

etik:LER

IN THE PHARMACEUTICAL INDUSTRY

Use of digital channels based on the
Ethical Rules for the Pharmaceutical
Industry in Sweden

Use of digital channels based on the Ethical Rules for the Pharmaceutical Industry in Sweden

Last updated: Sept. 2017

This document describes the most commonly used digital channels in Sweden and how they can be used to communicate both to the public and to healthcare personnel.

The ethical rules for the pharmaceutical industry in Sweden are technology-neutral and media-neutral, which means that the rules can, and should, be applied to both traditional channels and digital channels.

A few fundamental aspects:

- Medicinal product information must be easy to recognize as such, irrespective of the channel used, and it must not be disguised (LER chapter 1, sections 1 & 2, article 5/105)
- Medicinal product information regarding prescription medicinal products (Rx) may only be aimed at healthcare personnel (LER chapter 1, section 1)
- Medicinal product information about non-prescription medicinal products (OTC) may be aimed at the public (LER chapter 1, section 2)
- Medicinal product information may not include testimonials from individual patients/the public (LER, chapters 1 & 2, article 8/108)
- Pharmaceutical companies may not allow healthcare personnel to participate in medicinal product information and offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment (LER, chapters 1 & 2, article 8/108)
- The companies are responsible for medicinal product information; this applies to all media. For example, if a company contributes to the spread of an individual opinion in blogs, social media or websites, etc., the company is responsible for the information (LER chapter 1, section 1, article 27/127).
- Under pharmacovigilance legislation, companies have an obligation to report any adverse effects that are discussed about the company's drug (regardless of channel). The company should have a policy for managing adverse events when information about the informant or patient is incomplete.
- In their general use, social media are channels that are considered to be aimed at the general public

Note that in the event of a complaint, the Information Examiner (IGN) and the Information Practices Committee (NBL) ultimately always determine whether or not a procedure is appropriate under LER.

Due to the rapid pace of digital channel development, this document will be continually updated.

Websites

Websites are the most common digital channel and are classified as a channel that reaches the public, unless verification (e.g., pop-up or password) is required to access the website.

This practice has long been commonly accepted and there are many different types of websites with different target groups. Below is a link to a brief description in Swedish; see also common practice documents for more detailed information.

<http://www.lif.se/contentassets/741614860be242b796c28367de2bfe2a/information-fran-igm-om-lakemedelsinformation-pa-internet.pdf>

Therapy-oriented/Disease information website e.g. www.illness.se: Problem-oriented and product-neutral (prescription medicinal products may not be named), but where different treatment options relating to a disease may be named, e.g. beta blockers, calcium channel blockers or similar.

Hybrid website e.g., www.company.se: A hybrid website consists of two components; one part is aimed at the general public (homepage, etc.) with general information about the company, diseases, etc. as described above for therapy-oriented websites. The other part can be reached by readers who indicate that they are HCPs, and Rx information may be provided here. Readers select the category to which they belong according to the “library principle”. The common practice on the company’s website (www.company.se) is to provide information about the company’s products under the “our products” tab or similar, without this being considered to be Rx information aimed at the public, as long as only the name of the medication is provided, along with a link to the PIL or the company on fass.se.

Pre-approved website (public): A pre-approved website is a website about an Rx drug aimed at the general public. Pre-approved websites are only permitted if they meet the strict rules specified in LER and if pre-approved by IGN. There is a checklist for pre-approved websites based on the LER rules that can be used when designing the website.

Password-protected website: A password-protected website refers to a website that is aimed at patients and that confirms this via some type of verification, e.g., batch no. or similar. The website may provide various types of aids, patient brochures or similar, i.e. information material that contributes to maximum compliance for the prescription drug.

Other types of websites

Websites exclusively aimed at HCPs e.g. www.themedicine.se: Some websites are exclusively aimed at HCPs. Before entering this type of website, readers must first verify that they are HCPs, for example, via pop-up. Readers who are not HCPs are automatically redirected to a page aimed at the public, e.g., www.illness.se or www.company.se.

Websites about one or more non-prescription medicinal products aimed at the public, e.g., www.themedicine.se: Some websites about one or more non-prescription medicinal products are aimed at the public. Product names and information are allowed, but must comply with Article 117. The website may also contain general disease-related information as described above.

Other

Press: Company websites often have a “Press” tab to access various types of press releases. The Administrative Court of Appeal has ruled that a press release can be interpreted as marketing, and is therefore aimed at the public (journalists). See case no. 1477-13, Administrative Court of Appeal, Stockholm, for more detailed information.

Consequently a press release must not be intended for marketing purposes. General guidelines for press releases state that they should be of general newsworthiness, any reference to product name and active substance should be kept to a minimum, and they should provide objective, balanced and concise information about the medicinal product. Since journalists are the target group, the format must be adapted to them, and the message must not be distributed to the public or to healthcare personnel.

Keyword optimization of websites

Websites are the most common digital channel and are classified as a channel that reaches the public, unless verification or a password is required to access the website. Since many website visits come from search engines such as Google, keyword optimization has become an important tool to increase the number of visits to the website. Because the public may be reached by therapy-oriented information and information about non-prescription medicinal products, pharmaceutical companies may choose to optimize keywords on these websites. Keywords can also be optimized on websites with information about prescription medicinal products aimed at healthcare personnel. Since the website can only be accessed by healthcare personnel, keyword optimization is not a tool for distributing the information to the public.

Social media

Social media are websites or smartphone applications in which people can interact in social networks. There are exceptions, but in most cases social media are used to convey information to the public. Some points that are important to consider:

- texts about new findings in social media can be faulted as pre-launch information
- texts must refer to the PIL for an OTC drug
- healthcare personnel may never get involved in medicinal product information and recommend a specific product
- the pharmaceutical company is responsible for all content in the relevant social channel that is being used. This means that when someone comments on the company’s posts, the pharmaceutical company is responsible for deleting this as soon as possible, for example, if it is a patient testimonial or contains information that is not permitted by the LER rules (e.g., information about a prescription medicinal product)
- adverse effects mentioned in social media must be reported. This also applies if the company or its employees see information about adverse effects in social media for which the company is not the owner/responsible.

- medicinal product information may not target individuals under the age of 18.

Pharmaceutical companies may provide the public with information that is predominantly problem-focused and product-neutral, but in which different treatment options are mentioned, such as therapy groups like beta blockers, calcium channel blockers, or similar (compare with the logic for websites above).

In social media, it may be difficult for visitors to understand the difference between the professional role and the private role. Regardless of what your personal intentions may be with your presence in social media, other users may consider you to be an individual who has both a professional role and a private role. For this reason, we advise pharmaceutical company employees to always act as an employee in the pharmaceutical industry when participating in social media. This means that you as an individual must comply with the LER rules in the same way that your pharmaceutical company does.

There are many “social influencers” in social media. The concept refers to the company paying influential individuals to communicate about the company’s services or products in social media. These individuals often have many followers on social media or popular blogs. If the company collaborates with these persons, it should be clearly stated that the pharmaceutical company or drug name (if any) is the sender. The pharmaceutical company is also responsible for all content written by such individuals, which means that, for example, patient testimonials are not permitted.

Information aimed at the public

Facebook

Facebook is the most commonly used social media channel in Sweden. A pharmaceutical company can have a separate page on Facebook for its non-prescription medicinal products. However, it is important that the required minimum information is clearly displayed and can be quickly accessed on a computer, tablet or mobile device, if it is described under the “About” heading on the page. Facebook intends to launch a marketing service for medicinal products which, according to Facebook, will enable pharmaceutical companies to target advertisements/banners about non-prescription medicinal products at the public. Currently, Facebook’s ads/banners are static, but in the future, it will be possible to change the content, thereby creating space/opportunities to display the required minimum information, etc.

This document will be updated with more information when the service is launched in Sweden. The pharmaceutical company can also have a Facebook page with therapy-oriented information, or some other generally oriented page.

Twitter

Twitter is a social medium for communication/information/discussion using short texts. Since a “tweet” can only be 140 characters long, a pharmaceutical company is unable to communicate about medicinal products on Twitter because there is no room for the minimum information required for non-prescription drugs. It is also possible to upload photos and short videos with ads about non-prescription medicinal products in the form of links on Twitter. Remember that Twitter is primarily used on mobile phones, and it must still be possible to view the required minimum information despite the smaller format of the mobile phone screen.

Instagram

Instagram is a social medium for communication through photos and short videos. Pharmaceutical companies can post photos and short videos about non-prescription medicinal products on Instagram. Remember that Instagram is primarily used on mobile phones, and it must still be possible to view the required minimum information despite the smaller format of the mobile phone screen. The comments field on Instagram can be blocked, which means that one-way communication can be used without needing to regularly monitor the comments so that inappropriate comments can be deleted.

LinkedIn

LinkedIn is primarily a social medium for forging professional contacts. A pharmaceutical company can have pages on LinkedIn for information about non-prescription medicinal products, although this channel is primarily and best used to promote the company itself, e.g. for human relations purposes. If LinkedIn is used to communicate about a non-prescription medicinal product, the required minimum information must be clearly displayed and able to be quickly accessed.

YouTube

YouTube is primarily a medium for publishing and watching videos. YouTube can be used for advertisements about non-prescription medicinal products. Remember that the video can easily be shared, and that the pharmaceutical company is responsible for the content, even when it is shared. The comments field on YouTube can be closed, which means that one-way communication can be used without needing to regularly monitor the comments so that inappropriate comments can be deleted. Remember to clearly display or link to the required minimum information text in conjunction with the video on YouTube's homepage.

Pinterest

Pinterest is a social medium for organizing and sharing photos on digital bulletin boards. Pharmaceutical companies can post photos about non-prescription medicinal products or therapy-oriented information on Pinterest. However, remember that Pinterest is primarily used on mobile phones, and it must still be possible to view the required minimum information despite the smaller format of the mobile phone screen.

Information aimed at healthcare personnel

Facebook

Facebook offers closed groups, which means that in practice, pharmaceutical companies can gather HCPs in such groups and provide information that targets them. If the pharmaceutical company has created the group, the company is responsible for all content and the LER rules must be followed, with a special focus on articles 17 and 8.

LinkedIn

LinkedIn also offers two types of marketing: Display Ads and Sponsored InMail, which is only aimed at specific professional groups. According to LinkedIn, this enables pharmaceutical companies to exclusively target healthcare personnel with information focused on, for example, prescription medicinal products.

Blogs

The difference between a text on a website and on a blog is that a blog post usually has a personal sender and that new blog posts are posted with a certain periodicity.

Blog on the company's website

A pharmaceutical company can have its own blog in which the company, an employee or a partner is responsible for the blog posts. It is important that the blog is based on the same rules as the text content of the company's website, which means that the company is responsible for the content.

Therapy-oriented information fills an important function for people who want to read more about the illness from which they or their close relatives suffer. Pharmaceutical companies can write blog posts provided that they are primarily problem-focused and product-neutral. Various treatment options can be described in a neutral and balanced way and mentioned in the form of therapy groups, e.g., beta blockers, calcium channel blockers or similar. Prescription medicinal products may not be mentioned.

This type of blog can also target HCPs. Remember that HCPs must verify their professional role and that the text content must be based on the ethical rules.

Blog on external website

Marketing via "social influencers" is growing sharply in Sweden. The method involves the company paying influential people to communicate about the company's products or services.

If the company collaborates with a private individual (blogger/social influencer) who writes blog posts, it must be clear that the pharmaceutical company is the sender. The pharmaceutical company is also responsible for the content of the blog posts, which means that, for example, it should not involve patient testimonials or information regarding prescription medicinal products.

Podcasts

The content of a podcast episode can be compared to the content of a blog. A pharmaceutical company can have its own podcast in which the company or an employee is responsible for the content.

Podcasts should follow the same rules as the text content on blogs or websites.

Therapy-oriented information fills an important function for people who want to read more about the illness from which they or their close relatives suffer. Pharmaceutical companies can communicate about topics that are primarily problem-focused and product-neutral. Various treatment options can be described as therapy groups, e.g., beta blockers, calcium channel blockers or similar. Prescription medicinal products may not be mentioned. A podcast can target both the public and healthcare personnel and must comply with the ethical rules.

If the company pays a private individual to participate in a podcast, it should be clearly stated that the pharmaceutical company is the sender. The pharmaceutical company is responsible for what is said in the podcast, and it must be in compliance with the LER rules.

A podcast on prescription medicinal products targeting health care can be downloaded from any podcast distributor such as Podcaster, Acast, etc. It should be clearly stated that the podcast targets health care.

Applications

An application, usually referred to as an app, is downloaded to a smartphone or tablet. A pharmaceutical company can develop text-based applications provided that they follow the same rules as websites. An application can also be developed to improve compliance with a treatment method. If an application targets a specific patient group, it is important that only this patient group is offered access to the application. Limited access can be ensured by, for example, requiring the batch number on the medicinal product packaging or similar to log in. Remember that a medical device app must be CE-labeled. Most apps also gather some information about the app user, which could mean that in practice they handle sensitive information. Such handling must comply with the new Swedish Personal Data Act (PDA) and General Data Protection Regulation (GDPR).

Google AdWords

Google AdWords involves companies paying Google to ensure that their websites, etc., are displayed high on the list of hits when people perform a Google search. The company decides which keywords will lead to exposure of the relevant website. Since advertising through Google AdWords targets the public, pharmaceutical companies can only market websites, etc., that contains therapy-oriented information or information about non-prescription medicinal products.

Fass

Fass.se, is visited 4 million times annually and is an important tool for care providers, but also an important source of knowledge about medicinal products for the public. On Fass.se it is possible to link from a specific product to web pages outside Fass, linked to a specific product. Since the public and healthcare personnel use different access routes, it is possible to link to pages that may be offered to both the public and to healthcare personnel. Each product page has two links, and the public and healthcare personnel can use different links to gain access to the pages. The upper link "More information" has a predetermined name, but a pharmaceutical company can choose the name of the lower link

The screenshot shows the Fass.se website interface. At the top, there are navigation options: 'Ordförklaringar', 'Textstorlek', 'FAQ', and 'Söktips'. Below this is the 'FASS Allmänhet' header with dropdown menus for 'Allmänhet', 'Vårdpersonal', and 'Djurläkemedel'. A search bar is present with the text 'Sök på läkemedel, substans eller sjukdom' and a 'Sök' button. To the right of the search bar are links for 'Tablettidentifiering', 'Läkemedel A-Ö', and 'Företag A-Ö'. The main content area displays information for 'Ketobemix (fingerad produkt)'. It includes the following details:

- Ketobemix (fingerad produkt)**
- Läkemedelsbolaget
- Tablett 400 mg
- (vit, sköldformad, bikonvex, märkt GXCM1)
- Antiviralt medel
- Särskild receptblankett krävs**
- Narkotiskt analgetikum
- Aktiv substans:** Aciklovir
- ATC-kod:** J05AB01
- Utbytbarhet:** Utbytbara läkemedel
- Läkemedlet omfattas av [Läkemedelsförsäkringen](#)

On the right side of the product page, there are two sections:

- Receptbelagd**: Peka på symbolerna och beteckningarna till vänster för en förklaring.
- Kontakt och länkar**:
 - mer information
 - [Läs mer om smärtbehandling](#)
 - Fråga om läkemedlet** (highlighted with a red box)

Link from Fass.se for the public

- Therapy-oriented pages with a link to the indication for the medication
- Product pages about non-prescription medicinal products
- Instructional videos for e.g. injectable drugs
- Patient support programs, websites, apps, podcasts, etc.
- Product pages about prescription medicinal products, provided they are classified as a pre-approved website or are password-protected so that only patients who have had the medication prescribed have access

Link from Fass.se for healthcare personnel

- Product pages for healthcare personnel
- Instructional videos for e.g. injectable drugs
- Pages with information about risk management plans
- Therapy-oriented pages with a link to the indication for the medication
- Patient support program where the prescriber can also be involved, such as websites, apps, podcasts, etc.

More information about how the links work and can be edited in Fass can be found in the Fass Användarhandbok (Fass User Handbook), which can be accessed via Fass Medlemswebb (Fass Members Website), <http://medlem.lif.se/fass-medlemswebb>.

Cases in self-regulatory system

(In Swedish)

R090/16	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=3242 (Facebook)
948/12	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=1434 (Vägledande Läsbarhet)
R08/13	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=1135 (Facebook)
W1385/12	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=807 (Facebook)
R057-15	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=1153 (Youtube)
R076-15	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=2192 (Youtube)
944/12	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=1438 (Banners)
1001/14	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=2172 (Google)
W1396/13	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=796 (Google)
R078-16	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=3207
R062-15	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=1148
R064/15	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=1146
1015/15	http://www.lif.se/etik/ign-och-nbl/detaljer/?id=2160

Statutory copies

Under articles 31 and 131 in the LER rules, the pharmaceutical companies must send IGN all new, relevant drug information such as printed materials, advertisements, invitations, mailings, television commercials or information on websites. Naturally, this requirement also applies to social media. This information is known as statutory copies. This is a key fundamental principle in the LER rules that enables IGN to fulfill its brief of monitoring the market. The pharmaceutical companies must have internal procedures so that these statutory copies are sent to IGN. Statutory copies are sent by the pharmaceutical companies to pliktexemplar@lif.se.

More information

You can find Questions & Answers as well as IGN and NBL cases at www.lif.se/etik (in Swedish). Questions & Answers provide specific questions and answers about digital channels from the standpoint of the ethical rules. The IGN and NBL cases can provide guidance in how you should, or should not, use the various digital channels.



LIF *The research-based
pharmaceutical industry*

Läkemedelsindustriföreningens Service AB

Box 17608, SE -118 92 Stockholm, Tel +46 8 462 37 00, Fax +46 8 462 02 92

E-mail: info@lif.se www.lif.se www.life-time.se www.fass.se