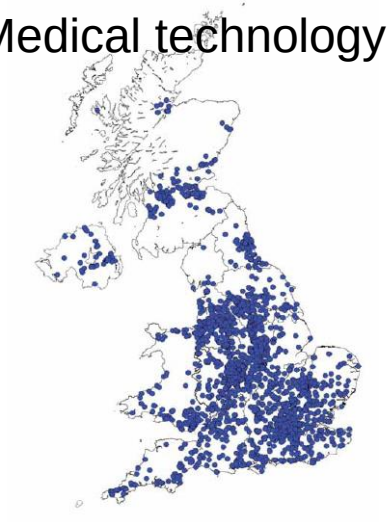


Medical biotechnology



Pharmaceutical

Medical technology



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The government has developed a number of initiatives to improve small companies' access to capital

1. **R&D tax credits**, which are more generous for SMEs than for larger companies;
2. The so called **Enterprise Investment Scheme**, which aims to help certain types of small higher-risk unquoted trading companies to raise capital by providing a range of tax reliefs for individual investors in qualifying shares in these companies.
3. **Venture Capital Trusts**, which are designed to encourage individuals to invest through collective schemes in a range of small higher-risk trading companies whose shares and securities are not listed on a recognised stock exchange; and
4. The **Enterprise Capital Fund** (ECF) scheme, where the Government leverages venture capital (VC) with debt in funds managed by the private sector. This was specifically designed to fill an 'equity gap' for investments of up to £2 million.

Several bodies aim to improve the knowledge-transfers between research and industry

UK Clinical Research Collaboration (UKCRC)

MRC Knowledge Transfer (KT)

Joint MRC/NHS Health Research Delivery Groups

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National Institute for Innovation and Improvement aims to “to speed up the development of pre-commercial technologies”

The **NHS Institute is an umbrella organisation of seven regional innovation hubs**. Each of these hubs act as a “point of entry” for small companies seeking to introduce new products within the NHS. Most notably the innovation hubs can:

- offer help to understand NHS procedures and the size and scope of the NHS market
- provide a clinical review of products and carry out market research
- assist in arranging trials and evaluations
- introduce companies to partners within the NHS and specialists who can offer expert advice, for example on procurement
- assist non-healthcare companies in transferring their products and expertise into the NHS
- help companies to find partners, collaborators and technology solutions within the North West academic community
- provide access to opportunities to partner with NHS organisations for licensing and/or development of NHS innovations.

NHS
Institute for Innovation and Improvement

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National Institute for Health and Clinical Excellence (NICE) is the main body for health technology assessment

- Since January 2005, the NHS has been legally obliged to provide funding for medicines and treatments recommended by NICE's technology appraisal board.
- Established to overcome problems of so called “postcode lottery” (differential treatments by geographical area)
- Provides evidence-based guidance and other products help resolve uncertainty about which medicines, treatments, procedures and devices represent the best quality care and
- NICE guidance and every NICE quality standard is developed by an independent committee of experts including clinicians, patients, carers and health economists which offer the best value for money for the NHS.
- NICE also plays an important role in pioneering technology assessment in other healthcare systems.

NHS
National Institute for
Health and Clinical Excellence

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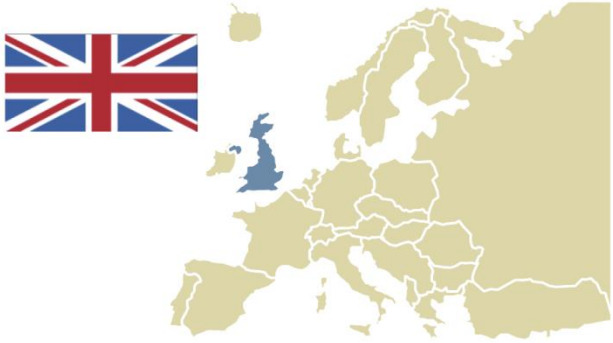

NICE's topic selection and assessment criteria

Governance of topic selection	• NICE topic selection consideration panels, Minister of Health, and DH.
Criteria for topic selection	• Burden of disease (population affected, morbidity, mortality) • Resource impact (cost impact on the NHS or the public sector) • Clinical and policy importance (whether the topic falls within a • government priority area) • Presence of inappropriate variation in practice • Potential factors affecting the timeliness for the guidance to be produced (degree of urgency, relevancy of guideline at the expected date of delivery) • Likelihood of guidance having an impact on public health and quality of life, reduction in health inequalities, or the delivery of quality programs or interventions.
Criteria for assessment	• Strength of the available evidence (nature, quality, and degree of • uncertainty), importance of outcomes, health impact, cost-effectiveness, • Inequalities, feasibility of implementation, impact to the NHS, • acceptability, broad clinical and government policy priorities, and • health need.

Overview of key NICE assessment processes and procedures

Key steps in the assessment process	• Preparation of project scope • Systematic review of evidence/appraisal • Drafting of the guidance • Consultation • Finalization of the guidance • NICE approval and issuance of guidance
Evidence reviewed	• **Technology appraisals:** Clinical and cost-effectiveness evidence. • **Clinical guidelines:** Existing literature, information submitted by stakeholder organizations, existing economic literature or original analyses. • **Public health guidance:** Evidence briefing (review of reviews); systematic review of primary data; existing, published primary research; and, new primary research, where available. • **Interventional guidance:** Primarily published, peer-reviewed literature.
Duration required to conduct assessments	• **Technology appraisals:** ~54 weeks (MTAs); ~39 weeks (STAs) • **Clinical guidelines:** ~72 weeks (full); ~40 weeks (short) • **Public health guidance:** ~52 weeks • **Interventional guidance:** ~46 weeks

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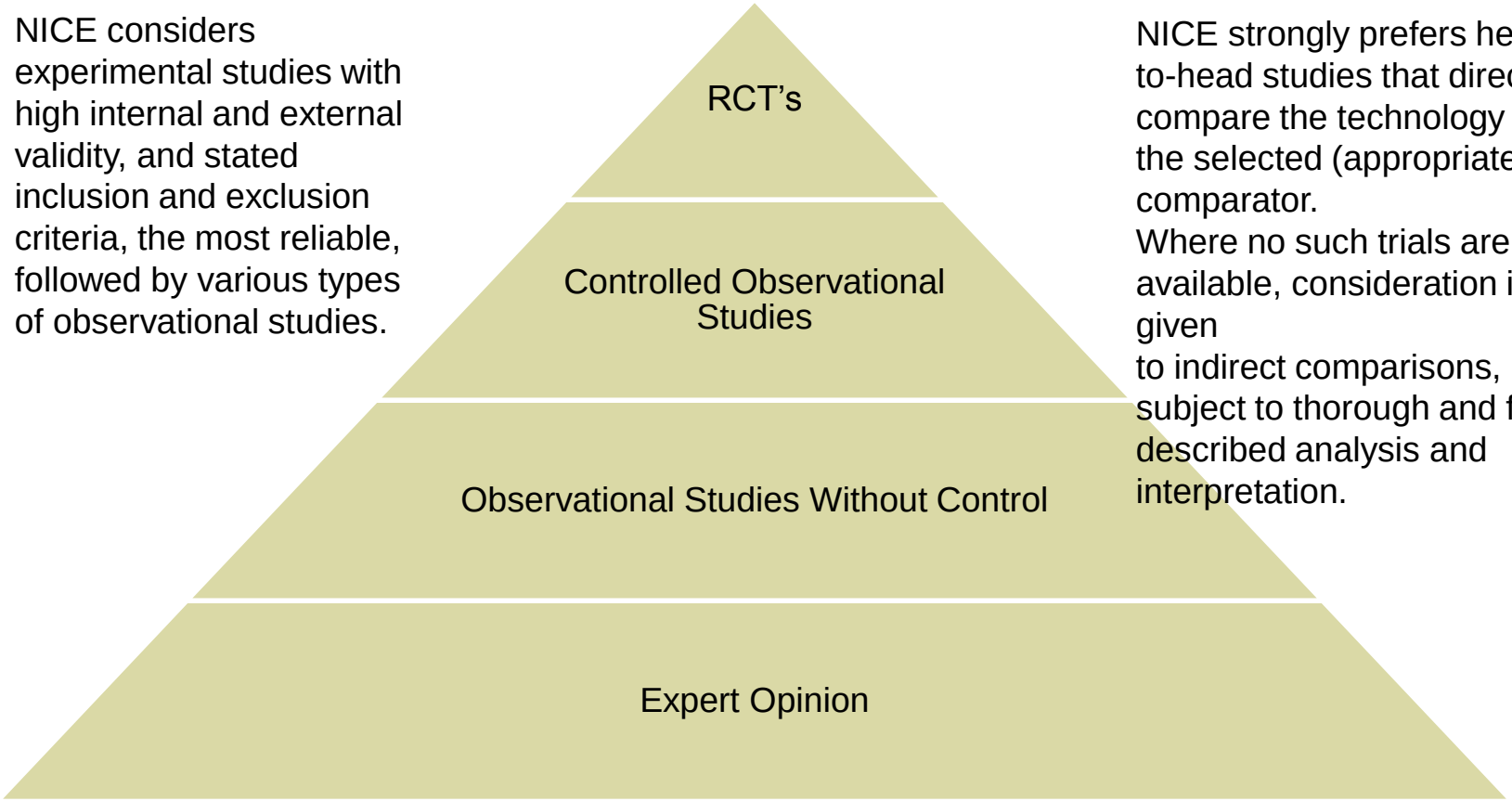
There is a clear hierarchy with regard to NICE's preferred study designs

NICE considers experimental studies with high internal and external validity, and stated inclusion and exclusion criteria, the most reliable, followed by various types of observational studies.



NICE strongly prefers head-to-head studies that directly compare the technology and the selected (appropriate) comparator.
Where no such trials are available, consideration is given
to indirect comparisons, subject to thorough and fully described analysis and interpretation.

NHS National Technology Adoption Centre (NTAC) assists companies to navigate the complexities of the NHS adoption landscape

Its **specific aims** are:

- To work with partners to **identify those technologies which will provide cost effective improved** patient outcomes in the NHS.
- To work with NHS Trusts to **support the sustainable implementation of new technology** as an integral part of service and system solutions.
- To **identify where changes to the pathway or service may be needed** to unlock the benefits of the technology.
- To produce detailed NHS focused guides detailing **how the technology can be successfully implemented** and the benefits to both patients and organisations that can be achieved.

NHS
Technology Adoption Centre

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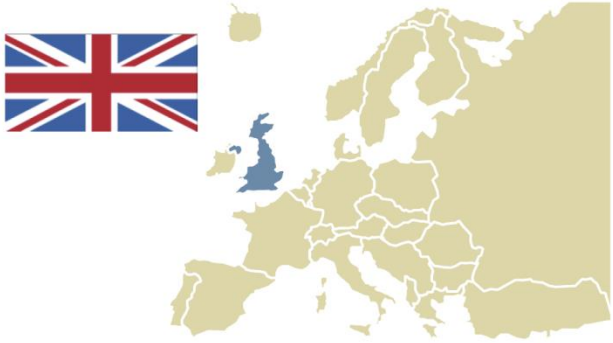

NHS Training for Innovation helps to create and disseminate innovative training tools

- Works in partnership with NHS, academic, educational and information technology bodies and medical device companies to **encourage knowledge exchange and promote best practice** in medical technology training.
- Activities include **identification of training gaps** created by changing technology demands and focusing on training needs arising from NHS priority areas.
- Principal aim is to **improve training tools for healthcare professionals** to ensure the correct implementation of high impact, advanced medical technologies.
- Furthermore NHS Training for Innovation develops skill assessment tools and tries to encourage local monitoring.

NHS
Training for Innovation

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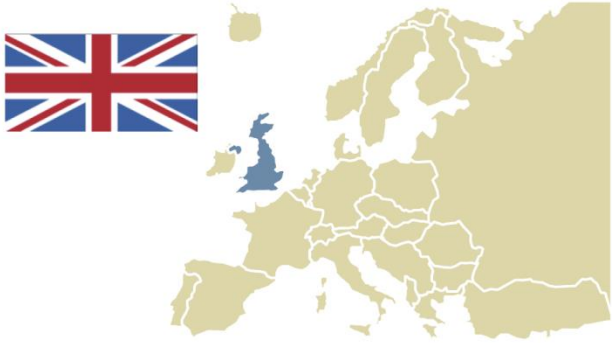
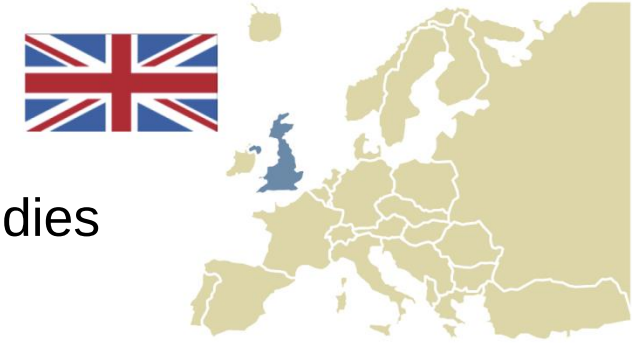


“Innovation” has central place in policy-making

- Constant **production of reports and reviews** by the government, parliament, think thanks as well as the NHS.
- The issue of innovation in healthcare is also **widely been followed by the media** in the UK (e.g. special series/issues in The Guardian or the BBC).
- England/UK generally is known for an **open business culture** and there is a comparatively high level of interaction between stakeholders at different levels.
- The issue is a **stated priority of the current government**.
- The aim of increasing the innovation-capacity thereby interlinks with the plans to reform the NHS as well as to boost the life-sciences sector in the UK.



The UK has a broad number of (semi-)public bodies to support innovation in healthcare sector

- In England/UK there exists a very **wide range of designated bodies** (public as well as private) with the goal of **facilitating innovation** in the healthcare sector
- National and regional **NHS Innovation Centers provide a commercial consultancy services** to help UK and international companies develop innovations
- The Innovation Centers especially help companies to understand NHS procedures and the size and scope of the NHS market, provide a clinical review of your product and carry out market research and also assist in arranging trials and evaluations.
- The NHS Technology Adoption Centre (NTAC) offers support to innovators in identifying those technologies which may provide cost effective improved patient outcomes in the NHS

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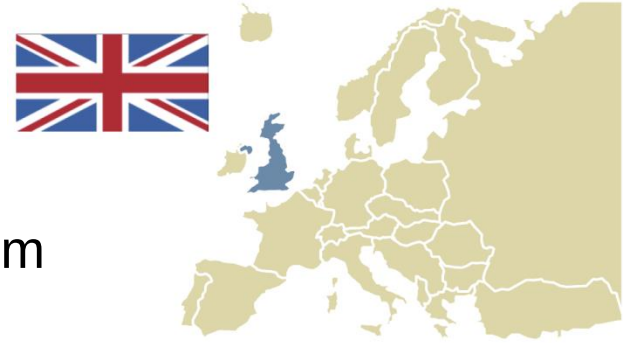

Bodies to support innovation in healthcare system

Regulation	SHA Directors Network	National Leadership Council	NICE
Support for innovators	Commercial Support Units	Innovation Hubs	
Diffusion	NHS Training for Innovation	National Innovation Center	NHS Technology Adaptation Center

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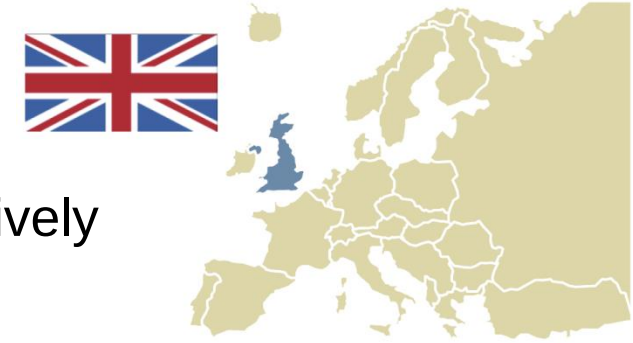
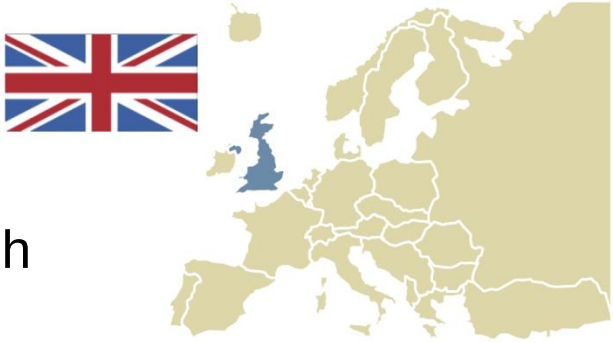


Generally the UK is seen as having a comparatively good availability of venture capital

- Availability of (venture) capital for research and/or marketisation is generally perceived as good.
- For SMEs, British government funding includes the £300m Enterprise Capital Funds programme and the £50m Business Angel Co-Investment Fund.
- About 60% of capital raised by UK biotech-companies is from venture-capital (highest within Europe).



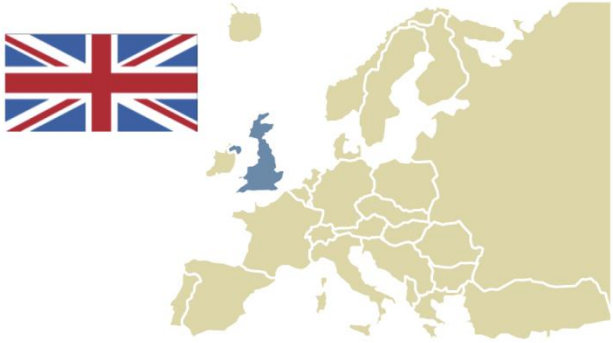
The UK is a world-leader in life-sciences research

- Among the top countries (2nd in Europe) **in terms of patents in the field of biomedical research** (European Patent Office); also very highly ranked in terms of patents with international partners.
- Comparatively (very) **high number of university graduates** in the field of health and life sciences.
- England (together with Japan and the US) is in the **top-group in terms of the number of publications** in the field of bio-pharmaceuticals and also in terms of impact factor/citations of these publications.
- UK accounts for 20% of all R&D expenditures in the field of bio-pharmaceuticals in the EU (top with Germany).
- Government funding for biomedical/life-sciences research is generally above EU/OECD average (2nd in Europe after Germany).

NHS is widely perceived as being slow at adopting new technologies and spreading them at pace and scale

- Of the 168 product launches since 2000, the UK makes up only 13.1% of the EU-6 share by value (population adjusted).
- For **non-appraised products, the UK has slow uptake**: of the 119 product launches since 2000 not appraised by NICE, the UK makes up only 13.7% of the EU5 share by value

➢ “The UK typically only optimises adoption and diffusion of medicines once a product has gone generic.” (Policy officer, Association of British Pharmaceutical Industry)



There still exists large regional variation in uptake of NICE-endorsed products

IMS Health report “Bridging the gap: Why some people are not offered the medicines that NICE recommends” (2011) commissioned by Department of Health found fundamental gaps in the uptake of NICE-endorsed medicines within the NHS.

The **main reasons** for these gaps according to this report are:

1. **Insufficient diagnosis** (e.g. only 32% of non-hip fracture patients had a clinical assessment for osteoporosis/fracture)
2. **NICE-required tests were not done** (in this context 75% of interviewed oncologists said access to, or the cost of, biomarker tests were major barriers to the use of personalised medicines)
3. **Varying access to specialist medical expertise** (e.g. in a multi-centre audit, 18% of people with glioma that could have received carmustine, chemotherapy, were not offered it, because their cases had not been discussed within the relevant multidisciplinary team)
4. **Insufficient capacity to deliver** (e.g. very long waiting lists at some memory clinics and some liver clinics delay initiation of treatment for Alzheimer’s disease and HCV)
5. **Commissioning is deficient** (thus commissioners and providers argue over who should pay for those drugs that are initiated in secondary care but followed up in primary care)

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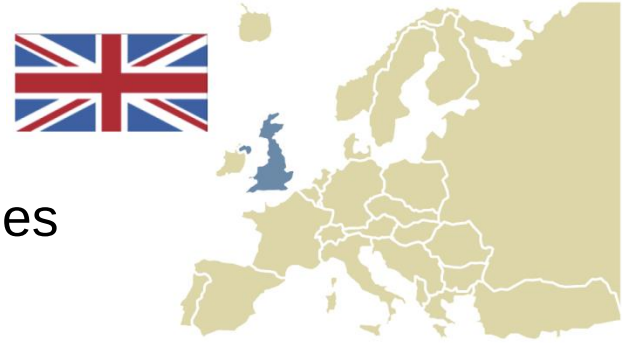
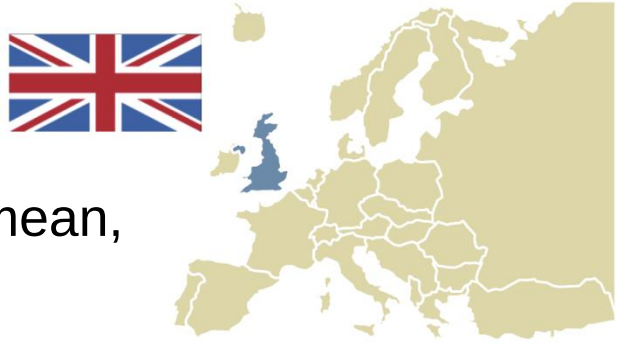


The UK ranks in the lower third of OECD countries in terms of drug usage

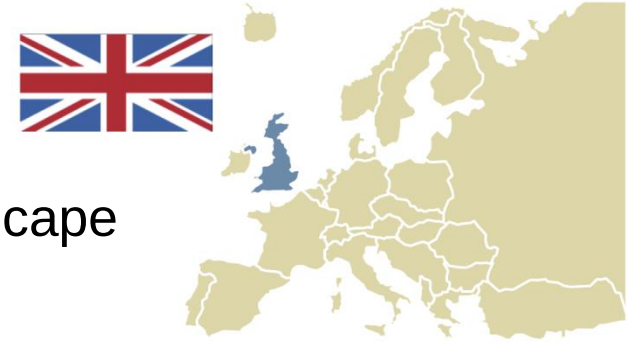
A recent report (201) “Extent and causes of international variations in drug usage” assessed the uptake of new medicines in a number of industrialised countries:

- France, Spain, the USA and Denmark all have generally high levels new of usage.
- Overall, the UK ranks eighth out of the 14 countries included in the study, when the usage ranking observed in each disease area or drug category is taken into account.
- It is notable that some categories of **drug which have received a strong NICE-endorsement are still used at significantly lower levels than in other countries** (for example, for hepatitis C treatments or some cancer drugs). Equally, drugs that receive positive guidance may also enjoy high levels of clinical support, which will also be an important factor in encouraging higher usage.
- **When NICE produces guidance recommending that a medicine should not be routinely used in the NHS, uptake in the UK tends to be low** and will mainly be restricted to patients in the private sector. This can be seen in the relatively low use of some newer cancer drugs such as Sorafenib, which is used to treat advanced kidney and liver cancers (ranking of 13th, 23% of the all-country average).



UK rankings and usage as a percentage of the mean, by disease area or drug group

UK usage as a percentage of the average of 14 countries	Higher than average UK rank (1–4)	Intermediate UK rank (5–9)	Lower than average UK rank (10–14)
>200%	Thrombolytics for acute MI		
125–200%	Surfactant for RDS Statins		
80–124%		Cancer (6–10 years) Cancer (hormones) Wet AMD	Cancer (>10 years)
50–79%		Osteoporosis Thrombolytics for stroke	Second-generation antipsychotics Dementia Hepatitis C Rheumatoid arthritis
<50%		RSV prophylaxis	Multiple sclerosis Cancer (<5 years)



Multitude of bodies within NHS innovation-landscape diffuses responsibility

- **Innovation funding is managed by different NHS organisations**, ranging from SHAs to PCTs to specialist commissioning groups to individual hospitals.
- Given the variety of “owners”, how and what these funds are used for can be extremely varied, and the process of applying for funding can be extremely complex.
- **Industry struggles to identify and then engage with budget holders**, the eligibility criteria to access funds may vary across geographies, and how funds are prioritised to address many potential needs is unclear.
- **Critique of lack of transparency** behind the decision making processes as there is no clinical scrutiny or accountability for these local decisions; which is especially problematic when they are contrary to the clinically published opinion of NICE.

➢ “It appears to us that the NHS puts in place multiple structural layers of decision-making which impede access to new medicines.” (Policy Officer, Roche)

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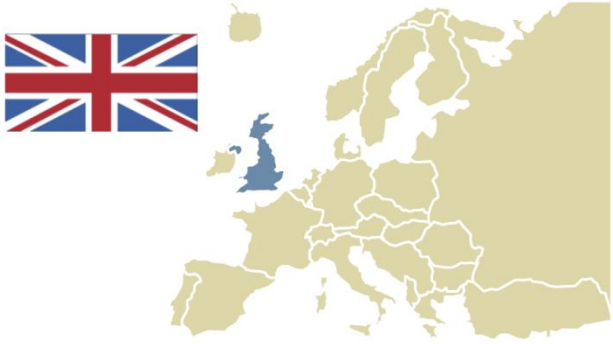
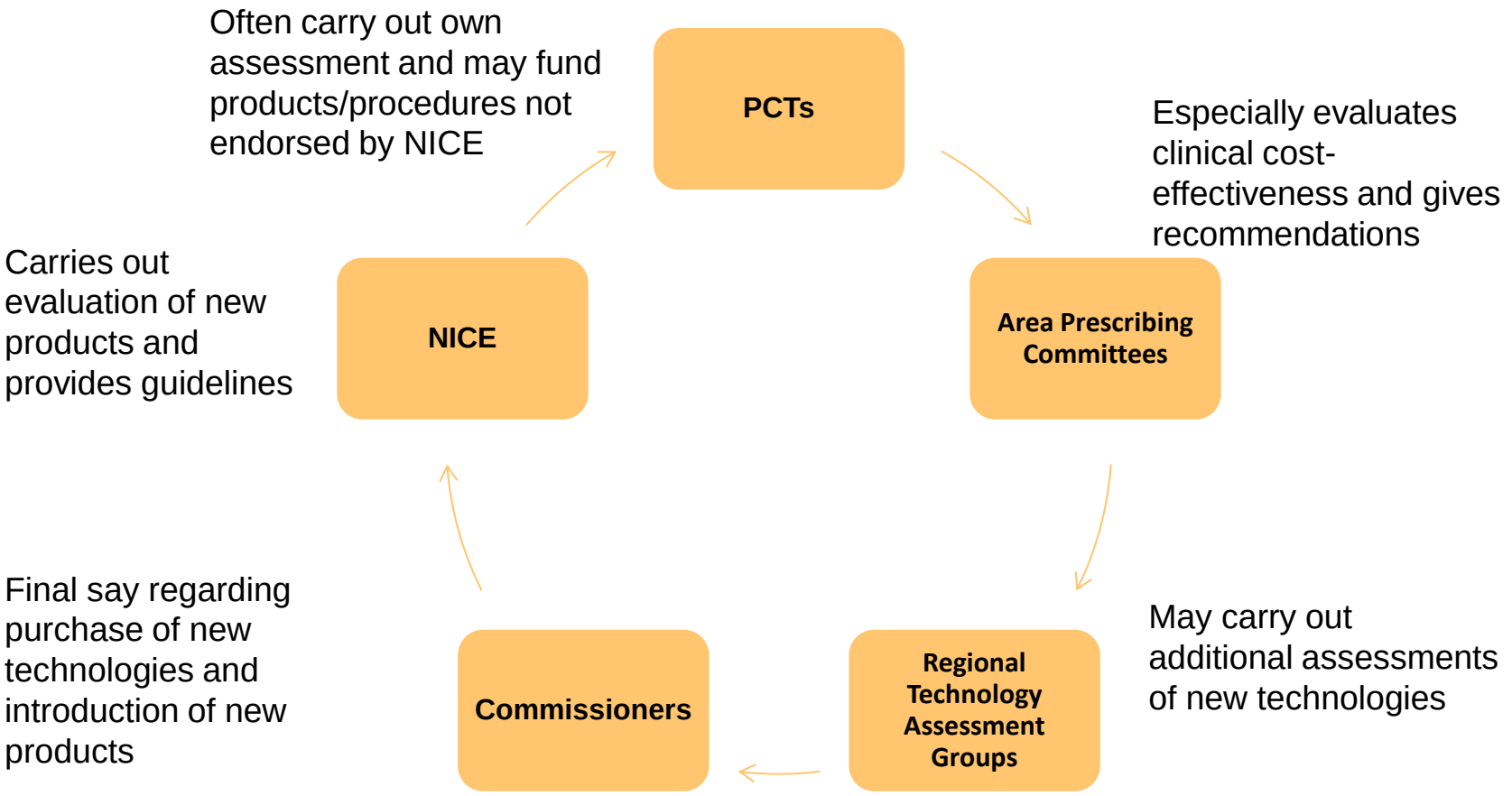
Multiple structural layers within NHS lead to inefficiencies, duplication and complexity in local decision-making and value assessments

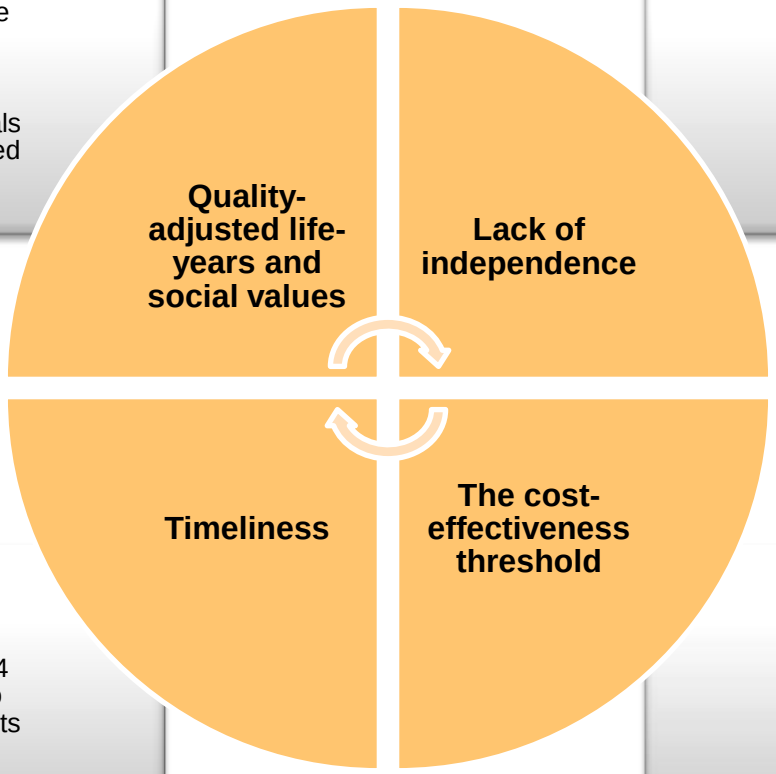




NICE is often criticised for the following reasons

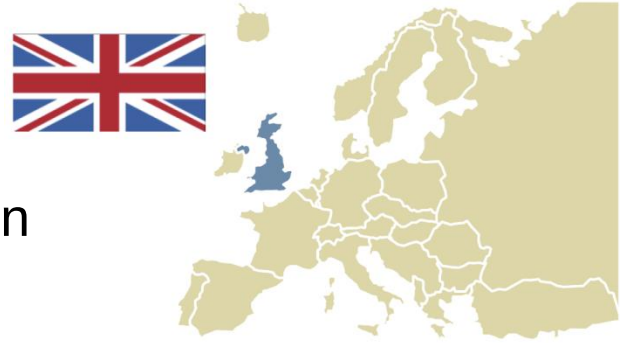
- From the outset, NICE has been quite clear that the measure of health benefit to use in technology appraisals is the quality-adjusted life-year

- Although NICE is classed as an 'arm's-length' organisation, there are accusations that the institute is essentially following a government, or payer's, agenda



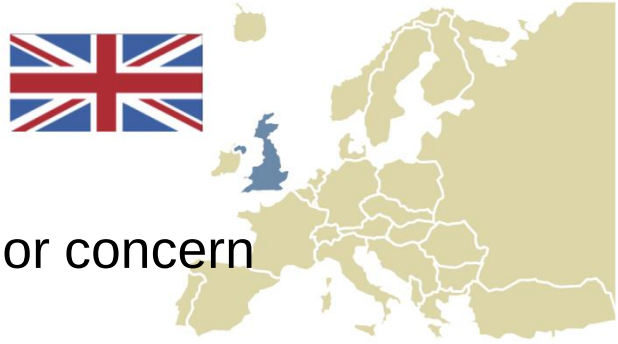
- The concern that a period of average 54 weeks (minimum) to conduct assessments is much too long.

- The use, or non-use, by NICE of a threshold has been a continuing topic for debate, since it would be clear evidence that NICE rations care.



NHS lacks control mechanism for implementation of NICE-guidelines

- One of the main issues identified by many stakeholders is the absence of a system which controls the implementation of the NICE-guidelines.
- Thus there is currently no mechanisms to “force” or “sanction” non-compliance within the NHS.
- Also, for patients it is very hard to find out how well their local NHS trusts have been adopting specific innovations/new technologies.
- There exists no formal appeal process for patients in cases treatment with NICE-endorsed medicines/procedures is refused by local NHS.



Within NHS a lack of managerial control is a major concern

- A recent study on the role of senior NHS management ("Organisational and Behavioural Barriers to Medical Technology Adoption") in facilitating adoption of innovation and concluded found that their role was potentially important but insufficiently defined.
- Contrary to much of the general literature on innovation, most of those NHS interviewed in this study felt that an absence of managerial control and organisational structure was holding back the adoption and diffusion of valuable innovations in the NHS.
- This highlighted the perception that the NHS was not short of inventions, but lacked the expertise, information and structures necessary to convert good ideas into innovations usable across the system.
- Historically managers in the NHS have not been judged by how innovative they are.
- Rather, they are judged by how well they stay within their budget and carry out the tasks demanded of them.
- According to a King's Fund (2011) report there is evidence that the NHS is over-administered as a result of extensive, overlapping and duplicating demands from regulators and performance managers.

Short-term budget-cycles often are disincentive to innovate

- PCTs or other budget-holders tend to manage their short-term cost constraints by restricting the use of the novel, irrespective of medium- and long-term benefits.
- Short-term budgeting cycles mean that there is a reluctance to make the initial investment on high value innovations even though they offer efficiency gains and improved patient outcomes in the long run, i.e. not necessarily in the same budget cycle.
- This is exacerbated by the silo nature in which budgets are held. Costs may often be incurred in one care setting/department but benefits accrue in others with no mechanism for those savings to be offset against the cost..
- “Silo-budgeting’ and ‘Service Line Reporting’ are key barriers to innovation as it encourages perverse incentives at a local level. For example, even if a technology can deliver an overall saving across a patient pathway it may not be adopted if an individual department has to increase its expenditure to deliver change.” (Policy officer, Johnson & Johnson)

In 2011 the NHS undertook a major review of it's innovation capacity

- In the call it was stated: "The NHS has a long and proud track record of innovation stretching back across its 63-year history. However, whilst the NHS is recognised as a world leader at invention, the **spread of those inventions within the NHS has often been too slow**, and sometimes even the best of them fail to achieve widespread use."
- The review received a very large media coverage with special programmes in all main media.
- **310 responses were received**. The responses were drawn from a **wide range of organisations** (e.g. industry, academia, NHS), mainly from within the UK.
- The majority of the responses welcomed the NHS Chief Executive's Innovation Review and many suggested it was important to look at radical uncomfortable solutions as well as improving existing systems incrementally.

➢ **Key actions described by respondents were:**

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Actions described by respondents during the innovation review include

- **Improve horizontal knowledge exchange, networks and links:** Respondents felt that the transmission of innovations happened through networks that cut across geographies and hierarchies, and bridged the gap between the NHS, the private sector, academia and social care. These networks play a crucial role in filtering ideas, assisting with practical implementation, and championing new practices. Supporting and sustaining these networks was a key recommendation.
- **Creating demand by looking more radically at regulation and performance management:** Respondents felt that the demand for innovation could be substantially increased by the correct use of centrally administered regulation. Compliance regimes, use of mandatory guidelines, and innovative commissioning arrangements could all play a part.
- **Improve information and evidence about innovation:** Respondents requested high quality clinical and financial justification for innovations, as well as practical implementation guidance. In an organisation of 1.3 million people, and with more than 500,000 medical articles published per year, matching the right innovation to the right adopter is a huge challenge. Respondents requested a central point where information on innovation could be found.

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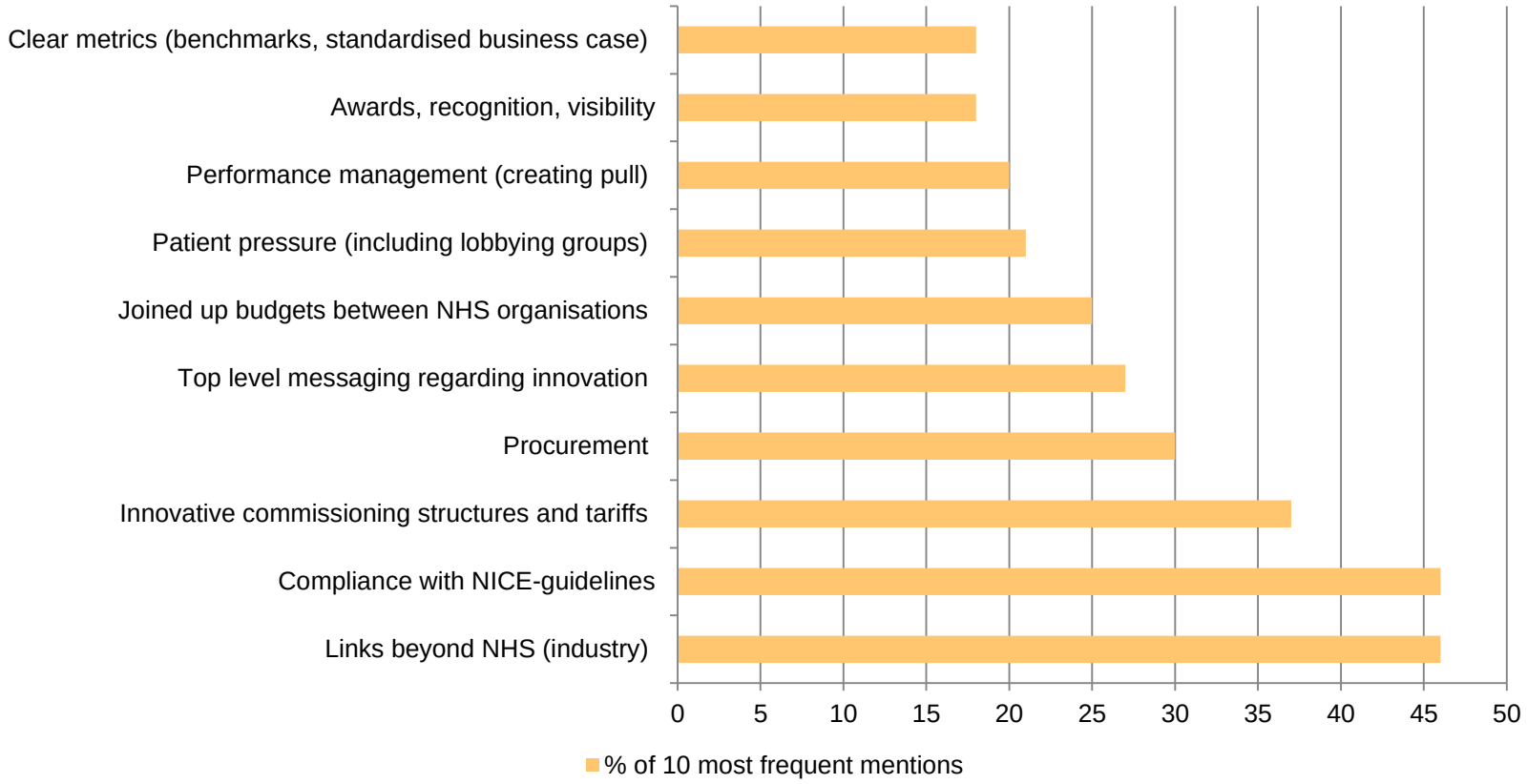
Actions described by respondents during the innovation review include

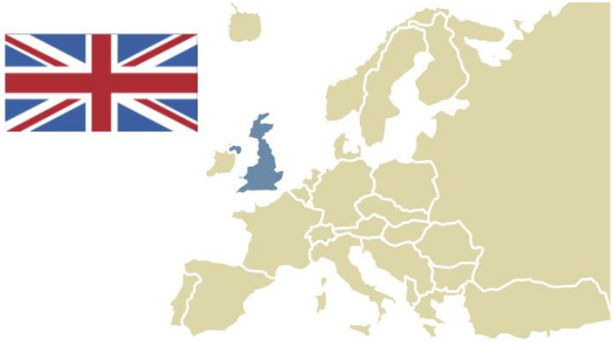
- **Deliver more clarity and support for the innovation pathway:** Respondents often felt there was a lack of clarity about the pathway that an innovation has to traverse to be accepted by the NHS. Often innovators felt unsure where to take their innovations, unclear about the processes they had to follow and uncertain about what support was available to them. Respondents also felt that skilled support specific to innovation was necessary to success.
- **Improve funding and budgeting for innovation:** Respondents felt that specialist innovation funding had, and could continue to play a critical role. More generally, respondents identified budgetary silos as a key barrier to innovation, whose costs and benefits often do not fit neatly within existing structures, both within and between organisations.
- **More support needs to be given to increasing systematic patient demand:** Respondents identified patients as an underutilised resource for the diffusion of innovations. When patients are empowered to demand best practice and personalised care, the NHS will have to respond by finding innovative patient-centred solutions.

Actions described by respondents during the innovation review include

- **Need to improve supply factors to make ideas visible and transferable:** Supply factors refer to standards and norms that make innovations easier to transfer between locations and across the system. These include benchmark metrics, standardised business cases, use of NHS branding, kitemarking and intellectual property (IP) rules. Respondents felt that there was room for considerable improvement here.
- **Improve incentives and rewards for individuals:** Respondents felt that innovators, and those who adopted innovations, needed to be better incentivised and rewarded for their work. Without recognition through awards or incentives as part of their job, it is difficult to find the time to adopt and diffuse innovation.
- **Improve the procurement of innovations:** A range of issues were identified by respondents regarding the procurement of innovation. In general there was the feeling that there could be significant improvements in this area – around greater transparency in the process and the advantages of a centrally procuring or in greater volumes.
- **Increase training, education and staff development around innovation;** Respondents identified the lack of relevant skills within the NHS around innovation. Producing reliable business cases, calculating return on investment and other such skills are not normally part of employees‘ jobs – training in this would help the uptake of innovation.

Links between NHS and industry as well as compliance are most frequently mentioned problems by industry stakeholders during the innovation review





Actions deriving from the review

- The results of the **review were summarised in a report by the NHS** CEO Sir David Nicholson titled “Innovation Health and Wealth – Accelerating Adaption and Diffusion in the NHS”
- This **report provides a detailed conclusion** of the review on behalf of the NHS.
- It also describes in detail the actions the NHS aims to undertake in order to facilitate innovation in the NHS.
- The report was published in early 2012 and most actions had a timeline of up to 9 months.
- Many of the actions have already been implemented or are planned to be implemented by 2014.

➢ **The following slides provide a summary of the actions implemented by the NHS or the government in reaction to the review:**

The following measures were suggested by the government and the NHS

Reduction of variation and strengthening of compliance	Legal requirement that NICE guidelines are implemented	NICE compliance regime	NICE Implementation Collaborative
Metrics of innovation	National innovation Scorecard	Single web portal for Innovation in NHS	Clinical Practice Datalink
System for delivery	Academic Health Science Networks	Review of innovation bodies	Double investment for Small Business Research Initiative

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The following measures were suggested by the government and the NHS

Incentives and investments	Increase investment in NHS Innovation Price	Specialised Services Commissioning Fund
Leadership for innovation	Clinical Commissioning Groups under duty to promote innovations	NHS operations framework to include innovation as key priority
High impact innovations	Assistive technologies	Reduce face-to-face contacts

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The government has implemented a number of measures to reduce the variation in the uptake of new innovations

Reduction of variation and strengthening of Compliance

Compliance regime

The government wants to establish a compliance regime to ensure rapid and consistent implementation of NICE appraisals and guidelines throughout the NHS.

The precise nature of this regime is still being discussed and will certainly evolve over time.

As a first step PCT's and Clinical Commissioning Groups are obliged from 2013 onwards to publish (online) information on how they are incorporating new guidelines.

NICE Implementation Collaborative (NIC)

This new body is supposed to unite stakeholders from the NHS Commissioning Board, NICE, the Chief Pharmaceutical Officer, the Royal Colleges, NHS Confederation and the main industry bodies.

The purpose of NIC is to identify issues or areas where support is needed to ensure implementation of NICE guidelines.

Requirement of implementation

The government also plans to oblige local decision makers to automatically incorporate NICE guidelines.

According to this plan, local formularies would be obliged to incorporate new guidelines within 90 days.

The planned compliance regime is generally lauded by industry

- Industry bodies have widely welcomed this step which has been one of the two top-demands brought forward during the innovation-review in 2011.
- It generally allows producers to better monitor the uptake of their products.
- The regime will create a legal obligation for PCT's to offer NICE-appraised medicines which can be claimed by patients through judicial review.
- According to the Association of the British Pharmaceutical Industry: "*This will act as an incentive to ensure implementation, which will be good for industry and patients in ensuring proper access to health technology that NICE has approved*."

However, how the new system will effectively function largely depends on how the courts in the UK will act:

- Up-to-date courts in the UK have generally abstained from making any decisions involving the NHS service provision, arguing that these would be political decisions involving the allocation of resources.
- It is widely unclear how courts will handle claims by patients against their local NHS-bodies.
- At the same time that (NICE-)endorsed treatments should enjoy a higher uptake in principal, the new regime also dramatically increases the role on NICE as a "gatekeeper", which potentially is more critical or reluctant to endorse new products if they are not sufficiently cost-effective.

The government has created a number of new systems in order to better evaluate uptake of innovations

Metrics and Evaluation

National Innovation Scorecard

The Department of Health has obliged all NHS trusts and hospitals to provide information for this scorecard.

Initially the scorecard will cover 20 treatments where NHS uptake is known to be variable.

Web Portal for Innovation

This new web portal is available for the public and NHS staff.

It offers information about new and innovative treatments and – in the words of the NHS – create “an intellectual market place” to discuss new ideas.

It includes a searchable database with case studies on “how to implement” innovations and also e-learning modules.

Over time it is supposed to also include a database of clinical trials.

Clinical Practice Datalink

This is a database of observational data and interventional research service.

It is designed to maximise the way anonymised NHS clinical data can be linked to enable many types of observational research.

It is part of the government’s strategy to boost the life sciences and is also connected to the aim to make more official data public.

Actions to incentivise innovation throughout the NHS

Incentives and Investments

Financial Incentives

The Department of Health is about to introduce a so called “shared saving formula” to break down soli-budgeting and encourage collaboration of different budget-holders.

Furthermore there will be a tariff for assistive technologies (telehealth, telecare) that – like in Australia and the US – would incentivise their rapid spread.

The already existing “payment for outcomes” framework will be strengthened.

The government also plans to evaluate options to create a new tariff for “new diagnostics” to encourage the uptake of new technology.

Specialised Services Innovation Fund

The government has pledged to establish a specific new fund to support research about new ways to treat rare conditions.

Innovation Prizes

The Department of Health wishes to increase the visibility and importance of the “Innovation challenge prize”.

The prize is awarded for the achievement of significant breakthroughs that have been focused on a specific objective relating to an important health challenge.

The prize money is about £100.000.

Currently all regional innovation hubs also have innovation prizes in addition to the national prize.

NICE plays a central role in determining which drugs and health technologies are made available in England and Wales - a significant source of influence for the UK pharmaceutical market

- NICE is an arm's length body, providing independent guidance in four categories: clinical guidelines, public health guidance, interventional procedures and technology appraisals. It was established in 1999 to reduce geographical variation in the uptake of health technologies in the NHS.
- **NICE is internationally recognized for methodological rigour throughout its technology appraisals process.**
- NICE encourages transparency and incorporates extensive stakeholder involvement throughout its assessment – during its scoping of appraisals, commenting on draft reports, and appealing against decisions
- NICE's Centre for Technology Evaluation coordinates the technology appraisal process. Considerations are:
  - **Clinical**: Does the health technology benefit patients?
  - **Infrastructural**: Is its purpose and approval in alignment with key NHS targets? (for example: reducing cancer survival rates)
  - **Economic**: Is the technology cost effective, providing value for money?
- Only a few of the proposed technologies are considered for appraisal, based on specific selection criteria:
  - Burden of disease (population affected, morbidity, mortality)
  - Resource impact (cost impact on the NHS and the public sector)
  - Clinical and policy importance (whether the technology/topic falls within a government priority area)
  - Presence of inappropriate variation in practice
  - Factors affecting the timeliness for guidance to be produced (degree of urgency, relevancy of guidelines at expected date of delivery)
  - Probability of guidance impacting the public's quality of life (reduction in health inequalities, delivery of quality programmes)
- NICE commissions independent academic centres called 'technology assessment groups' to prepare assessment reports for consideration by the Technology Appraisal Committee (TAC), which is the primary decision making body in the production and guidance of new health technologies.

NICE's HTA process: NICE's standard approach to technology appraisals is referred to as the **multiple technology appraisal (MTA)**

- **Key features** of the appraisal process include:
  - scoping of the topic including a scoping workshop which involves the manufacturers and other key consultees
  - a company submission
  - an independent technology assessment report (TAR) by one of the technology assessment groups
- The TAR generally includes a systematic review of the clinical literature and an economic model to comprehend its cost implications followed by an appraisal consultation:
  - Consultees are given the option to comment prior to issuance of the final appraisal determination which follows a second discussion of the technology by the TAC
  - Consultees have the option to undergo an appeals process in which case a hearing will take place. In the absence of a launched appeal, the guidance is issued to the NHS within six weeks
- Due to the fact that multiple technologies are being assessed, the MTA is generally an extensive process. It takes 54 weeks from initiation of the process to issuing of guidance.
- NICE also developed a single technology appraisal (STA) process in 2005 for reviewing single technologies for a sole indication.
- STAs require less time to produce than MTAs, namely 39 weeks from initiation of appraisal to publication.
- STA process is similar to the MTA process, but in this case, only evidence submitted by the manufacturer is formally considered in the independent review.
  - Also, formal consultation procedures only take place if the TAC's preliminary recommendations are substantially more restrictive than the terms of the licensed indication of the product
- STAs have generally been applied to cancer drugs, but is increasingly being employed in other disease areas.

Despite the methodological rigour of NICE's technology appraisal process, it has also received the following criticisms:

- **Lack of independence:** The institute is essentially following a government or payer's agenda since NICE's remit is to ensure clinical- and cost-effectiveness throughout usage of NHS. However this can, on occasion, result in NICE's issuance of negative guidance for a given technology due to its high costs, despite its clinical potential and implications.
- **Timeliness:** A minimum of 54 weeks has been criticised as being far too long to conduct assessments – this can be a potential issue if a higher proportion of appraisals go to appeals.
- **Uses/Disuses of a cost-effectiveness threshold:** A NICE cost-effectiveness threshold has continuously been debated, clearly highlighting the rationing of care. Criticisms have been raised as to whether
  - the cost-effectiveness threshold should be explicitly stated
  - the threshold has been set at the wrong level or is arbitrary
  - different thresholds should apply, depending on the nature of the treatments or patient populations being studied
- **Cost-effectiveness Thresholds:** Interventions with an incremental cost per QALY ratio of less than £20,000 have high probability of being funded, while QALYratios exceeding £30,000 have a high probability of being rejected. QALYs are a crude measurement which do not factor in all elements of value.
- Applying a single cost-effectiveness threshold is problematic for the appraisal of drugs for rare diseases (so called, orphan drugs).
- Even if these treatments do not appear cost-effective initially, they may have positive implications for subsequent research and drug development.

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The **implementation** of NICE guidelines is mandatory and expected to be carried out through all NHS trusts within three months

- However, studies have shown considerable **geographical variation** in uptake of NICE guidance, suggesting a persistence of the former 'post-code lottery system' of rationing healthcare.
  - Implementing NICE technology guidance within three months is supported by funding for PCTs based on estimated costs.
  - However high capital costs, implementations of expensive drugs or prostheses, and competing local priorities, have disincentivised PCTs from funding expensive guidance from their allocations.
  - The estimated cumulative total cost of implementing NICE guidance between 1999-2004 was £800 million, which at that time, represented a total of 1% of NHS expenditure.

- A study by the UK National Audit Commission indicated that improving the implementation of NICE guidance is more likely with the following motivations:
  - **Established systems of *tracking* implementation:** A system must be inclusive of professionals involved in implementation to motivate them and hold them accountable.
  - **Weaknesses in financial management:** Costs of implementation are generally unknown when budgets are set at a local level because of 1) lack of knowledge of current and future guidance, 2) uncertainty of the full costs. Funding as historically only included the actual costs of the drug/technology appraised, not the associated costs of staffing, training and equipment.
  - **Clinical resistance:** Perceived as a bigger challenge than funding restrictions. An enthusiastic champion (usually a clinician) who develops a strong business case as part of their local delivery plan is more likely to secure the funds needed.

Implementing NICE Guidance is affected by 'Payment by Results' (PbR), the national tariff system to reimburse healthcare providers in England

- PbR consists of fixed prices for packages of healthcare activity (ie: patient episodes, outpatient attendance, diagnostic tests), known as Healthcare Resource Groups (HRGs). PbR incorporates a market forces factor index (MFF) to factor in variations of unavoidable costs for NHS organisations.
- The funding of NICE appraisals are generally supported by a 'three month' funding direction.
- The cost implications of NICE guidance are taken into account in PbR in three ways:
  - Through the adjustment within the gross national tariff uplift which applies across all HRGs
  - Through specific adjustments to individual HRG national tariff prices directly
  - Through an exclusion to PbR, for example the list of excluded high cost drugs
- Historically, each year the tariff underwent an inflationary uplift, which included an element for NICE guidance. However in 2010/11 tariff inflation was set at 0%, based on the assumption that any inflation would be offset by gains in efficiency and productivity. This presents a potential challenge as uplifts can be eliminated by efficiency gain targets, amidst a rise in cost for drugs and technologies
- High costs drugs which are excluded from the PbR tariff for the following possible reasons. .
  - The number of patients is low and unpredictable
  - The relevant HRG may reflect more fixed treatment pathways
  - There may be large variations between providers in the use of these high cost drugs
- In this case, commissioners and providers will need to have local agreements for the use and funding of such drugs.
  - Currently, up to 60% of the cost of drugs used by providers of secondary and tertiary care fall outside the scope of PbR
  - While this percentage varies between providers, it presents a significant local responsibility for the local commissioning of these medicines to ensure fair and robust arrangements for individuals of the population

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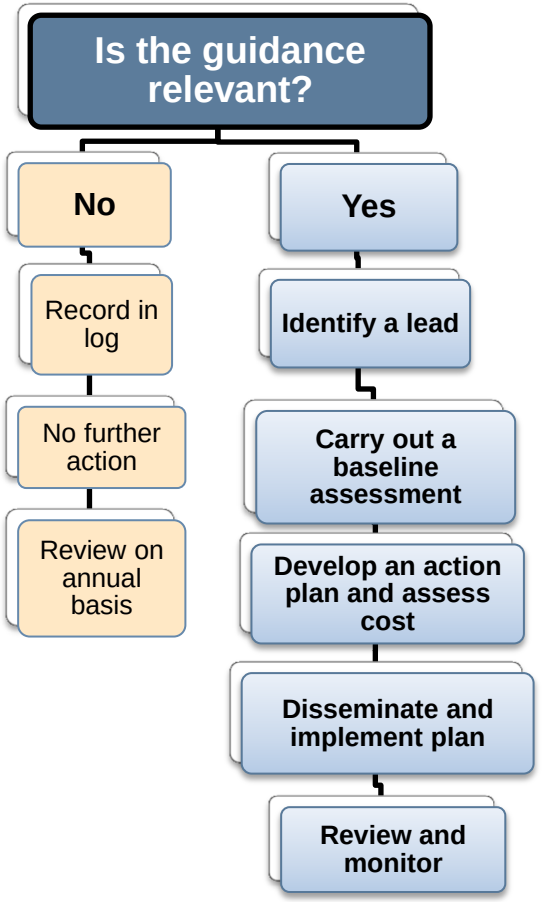
Implementation: A recommended process by NICE to putting technology appraisals into practice

- An **implementation team** should decide if a guidance is relevant to the organisation
- A **lead** should be a figure that can champion the guidance an inspire a relevant multidisciplinary team
- **Baseline assessments** can compare current practice to recommendations; it should consider the guidance's impact on factors like at-risk groups, staffing, equipment, training, budget planning and configuration of services
- Develop an **action plan** based on the costs involved. Assess cost impact to implement action plan and achieve compliance
- After completion of action and cost-impact, the action plan can be **disseminated and implemented.**
- A **review** of the implementation process should be conducted, with results fed back to the board



The Health and Social Care Bill will expand the remit of NICE, reduce variation and strengthen the compliance to NICE technology appraisals throughout the NHS

NICE Implementation Collaborative (NIC)

- The Government will establish the NICE Implementation Collaborative (NIC) to **develop strategic guidance** and support implementation of NICE approved drugs.
- NIC will consist of NICE, the NHS Commissioning Board, the Chief Pharmaceutical Officer, main industry bodies, the NHS Confederation, the Clinical Commissioning Coalition, and the Royal Colleges.
- Some of its main initiatives are to:
  - identify areas requiring support, developing implementation guidance and solutions for the NHS.
  - help pharmaceutical companies to improve their value propositions to NICE.
  - set out how use of existing tariff flexibilities at a local level could further support diffusion

NICE Compliance Regime

- The Government will introduce a NICE Compliance Regime for the funding direction attached to NICE technology appraisals.
- The NICE Compliance Regime will **ensure rapid and consistent implementation** of clinical- and cost-effective technologies and medicines throughout the NHS.
- Its will **address local barriers** to accessing NICE technology appraisal recommendations, with the exception of clinical decisions relating to an individual patient.
- The NICE Compliance Regime **will monitor the compliance of local formularies** failing to implement NICE guidance.

Prioritizing and Re-designing Local Formularies

- Standard processes in the design of formularies have been lacking and raising concerns that NICE technology recommendations do not uniformly get incorporated into all local formularies;
- The Government proposes that – where clinically appropriate – NICE Technology Appraisal recommendations will **automatically be incorporated** in to the local formularies within 90 days of the completion of a technology appraisal process.
- All PCT clusters in England will now have to publish, no later than 1 April 2013, information on what NICE recommended medicines and technologies they have available for patients.
  - This will make data on local formularies available as part of the standard terms and conditions of NHS contracts
  - This is advantageous for pharmaceutical companies who can monitor the implementation and uptake of their drugs at a local level

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The NHS Technology Adoption Centre (NTAC) was developed in 2007 to address the barriers to implementation of health technologies throughout the NHS

- Clinical resistance is recognised as one of the biggest challenges to implementation of innovative technologies. But it cannot fully justify the geographical variation throughout the NHS with a systematic approach
- The NTAC works with NHS organisations on adoption barriers, **by supporting the redesign of care pathways**, and providing guidance on new training, and the decommissioning of obsolete services as a result of new technologies.
- NTAC **also guides technology and diagnostics suppliers in navigating through the NHS** to support sustainable implementation.

Case Study: Oesophageal Doppler Monitoring

- Three NHS hospitals implemented Oesophageal Doppler monitoring (ODM) to guide fluid management during major surgery with the aim of improving the quality of care for surgical patients.
- More than 20,000 patients die each year following surgery, raising concerns of UK's significantly high mortality rate when compared to other healthcare systems in comparable countries.
- Optimal management of cardiac output and fluid balance is a major indicator of success after high risk surgeries because it allows optimal monitoring of blood flow to the body.
- Monitoring can reduce mortality, complication rates, lengths of stay in critical care facilities and overall hospital stays, all indicating considerable boosts to quality and efficiency savings.
- Despite the strong evidence for the uptake, currently fewer than 10% of major operations utilise ODM to facilitate targeted fluid management during surgery.
- NTAC set out a project to incorporate ODM into major surgical procedures in three implementation sites: Central Manchester University Hospitals Foundation Trust, Derby Hospital NHS Foundation Trust and the Whittington Hospital NHS Foundation Trust.
- The results of the implementation project were:
  - **3.5 decrease in length of stay,**
  - **23% decrease in central venous catheter insertion rate,**
  - **29% decrease in readmission rate,**
  - **5 day reduction in length of stay within Critical Care**

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The UK Life Sciences Strategy aims to build a fully integrated life sciences ecosystem to attract investment and world-class expertise to boost sustainable economic growth and innovation in R&D

- The **National Institute of Health Research (NIHR),** funded by the Department of Health, will put clinical research at the heart of NHS innovation and turn every willing NHS patient into a research patient to support the health research system.
- The **NIHR-Office of Clinical Research Infrastructure (NOCRI)** has been set up to help research funders in both the public and charity sector to work in partnership with NIHR infrastructure
- NOCRI is the single point of access for Translational Research Partnerships (TRPs) and can manage research collaborations.
- NOCRI can provide speed and ease in the access to UK's clinical research infrastructure, including well-characterised groups of patients of over 60 million people accessing NHS services.
- The UK life sciences industry should value NOCRI for two reasons:

1) In early-phase clinical research, NOCRI can provide access to the nation's experimental medicine experts who can help life science companies understand the potential of their developmental drugs, shortening cycle times, and enabling earlier decisions to proceed or not to proceed.

2) In later-phase research, NOCRI can provide rapid links to the NIHR's Clinical Research Network to ensure efficient and effective delivery of larger and multi-centre clinical studies.

The Government has invested a record £800 million in NIHR Biomedical Research Centres (BRCs) and Units (BRUs) since April 2012

- Biomedical Research Centres and Units (BRCs and BRUs) are intended to boost translational research in areas such as cancer, neuroscience, dementia, diabetes, heart disease, and ageing.
- The NIHR established the first round of BRCs and BRUs in 2007 for a five-year period which lasted until March 2012. The second round of BRCs was selected by open competition during 2011.
- Funding for each BRC is awarded to a single NHS organisation (in partnership with academia). The amount allocated to each BRC is determined by the scale, nature, and quality of the research activity to be conducted by that centre.
- The selection process was based on the following criteria:
  - Quality, volume and breadth of internationally-excellent biomedical and translational research and researchers
  - Existing research capacity, and plans for increasing capacity and training
  - Strength of the strategic plan
  - Relevance and the research portfolio to the health of patients and the public
  - Track record in translating advances in basic biomedical research findings into benefits for patients, the public and the NHS.
  - Strength of the strategic partnerships with industry and other NIHR-funded research infrastructure
  - Value for money
- Each BRC has a very substantial portfolio of world-class biomedical research in either across a range of, or a specific clinical and research areas.
- Performance is monitored by the NIHR Central Commisssioning Facility, which prioritises value for money and productivity of each BRC.

Case 1: NIHR Biomedical Research Centre at Moorfields Eye Hospital, University College London, and the Automation Partnership

A method for growing transparent tissue, developed by academics at University College London (UCL) was licensed to The Automation Partnership. Collaboration with the NIHR BRC at Moorfields Eye Hospital brought therapeutic applications to cure blindness through the proposed generation of a complete ocular surface.

The technology has major implications in the field of regenerative medicine.

Key Success Factors

- Availability of collaborative funding to kick start the development of a commercially higher-risk technology.
- A protected academic idea developed by commercially aware scientists.
- A 'Collaboration Steering Committee' to quickly escalate issues and keep the project on track.
- The cell therapy unit hosted by the NIHR Biomedical Research Centre at Moorfields.

Academia	Initiation	Industry
University College London (UCL) NIHR-BRC Moorfields Eye Hospital		The Automation Project

Offered

- Translational research expertise in the field of ocular therapy
- Patented technologies
- Academic contracts in further therapeutic areas
- NIHR-funded research infrastructure
- Funding
- Robust protocols and standardisation of techniques
- Experience in automated cell culture systems

Collaborative Functions

- The Automation Partnership won a collaborative grant from the Technology Strategy Board
- Appropriate patents are filed in open negotiation between the partners
- Twenty individuals from both academia and industry involved in the project

Outcome

- A patented automated workstation capable of producing consistent 3D tissue structures
- Grant applications submitted for spin-off projects in further areas of regenerative medicine

The Government's funding has also contributed to the establishment of NIHR's two Translational Research Partnerships (TRPs)

- *TRPs offer "an efficient and effective way for companies to work with some of the UK's leading translational research experts" --Dr. Allison Jeynes-Ellis, Medical and Innovation Director at the Association of the British Pharmaceutical Industry (ABPI)*
- TRPs facilitate collaborative efforts between the NHS, university clinical researchers, and life science companies in certain fields of clinical interest and unmet clinical need.
- The rationale behind TRPs is that they will attract investment from pharmaceutical companies, by providing access to a unique network of world-class research expertise, infrastructure, and cohorts for well-characterised patients for early stage research.
- There are currently two TRPs in operation:
  - Inflammatory Respiratory Disease - including asthma, allergy, COPD, cystic fibrosis, acute lung injury, respiratory infection
  - Joint and Related Inflammatory diseases - including, rheumatoid arthritis, osteoarthritis, synovitis
- A key feature to facilitate partnerships is the new set-up for a single legal agreement for collaboration with TRPs, thus cutting red-tape and eliminating the need for companies having to negotiate with NHS Trusts and universities individually. The NIHR Office for Clinical Research Infrastructure **(NOCRI) provides a single point of access** for companies to carry out research with TRPs.
- **TRPs build on the £800 million investment committed to the BRCs and BRUs. The launch of the two TRPs is supported by the allocation of £1.3 million in developing collaborations with industry, via NOCRI.**
- The activities of TRPs span a range of translational research, including pre-clinical models, exploratory trials, phase I and phase II proof of concept clinical drug trials and other studies of medical technology and diagnostic applications.

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The DH has provided £300 million to fund the NIHR Clinical Research Networks (CRNs) to strengthen the clinical research infrastructure for the NHS in England

- CRNs aim to strengthen research collaboration with life sciences industries and ensure that the NHS can meet the health research needs of the industry by:
  - Facilitating NHS patient recruitment and participation in clinical research
  - Streamlining the clinical study set-up process and providing technical support that NHS Trusts require in conducting clinical trials.
- CRNs allocate and manage funding to meet NHS Service Support (eg: additional nursing time, pathology sessions, lab costs, imaging and additional out-patient costs) for eligible randomised controlled clinical trials focusing on prevention, diagnosis, treatment and care.
- The NIHR CRN comprises of a 1) Coordinating Centre, 2) a Primary Care Research Network, 3) a Comprehensive Research Network, enabling research to be conducted across a full spectrum of diseases and clinical need, and 4) six topic specific research networks:
  - NIHR Cancer Research Network (NCRN)
  - Medicines for Children Research Network (MHRN)
  - Dementia and Neurodegenerative Diseases (DeNDRoN)
  - Stroke Research Network (SRN)
  - Diabetes Research Network (DRN)
  - Mental Health Research Network (MHRN)
- Over the past year NIHR CRN has made good progress in meeting its High Level Objectives as agreed by the DH.
  - **99% of NHS Trusts** in England now participate in NIHR CRN Portfolio studies.
  - **73% of commercial studies** approved by the MHRA were part of the NIHR CRN Portfolio, in 2011/12; a strong indicator of CRN's capacity to actively engage with industry.
  - **Exceeded quarterly target of 125,000 participants** every quarter in the last year.

Case 2: AstraZeneca and NIHR Cancer Research Network

- A collaboration between the NIHR Cancer Research Network offered academic investigators the chance to research promising molecules outside the industry's core programme for treatment of cancer patients.
- AstraZeneca wanted to evaluate their compounds in a broader range of cancers, and the Network (comprising of multiple clinical investigators) would gain access to novel molecules for improved oncology research.

Key Success Factors

- Access to, and engagement of AstraZeneca's decision makers in the company's UK Cancer Division Headquarters
- Ideas and innovative approaches to the development of drug candidates through effective workshops involving industry product and disease teams and academic study groups.

Academia	**Initiation**	Industry
NIHR Cancer Research Network		**AstraZeneca**
Offered		
Research Infrastructure NHS patient access Novel protocol development Objective molecule evaluation Integrated disease knowledge		Defined collaboration budget Portfolio of novel molecules Patient support costs Drug development expertise
Collaborative Functions		
• Joint protocol sign-off • Early stage data sharing • Collaborative choice of lead candidate molecules • Systematic collaborative support including model agreements • Combinational therapeutic approaches		
Outcome		
• R&D of drugs for cancers outside company's core programme • Earlier patient access to new and more innovative drugs • 14 Phase II Clinical Studies • A model of collaboration that can be rolled out in other disease areas with other industry partners		

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The NIHR is also investing £102 million in the NHS infrastructure for 19 **Clinical Research Facilities (CRFs)** for experimental medicine between September 2012 and March 2017

- **CRFs** are dedicated purpose-built facilities meant to support world-class experimental medicine research to translate scientific advances into benefits for patients.
- The NIHR funding will meet the necessary recurrent NHS infrastructure costs of CRFs such as clinical research nurses, technicians, and costs to run the facility.
- During 2011/12, NIHR held an open competition to renew NIHR funding for CRFs; they were selected by a national Assessment Panel. Funding for each CRF was designated to a single NHS organisation. Eligible costs include:
  - Research support staff supporting patient-focused experimental medicine research (ie: clinical and managerial leadership, research nurses, scientific and technical staff).
  - NHS service support costs within the CRF (ie: pathology, pharmacy, radiology).
  - Non-pay recurrent costs associated with running and maintenance of CRFs (ie: consumables, travel and subsistence, software and equipment.
  - Other legitimate and reasonable, indirect costs within NHS (ie: accommodation, payroll, HR, finance). NIHR does not meet indirect costs incurred by university partners.

The NIHR has also established **Healthcare Technology Co-Operatives (HTCs)** to address clinical areas of high morbidity and unmet clinical need

- HTCs address clinical areas by providing leadership in developing new medical devices, healthcare technologies, or technology dependent interventions.
- HTCs will engage with Academic Health Science Networks to accelerate adoption and diffusion of new technology-related health interventions throughout the NHS
- HTCs will be led by a clinical director and involve multidisciplinary teams working collaboratively with patients, charities, industry and academia
- In January 2012, the NIHR launched a new competition for HTCs, inviting clinicians and researchers to bid for infrastructure funding. This was to support collaborations between the NHS and industry, to lead the development of medical devices and healthcare technologies.
- The new scheme is built on a pilot scheme that funded two HTCs in 2008 through the Invention for Innovation funding programme, in partnership with the Technology Strategy Board, the Engineering and Physical Sciences Research Council and the Medical Research Council:
  - **The Devices for Dignity HTC** – focused on assistive technologies to help people with long-term debilitating conditions affecting their dignity and independence
  - **The Bowel Function HTC** –focused on new technologies to improve lives of people with Crohn's disease, ulcerative colitis, bowel cancer and other disorders affecting the bowel

Key Successes:

- **NHS Innovation Award, 2009**: awarded for an HTC innovation of a dignity bidet commode for stroke survivors
- **Cutlers Surgical Award, 2011:** a prestigious award for the development of the APPEAR and SMART surgical procedures and instrumentation for bowel surgery

The **Medical Research Council (MRC)** is a public organisation supporting world-class research across a spectrum of medical sciences

- The MRC works closely with key stakeholders like other UK research funders and organsiations, UK health departments, six other research councils, the Technology Strategy Board, industry, academia, and charity sectors.
- **The MRC is committed to translational research** and works closely with NIHR and other bodies to ensure there are integrated funding schemes and the needed infrastructure and facilities.
- **The MRC leads translational research on themes of experimental medicine, methodology and regenerative medicine, whereas the NIHR leads on clinical evaluations and trials.**
- The MRC prioritses partnerships and collaborations with industry and other public bodies **to accelerate the commercialisation** of laboratory research to products and interventions that add value to the economy and standard patient care.
- In 2011/12 the MRC's gross research expenditure was £768.8m (compared with £797.7m in 2010/11). This included:
- £309.9m on 1,100 grants to researchers in universities, medical schools, and research institutions.
- £354.6m on 440 programmes within the MRCs own research, units and institutes.
- £86.0m on studentships and fellowships, including those in MRC's own units and institutes.
- £18.3m for international subscriptions.

As part of the Government's Life Sciences Strategy, a landmark translational partnership was announced in December 2011 between the **MRC and AstraZeneca**

- The MRC supports successful translational research through the MRC Industry Collaboration Award (MICA), enabling academic-industry partnerships to apply for funding through MRC schemes. Seven MICAs were awarded 2011/12.
- **In a new type of collaboration, academia will be granted access to 22 compounds, developed by AstraZeneca**.
- Through MRC funding, UK academia will conduct studies to better understand what drives a range of diseases with a view to exploring new treatment opportunities.
- After evaluations of scientific research proposals from the academic community, **the MRC will fund £10m** in total to fund research across a broad range of diseases
- The rights to intellectual property (IP) generated using the compounds will vary from project to project, but will be equitable and similar to those currently used in academically-led research.
- AstraZeneca will retain rights over the chemical composition of the compounds, which have taken millions of pounds to develop so far, and any new research findings will be owned by the academic institution.

MRC Medical Research Council

AstraZeneca

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The Biomedical Catalyst fund is a three year **£180 million** programme intended to boost the commercialisation of new medical treatments

- The **Biomedical Catalyst** fund is an integrated translational funding programme jointly operated by the Technology Strategy Board (TSB) and the Medical Research Council (MRC).
- The fund is intended to provide seamless support for initial research conducted in universities, through to the commercial development in small and medium sized enterprises (SMEs). Three categories of funding are available:

Feasibility Award	Early-Stage Award	Late-Stage Award
Key Features: ◆ A feasibility grant enables the exploration and evaluation of the commercial potential of an early-stage scientific idea through: ◆ Gathering and review of evidence to inform decision making ◆ Assessment of business opportunity ◆ Investigation of intellectual property position ◆ Experimental studies to validate initial concepts of existing pre-clinical work ◆ Scoping for further development **Business-led applications:** Duration - up to 12 months Maximum grant - £150K Funding proportion - up to 75% of total eligible project costs **Academic-led applications:** Confidence in Concept Awards will be made available to researchers in major universities.	**Key Features:** ◆ An Early-stage grant is to evaluate the technical feasibility of an idea and establish proof of concept in a model system through: ◆ Experimental evaluation (lab-scale) ◆ Initial Demonstration in vitro and in vivo models (not human trials) **Business-led applications:** Duration - up to 3 years Maximum grant - £2.4M Funding proportion - up to 50% of total eligible project costs **Academic-led applications:** Duration - up to 3 years Maximum grant - £3M Funding proportion - awarded at RCUK FEC rules	**Key Features:** ◆ The Late-stage award is for the purpose of carrying a well-developed concept and demonstrate its effectiveness in a relevant environment through: ◆ Initial human proof-of-concept studies ◆ Demonstration of safety and efficacy (including phase I and II clinical trials) ◆ Development of production mechanisms ◆ Prototyping ◆ Market testing ◆ Intellectual Property Protection **Business-led applications:** Duration - up to three years Maximum grant - £2.4M Funding Proportion – up to 50% of total eligible project costs **Academic-led applications:** Duration – no formal limit Maximum grant – no formal limit Funding Proportion – awarded at RCUK FEC rules

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All applications for the **Biomedical Catalyst Fund** are assessed by independent reviewers drawn from academia and industry

Funding Criteria:

- The project – whether individual or collaborative— **must be led by a UK business.**
  - Publicly funded bodies are generally unable to receive grants and a public sector collaborator's costs may reduce the overall grant available from the TSB. However, public sector organisations with commercially generated revenues may be counted as an industry partner.
- In terms of eligible costs, funding provisions will consider the defining criteria of collaboration, specifically:
- Between two partners – one partner must undertake at least 30% of the work
- For more than two partners – any one partner cannot carry out more than 70% of the work
- Total Funding Limits:
  - Up to 75% for Basic Research projects
  - Up to 50% for Applied Research projects
  - Up to 25% for Experimental Development projects

Recent Developments:

- On August 2012, the Medical Research Council (MRC) and the Technology Strategy Board (TSB) made the first funding awards.
- **£39 million** worth of grants have overall been awarded to universities and small and medium-sized businesses (SMEs) supporting 32 projects, leveraging in significant private finance making the total value of the work in excess of £63 million.
- Grants to the 22 SME-led projects, totalling £29.6 million, will be administered by the Technology Strategy Board.
- Grants to the 10 university-led projects, totalling £9.5 million, will be administered by the Medical Research Council.

Ixico, a world-class medical imaging company has won a significant funding amount of **£2.1 million from** the Biomedical Catalyst Fund

- The London-based medical imaging company **Ixico** and the British developer of neuropsychological tests, Cambridge Cognition were awarded a grant from the Biomedical Catalyst Fund in November 2012.
- Ixico will work alongside **Cambridge Cognition**, a leading UK developer of neuropsychological tests, and their projected partners at King's College London, University of Sussex and Imperial College London.
- The grant will fund a project to build and test a novel digital healthcare platform, which will provide an earlier, more accurate, and cost-effective diagnosis of dementia.
- The three year collaborative project aims to demonstrate a significant decrease in the diagnosis of dementia – **from an average of 18 months to just 3 months,** thus enabling patients to access timely treatment.
- World-class computer-based tests of memory and thinking will be integrated with computerised analysis of MRI brain scans, to make automated and accurate diagnostic reports that lead to rapid treatment for patient.

IXICO

cambridge cognition

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NOCRI has worked together with MRC to draft templates of model agreements between life sciences industries, universities and the NHS, to streamline the research contracting process.

- The Government has supported the development of a series of model Agreements, to help **speed up the contracting process** for clinical trials, clinical investigations of medical devices carried out in the NHS, and research partnerships involving pharmaceutical and biotechnology industries, universities, and NHS organisations. These include:
- **model Clinical Trial Agreement (mCTA)** for pharmaceutical industry funded trials in NHS hospitals.
- **model Clinical investigation Agreement (mCIA)** for medical-technology industry funded trials in NHS hospitals
- **model Industry Collaborative Research Agreement (mICRA),** launched in February 2011, for research collaborations involving the pharmaceutical and biotechnology industries, academia and NHS organisations.
  - Representatives from industry, universities and the NHS, and the Intellectual Property Office, were brought together with expert legal opinion to develop a model Agreement that can be used to support all collaborative research scenarios.
  - One of the key features of mICRA is that it provides a series of options for handling the ownerships of any intellectual property rights resulting from collaboration. It provides guidance to collaboration partners to decide which option is most suitable for them.

Cell-based therapy will be of clinical significance and a key priority in developing the future of UK healthcare

- **Cell-based therapies** have shown many uses, including regenerating tissues and drug development mechanisms. They already demonstrated **significant medical advances** such as skin regeneration in patients with wounds, and therapeutic vaccines for prostate cancer.
- The global commercial cell therapy industry has been estimated to have an annual turnover of $1bn in 2011; this is estimated to rise to $5bn by 2014.
- The UK is well-positioned to gain a substantial share of this market with an infrastructure that eases access to NHS patients, a mature capital market and established life sciences industries.
- **Through the NIHR and the Technology Strategy Board (TSB) the Government will invest up to £10m per annum in the Cell Therapy Catapult (formerly known as the Cell therapy Technology Innovation Centre).**
  - This will be supported by a joint investment of £25m over the next five years by the MRC, Engineering Physical Sciences Research Council (EPSRC), and the Biotechnology and Biological Sciences Research Council (BBSRC).
- The Cell Therapy Catapult Centre will aim to assist SMEs in the scaling-up, repeatability, quality control and assurance, developing manufacturing processes and establishing supply chains.
- It is common to the French consortium of biotechnology companies and academic centres, CellforCure (C4C), with funding of €30 million from the French government innovation agency OSEO, for the purpose of developing the first French technical support centre for manufacturing of cell therapy products
- The Cell Therapy Catapult Centre is located in London within the NIHR Biomedical Research Centre at St. Guy's and St. Thomas's NHS Foundation Trust and King's College London. It expects to move into the heart of a cluster of hospitals, clinical research centres and universities, at the end of 2013.

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Academic Health Science Centres (AHSCs) will be distinguished by world-class research capability and clinical excellence

- An AHSC strategically and operationally integrates clinical service, research and teaching from geographically co-located leading academic and healthcare institutions.
- **The AHSC model is well established in Sweden and the United States with the leading international equivalents being:**
  - **Karolinska Institutet in Sweden**
  - **Johns Hopkins Medicine in US**
- The first UK AHSC created was between Imperial College Healthcare NHS Trust and Imperial College London, in October 2007.
- On March 9th 2009, the DH announced the successful accreditation of five AHSCs in the UK.
- Accreditation is awarded for a set period of five years and the centres are subject to review with a re-application process.

Recent Developments

- An AHSC delivers a whole greater than the sum of its parts.
- AHSC between Imperial College Healthcare NHS Trust and Imperial College London expanded to the Imperial College Health Partners.
- Imperial College Health Partners will work with providers in North West London, and the North West London Local Education and Training Board to share innovations and train healthcare workers.
- **The partnership provides access to the population of 1.9 million.**
- **This presents significant research opportunities to be operated at a large and meaningful scale for effective clinical trials.**

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Academic Health Science Networks will focus on the rapid diffusion and adoption of innovative health technologies

- AHSNs will bring together many different stakeholders to focus on identification, adoption and spread of innovative healthcare.
- AHSNs are meant to play a crucial role in the translation of research into practice; they will complement and support AHSCs, which are smaller in scale (in terms of geography and organisations) by creating a system for the ***delivery*** of innovation.
- The aim is that all NHS organisations should be affiliated with their local AHSN. They are meant to provide the following functions:
  - Research participation
  - Translating research and learning into practice
  - Service improvement
  - Information
  - Education and training
- AHSNs will hold a five-year license with plans to see the first networks emerging by March 2013; they will develop infrastructure and plans regarding process and functionality between April—September 2013, and are expected to be fully operational by October 2013;
- **The pharmaceutical industry is keeping a close eye on the nascent AHSNs.** Its key feature is that they have been designed to provide the industry with points of access to the NHS.

12 to 18 AHSNs will be established and spread across the country

3 – 5 million population size covered by each AHSN

£2 million per one million of population, per year, (up to a maximum of £10 million)

What can Sweden learn from the UK?

- The healthcare system in the UK is going through massive reform – the result of which remains to be seen
- The UK is partly struggling with the same issues as Sweden when it comes to innovation: there are excellent structures for the assessment of new technologies, but the national recommendations are non-binding and consequently there are large variations in the technology uptake.
- There are no structured reimbursement systems for innovative products or services in the UK. However, the NHS has identified innovation as one of their key objectives and has built up an infrastructure to support innovation.
- "Innovation" has central place in policy-making. There is an innovation directorate on the national level, at the Department of Health
- The UK holds some of the most prestigious universities in the world. The country has well-developed medtech and biotech sectors, but given the competitiveness of its academic training and research the size of the medical industry is less impressive. Some stakeholders in the UK suggest that this is a consequence of scepticism among academics towards collaborating with commercial companies.
- **Actions are taken to ensure that NICE recommendations on innovative products are implemented across the country.**
- Interestingly, the UK say that they have taken the idea of *academic health science centres* from Sweden.
- Since the measures applied in the UK and Sweden are fairly similar, the lesson we can learn is not *what* to do, but *how* to do it.
  - Will the efforts to enforce NICE guidelines at the local level across the country be successful?
  - Effects of the new infrastructure – the centres, clusters etc?

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The Danish Healthcare System – Infrastructure For Innovation

Facts – the proportions of Danish healthcare

- 9 of 10 Danes, are each year in contact with the Danish healthcare system, via hospitals, their GP or a specialist.
- 2,5 million each year are treated at hospitals, additionally around 120.000 patients are in psychiatry treatment (in- or outpatient)
- 1,1 million patients each year are hospitalised on somatic hospitals, additionally around 40.000 patients are hospitalised for psychiatric treatment
- Each year the Danish Hospitals undertake 7,8 million ambulant somatic treatments. Out of this, 950.000 emergency room visits. In addition there are 950.000 ambulant visits on psychiatric hospitals.
- In 2011, there was undertaken 1,3 million operations. This number has increased with 150.000 since 2007. Also hospital services has experienced growing activity. From 2007 till 2010, there has been a growth in treatment-activity with roughly 25 %.
- It is estimated, that 41 million contacts are established to GP's annually. Further it is estimated that patients pay 5 million annual visits to private specialist doctors.

The hospitals

- Denmark has 53 public hospitals, with the capacity of roughly 18.300 inpatients.
- There are 104.000 full-time employees at public hospitals, distributed as follows: 14% doctors, 33% nurses, 23% with other health professional background, 30% additional personnel, involving psychologists, social worker staff, administrative personnel, cleaning staff, technical personnel etc.

Denmark in total

- There is a total of 18797 doctors in DK, amounting to 34,24 doctor pr. 10.000 Dane.
- Nurses and midwives amounts to a total of 88.335, corresponding to 160,93 nurses and midwives pr. 10.000 Dane.

According to the Euro Health Consumer Index (Health Consumer Powerhouse), Denmark has the second best healthcare system in the EU. The patients rights and patient information are core priorities.

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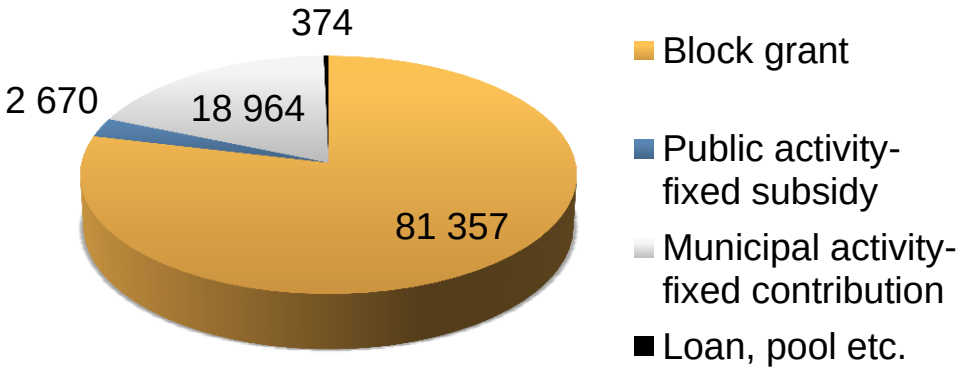
The Danish healthcare system is structure in three levels, but the regions has the primary responsible for public healthcare

- With the 2007 Danish structure-reform, the Danish political structure and healthcare system, went through some major organisational changes.
- The 271 local councils where reduced to 98. The 14 county authorities, was restructured into 5 new-established regions. This means that the Danish healthcare system is now structured in three levels: State, regions and municipalities.
- The state task involves the overall planning of public healthcare.
- The 5 regions has the main tasks of handling public healthcare with responsibility including hospitals, psychiatry treatment, and national health insurance (general practitioners, specialist doctors, and medical subsidy).
- Since 2007 the newly established regions have played a central role in public healthcare, however they also handle tasks within social policy and regional development.
- Since it is both up to the region to handle public healthcare and regional development, it is understandable that the regions has taken several initiatives in developing programs for Innovation with the purpose of helping the healthcare sector provide better healthcare, and at the same time, help Small and Medium Enterprises (SME) within healthcare to experience growth.
- For the municipalities, the main tasks involves the outpatient segment: Prevention, nursing and rehabilitation (not taking place during hospitalisation or in continuation of hospitalisation), treatment of alcohol and drug-abuse, home nursing care, the municipal dental care, specialist dental care and social psychiatry.

The Danish healthcare system is primarily financed by public means

- The government block grant for financing the healthcare sector, did in 2012 amount to 81.356,6 million DKK corresponding to 79 % of the regions revenue within healthcare.
- The extensive amount on healthcare financed by government resources means that Denmark has an almost record low 14,9 % private spending on health, as of all health spending.
- The Danish healthcare system has annual expenses exceeding 100 billion DKK. This converts to 17.920 DKK per Dane.
- Hospitals are by far the area with the biggest expenses with 78 Billion DKK.
- GP expenses amounts to 15 Billion DKK.
- Pharmaceutical subsidy amounts to approximately 7 billion DKK.

Regional revenue for financing the healthcare sector in million DKK.



The trend

Healthcare expenses are rising. Within the last 12 years, expenses have gone up by 30 billion DKK amounting to a 43 % increase. This means an annual increase of around 3-4 %.

Analysis shows that from 2004-2010, the productivity on public hospitals in Denmark has gone up by 12 %.

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The legal framework for innovation – The public ownership of inventions

Opfinderloven (The Inventor-law):

- Since 2000, all employees at private companies, public Danish research institutions, universities and hospitals, are obliged to report inventions to their institution.
- The Inventor-law reflects the employers interest in ensuring the inventions that is done by employees as part of their job – but also the wage-earners right to compensation for an extraordinary invention, which extends the work an employer can reasonably expect.
- A major problem for the inventors, is the main rule of a three year period of limitation, which mean that the inventor have to demand a reimbursement before no one knows the actual value of the patented invention. As inventions may take more than 10 years to reach the markets, a three year period of limitation gives an advantage to the employers.

Lov om opfindelser ved offentlige forskningsinstitutioner (The law on inventions made by public research institutions)

- If a university decides to take over the rights to the invention, it must assist in seeing to it that the invention is used commercially. The research institutions are not to be viewed as extensions of the companies' own product oriented laboratories. Rather, the knowledge institutions' task is to ensure that research results, which have a certain probability of being used commercially, will be patented.
- The purpose is to ensure that research achievements generated by public means, also benefits the Danish society as such, through commercialization. The research institutions does not only have the right, but also the obligation to work with patenting and commercialization which enhances the cooperation between public and private actors. Even though it is formally the employer that owns the invention, the researchers behind a commercialized invention, often gets part of the economic return.

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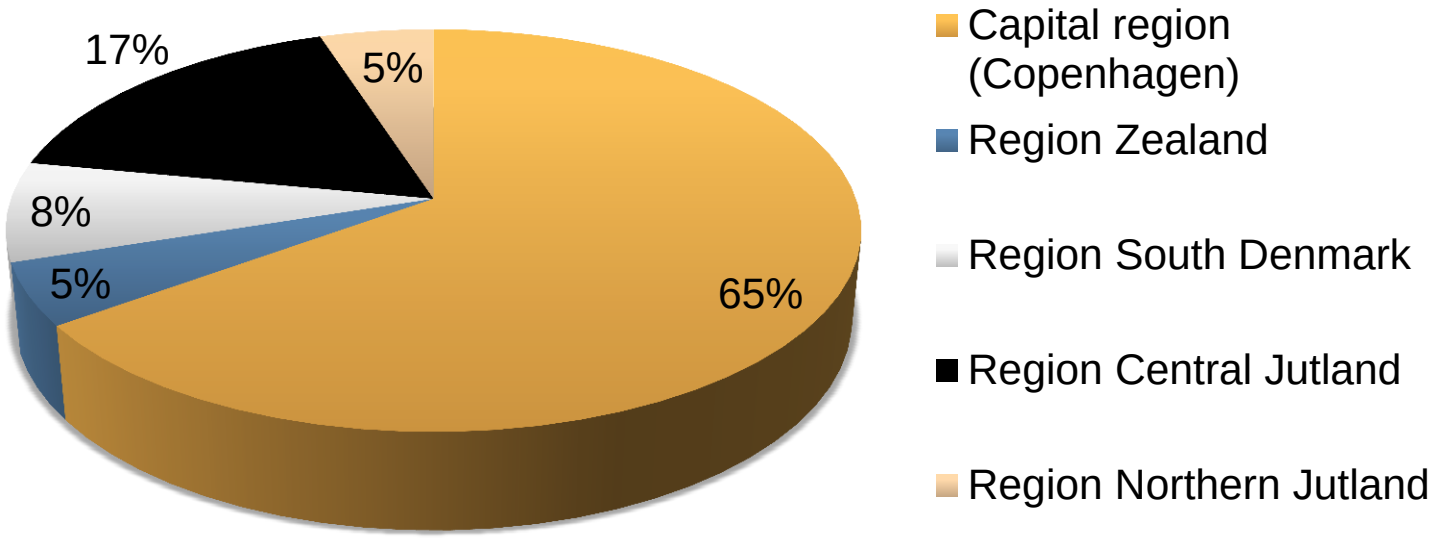
Public-private investments in R & D mainly takes place in the capital region

Total overall public and private investments in research and development divided in regions.



Notice that there is done no distinct statistic for the healthcare investments, but healthcare is the biggest area in regard to R & D. 70 % of the innovation investments, takes place in and around the capital of Copenhagen, within the region of Medicon Valley.

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Medicon Valley - The physical infrastructure for innovation

Medicon Valley is the transnational cooperation between Denmark and Sweden within life-sciences. The cooperation was formalised in the 90's with financial support from the European Regional Development Fund (ERDF).

With several airports, the Öresund bridge, close cooperation within sharing of knowledge, Medicon Valley has a well established physical infrastructure.

Public investments in R&D and education, combined with International co-operation within pharmacy and biotech gives spin-off potential to SME's in Medicon Valley.

"According to the hospitals, the biggest challenge, in regard to innovation in healthcare, is that it is very difficult to convert innovation in cost reduction, since large parts of the expenses are for objects, instruments and personnel that is already there. The problem is similar to the costs of flying an airplane. Prize is the same regardless if the airplane is full of passengers or empty". - Innovation manager Health Innovation Zealand

The Danish healthcare industry is a significant sector

Specialised in Diabetes care and Biopharmaceuticals.

Measured on market value, Novo Nordisk is by far, the biggest company in DK. It has a global workforce exceeding 33.900 employees, out of these around 14,600 is employed in DK. 18% of the total employees work within R & D.

LEO Pharma

Specialised in dermatological sufferings, and prevention and treatment of blood clots

LEO Pharma has around 5000 employees world wide, out of these, 1.600 are placed in DK. 500 of the companies employees work within R & D. Its turnover and employment rate has been growing steady for many years in a row.

Specialised in disorders such as, psychotic disorders, epilepsy and Huntington's, Alzheimer's and Parkinson's diseases

Lundbeck employs 6.000 people worldwide, 2.000 of whom are based in Denmark. Production is taking place in several different countries. Lundbeck ploughs back around 20% of its revenue into R&D of new pharmaceuticals and as a result, the company has research centres on 3 different continents. Lundbeck generated revenue of approximately 16 billion DKK in 2011.

- With a population of 5,58 million, Denmark has a relatively high employment within Medtech and pharmaceutical production.
- In 2010, the export of pharmaceutical products reached a record of 52 billion DKK. Today 90 % of the Danish pharmaceutical production is exported.
- Including the areas of non-pharmaceutical healthcare products and assistive technology, the overall healthcare export amounted to 68 billion DKK in 2010, corresponding to 12 % of the overall Danish export.

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The Danish DRG system

- The DRG-system was originally introduced in 2000 as part of the political Initiative: “free choice of hospital”. Since patients could freely chose between which hospital to get their treatment, there emerged a need for a system that could settle rates for payment between the counties which are now replaced with regions.
- The system has developed since then. First as part of a public activity pool, a political initiative to reduce the waiting time which enhanced the activity on the hospitals and the activity between the them. Also in 2004 the system was further developed with further rate regulations.
- The DRG-system is now used in carrying out the distribution of the public activity pool, calculating the municipal activity-fixed contribution, settlement of accounts between the regions in matters of cross-regional patients, in regard to rate financing and as a tool in analysing expenditure and activities on the hospitals.
- The DRG system serves as foundation for the future structure of the hospitals, where there are expected an increase in cross regional activity.

The DRG, which is used for the inpatient segment

And the DAGS (Danish Ambulant Grouping System) used for the ambulant patients on the somatic wards.

Interactive DRG

- With the interactive DRG, it is possible to find the DRG-group for a specific patient. It uses specific combinations of diagnose and procedure codes, in determining the DRG group for the patient and it gives information on the rate for the DRG-group.

Visual DRG

- Visual DRG can’t be used for classifying patients. Visual DRG is a visual summery that illustrates the grouping for the whole somatic segment with the purpose of giving the users a clear overview of the different groupings.

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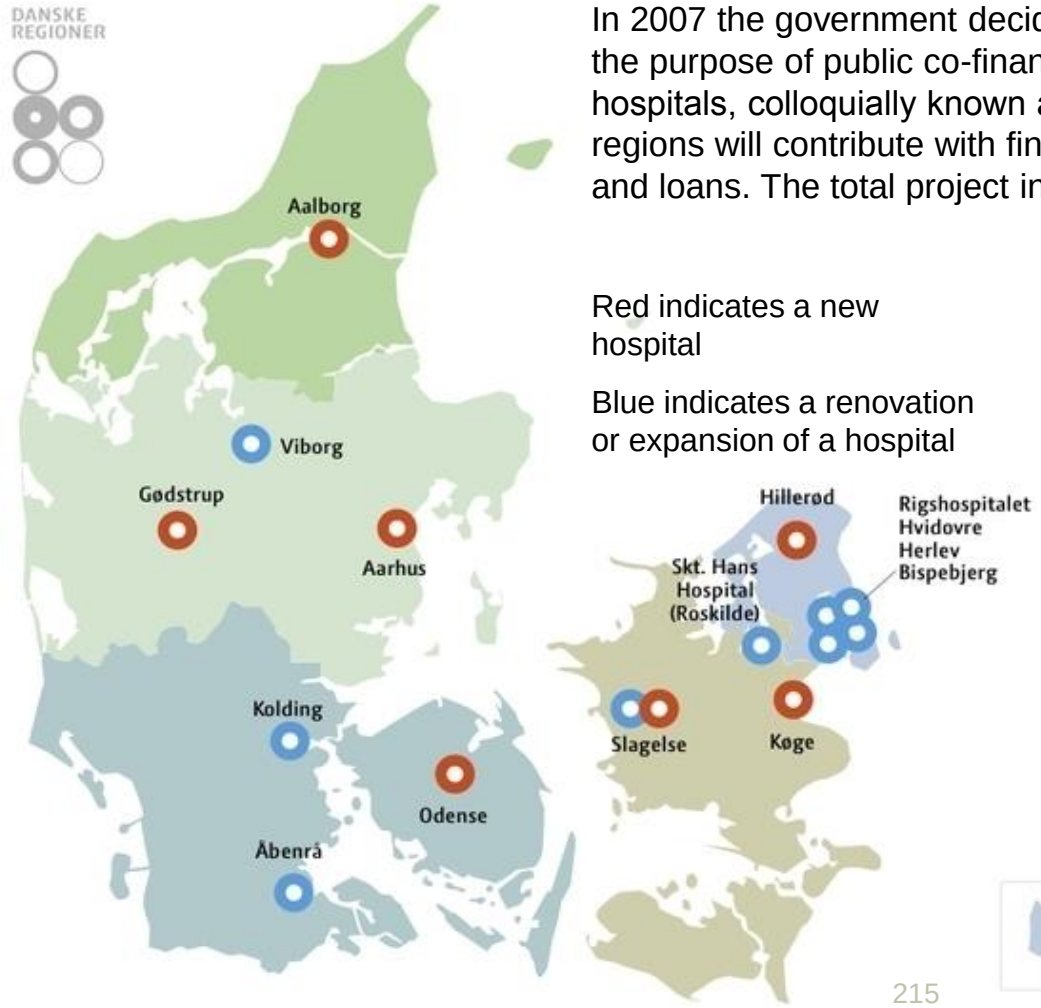
Public investments in the future structure of the Danish healthcare system – The Super Hospitals



In 2007 the government decided to allocate 25 billion DKK in a fund with the purpose of public co-financing of investments in a new structure for the hospitals, colloquially known as “The Super Hospitals”. In addition the regions will contribute with financing through ordinary construction funds and loans. The total project investment is fixed at around 45 billion DKK.

Red indicates a new hospital

Blue indicates a renovation or expansion of a hospital

- As an overall requisite and goal, the new structure should gather the functions, knowledge and expertise on fewer units, with the intention to enhance the competences and efficiency on the Danish hospitals.
- In total, 16 building projects will be supported. Some of the funding will be used for renovation and expansion, but a total of 7 new hospitals will be build over the next 10-15 yeas. 3 out of the 7 new hospitals began constructing in 2012.
- It is estimated that 20-25 % of the total expenditure will be used on IT and different kinds of apparatus.

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The public renewal fund is meant to support Innovative solutions in regard to the new Hospitals

- The 100 million DKK public renewal fund has been established in connection to innovative healthcare solutions on the new super hospitals.
- “The Hospital Partnership” administers the 100 million DKK fund.
- The fund is meant to support the Public-Private cooperation and innovation projects. The partnership can choose to support innovation projects where private enterprises in cooperation with the hospitals and other relevant partners, can develop commercial concepts or prototypes, which has relevance for the new Super Hospitals.
- The criteria for granting the funds, has to live up to criteria such as growth, employment, effect on welfare, news value, user driven innovation and commercial affiliation.

The fund is supporting projects, dealing with concrete evolving problems on the hospitals. During the last couple of years, there has been a dramatic increase in intestinal bacteria obtained by inpatients. Further the council for better hygiene; estimate that bad hygiene causes 3000 deaths each year, some of these on Danish hospitals. The fund is therefore especially encouraging innovative solutions, targeting this problem.

The public renewal fund has initiated an initiative regarding innovative public procurement where hospitals can get support for the use of “functional tender” (funktionsudbud) in the demand process of new innovative solutions. Instead of setting demands for the activities leading to the delivery of services, Funktionsudbud put demands to the function of the delivered good or service.

An analysis carried out by the tender-council shows, that Funktionsudbud can contribute in fostering innovation and enhancing the quality and flexibility in the solutions of public tender.

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The public renewal fund is meant to support Innovative solutions in regard to the new Hospitals

Two other examples of projects supported by the innovation fund

Project owner: Nordic Medical Supply A/S
Grant: 3,5 million DKK

Project budget: 6,5 million DKK

Anticipated effect of the project: 113 jobs created after 5 years. 200 million DKK Increased turnover after 5 years.

- The objective of the project is to create a flexible suspension system for surgery equipment, hanging from the ceiling.
- The new system should make it possible to configure the operating room to different kinds of operations. Hereby optimizing coefficient of utilization and simultaneously minimize the hard manual work, which the surgical nurse and operators are exposed to when moving around the equipment by pushing it across the floor.
- This is achieved among other things, by smaller surgical lights with more effective lightning and a motorized rail system.

Project owner: DELTA A/S

Grant: 10,6 million DKK.

Project budget: 23,6 million DKK.

Anticipated effect of the project: 35 jobs created after 5 years. 32 million DKK Increased turnover after 5 years.

- 12.000-20.000 Danes each year suffers from a stroke. Each patient aggregates to 100.000 DKK in direct immediate costs. Taking into account rehabilitation and extra home help a society cost estimation amounts to around 7 billion DKK.
- DELTA A/S cooperate with the German firm Apoplex Medical concerning “e-Patch”, an electronically plaster based on a wireless sensor system for measuring of specific heart rhythm disturbance which typically is a warning for strokes.
- The plaster can screen people in the risk-group with a view of initiating preventive treatment.

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The Ministry of Science, Innovation and Higher Education together with the Ministry of Business and Growth are in charge of the overall Innovation planning

The four main public actors identified in linking SME's into RDI activities

The regions

- Responsible for the hospitals and regional development, the Danish regions are the most important actor regarding innovation in the healthcare sector.

The innovation environments

- Consist of 6 units deployed around the country. On behalf of the state, the innovation environments invest venture capital in new innovative companies. The contribution can either be in form of loan or as a owner's share. To a greater or lesser extend, all 6 units has healthcare related companies in their portfolio.

The GTS- institutes

- There are 9 GTS-institutes in Denmark. Their objective is to spread the most recent knowledge and technology to the business community, enhancing the competiveness of Danish companies. 4 out of the 9 institutes work within healthcare.

The 22 innovation networks

- The 22 Danish innovation networks helps companies find business partners. Innovation Network Denmark has 22 nationwide innovation networks and three strategic platforms. An innovation network is a forum where companies and knowledge institutions share experience and develop new ideas within a specialised or technologically delimited field. 4 out of the 22 networks are specified within healthcare and Medtech.

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With the responsibility for administration of the hospitals and regional development, the regions are the most important actors in innovation

- Danish regions is the professional body for the 5 regions.
- The five Danish regions, have established their own innovation strategy, each region with their own focus and goals within healthcare innovation.
- Danish regions safeguard the interests of the regions on a national and international level. Further it manages the overall strategy for the regions and make sure that important knowledge acquired in one region are passed on to the others. Two executive initiatives are:

The regions Health-IT organisation (RSI)

- RSI engage in joint tender processes and procurement of new IT-systems, coordinating and further developing on the hospitals IT-systems and developing new services, making it possible to share data across the different sectors of the healthcare system.
- Further the RSI has set up several goals for how IT-solutions can be used in innovative solutions in the future:
- Electronically boards in the bigger emergency departments.
- Strategy on how telemedicine can be used as a solution for optimizing the operation of the hospitals.
- Plan for IT-support of the preventive healthcare effort for the outpatients.

Knowledge sharing in the healthcare system (ViS)

- As a result of ViS, their website allows knowledge sharing in different networks. The users can share their knowledge, ideas, experience and get inspiration in professional networks.
- There has been established knowledge and idea-banks supporting the regions efforts in spreading good ideas in the relation between users, patients and relatives, easing the distance between initial idea and innovative product.
- Further the ViS unit work in method development and organise courses for both patients, relatives and healthcare professionals.

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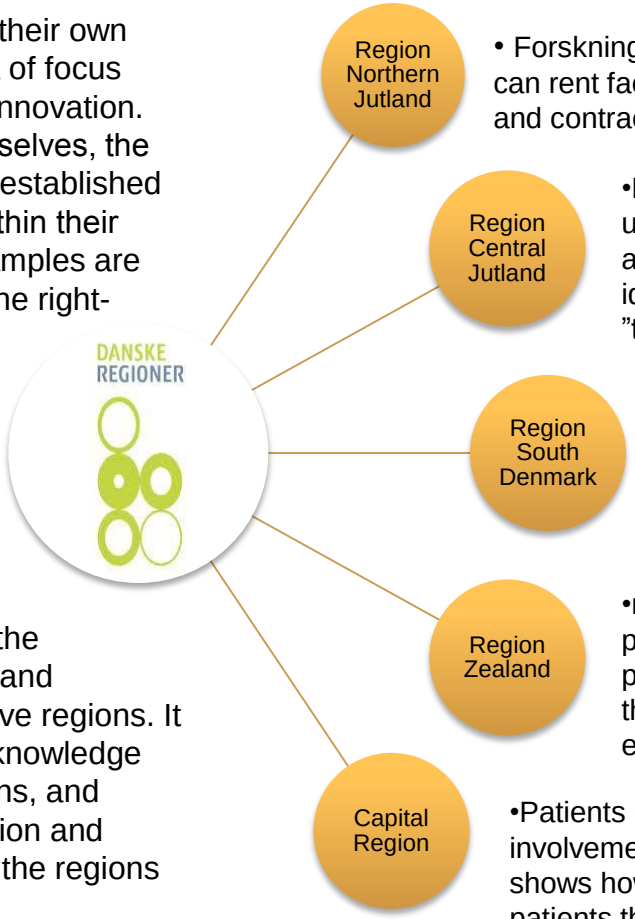
Each region has made their own innovation strategy to suit their specific business environment

Each region have their own structure and area of focus within healthcare innovation. Being TTO's themselves, the regions have also established new sub-TTO's within their regions. A few examples are accounted for, in the right-side text-boxes.



• Forskningens hus, the science and innovation centre of Aalborg Hospital. Employees can rent facilities for the early phase of new companies. The centre also have patent and contract-unit, Further the centre provides help for fundraising.

•MedTech Innovation Center is created with the purpose of unfolding the potentials in the regions Biotech and Medtech projects and companies. With an increased focus on implementation of ideas, inventions and research results, MTIC helps optimising the "time to market".

•Velfærdsteknologi.nu is an initiative that functions as a promoter for entrepreneurship, creating an overview of possibilities for venture capital. Velfærdsteknologi.nu works as a gathering point for actors that wish to create expenditure savings through welfare technology.

•mHealth is the regions focus on how to involve the users in their own patient security. Smartphone's, mobile sensors and Apps, open the possibility for increased patient security, since the patients can monitor their own vital data. Region Zealand will be used as a more explicit example of the regions infrastructure, on the next slide.

•Patients house is a project aiming at enhancing the involvement of the patient. In doing this, the project shows how patient involvement can creates value for the patients themselves and hereby also for the hospitals. User-driven innovation and PP-innovation cooperation are keywords in reaching this objective.

Danish regions is the professional body and caretaker for the five regions. It helps distribution knowledge between the regions, and helps communication and coherence across the regions

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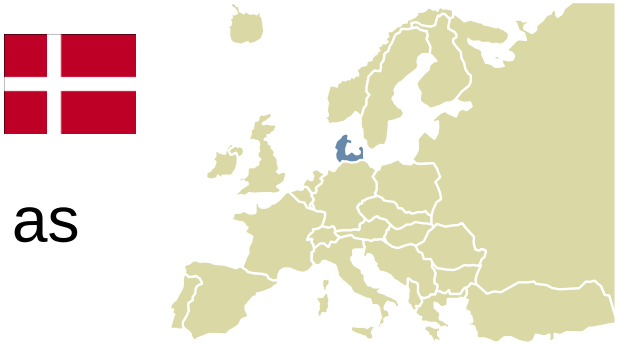


Organisational chart – the capital region as an example

The Capital Region council and other political organs

The region is lead by 41 politicians elected by the people

Concern-executive board

Consisting of the region chief executive officer and 4 group managing directors

Extended executive board

Consists of the concern-executive board and 14 hospital managing directors

The unified group management board

Consists of the concern-executive board, the 14 hospital managing directors, the hospital manager of Bornholm Hospital, de 8 centre-managers on Rigshospitalet and 9 staff managers.

The 15 hospitals in the capital region

The 9 groups of region staff within HR, IT, economy, communication etc.

Healthcare Innovation Zealand (HIZ) is the innovation body established by the Zealand region

- HIZ is a public regional actor, established by Region Zealand in 2011. The organisation has a vision to improve patient security and life quality through the development of new technologies for patients.
- The staff is assembled by persons with different backgrounds, who are used to work and communicate interdisciplinary and use knowledge from different sectors, thus creating a basis for innovation.
- HIZ helps people unfold their ideas within healthcare innovation. The work involves creating contact and network between institutions of knowledge, relevant public and private actors, patent research, legal research and consultancy etc. HIZ test ideas and serve as a helping public body for innovation.
- HIZ has a clear focus on user-driven innovation. It is the doctors, nurses and patients that deals with the healthcare problems in their every day lives. They are the one's who knows what the exact problems are and therefore they are also the origin of the solution. Though, the users may also contribute in another way:
- *"The biggest challenge is to strengthen the citizens to increase their own responsibility for their own health. Among other things this can be done through new mobile technology and medical technology evaluation tools. It is the self-service that has increased productivity over the last 10 years in other sectors, there is still a big potential for this within healthcare."* – **Innovation manager - HIZ**

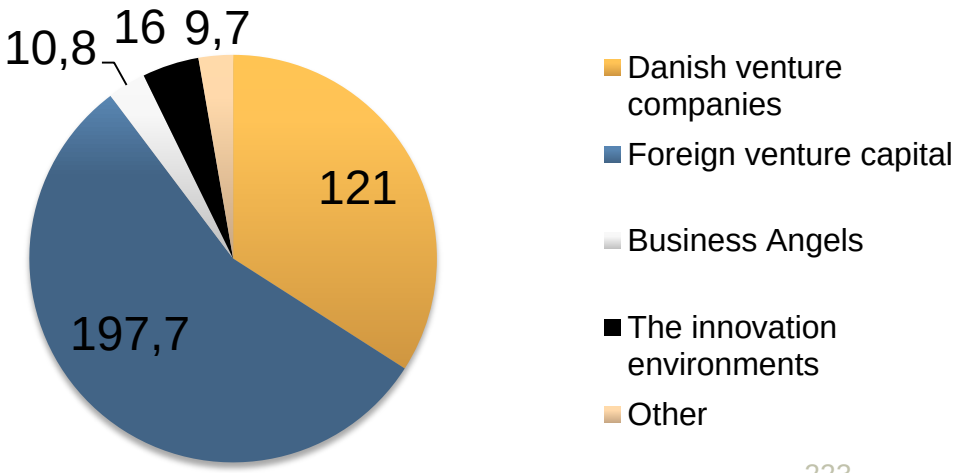
The Innovation environments invest in the early phase before private venture capital will even consider investments

On behalf of the state, the 6 innovation environments invest venture capital in new innovative companies. The contribution can either be in form of loan or as a owner's share. To a greater or lesser extend, all 6 units has healthcare related companies in their portfolio.

In 2011 the biotech and medico companies attracted 355,2 million DKK. This amounts to 39,6 % of the overall capital for the innovation environments.

The companies in the business environments portfolio, attracts a high amount of venture capital from private investors. Though many of the companies would never have seen the day of light, had it not been because of the even higher risk capital, provided by the innovation environments.

Capital supply in companies where Innovation environments have shares within Biotech/medico. DKK in millions.



The 6 innovation environments:

- **CAT Innovation A/S**
- **DTU Symbion Innovation A/S**
- **Innovation Midtvest A/S**
- **NOVI Innovation A/S**
- **Syddansk Teknologisk Innovation A/S**
- **Østjysk Innovation A/S**

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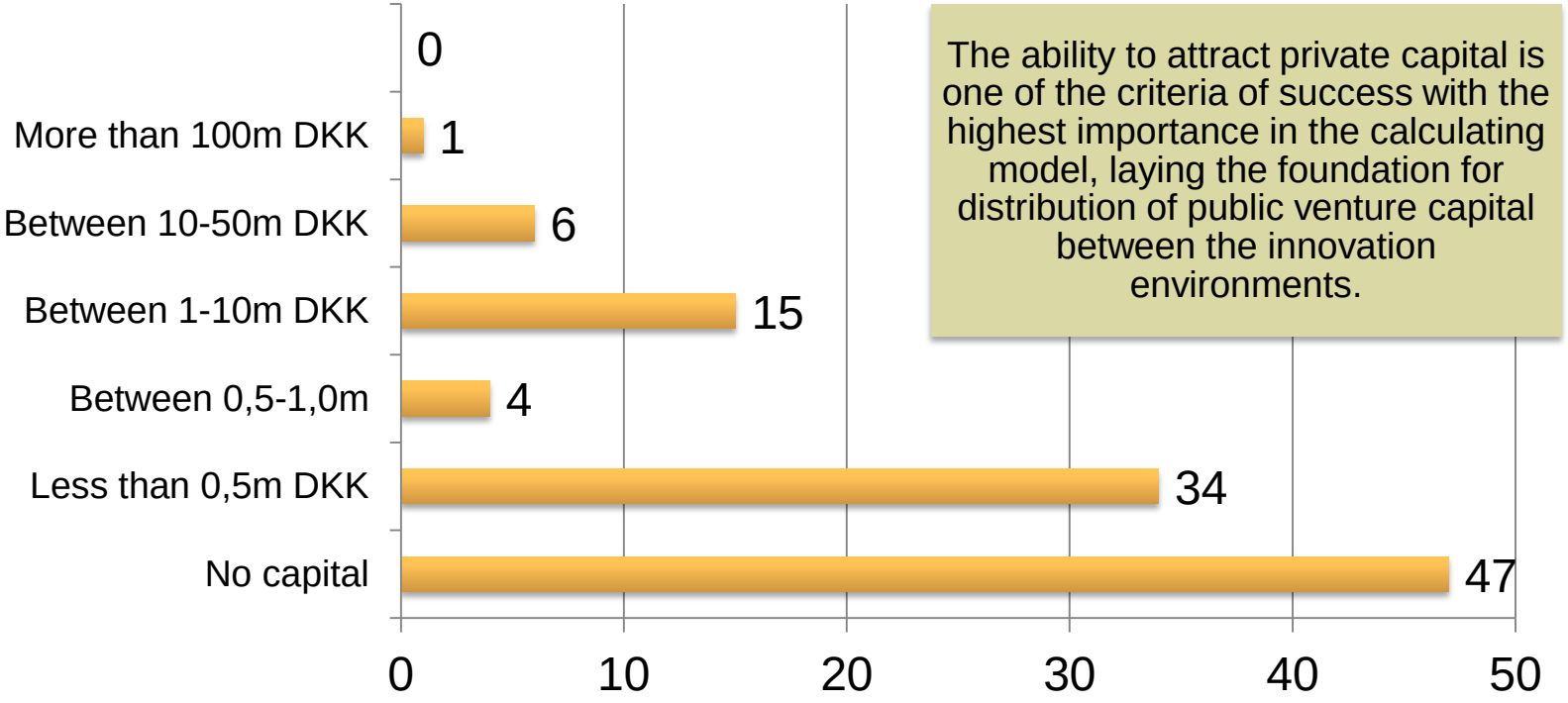
The innovation companies ability to attract private capital – innovation environments

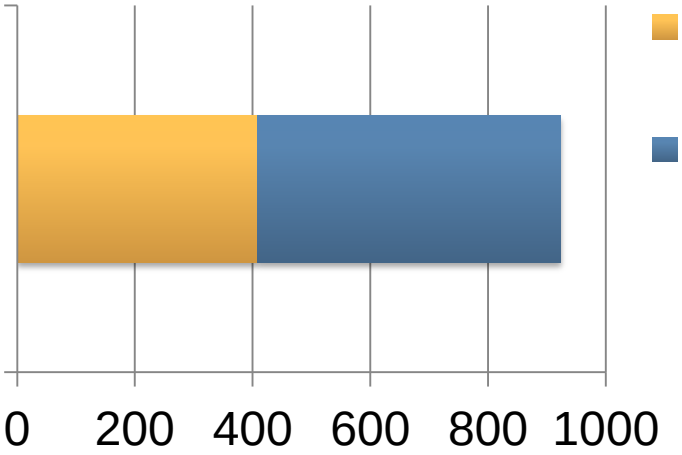
Numbers of biotech and medico companies in the portfolio, that attracted private capital in 2011



The ability to attract private capital is one of the criteria of success with the highest importance in the calculating model, laying the foundation for distribution of public venture capital between the innovation environments.

Overall the innovation environments shows a low survival-rate, but many innovation companies base their business-model on sell-offs

Newly established companies in the periode 1998-2011



Compared to other sectors, the Biotech and medico companies does, to a high extend originate from research. 55 out of the 107 companies in the portfolio, origins from research on universities, research institutions, GTS or research carried out on hospitals.

Compared to IKT, which also had 107 companies in the portfolio, only 24 companies origin from research carried out on these institutions thus emphasising the importance of interaction between Healthcare innovation and institutions of knowledge.

It should be noted that this is the overall numbers, also including IKT, Industry and environmental companies. Further some companies base their business model on sell offs, meaning that their patent gets sold after some time, thus undermining the companies reason for being.

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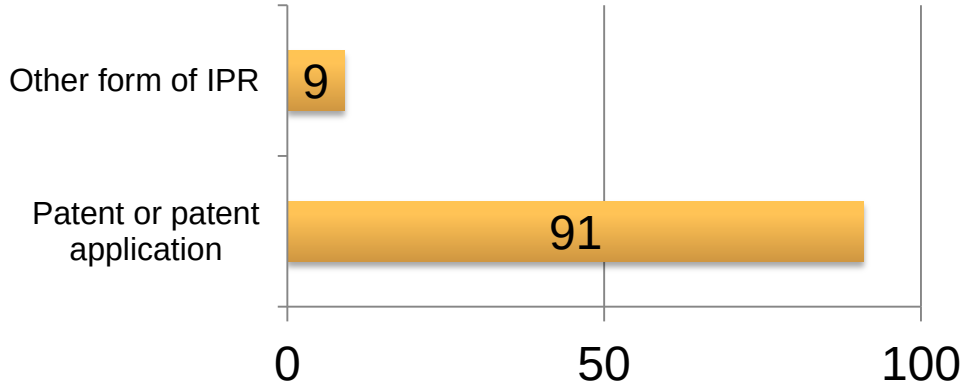
The companies in the Innovation environments often base their business model on selling IP rather than manufacturing and marketing products

- The environments invest in project where the risk to begin with are too high to attract capital from private sources, but at the same time the projects hold a high potential. If the company performs well in the initial phase, private investors gets interested. This strategy creates successful companies, but the high risk profile also mean that some companies must close.
- *"Being an innovation environment is not good business in itself. The risk is simply to high, since all of our investments are in the early stage. 75 % of our investments take place in scheme design- and pilot project phase. Since we play a vital role in the early phase, it is hard to make exact calculations of the actual socio-economic outcome, but businesses does emerge thus contributing to job creation."* **- Finance director at Østjysk Innovation**
- Further it is worth noticing, that many of the portfolio companies, does not have as their objective to begin their own production. The business model is often based on licensing and sell-off.

Number of biotech and medico companies with patents, patent applications or IPR (Intellectual Property Rights) in 2011



By basing the business model on licensing and sell-offs, many of the innovations does indirectly create growth and employment in other companies. This is well illustrated by the relative low employment rate. In 2011 the biotech and medico companies in the portfolio only employed 333 people, though there is a high level in patent and Intellectual Property Rights.

Sara established a successful business and the business environment got a 25 % owners share in return

- Sara did not know anything about financing or running a business, but being a midwife Sara wanted to expose her knowledge about optimal treatment for women who had recently given birth. She wanted to pass on her knowledge by offering an online research based education programme for students.
- By making it online, the teaching could become interactive, effective and always up to date. *"I wanted to make a educational book with electricity".*
- From the beginning she didn't know anything about running a business. Nor did she know that there was an innovation environment that offered both money and competent feedback.
- This changed when her mentor and professor at the clinical institute on Aarhus University Hospital told her about Østjysk Innovation A/S (Eastern Jutland Innovation) a state authorized innovation-environment that invest public and their own means in business development in new innovative and high technology business ideas.
- The environment could see a potential in Gynzone ApS and made a loan of 1,7 million DKK with a return of an owner's share of 25 %. Equally important, Gynzone gained access to important knowledge and relevant feedback regarding everything from Business development, licence agreements, supplier contract, marketing, tax consultancy etc.

Sara started the company Gynzone ApS in 2008 together with two doctors. As the only employee in the company, she has developed the e-learning material which has been sold to hospitals and educational institutes all over Scandinavia. It has recently been translated to German and soon there will be developed an English version.

"It has been a very secure and confident way of starting up a business, where I didn't risk my house and personal economy" – Sara

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The GTS institutes function as a technological engine for innovation

- The GTS institutes – Godkendte Teknologiske Serviceinstitutter (Authorised Technological Service Institutes) are the Danish counterpart to Sweden's IRECO Group.
- The GTS institutes are a group of 9 independent not-for profit and mainly self-owning institutions. Their role is "to deliver on a market basis solutions to tackle capability failures that may arise in companies in connection with innovation." 4 out of the 9 institutes work with healthcare.
- They therefore make up a key part of Denmark's knowledge system, aiming to support industrial innovation and economic growth. Their purpose involves a testing, calibration service or researching in order to help solve industrial problems.
- In 2010 the GTS institutes had a total turnover of around 3,4 billion DKK and served 20.664 unique costumers, of which 65% was SMEs.

The 4 GTS working within the health sector

- Alexandra Institute
- Healthcare-it etc.
- Bioneer
- Medicaments, biotechnology, lactic acid bacteria, enzymes etc.
- DHI
- Drugs harmful to health, chemicals, water in health, enzymes etc.
- Technological Institute
- Life science, chemistry, water and water quality. Etc.

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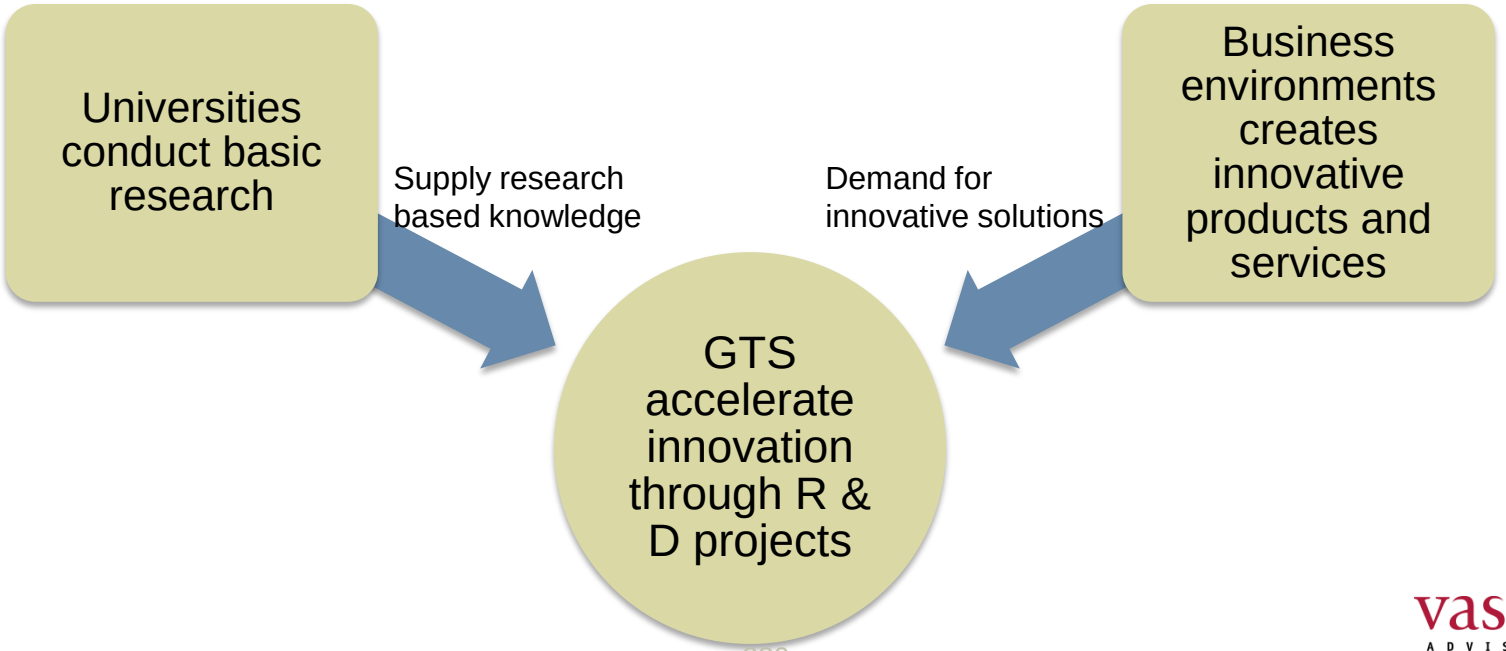
Infrastructure for Innovation – The role of GTS

- It is a task for the institutes to contribute to a more efficient knowledge distribution and use of technology in the business community with a special focus on the SMEs.
- Further the GTS institutes want to accelerate the innovation. Denmark is now placed as the third from bottom amongst OECD countries concerning the numbers of innovative companies that state universities as a primary source of innovation. (Notice that this is overall innovation, it has not been possible to find specific numbers for healthcare)



An example of healthcare Innovation with the help from a GTS-institute

About the product: The Danish invention, SuPARnostic Quick Triage, was first introduces on the markets in the end of august 2012 after a 11 year process, it is on it's way to the hospitals in the western world, as well as Africa.

Through blood-test it can, within 30 min. determine whether or not a patient is in the danger zone for a long line of diseases, among these HIV, tuberculosis, meningitis. Further the invention can forecast the development of cancer, diabetes and cardiovascular diseases.

The SuPARnostic-testmethod respond to inflammation in the body, through measurement of the suPAR-protein presence in the blood. This gives doctors and nurses justification of determining if a patient should be hospitalised or not. In saving resources in healthcare, this product optimize the treatment through fast diagnosing.

The process of Innovation, is the process of co-operation: In the end 90's a trained Biochemist by coincidence discovered that the suPAR-protein, which exist in every human body, gained a greater volume when the HIV-virus was added. By cooperation with Rigshospitalet it was discovered that the suPAR-level in the blood did not only meant a bad prognosis for HIV, but also for a long line of other diseases. This meant that the suPAR-test could be used as a general predictor.

Opfinderrådgiveren ("The Inventor adviser") is a body under the Danish Technological Institute (one of the GTS-institutes) and the ministry of research and innovation. This body helped getting funding from The Danish Agency for Trade and Industry (erhvervsfremmestyrelsen), partly help for the patent application and advise regarding private enterprises helping to develop, invest and carry on the invention towards a licensed agreement. The product was also developed in a close cooperation with Hvidovre hospital. The co-operation agreement with the hospital is now so well-developed, that the firm behind the product and the hospital, has common employees.

Involving business partners kick-started the project and helped it become what it is today. It has demanded a great deal of patience from the investors and a lot of testing on animals and humans. Now the product is on the market and it is estimated that it has a quantitative market potential of earning billions of euros on an international scale.

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The networks consist of 22 innovation units, 4 of which work within healthcare, medtech and pharmaceutical.

- **BioPeople – Innovations network for Biohealth**

  Biopeople brings Danish and international researchers and stakeholders together in collaboration for life science, food, biotech, biomedical, pharmacy and medtech innovations. The concept relies on the cooperation in wider competencies than usual. Biopeople therefore represent an advanced form of networking where synergies are both created and exploited.

- **LEV VEL – Innovation for the elderly**

  The objective is to help more elderly helping themselves. Supporting their own resources makes the elderly more self-sufficient. In the next 30-40 years, Denmark will experience a increase in the elderly part of the population with 400.000 persons. The aim is to secure the life quality of the elderly by making them self-sufficient for as long as possible. This will contribute to resource savings in the healthcare sector and greater focus on the actual need of the elderly. Further the innovative ideas serving this purpose will help SME's develop new services and products for the elderly.

- **UNIK – innovative solutions for chronic diseases**

  UNIK is a partnership of companies, universities, hospitals, patients associations and interest groups. The objective of Partnership UNIK is to provide innovative solutions for chronic patients by means of new technologies and user-driven innovation for the benefit of users, society and economic growth. The partnership focuses on diabetes, COPD, cardiovascular disease and muscle and skeleton.

- **Patient @ home – Innovative solutions for treating patients in their own homes**

  Through a interdisciplinary Public-Private cooperation between the healthcare personal, patients, private companies and research institutes, Patient@home develop a line of new welfaretech products and services that contributes in reducing the hospitalisation both in numbers and in length. In increase the ambulant treatment, and letting patients become inpatients in their own beds, the patients will play a more active part in their own rehabilitation and the pressure on the hospitals will be reduces.

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The contribution from the network Patient@home in an innovation process

- Fainting and dizziness causes many hospitalisations. Often this results in a several day hospitalisation with monitoring the function of the heart, the symptoms are there, but the actual medical condition is unknown or insignificant. With no reason, many beds are occupied without reason to monitor.
- The innovation network investigated the option of letting this group of patients in to their own homes while monitoring using an ePatch technology ending data to the patient and on to the hospital. This is done by a clinical study conducted by the innovation network patient@home. Further the network investigates how ePatch can communicate with the additional IT-system of the healthcare sector.
- It is the objective that the involvement of the patients can help them being an active actor in regard to their own health. Besides the objective of satisfied patients and involving them as an assed, the healthcare sector will be able to release hospital beds and doctor hours on the hospitals.

This innovation project has been granted money from the public renewal fund, established in connection to innovative healthcare solutions in regard to the new super hospitals.

Private companies can get both public funding and public help for their innovation projects

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The overall Danish Innovation infrastructure is relatively well functioning, but there is room for improvements.

- In a Review of the Danish Research and Innovation System, carried out on behalf of the European Commission in September 2012 by the European Research Area Committee (The ERAC-report) it is emphasised that the relative size of the Danish public sector provides good opportunities for innovation trough public procurement, especially in the healthcare sector. Further the Business Innovation Fund (Containing the 100 million DKK public renewal fund for healthcare innovation) is praised as a good step towards a further increase in innovation through public procurement.
- Also the Danish research institutes and universities are seen as a strong part of the successful innovative infrastructure. Though the report also emphasizes infrastructural problems with the system for innovation: Denmark has an infrastructural overload of innovation. <u>There are simply so many councils, committees and funds supporting innovation, that the system has become too complex.</u>
- Further the investments could have a more strategic aim. Instead of granting money for isolated innovation projects, the innovation investments should, to a larger degree than today, be coordinated strategically in accordance with areas of political prioritisations and national positions of strength.

- In an overall perspective many actors in Danish innovation offer overlapping services. Both the regional innovation units, the innovation environments and the innovation networks all offer a broad spectrum of counselling services.
- In regard to investments, both the regional units and the networks help innovators get in contact with investors whereas the environments invest directly in the projects they find lucrative.
- It could seem that there is a general potential for efficiency improvements through better division of tasks in linking the SME's to RDI activities.

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The new Danish Innovation strategy has the objective to make Danish innovation more coherent

- The Danish Innovation strategy was published in late December 2012 and has it's overall objective to make sure that public investments in research, education and innovation, to a larger degree than today, is converted to growth and job creation.
- The objective of the innovation strategy is to increase the demand orientated innovation policy, increased knowledge sharing and enhance the focus on innovation competences in education.
- The many different funds and councils each has a role in Danish innovation, but the overlapping responsibilities is a hindrance for a united and flexible prioritisation. It is difficult to support a greater national strategy and target and coordinate investments due to the current structure.
- The government therefore plan to carry out changes in the organisation of the strategic innovation investments. The tasks today carried out by The strategic research council (Det strategiske Forskningsråd), The council for technology and innovation (Rådet for Teknologi og Innovation) and also the Advanced Technology Foundation (Højteknologifonden) will in the future be condensed into one singe council for strategic research, innovation and advanced technology. The three councils together has a total fund of 2,2 Billion DKK for 2013.
- The reorganization into one new council shall insure that the concrete innovation projects is supported with means in more phases of the process from idea to the final product and solution with a special focus on the SME's.

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The new market maturing-fund will help products on their final way to the markets

- Another initiative to meet the recommendations from the ERAC-report is the reorganization of the Fornyelsesfonden (The Business innovation-fund) into the Markedsmodningsfonden (The market maturing fund).
- The reorganization enhances the focus on helping SME's overcome the barriers they encounter in the phase of market maturing.
- The ERAC-report emphasise the need for enhanced public demand orientated instruments, including market maturing. Concrete innovative products and services can mature through public demand and tender processes with functional requirements, where the public sector through its procurement policy to a greater extend promote the development of the businesses innovative solutions.
- Hereby the companies can get their solutions on the market faster with the benefit of job creation and export, while it for the public sector means a better service and therefore also efficiency improvements for the public services. The market-maturing fund will have an annual budget of 135 million DKK.

- The new fund shall take charge where other innovation and development programs let go and help products on the last steps towards the market.
- Where the business-innovation-fund also took part of the development phase, its replacement will only focus on the last steps towards the market.
- The reorganization will therefore contribute with a more clear division of tasks in the public innovation system.

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The innovation strategy contains several initiatives for involving innovation into educational activities

- Enhance the focus on innovation on the knowledge institutes and expand the use of best practice.
- The students should, to a greater extend play a role as an independent resource, enhancing the linkage between the institute of knowledge and the enterprises.
- Through development contracts, the education institutes shall enhance the cooperation with SME's and more students should write their graduate exams with point of departure in concrete problems in the SME's.
- Enhanced external co-financing of the R & D activities on the educational institutions.
- There will be established regional patent-libraries on the university libraries; the target group for Denmark's Electronic Research Library (DEFF) is expanded and there will be worked on increased access to the public financed research articles ("Open Science").
- The institutions of knowledge will, to a larger degree than today, incorporate the innovation competences in the education of the educators.
- The government has established a business-education-council that will develop concrete proposals on how the business educations can enhance the possibilities on how students can obtain competences within innovation and entrepreneurship.

An example of closer cooperation between the SME's and institutes of knowledge are seen on Aalborg University. An arrangement has been established with part-time professorships, where researchers are both employed on the universities and enterprises at the same time.

Through the arrangements, high profile business individuals are hired on the universities on part-time contracts, where e.g. 20 % of the working hours take place on the universities. The arrangement has contributed to attracted business units to the university and has opened up the possibility of involving the students in cooperation with the businesses concerned.

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The new Danish Innovation strategy has several different objectives

- The innovation strategy contains a national strategy for Danish participation in the EU-partnerships in research, business and innovation. It points out the EU-instruments that are of particular relevance for Danish interests.
- While the innovation strategy states that undesirable overlap between the different innovation structures should be avoided, measures are taken to establish cooperation agreements instead of competing arrangements between initiatives on e.g. state and regional level.
- The administration of the innovation infrastructure should be simplified and streamlined. A greater effect of the public means for the innovation arrangements should be secured through a common method-design and systematic cross-disciplinary evaluation and measurement of the results of the arrangements.
- The innovation strategy states that the innovation environments in 2013 will be put to tender. The tender shall ensure that the critical mass in the innovation environments is increased and that the competences are united in fewer innovation environments with a greater volume and closer relations to private venture funds.

A simplification of the innovation system is also supported by the minister of Science, Innovation and Higher Education:

- *" We should simplify the structure and reconstruct in the number of innovation instruments, in order to create the possibility for greater and more determined investments. We have to think in solutions instead of boxes"* **– Minister of Science, Innovation and Higher Education**.
- The question remains if the strategy will meet its own requirements of simplification. While the strategic innovation investments are condensed from 3 units into the market maturing fund, a number of new initiatives are still initiated. The strategy will establish the innovation partnerships, a joined program for knowledge-based innovation in SME's and a number of new councils.
- It is therefore still questionable if the strategy will meet its own objective of simplification.

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The assessment of public subsidy to outpatient pharmaceuticals

If a member in the reimbursement committee has a conflicting interest, he or she must must leave the room during the processing of the case concerned. Thus, the member concerned is not part of the decision-making process.

The Reimbursement Committee advises the Danish Health and Medicines Authority in cases regarding reimbursement from the Danish regions - both general reimbursement and individual reimbursements for medicines.

The Danish Health and Medicines Authority recommend the ministry on subsidy for pharmaceuticals

The final decision on which products to subsidise, is done by the Healthcare ministry

- A subsidised medicinal product in Denmark, is either supported with 100%, 74,7 % or 49,8 %.
- It is administrative practice that the 49,8 % is given to medicaments with a evidence based, and valuable effect.
- There is provided 74,7 % to the medicaments that, besides already mention requirements, can be used in the treatment of life-threatening conditions.
- In accordance with the national health service law, there is given 100 % subsidy to the GP prescribed Insulin preparations.

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Subsidy for new outpatient medicaments - evaluated by the Danish health and Medicine Authority (Lægemiddelstyrelsen)

- A medicament is granted general subsidy:
- *If it has a safe and valuable therapeutic effect within a well-defined indication and that the prize of the medicament is considered in a reasonable span according to its value of treatment".*
- In other words, it is only granted subsidy if it proves to have a socioeconomic effect.
- <u>A medicament will on the other hand not de granted subsidy if:</u>
- It does not rely on clinical documentation.
- If there is no reasonable value of treatment for the public healthcare service.
- If the medicament has a too broad area of indication or if there is a risk that the medicament will be used outside the accepted area of indication.
- If there is a risk that the primary use of a medicament, which according to the Health and Medicine Authority should not be the first choice.
- If the medicament is primarily used in the hospital treatment.
- If the product is regarding pharmaceuticals with a potential of abuse.

"I can't say anything specific about innovative new medicines, as it is the same criteria that apply. If you do not have certain knowledge about the drug's health economic value, we will make our assessment based on the evidence that is available. We do this on a case to case basis"

-Pharmacist - National Board of Health - department of pharmacist and medical reimbursement.

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The assessment of public subsidy to outpatient medicaments - The Danish Health and Medicines Authority (Lægemiddelstyrelsen)

- There are two main criteria that must be full filled in order for a drug to be granted general reimbursement That is:

  - The product should be a safe and valuable therapeutic effect on a well-defined indication.

  - The price of the medicament must be proportionate to its therapeutic value

- In making this assessment, what is considered is the drugs efficacy, side effects and costs - preferably in comparison with other appropriate treatments, if such treatments exist.
- In assessing new drugs, the clinical studies as basis for a marketing authorisation is evaluated.
- The applier can send a health economic analysis to elucidate whether the treatment is cost-effective. The analysis should be carried out in accordance with the lægemiddelstyrelses guidelines for such analysis'. It is optional whether the applicant company will enclose such an analysis. If no such is attached, the board assess whether the price is reasonable compared to its therapeutic value.

If a health economic analysis is attached to the application of a new drug, the first consideration deals with the fact, if it will matter for the decision of subsidy grant.

If that is the case, the health economic analysis is assessed by an external healthcare economist from KORA (The national institute for the municipalities and regions analysis and research).

In assessing the subsidy, there is no economic framework or budget that Lægemiddelstyrelsen has to take into consideration.

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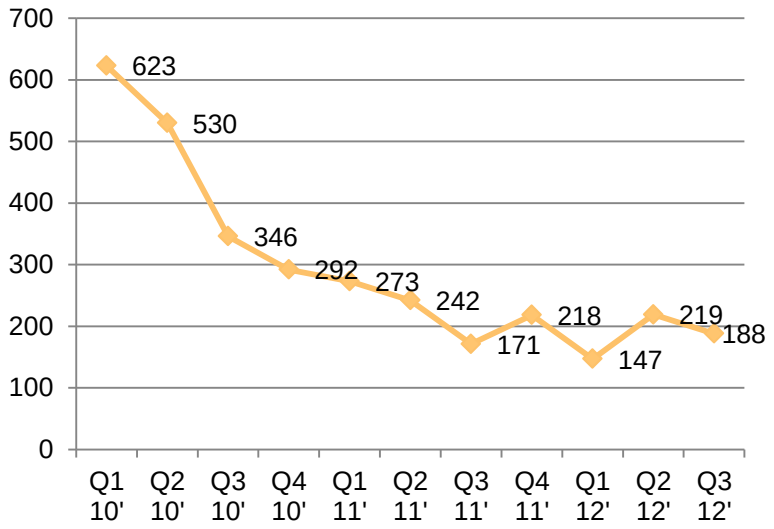
The evaluation and assessment of new pharmaceuticals – four different ways for how companies can apply for authorisation

- The centralised procedure: new and high-technology medicines are authorised in the entire EU simultaneously. The European Medicines Agency (EMA) is responsible for this procedure. In turn, the individual Member States are responsible for the scientific evaluation of applications. The centralised procedure is compulsory for biotechnological medicines, new medicines for the treatment of certain diseases as well as for orphan drugs.
- The decentralised procedure in which companies can apply for authorisation in more than one EU or EEA country simultaneously and where no EU or EEA country has granted a national authorisation in advance. The reference member state is responsible for the procedure and the scientific evaluation of the application.
- The mutual recognition procedure in which the marketing authorisation for a medicine, which has already been authorised in accordance with the national procedure in one EU or EEA country, forms the basis for authorisation in another EU or EEA country. The reference member state is responsible for the procedure and the scientific evaluation of the application.
- The national procedure in which the medicine is only authorised in one EEA country. This authorisation may later form the basis for approval under the mutual recognition procedure.

The Assessment times for new national applications for the licensing of medicine, days



During 2011,the Danish health and Medicines authority finalised the last cases that still remained from the period with bottleneck problems in assessments.

In 2012, 91% of the cases finished within the performance requirement's maximum of 240 days (195 days on average)

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The hospitals procurement and tender processes of inpatient pharmacies is done by the pharmaceutical organisation Amgros

- Amgros is the pharmaceutical organisation owned by the regions. The organisation is responsible for purchasing 99 percent of the pharmaceuticals that are used in public hospitals in Denmark.
- Through tendering and bulk purchasing, it’s purpose is to create economies of scale and administrative savings by consolidating the purchase of pharmaceuticals in one place.
- Amgros send a tender out for pharmaceuticals with the help of a internet based tender system. (www.levportal.amgros.dk)
- The tenders are conducted in accordance with the relevant EU legislation.
- Amgros own the marketing rights for the Hospital Pharmacies in Denmark (SAD) preparations, which is also produced by SAD. The production meets other important needs in relation to safety of preparation and supply. The production is also called 'The registered Production', because it requires registration and approval from the Danish Medicines Agency. It is a comprehensive task to prepare the documents for these products.
- Amgros has a team who takes care of the registration. The registrations team ensure that the documents that form the basis of the marketing authorisation are prepared and updated. In this way, Amgros supports the hospital pharmacies' work.

Cost reduction in expensive hospital medicine is done through bulk purchasing

- The board in the Danish Regions wants to standardise the use of medicine throughout the regions and have therefore put together the 'The Council for Use of Expensive Hospital Medicine' (RADS). The aim is to agree on the use of expensive hospital medicine at a clinical level. This is done with the intention of getting the best health for the money and also ensures a high quality of treatment.
- RADS have put together a number of different specialist committees with members designated by the relevant medicinal field.
- The idea behind RADS is that the incentive for the pharmaceutical companies to give greater price reduction is increased, since the company will gain a great sale when the procurement is streamlined throughout the country.
- RADS was not established before October 2009, and have already established 14 different specialist committees. There has not been published an overall assessment of the economical outcome of introducing RADS, but an example of a standardisation is here accounted for:

On basis of the RADS recommendations, Amgros held a tender on the medicaments Letrozol, Anastrozol and Exemestan, used for treating breast-cancer in the medical aftercare. For this group of medicaments there was gained a cost reduction amounting to 130 million DKK in 2012.

It should be noted though, that part of the explanation for the cost-reduction, is due to patent expiry. Further, a condition to be especially aware of in the standardisation of treatment is the fact that patients should still be treated in their own specific medical context. An analysis from 2010 shows that postmenopausal woman are especially vulnerable of developing cardiovascular diseases, if treated with (aromatasehæmmere, cant figure out how to translate)/this group of medicaments. The standardisation therefore have limits, since there should still be some diversity in the available medicaments for the healthcare professionals, so that they can meet the context dependent medical situation from patient to patient.

The hospitals assessment of new forms of pharmaceutical treatment

- In the fall of 2012 the regions established a coordination-council for the commissioning of new hospital medicine (KRIS).
- KRIS shall insure that patients regardless of place of residence are offered equal access to different kinds of new approved medicine, but especially in regard to cancer-medicine.
- On behalf of applications from the Regions, the Danish Medical Societies (Læge-videnskabelige selskaber) and the Danish Multi-disciplinary Cancer Groups, KRIS shall decide whether cancer-medicine, including cancer-medicine approved to new indications, shall be used in the standard treatment – in other words if the medicine should be available to the cancer-treating hospital units.
- In the applications to KRIS, there should be filled out a mini-MTV for use of the assessment of the medicament.

The tasks for KRIS involves:

- Assessing if new medicine should be used as a standard treatment in the regions.
- Secure coordination of the commissioning of new medicines across the regions.
- Secure coordination of the commissioning of medicaments with new approved indications across the regions.

"In regard to innovative medicaments in the hospital-sector, I can inform that there as a rule is not preformed a health-economic analysis before the medicament is in use". - **Head of section – healthcare-law and medicament-policy, Ministry of Health and Prevention.**

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The public procurement of Medtech – the assessment new Medtech products

- Procurement of new innovative products will often be subject to a Medical Technological Evaluation (MTV), a systematic and evidence-based method for decision-making on introducing new methods of treatment. The MTV takes into account the medical technology, the organisational circumstances, patient related aspects and the health-economic aspects.
- A mini-MTV is often developed on a case-to-case basis, in order for the new technology to be assessed in the context of the budget of the hospitals, the regional budget and process planning.

"We prefer that cost reduction in the healthcare service is done through intelligent procurement of public-private innovation. That will promote innovation. If everything is about finding the lowest price it will suck the innovation capacity out of the enterprises". **– CEO - The Danish medico-industry.**

- When the application of procurement has been accepted, the actual procurement can be carried out in two different ways:
- In accordance with official guidelines, the procurement-responsible, form a user-group together with the relevant clinical department. A user-group can consist of everything from a single representative from the clinical department, to a regional user-group with representation from all the hospitals in the region. In regard to bigger regional user-groups, the guidelines are followed much closer, while the guidelines are used more as a checklist in regard to procurement of smaller acquisitions of Medtech. The procurement will still have to live up to conditions established in the "regional standard procurement requirement" setting standard for documentation, education, training of the users etc.
- Secondly the hospital unit makes their own procurement in accordance with the hospital specific procurement catalogue.

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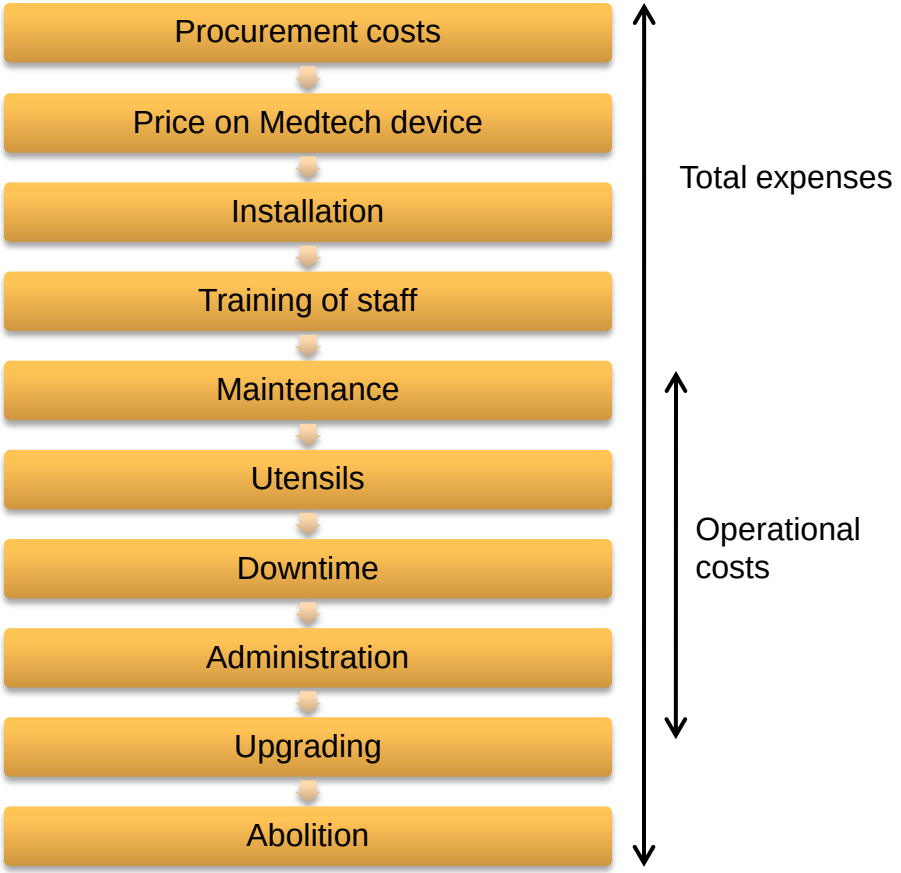
The public procurement of Medtech – the assessment of expenses – Region Southern Denmark



- The procurement of Medtech equipment in Region Southern Denmark is done in accordance with three different models:
- Region round of apparatus applications where the hospitals in the region can apply for elective procurement of apparatus' at a price exceeding 200.000 DKK apiece.
- Procurement of apparatus for a hospital unit where the apparatus is financed by the hospital itself.
- Procurement of apparatus for a hospital unit regarding sudden breakdown where the apparatus is financed by a local or regional acute pool.

Innovative public procurement of Medtech is done through demand-oriented tender

- In just 10 years, the elderly part of the population will grow with around 30 % and 1/3 of the current workforce will retire lowering the tax-revenue and increasing the healthcare expenditure.
- Since about 85 % of the healthcare spending in Denmark is financed by public means, the public is therefore described as a significant market-actor.
- Its strong purchasing power, work as an effective tool that, if applied correctly, can work as a strong stimulator for Innovation.
- The public sector creates the frame for demand through tender of public tasks. The public sector therefore plays an essential role as a demanding client that demands innovative solutions rather than tendering predefined tasks.
- Innovative procurement stands out since the public sector can use their special position in demanding innovative solutions instead of the traditional procurement process where the price is the crucial parameter.
- The public renewal fund has initiated an initiative regarding innovative public procurement where hospitals can get support for the use of **"functional tender"** (funktionsudbud) in the demand process of new innovative solutions. Instead of setting demands for the activities leading to the delivery of services, Funktionsudbud put demands to the function of the delivered good or service.
- An analysis carried out by the tender-council shows, that Funktionsudbud contributes in fostering innovation and enhancing the quality and flexibility in the solutions of public tender.

Randers Hospital, Region Central Jutland together with a consortium of companies has worked together in the process of buying new hospital beds as an example of innovative procurement.

Through a process of dialogue, the users needs, both the patients and the healthcare professionals, has been identified in a process of close involvement of the companies. A central part of the tender process was that Randers Hospital guaranteed the procurement of the first 24 hospital beds, with an option on more beds at a later stage in the process.

The tender process was based on **"competitive- dialogue"** which is a form of tender that allows public and private actors to work together in development tasks without coming in conflict with the competence to act. The competitive dialogue is divided in two phases where the first is a dialogue-phase and the second is there is given an actual offer.

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The innovation system has potential for improvements

- The common recognition of the Danish public endeavours for fostering innovation should first and foremost be considered as an acknowledgement of the political intentions for reaching the objective of being a leading nation within innovation in the healthcare sector.
- Several tendencies can be identified as restraining for the optimization of utilisation of the resources invested in healthcare innovation.
- The structure of the Danish R&D and innovation funding and advisory system has a high level of complexity. The many actors has been established to meet the many specific needs of companies, but taking into account the relative small size of Denmark, the long line of political initiatives on both government and regional level, has established a variety of actors with identical mechanisms, competences and objectives, given rise to overlapping responsibilities.
- An enhanced clarification of the division of tasks between the public actors in the innovation system has the potential of enhanced utilisation of invested resources and can allow enhanced strategic investments based on the special Danish position of strength such as supplying domestic and foreign healthcare systems with pharmacy and medical devices.
- First of all, a centralisation of specific competences into fewer actors will have several advantages. In regard to the public actors, the competences such as counselling in matters of business cooperation, financial or legal questions can be optimized though centralisation. This could help release resources for other innovation purposes and at the same time prevent that public actors from entering into disputes or competition in matters of conflicting interests.
- Secondly, the representatives of the Danish SME federation have described the funding programmes as the “innovation jungle”. An analysis shows that the numbers of funding programmes entails the risk that some SME’s have difficulties navigating in the instrument jungle. A clearer division of tasks can therefore be recommended which will make it easier for the entrepreneurs to know where to find the exact and most qualified help or funding they need.

What can Sweden learn from Denmark?

- Denmark has a healthcare system and an approach to innovation that is similar to Sweden's. Despite this, Denmark has been more successful than Sweden in the biotech and life science sector.
- *"What's the reason for the success? I don't know – I think it has to do with the fact that many large Danish medical companies are owned by foundations. The profits are reinvested*" suggests a CEO in a Danish pharmaceutical company
- In terms of the national innovation strategy, two clear differences between Sweden and Denmark can be identified:
  - The political focus on the medical industry is greater in Denmark;
  - The Danish Innovation strategy, published in December 2012 , has the overall objective to ensure that public investments in research, education and innovation, to a larger degree than today, is converted to growth and job creation.

The lesson for Sweden:

- Swedish policymakers should put **more emphasis on translational research and commercialisation** of innovation in healthcare
- The healthcare system should consider **clinical research** and collaboration with the medical industry **part of their responsibility**

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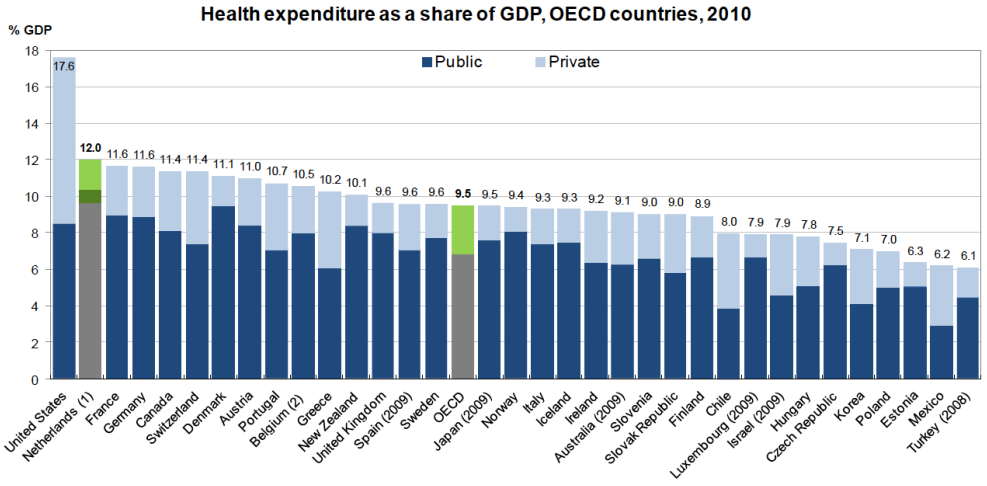
The Netherlands

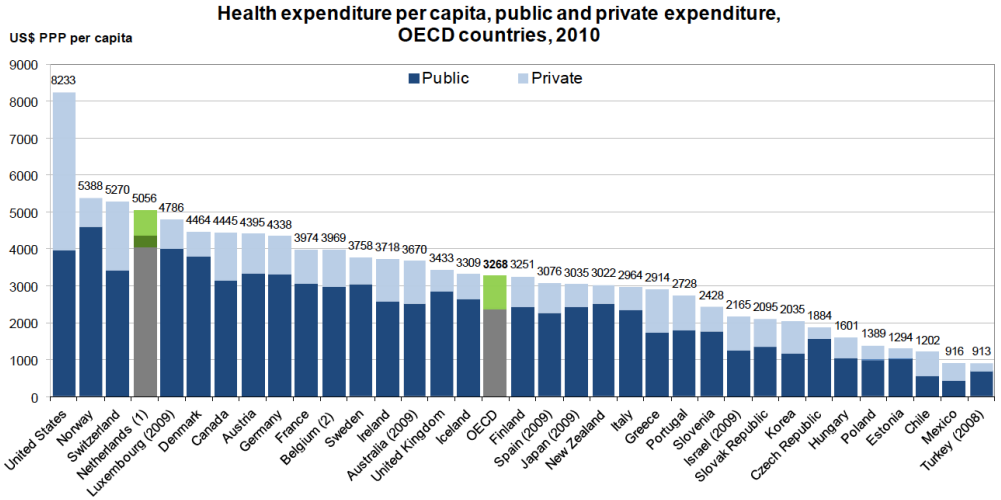
The Dutch health care system was intensively reformed starting from 2006, implementing a system of ”regulated competition”

Innovations are often driven by governmental research institutes

Implementation fellows help with the implementation of important innovations especially in university hospitals

The Netherlands are spending more one healthcare than most European countries

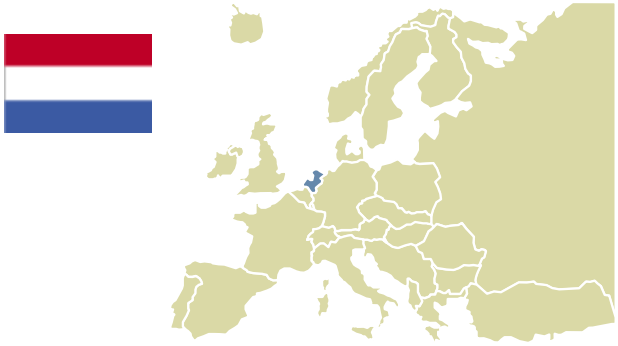




1. In the Netherlands, it is not possible to distinguish clearly the public and private share for the part of health expenditures related to investments.
2. Total expenditure excluding investments. Source: *OECD Health Data 2012, June 2012.*

- Total health spending accounted for 12.0% of GDP in the Netherlands in 2010
- Health spending per capita: 5056 USD in 2010 (adjusted for purchasing power parity)

Health Care Expenditure in 2010	€ mn
Public Health	102,6
Health Care	34.685,5
Long Term Care	23.552,1
Social Support	180,7
Nominal Costs and contingencies	39,3
Social Support Act (Municipalities Fund)	1.544,6
Training Funds	845,0
Chronically Ill and Disabled Persons	520,4
Bonaire, Saint Eustasius and Saba	1,5
Budget-financed Budgetary Framework for Care Expenditure	0,4
Total	**61.472,1**

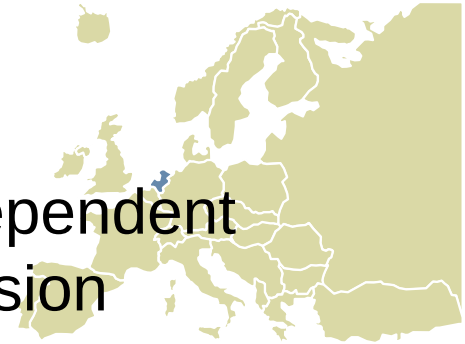


The Dutch Healthcare System – managed competition at the center

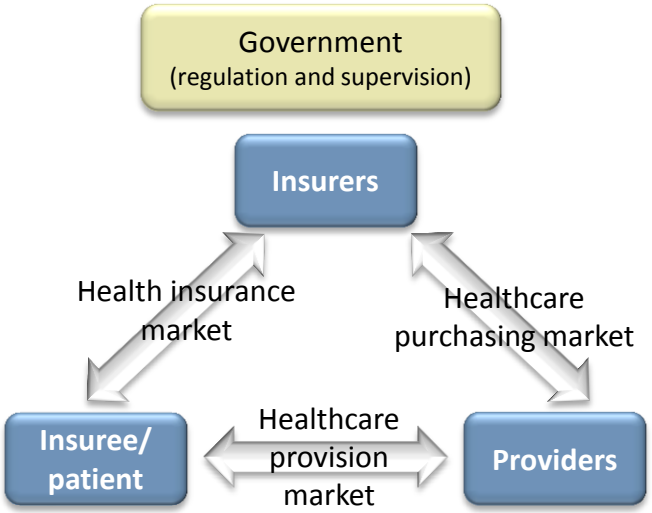
- A major health care reform in 2006 (Health Insurance Act - Zvw) abolished the distinction between mandatory sickness fund insurance and voluntary private insurance and introduced a single compulsory insurance scheme for curative care, in which multiple private health insurers compete for insured persons
- As a central regulatory mechanism the reform introduced managed competition among actors in health care
- The government changed its role from direct control of volumes, prices and productive capacity of the system to safeguarding the system
  - The government controls the quality, accessibility and affordability of health care Health insurers can negotiate to a certain extent with health care providers on price, volume and quality of care
- Patients are free to choose their health insurer as well as providers
- Insured persons can change health insurer once a year
- The government provides information on waiting lists, quality and prices of care

Health insurers are allowed to make profit and pay dividends to shareholders

- Health insurers are obliged to accept new applicants and they are not allowed to differentiate their premiums according to the risk profile of the applicants
- Insurers are obliged to provide all care as defined in the basic health insurance package
- Insurers can compete for patients on the price of the basic health insurance, the quality of care and may offer complementary voluntary health insurance
- Insurers are free to contract health care providers (selective contracting) based on the quality and cost of care that providers offer
- The Dutch Health Care Authority (Nederlandse Zorgautoriteit, NZa) was established to monitor and administer the markets for health care provision, health insurance and the purchasing of health care
- Nza may also impose tariff and performance regulation
- The Health Care Inspectorate (IGZ) supervises compliance with laws and regulations by care providers and institutions and the quality and accessibility of health care



The healthcare system is based on three independent markets: insurance, commissioning and provision



First compartment
AWBZ: Obligatory national insurance for long-term and unaffordable care
Second compartment
Zvw: Obligatory Basic insurance for essential curative care
Third compartment
Supplementary insurance: Voluntary insurance, range of cover

- Three compartments:
  - 1st compartment: Long-term care (Exeptional Medical Expenses Act - AWBZ / compulsory; contribution is 12,55% of taxable income)
  - 2nd compartment: Curative care (Basic health insurance – Zvw; mandatory)
  - 3nd compartment: Supplementary care: (additional voluntary health insurance VHI)
- The standard package *(basisverzekering/basic medical care - Zvw) is defined by the govermnment and* generally covers:
  - hospital care
  - medication
  - rehabilitation
  - medical care by specialists, GPs and midwives
  - dental help for persons younger than 22
  - therapists, such as speech therapists and dieticians
  - mental health care
  - maternity care
  - necessary medical help during a holiday or business trip abroad, worldwide
- The insured can choose between three types of insurance policies:
  - policy in kind: the insurance company concludes sufficient contracts with health care suppliers in order to deliver health care. The insurance company pays the bill directly to the health care supplier.
  - restitution policy: the insured chooses the health care supplier himself and pays the bills, after which the health insurance company reimburses the insured (deductibles 100-500€)
  - combination policy: part of the bill is paid by the insurance company and the rest is paid by the insured

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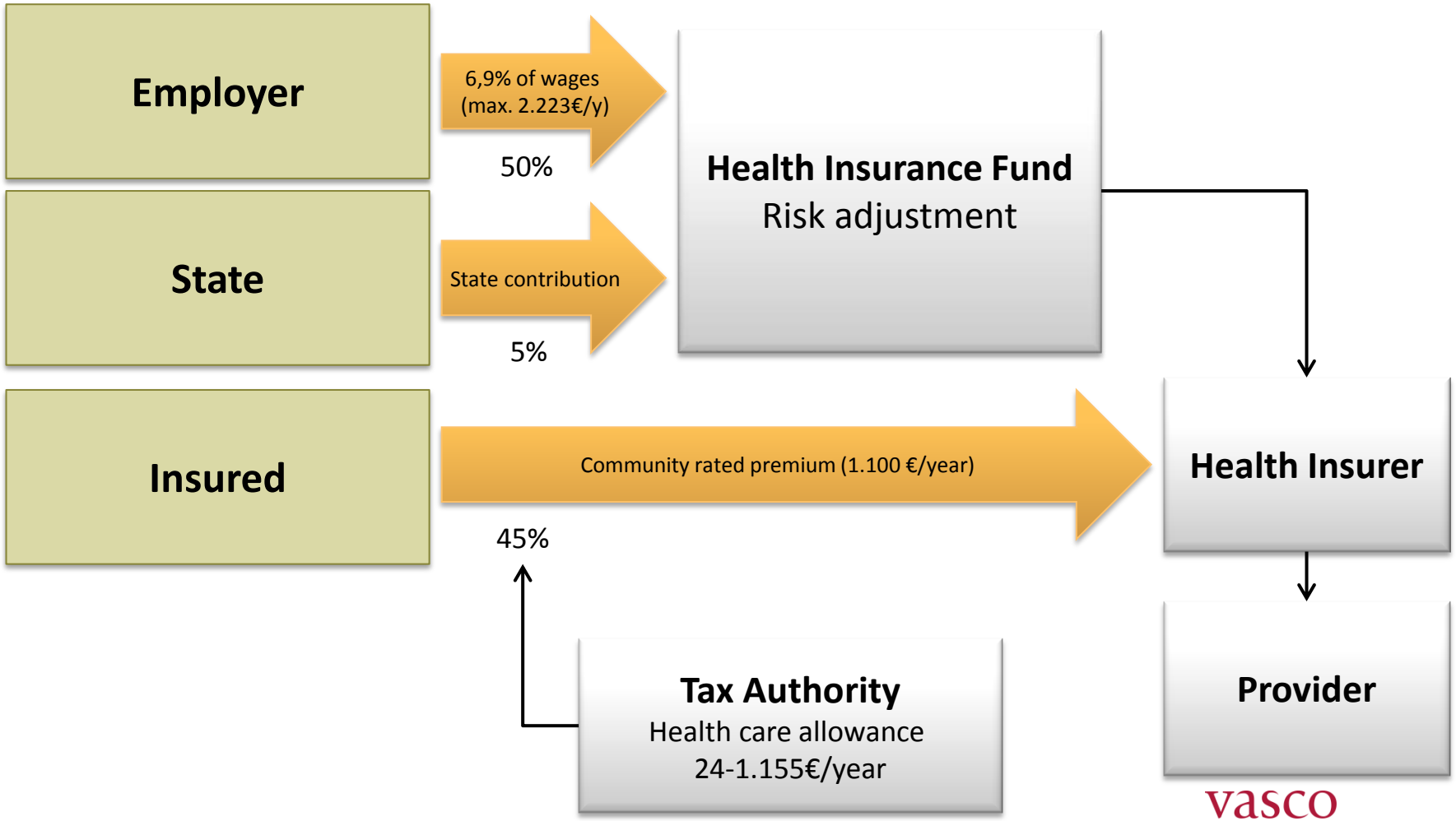
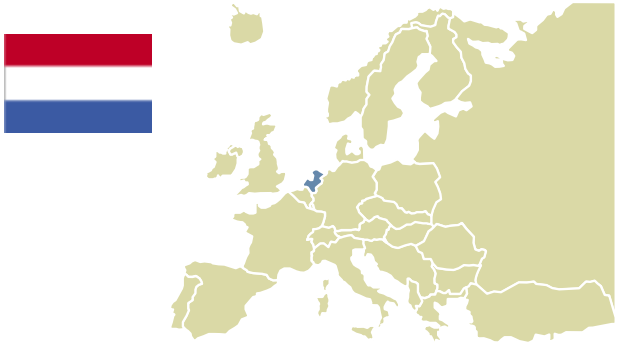
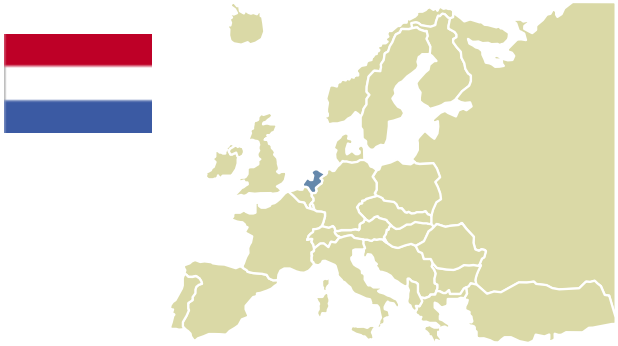
Financial flows in the Dutch health care system under the Health Insurance Act (Zvw)





Impact of the reform on health insurers

- Health insurers now have to compete at national level
- Losses in enrolment up to 25%, increases up to 30%
- ‘Losers’ seem to be some of the old sickness funds
- Health insurers have received instruments to contain costs: e.g. selective contracting and volume/quality/price negotiations
- Problems:
  - scarcity of providers and regional monopolies
  - only 34% of hospital care (2009) was freely negotiable
- Need to develop more expertise
- Health insurers are now allowed to make profits

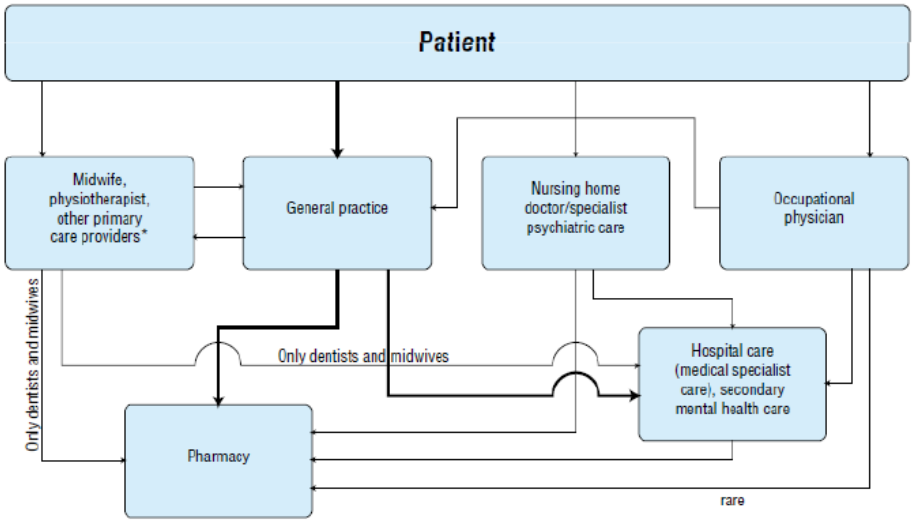


Impact of the reform on providers

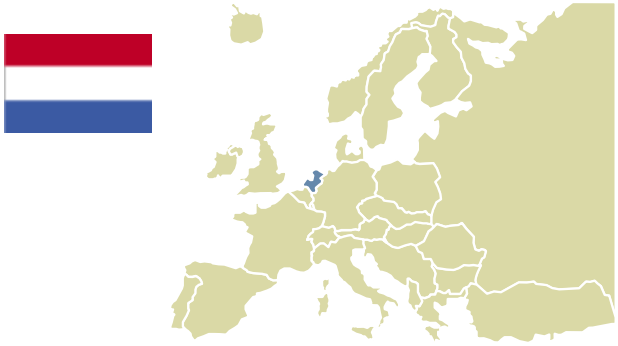
- Hospitals have both inpatient and outpatient departments as well as 24-hour emergency wards
- Consolidation trend (private non-profit providers) to increase negotiation power against health insurers - mergers led to fewer hospital organizations with several locations
- In 2011 there were 84 general hospitals, 8 university hospitals and 59 specialist institutions (e.g. rehabilitation centres)
- Investments are included in tariffs for hospitals (2008) and long-term care institutions (2009)
- For hospitals and mental care a performance-based DRG-type system (29.000 Diagnosis and Treatment Combinations - DBCs) was introduced in 2005
- In 2009 the price of 34% of all DCBs was freely negotiable between health insurers and hospitals
- Reform of DBC-system started in 2012 -> reducing the number of DBCs to around 4.400 in 123 groups; new name: DOT system; 70% are now freely negotiable
- For the development of the DOT system exists a special state agency (DBC-Onderhoud)
- The DOT structure can be roughly divided into three categories:
  - 1. Intensive, surgical products
  - 2. Conservative inpatient care products (diagnostics and small treatment for inpatient care; no large surgery)
  - 3. Conservative outpatient care products (diagnostics and small treatment for outpatient care; no large surgery)
- Instead of a fixed budget per year, from 2012 onwards health insurers negotiate with hospitals regarding the purchase of care and the related conditions

Impact of the reform on providers - GPs

- Strengthened role of General Practitioners:
  - General Practitioners have a strong gatekeeping role in the Dutch healthcare system
  - To visit a specialist, a referral from a GP is necessary
  - Only 4% of GP contacts result in a referral to secondary care
  - dentists, midwives and physiotherapists are directly accessible
  - General Practitioners are paid via a combination of capitation fees and fee-for-service

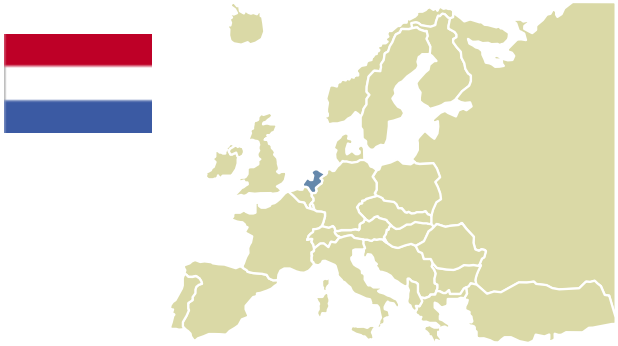


Notes: *Only for dietitians a referral from the GP is required; Bold arrows = largest patient flows.



Impact of the reform on patients/insured

- Clear empowerment of citizens
  - purchasing power through collective contracts – in combination with risk equalisation scheme: more than 1000 collective contracts until 2009
- More individual choice
- No more health-related discrimination
- However, problems occurred with specific groups (e.g. self employed)
  - In 2008: 170,000 people (1% of population) remained uninsured
- Flat rate premiums go up faster than contribution rates
- In 2012 a Dutch family with two parents earning average incomes spends 25% of the family income on healthcare
- Premiums (about 14,000 euros/year)



Impact of the reform on drug supply

- The Pricing Act since 1996 sets maximum prices for pharmaceuticals based on the prices of medicines in four reference countries (Germany, Belgium, France and the United Kingdom)
- Since 2004 yearly price negotiations take place between the Ministry of Health, Welfare and Sport, pharmacists and producers of generics
- Since 2005 health insurers can identify “preferred pharmaceuticals” for the three very often used active substances omeprazol, simvastatine and pravastatine
  - From these categories of pharmaceuticals, only those are reimbursed that are at same price level as the cheapest pharmaceutical (mostly a generic) plus 5%
  - The list of preferred pharmaceuticals is revised every six months
  - If a physician decides for medical reasons that the patient should receive a non-preferred pharmaceutical, he can indicate this on the prescription. The non-preferred pharmaceutical will then be fully reimbursed to the patient
- There is no reimbursement limit for a medicine included in the cover, which cannot be substituted by other medicines
- But insurers are permitted to limit the reimbursable medicines to those they designate

Impact of the reform
The Dutch health care system (Zvw) in 2012

- All Dutch citizens – with the exception of conscientious objectors - have obligatory insurance under the Zvw
- The Minister of Health, Welfare and Sport (VWS) determines the scope of the basic insurance package.
- Health insurers are required to purchase health care efficiently so that they can compete on the health insurance market.
- Health insurers have an acceptance obligation and are not allowed to refuse to provide people with health insurance. This does not apply to group insurance

- **The health insurance market - Market characteristics**
- A concentrated market with 26 risk-bearing health insurers divided across 9 insurance groups in 2012
- In 2012 the four largest insurance groups jointly had a market share of 90%
- Insurance policies are offered on a non-monetary and reimbursement basis and as a combination of the two
- Health insurers are allowed to make a distinction between the reimbursements for healthcare providers with and without contracts.

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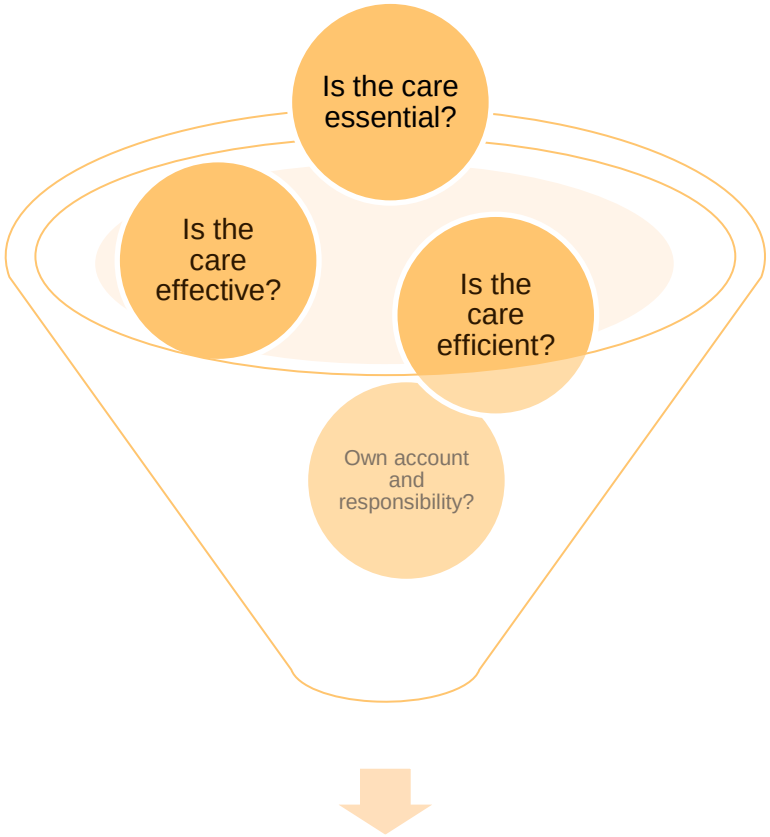
The Netherlands is using the “Dunning Funnel”

- Decisions about the composition of the benefit package are guided by an algorithm, which has become known as the “Dunning Funnel” (The Dunning Funnel resulted from a committee which was chaired by Dunning in 1991)
- The committee defined four cumulative criteria:
  - (1) services should be essential,
  - (2) effective,
  - (3) cost-effective and
  - (4) unaffordable for individuals



Basic benefit package

Innovations in the Dutch healthcare system
Role of Government and CVZ

- Central idea for the SHI (Zvw):
  - Cover under the Zvw provides for essential care, as checked against its demonstrable effect, cost effectiveness and need for collective financing
  - It is necessary to check the insured cover against these criteria from time to time to determine whether certain types of care need to be removed from or indeed added to the health insurance package, with a long-term view to keeping cover affordable
- The Dutch government decides about the principal scope of the standard package and changes of the standard package within the statutory health care insurance
- Ministerial proposals for changing the benefit package have to be passed by parliament
- Decisions about the possibility of reimbursement of medical-technical products within the DBC system for specialist care are taken by CVZ
- Innovative medical devices in outpatient care: application dossier -> CVZ
- Yearly advice of the CVZ on the basis of all application dossiers
- Possible additional guidelines of the insurance companies for reimbursement:
  - Maximum reimbursable tariff
  - Maintenance devices
  - Preferred providers
  - Co-payments of patients

In contrast to many other European countries, the uptake of innovation is decided on the national political level

For decisions about the scope of the basic package the government is relying upon advice from the Health Care Insurance Board (CVZ)

- The CVZ renders account as requested to the Minister on proposed policy concerning the nature, content and scale of the package of cover
- It also reports to the Minister as requested and on its own initiative about factual developments in the field of medicine that could necessitate changes to the package
- Advice provided by CVZ is based not only on the health care itself, but also on considerations involving finance and society
- In addition, CVZ assesses forms of care for inclusion in the statutory insured package
- CVZ uses an assessment framework that is consistent for all forms of care. The framework is based on the principles of evidence-based medicine (EBM)
- Also new drugs are subject to assessments from the CVZ. CVZ uses special guidelines as an assessment framework for pharmaco-economic evaluations which are part of a reimbursement file
- The assessment framework is used to check whether the cost effectiveness of a drug for which reimbursement has been requested has been sufficiently substantiated

The reimbursement system should allow and stimulate innovation – though there are hurdles on the national political level

- CVZ also decides - on the basis of the work of DBC-Onderhoud - whether new DBCs are covered by the basic benefit package of the Dutch SHI (Zvw)
- An innovative treatment method thus only can become part of the DBC/DOT catalogue if it is approved by CVZ
- But: The DOT system is „allowing and stimulating innovation“ (DBC-Onderhoud)
- For an innovative treatment the support of scientific organizations is necessary
- Then an application has to be made to DBC-Onderhoud
- The application dossier has to cover:
  - Short description of the treatment, Clinical description, Indication, Epidemiology, Technique and working mechanism, Safety and effectiveness, Available scientific studies (3-years data are preferred), current treatment, Changes compared to current treatment, Cost-effectiveness, expected costs and Developments
- After the decision of DBC-Onderhoud, if a new DOT is possible/necessary, Nza and CVZ decide, if the new innovative treatment is covered by the Dutch SHI (Zvw)
- The final step is a decision by the ministry of health
- Timeline: 1-5 years

Innovations in the Dutch healthcare system
New Medicines

- Admission of new medicines
  - Before a new medicine is admitted to the market in the Netherlands, it must be tested for efficacy, quality and health risks
  - The Medicines Evaluation Board (CBG) decides which medicines are suitably safe and proven to be sold in The Netherlands
- Second hurdle: Reimbursement
  - The reimbursement of new drugs under the Svw scheme will be based on the budgetary impact of a new drug on JOZ (Jaaroverzicht Zorg: Annual National Health Care Budget)
  - Therefore, the authorities (CVZ) require an assessment of the impact of a new drug on the annual health care budget, and especially the drug budget.
  - For the financial analysis, data on the following subjects will be required:
    - descriptive epidemiology (data on incidence and prevalence)
    - the patient group that is indicated for the drug and the anticipated substitution effects (i.e. the extent to which the existing treatment will be replaced)
    - the use of the drug (posology, length of the treatment, etc.)
    - the price of the drug
    - off-label use
    - variables that would facilitate or slow down the drug sales and the total treatment costs

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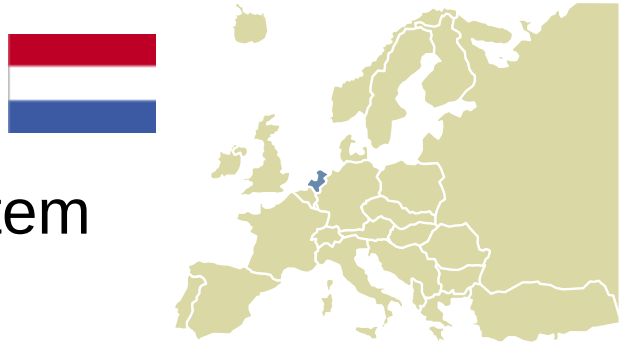
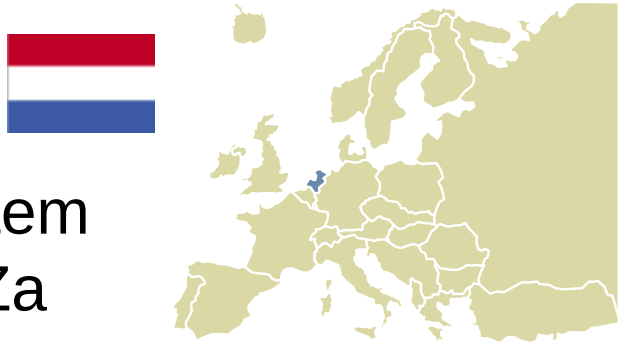


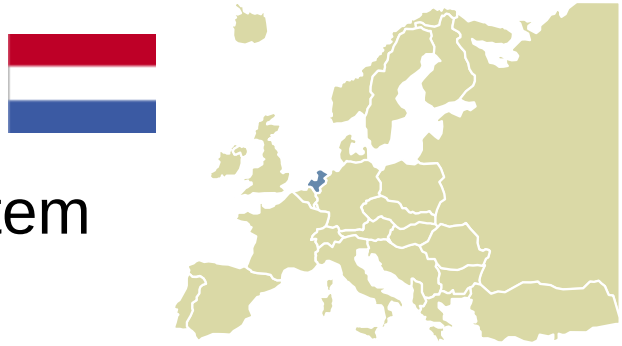
Innovations in the Dutch healthcare system
New Medicines II

- Maximum prices
  - The ministry of Health, Welfare and Sports is responsible for the policy that regulates the price development of medicines in the Netherlands
  - This happens by conducting a selective policy regarding the admission of new medicines
  - Insurance companies must not necessarily include the compensation of all new medicines in their packages
  - The minister decides which new medicines are admitted in the insurance packages
- Least expensive variant compensated
  - When there is a choice of several medicines of equal efficacy, mostly only the costs of the cheapest medicine are remunerated



Innovations in the Dutch healthcare system
Structural innovations and the role of NZa

- Structural innovations of the health care system are mainly driven by the Dutch Health Care Authority (Nederlandse Zorgeautoriteit – NZa)
  - The Dutch Healthcare Authority (NZa) is the supervisory body for all healthcare markets in the Netherlands
  - The NZa supervises both healthcare providers and insurers
  - The NZa has to create and monitor the properly functioning of healthcare markets
  - The Nza has to inform the Minister regarding the practicability, effectiveness and efficiency of proposed policy concerning the performance of its regulatory role
  - The NZa has an advocacy role – providing recommendations about policy and regulations, based on implementation assessments and supervision assessments
  - Decisions about new structural innovations in the health care system always need a decision of the Dutch government and have to be passed by the Dutch parliament



Innovations in the Dutch healthcare system
Role of contracting and of the VHI

- Since 2012 all healthcare insurers and suppliers have much more possibilities to contract scope, quality and price of healthcare
- Now health insurers have a strong negotiating position against hospitals as regards what care can be provided, the quality of that care and the price.
  - The aim is to allow the best possible care to be purchased on behalf of policyholders for the most favorable price
- Insurers have the possibility to contract with individual GPs about Modernization and Innovation (M&I) activities
  - These activities are aimed at increasing the efficiency of GP care and relieving secondary care
- Through the structure of the new health insurance system many medical and MedTech innovations can be introduced into the system through the 3rd compartment (voluntary health insurance VHI)
- In this compartment health care insurers are free to design packages for the insured, which may include also innovative methods and drugs, which are not covered within the SHI, or methods, which are not evidence-based

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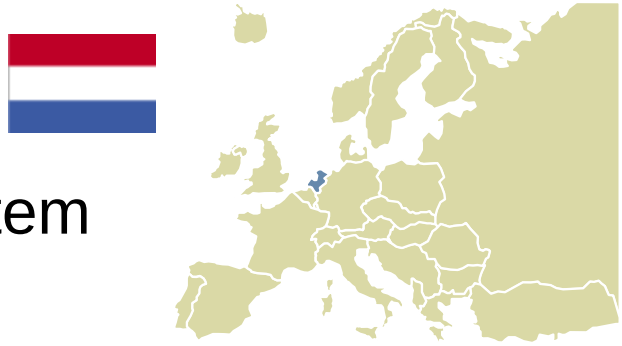

Innovations in the Dutch healthcare system
The role of HTA and ZonMw

- Medical, pharmaceutical and medical-technical innovations are mainly assessed by the Netherlands Organiozation for Health Research and Developement (Nederlandse Organisatie voor Gezondheidszoek en Zorginnovatie – ZonMw)
  - ZonMw is mainly commissioned by the Dutch Ministry of Health, Welfare and Sports as well as the Dutch Organization for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek, NWO)
  - ZonMw‘s duty: to study priorities, innovations and problems in health care
  - ZonMw **funds the necessary research and development to ensure the continual development and introduction of innovations**
  - ZonMw therefore formulates **programmes**, in which research and health care institutes can conduct research and develop, **test and implement innovations**

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Innovations in the Dutch healthcare system
The role of HTA and ZonMw II

- **Pearl status:**
  - ZonMw awards selected outstanding projects with the ‘Pearl’ status to boost the implementation of their results
  - ZonMw also offers extra support in disseminating and implementing the results of these projects
- **Dissemination and Implementation Boost:**
  - ZonMw can give projects extra support in the form of a ‘Dissemination and Implementation Boost’ (VIMP). A VIMP gives the project an extra financial injection of up to 50.000€ for this purpose
- **Implementation fellows:**
  - ZonMw has appointed ten implementation fellows at the eight teaching hospitals (UMCs) and two of the larger regional hospitals in the Netherlands
  - The implementation fellows advise clinicians and researchers in their own organisation on implementation and implementation research
  - Over a period of three years the implementation fellows research what factors foster or hamper implementation at their own institution
  - The implementation fellows also highlight problems at their institutions, and ensure internal dissemination of implementation knowledge, thus raising institutes’ implementation awareness

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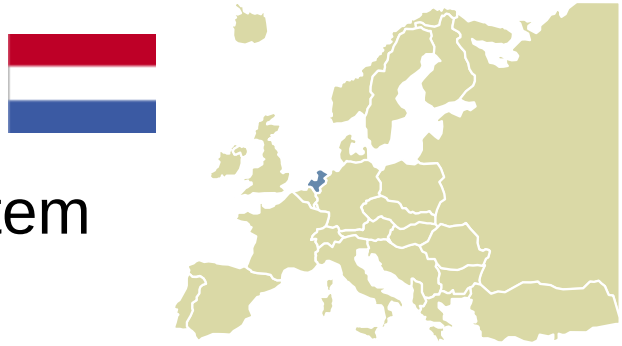
Innovations in the Dutch healthcare system
Private shareholders in the hospital system

- Hospitals generally are non-profit institutions
- Since 2008, however, a few pilots have started that allowed paying out a part of the profit to shareholders
- The idea: Attracting shareholders might give hospitals the opportunity to generate more investment for quality improvement and innovation



Innovations in the Dutch healthcare system
Governmental programs and activities

- The Dutch government has impelented a program named „Entrepreneurship and innovation“
- The responsibility lies upon the ministry of economic affairs
- One central goal is the Use of international sales markets
- The government plans to addresse five main areas:
  - Fewer subsidies in return for lower taxes;
  - Fewer and simpler rules;
  - Better access to corporate financing;
  - Better access to knowledge infrastructure for businesses;
  - Better harmonisation between the requirements of businesses and fiscal, educational, and diplomatic activities.
- So the government has decided to cut business subsidies by €500 million and use the capital for business loans and tax benefits in the fields of life sciences, horticulture and food, chemicals and water
- Entrepreneurs are encouraged to be innovative through government innovation loans and tax benefits

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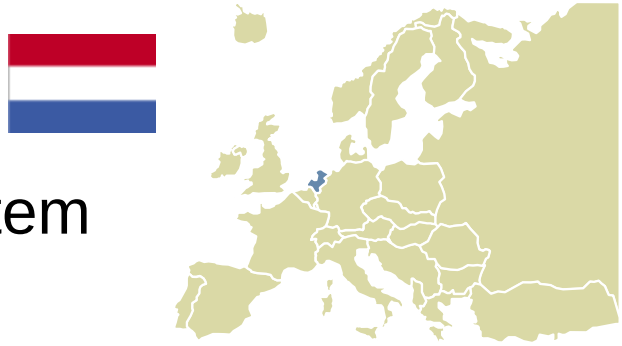
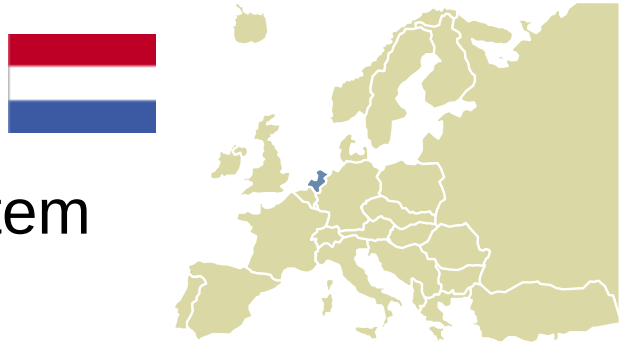


Innovations in the Dutch healthcare system
Governmental programs and activities

- One out of 10 top sectors of the program is „Life Science and Health“
  - The government here plans to optimise legislation to create enough scope for the development of new products and services
  - Examples mentioned include new fast-track procedures for medical-ethical assessment and greater scope for conditional reimbursement on medicines
  - But until now no concrete steps taken
  - A top team has been created for this sector, comprising a scientist, a senior official, an innovative SME entrepreneur and a standard bearer for the sector
  - The top team develope an action plan and turn it into concrete points for action and innovation contracts
  - These innovation contracts set out arrangements and financial agreements between businesses, scientists and the government



Innovations in the Dutch healthcare system
Governmental programs and activities

Conclusion:

There seems to be a gap between

- the innovation policy of the ministry of economic affairs on one hand, and;
- the policy of the ministry of health in the health care sector with clear restrictive policy and governmental decisions about the reimbursement of innovative products in the basic health insurance package on the other hand

Innovation policy seems to aim especially at export markets

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What can Sweden learn from the Netherlands?

- The Netherlands went through a major healthcare reform, based on a well thought through plan for the creation of three healthcare markets, but the overall objectives were not reached
- Neighbouring countries, like Germany, initially considered the Netherlands as an example that should be followed, but the Germans now consider the Dutch experience a failure.
- One of the factors contributing to this failure was that the system was built on political control, rather than the dynamics among a multitude of stakeholders that is found in four example Germany, or France.
- In terms of innovation in healthcare, **Sweden has little to learn from the Netherlands**
- However, the *Implementation fellows* at the University hospitals are worth mentioning.

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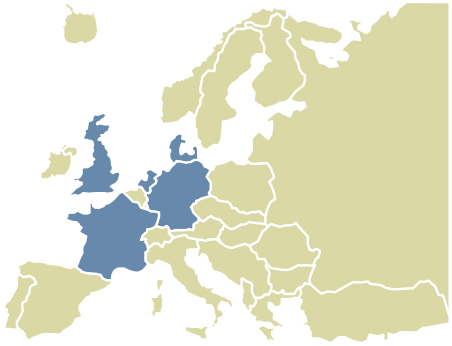
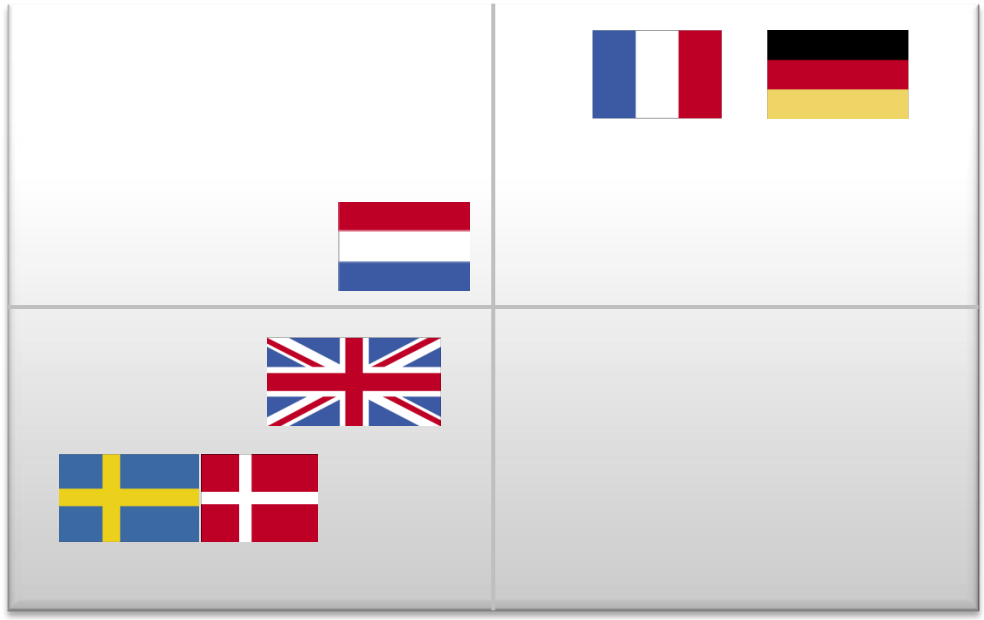
Summary and conclusions

Summary and conclusions – five European countries



- There are two main systems for financing on healthcare in Europe: through statutory health insurers, or through taxes. The method for financing influences the preferred instrument to support innovation:
  - Countries with statutory health insurance tend to rely on the reimbursement system
  - Countries with tax financed healthcare put emphasis on the infrastructure for innovation.
- All European countries are struggling to improve the productivity of healthcare, and they have all experienced that the consequence of this is that the room for innovation in the healthcare system has shrunk.
- Germany is an interesting example of a country that introduced reforms for increased productivity – while at the same time opening up new channels for innovation.
- Countries with statutory health insurance have a multitude of providers and innovation is part of the individual provider's competitiveness.
- Countries with tax based healthcare have large variations in the technology uptake and innovation.
- The effects of measures to support innovation are difficult to detect and evaluations of innovation policies are based on proxies. The UK is the only of the five countries that has made a serious attempt to evaluate results.
- There are lessons to be learned from each of the analysed countries, the two most important being:
  - The reimbursement system should be used to drive innovation
  - The healthcare system must consider innovation and clinical research to be part of their overall objectives.

There is a correlation between a country's system for financing of healthcare and the preferred mechanism for innovation



Countries with a statutory health insurance have been found to be more inclined to use structured financial incentives and reimburse-ment to promote innovation and create a desired behaviour.

In tax based systems, local budgets tend to take precedence over national recommendations

Countries with a statutory health insurance generally have diversity in healthcare provision, with a multitude of providers – private and public

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Policy-making – reforms	Strong political emphasis on healthcare innovation and the medical industry	Struggling to control cost, introduction of expensive innovations not in focus. Political micromanagement.	Innovation a key component of the far-reaching healthcare reform. Push to get NICE recommendations implemented.	Innovation in health-care is on the political agenda, though not at the top of it. No new reforms at the moment.	Healthcare reforms in consensus. Reforms may take time to decide, but compliance among stakeholders is high
Infrastructure for innovation	Infrastructure aimed at supporting commercialisation and the medical industry	No significant activities to support commercialisation and the medical industry.	Well-developed infra-structure gravitates towards academic research. Collabora-tion with private sector not entirely accepted.	Complex infrastruc-ture, companies and institutions find it difficult to get support	Companies and institutions mostly satisfied with the support they get
Reimbursement systems and financial incentives	No structured reimbursement for innovative products	No structured reimbursement for innovative products	No structured reimbursement for innovative products	Innovative products and services can receive reimburse-ment through the normal national sys-tem, though this is a time consuming procedure	Innovation was incorporated into the DRG reform. Innovative products and services can apply for special reimburse-ment.

Conclusions – what can Sweden learn from…

Germany has a healthcare system with a multitude of providers

The country introduced an all embracing DRG system a few years ago.

When the system was designed, it was understood that emphasis on productivity would reduce the room for innovation. Therefore, special reimbursement structures were created – inpatient as well as outpatient sector.

There are ”good” and ”bad” costs in healthcare – which can be incorporated into the reimbursement system.

Sweden should consider establishing a national **reimbursement method for innovative solutions** – preferably incorporated into the DRG system

The German **integrated care contracts are** useful for innovative healthcare services or technologies that are integrated with services, to establish new pathways, treatment of chronic patients etc, in situations where innovation needs to cross barriers in the healthcare system.

France has a healthcare system with diversity and a multitude of providers – both private and public

There is a national reimbursement system, which has been harmonised to cover all providers, private as well as public

National recommendations on innovative products are incorporated into the reimbursement system

However, the average time to get approval for reimbursement is long, compared with Germany or Sweden.

France has also introduced a “fast track” for innovations that are difficult to evaluate in terms of expected medical outcome.

In conclusion: like Germany, France shows that **specific and predictable reimbursement for innovative products** is important, but in terms of implementation we have more to learn from Germany.

The stakeholders in France emphasise the importance of local headquarters of global companies. The lack of global French medtech companies is seen as a main reason for the sector’s decline.

The healthcare system in the **UK** is going through massive reform – the result of which remains to be seen

The UK is struggling with the same issues as Sweden in innovation: there are excellent structures for the assessment of new technologies, but the national recommendations are non-binding, leading to large variations in the technology uptake.

There are no structured reimburse-ment systems for innovative pro-ducts or services in the UK. The NHS has identified innovation as a key objective and has built up an infrastructure to support innovation.

“Innovation” has central place in policy-making. There is an innovation directorate on the national level, at the Department of Health

Actions are taken to **ensure that NICE recommendations on innovative products are implemented across the country.**

The UK and Sweden apply similar measures, why the lesson we can learn is not what to do, but how to do it. Will the efforts to enforce NICE guidelines at the local level across the country be successful?

Denmark has a healthcare system and an approach to innovation that is similar to Sweden’s. Despite this, Denmark has been more successful than Sweden in the biotech and life science sector.

In terms of the national innovation strategy, two clear differences between Sweden and Denmark can be identified:

The political focus on the medical industry is greater in Denmark;

The Danish Innovation strategy, published in December 2012 , has the overall objective to ensure that public investments in research, education and innovation, to a larger degree than today, is converted to growth and job creation.

The lesson for Sweden:

Swedish policymakers should put more emphasis on translational research and commercialisation of innovation in healthcare

The healthcare system should consider clinical research and collaboration with the medical industry part of their responsibility

The Netherlands went through a major healthcare reform, based on a well thought through plan for the creation of three healthcare markets, but the overall objectives were not reached

Neighbouring countries, like Germany, initially considered the Netherlands as an example that should be followed, but the Germans now consider the Dutch experience a failure.

One of the factors contributing to this failure was that the system was built on political control, rather than the dynamics among a multitude of stakeholders that is found in four example Germany, or France.

In terms of innovation in healthcare, **Sweden has little to learn from the Netherlands**

However, the Implementation fellows at the University hospitals are worth mentioning.

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Recommendations

Two general recommendations and one concrete suggestion

”Innovationsmiljard” – varför inte från de 1,2 miljarder kr i minskad läkemedelsnota 2012?

Reimbursement system

- Establish a national reimbursement system for innovative products and services – similar to the German NUB

Infrastructure for innovation

- Clinical research should be part of the overall objectives for the counties and healthcare systems – not only expressed, but also enforced
  - Evaluation of management in Swedish healthcare should include their ability to drive innovation and clinical research
  - Technology uptake, endogenous innovation, clinical trials, partnerships, etc

A concrete suggestion concerning clinical trials

- It is important for Sweden to be an attractive environment for clinical trials. It would be futile for Sweden to try to become a “world leader”. However, it is realistic to become the best development and testing ground for drugs with companion diagnostics

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Establish a national reimbursement system for innovative products and services

National system

- A way of enforcing national guidelines, similar to the LOV
- Can be monitored by *Socialstyrelsen* which is administering the Swedish part of *NordDRG*
- Assessments and recommendations by TLV in coordination with *Socialstyrelsen*
- Will meet resistance among elected officials in the counties, unless supported by additional government funds
- Would promote innovation in the entire country
- Would support equity in access of healthcare

Consensus through SKL

- Could be based on an initial agreement among a limited number of counties. Pilots that may later become national examples.
- Would not promote innovation in the entire country or equity in access of healthcare, but is probably a faster way to implement change
- Assessments and recommendations by SKL
- Determine financial responsibility: individual or shared? Should every county pay their own bill, or should the agreement be a potluck?

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