GUIDE

regarding use of digital media

in advertising activities

NB! You can search in the guide by pressing "Ctrl + F" and enter your search word.

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1. Introduction

The purpose of this guide is to give some practical approaches to pharmaceutical companies' use of digital media in advertising activities towards healthcare professionals. This guide intends to provide a basis for a good navigation on the digital media. The guide should thus not be regarded as an exhausting review of the Danish legislation as well as the industry's ethical rules on this topic.

2. Generally regarding digital media

As a starting point, use of digital media in the advertising context will be regarded in the same way as the use of any other media, and it is therefore also the same assessment, cf. the Promotion Code, that is taken into account regarding activities towards healthcare professionals.

When is an activity directed at the public, respectively healthcare professionals?

Activities on the Internet, including the use of social media, is considered, as the starting point, as activities aimed at the general public, and the Promotion Code thereby shall not apply, cf. Promotion Code Art. 2(1) and (2), as well as the advertising Order, section 9 (2).

Activities that, on the other hand, are solely directed to healthcare professionals, and which takes place in a closed forum, will be covered by the rules in the Promotion Code. According to the Executive order on Advertising, section 9(3), advertising on the Internet, where access to information is limited to healthcare professionals and individuals employed with the sale of medicines outside pharmacies, will be treated as advertising to healthcare professionals, etc.

As a starting point, there is nothing to hinder the pharmaceutical company's use of digital media, as long as it only regards information on health and diseases or lawful advertising.

Concept of Advertising

By **advertising** of pharmaceutical products to humans, cf. section 1(1), in the Advertising Order, this means "any kind of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products to humans". All activity, regardless of medium, is covered by the definition of advertising.

Any advertising to healthcare professionals, must comply with the rules in the Promotion Code, the Danish Medicines Act Chapter 7 as well as the advertising Order.

Thus, inter alia, an advertisement for a medicinal product shall be adequate and factual, and it must not be misleading or exaggerate the medicine's properties. In addition, the advertisement shall be in accordance with the approved summary of product characteristics of the medicinal product. In addition, a number of requirements relating to the compulsory information, documentation and comparative advertising apply cf. Art. 5, 7 and 8 of the Promotion Code.

Any advertisement for a specific medicinal product must also be followed by **compulsory information**[1], cf. the Promotion Code Art. 5. It is ENLI's view that it is in accordance with the Promotion Code to link to the compulsory information, when this information maximum is one click away from that advertising page, and it clearly appears from the advertisement that the link provides access to the compulsory information.

Note that in the case of advertising activities covered by the Promotion Code, the activity in question will be subject to the notification obligation under the code, cf. the Promotion Code Art. 21(1) and (3).

Scope of the advertising concept

According to the Danish Medicines Agency's guidance for the advertising order the definition of advertising for medicinal products is interpreted broadly in accordance with the wording of the provision and the main objectives of the advertising regulations, which are the protection of e.g., public health. The Danish Medicines Agency's guidance section 2.1. it also states that:

> *"It depends on a concrete assessment of the circumstances at hand, including the nature of the business (activity) carried out and the content of the message, whether it is advertising for medicinal products.*
>
> *The definition of pharmaceutical advertising is not limited to specific senders or media. It is not a requirement that a message about a medicine must be disseminated in connection with a commercial enterprise in order to be considered advertising, or that the person who disseminates the message about a medicine must be associated with the pharmaceutical company/holder of the marketing authorisation. It can be both pharmaceutical companies and others who are senders of advertising for pharmaceuticals.*
>
> *An association with the pharmaceutical company is included as a factor in the assessment of whether it is advertising together with other relevant circumstances. If, for example, an employee in a pharmaceutical company shares or likes an advertisement about one of the company's medicines, or if the employee shares and likes, for example, other material that contains claims or other positive mention of the medicine on a social media, it may, after a concrete assessment be considered as advertising for the medicine, even if the person in question acts on his own initiative. During the assessment, emphasis will be placed on the nature of the business carried out, the content of the message, the employee's connection to the company and any other relevant conditions. It is not a condition for it to be an advertisement for a medicinal product, that the material in terms of form appears like a typical advertisement, e.g., an advertisement, as the concept of advertisement is not limited to specific forms, but it will, if necessary, be included as a factor together with other relevant matters in the assessment. By virtue of their employment, the employee has a special connection to the pharmaceutical company, and this can be a motivating factor in relation to sharing and liking information about the company and its medicines. An advertisement that contains both advertising for the pharmaceutical company and advertising for one of the company's medicines is also treated as a pharmaceutical advertisement, which must be in accordance with the rules on advertising for*

[1] Reminders are excluded, cf. Art. 6 in the Promotion Code

medicines. The company will not be considered responsible for the employee's action (advertising) on social media, if the company has not encouraged the action or otherwise contributed to it, and the action has not been carried out under the company's auspices.

It is not considered advertising for a medicinal product if an employee of a pharmaceutical company provides information about one of the company's medicinal products on social media, and it has a purpose other than advertising the medicinal product. It may, for example, be for the purpose of self-promotion of one's own professional competences on LinkedIn, where the employee provides factual information on his profile about the medicine in a description of his professional competences. It is also not considered to be advertising for pharmaceuticals if the employee shares general information about the pharmaceutical company with a view to promoting the company as a good workplace and to draw attention to good career opportunities in the company on social media.

It is not included as a criterion in the advertising definition that the person who advertises a medicinal product must have a special, typically financial, interest in promoting the sale of the medicinal product. If, for example, a person or company, through public statements, clearly aims to influence others to buy a certain medicine, and the statements appear in form to be an advertisement, this will be a pharmaceutical advertisement, even if the person or company acts on their own initiative and legally and actually is completely independent of the holder of the marketing authorization for the medicinal product."

The definition of advertising stems from a European Parliament and Council Directive 2001/83 and is interpreted by the Court of Justice for the European Union, which typically adopt a broad interpretation of the concept.

An example is the so-called **"Damgaard case" (C-421/07)**, where the Court concluded that a third-party dissemination of information about a medicine, may be considered advertising, even if this third-party is acting on its own initiative and completely independent, de jure and de facto, of the manufacturer or seller of such a medicinal product.

According to the casefile, Damgaard was a journalist who, through his website, disseminated information about a medicinal product that was not approved for marketing in Denmark. Damgaard had indicated that the medicinal product could relieve pain induced by different kinds of arthritis or osteoarthritis, and that the medicinal product was sold in Sweden and Norway. The Danish Medicines Agency reported Damgaard to the police for violation of the Danish Medicines Act (prohibition on advertising of medicinal products which cannot be sold or supplied lawfully in Denmark). Damgaard was fined for violation of the Danish Medicines Act in the District Court.

Damgaard appealed to the High Court of Western Denmark, as he argued that he was not employed by the manufacturer of the medicinal product, had not received any payment from the company to write about the medicinal product and, in general, had no interest in neither the company nor the sale of the medicine. Damgaard did also claim that the information on the medicinal product on the website was not advertising, since the definition of advertising, in his opinion, does not include information activities

carried out by an independent third party. The Prosecution Service on the other hand, argued that Damgaard's dissemination of information about the medicinal product, in any case, encouraged consumers to buy the medicinal product, and that it was irrelevant whether there was any connection between Damgaard and the manufacturer or the seller of the medicinal product. On these grounds, the High Court of Western Denmark decided to ask the EU Court of Justice for a so-called preliminary ruling on the interpretation of the definition of advertising of medicinal products. The High Court asked whether the definition of advertising for medicinal products in the directive's article 86(1), must be interpreted as meaning that a third-party dissemination of information on a medicinal product, shall be deemed advertising, even if the third party is acting on his own initiative and completely independent, de jure and de facto, of the manufacturer and the seller.

The European Court of Justice said in the preliminary ruling that the definition of advertising of medicinal products must be interpreted as meaning that a third-party dissemination of information about a medicinal product can be considered advertising, although this third party is acting on its own initiative and completely independent, de jure and de facto, of the manufacturer or seller of such a medicinal product. The European Court of Justice stated in the preliminary ruling that the definition of advertising explicitly emphasizes the purpose of the message, while it does not mention the people who disseminates that information. Therefore, the definition does not rule out the possibility, that a message originating from an independent third party may constitute advertising. The European Court of Justice notes that even if it is carried out by an independent third party outside any commercial or industrial activity, advertising of medicinal products is liable to harm public health, the safeguarding of which is the essential aim of the pharmaceutical directive. The European Court of Justice stresses that it is for the national court to determine whether third party dissemination of information about the medicinal product constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

The issue of freedom of expression was also dealt with by the European Court of Justice in the Damgaard-case. In addition, the Court of Justice observed that freedom of expression may be subject to certain limitations by objectives in the public interest. It follows from the ECHR article 10(2) that freedom of expression may be subject to certain limitations, restrictions and criminal provisions that are prescribed by law and are necessary in a democratic society, inter alia in order to protect public health. The rules on advertising of medicinal products, as referred to, aims to protect public health. The European Court of Justice noted that if the information, which Damgaard disseminated on the Internet, should be considered advertising, his conviction could be considered reasonable and proportionate in the light of the legitimate aim pursued, namely the protection of public health.

The criminal case was then completed by the High Court of Western Denmark, and Damgaard was fined DKK 10,000 for unlawful advertising.

It must be based on a specific assessment, as mentioned, whether the dissemination of information about a medicine on the Internet is advertising (door-to-door information, canvassing activity or inducement designed (aimed) to promote the prescription, supply, sale or consumption of medicinal products). It shall not be considered advertising, if e.g., a person, who is employed by a pharmaceutical company, uses social media for other purposes, e.g., self-promotion of own skills on LinkedIn or to participate in a debate about health and illness (without mentioning the company's medicines).

Advertising or health and disease information

As for any other assessment in relation to the Promotion Code, mere **health and disease information activities,** will be excluded the rules, cf. Art. 2(2)(c) in the Promotion Code, cf. section 2(5) in the Advertising Order. Thus, for example, websites, Facebook groups and Twitter sites that exclusively concerns mere illness information will not be deemed advertising.

Consider the purpose

The pharmaceutical company should decide, before a website or a page on social media is generated, what the purpose of that page is, including whether or not the page is an advertisement for a specific medicinal product, or whether the purpose solely is to raise awareness for disease areas and treatment in general.

You should be aware that a website or a site on social media, which contain information about health and diseases via users' interaction, could develop from being a legitimate disease information to an advertising of a medicinal product. A Facebook group or a page on Twitter about, for example, diabetes, where users engage in a dialogue and share their experience with the use of specific medicinal products, may constitute an advertisement for the medicinal product. The company should therefore pay attention to whether the dialogue at the mention of a specific medicine is evolving to become unilateral in nature, and thus possibly become an actual advertisement for the medicinal product concerned. When a pharmaceutical company is responsible for the creation of a site, is it ENLI's view that this company, as a starting point, also will be responsible for the communication on the site.

Whether it constitutes advertisement or not will always rely on an assessment of the entire site, which the pharmaceutical company is responsible for. Thus, both permanent and temporary information and images will be included in the assessment. A pharmaceutical company may reproduce, on its website, a medicine **packaging, package leaflet and summary of product characteristics** in unedited and unabridged version, without this being considered an advertisement. The European Court of Justice has accepted this in the case of MSD Sharp & Dohme, C-316/09, in which the Court had to consider whether the disclosure of information on the Internet about a prescription medicine was in breach of article 88(1)(a) of Directive 2001/83, after which the Member States shall prohibit the advertising of prescription medicines to the general public. The Court made it clear that, if the information relating to the medicinal product is selected or reworded by the manufacturer, the dissemination of such information could solely be explained by an advertising purpose. It is for the national court to determine if it constitutes advertising. In this respect, it should be noted that the definition of advertising must be interpreted broadly, in accordance with both the Promotion Code and the Advertising Order. The Court also pointed out that among the other circumstances that are relevant to the assessment of whether the disseminated information must be deemed advertisement, is the type of the medium used for dissemination (pull and push services respectively - there is a strong presumption of advertising by push services). The Court also highlighted the circle of recipients, which was interesting in the case in question, in that this regards the interpretation of article 88(1)(a), which concerns a ban on advertising for prescription medicines to the general public.

Third party dissemination of information

The European Court of Justice stated in connection with the case C-421/07 Damgaard, that a third-party dissemination of information about a medicinal product, may be considered advertising, even if he or she is acting on his/her own initiative and is completely independent, de jure and de facto, of the manufacturer or seller of such a medicinal product. It must therefore be determined whether the dissemination constitutes a form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.

It is ENLI's's assessment, after the above-mentioned two judgments from the European Court of Justice, that the purpose of the website is seen in the light of the communication, which appear on the website when deciding whether it constitutes advertisement. Thus, it will be of importance whether the activities in question can be considered to be door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. It should be noted in this context that the advertising concept in both the Promotion Code and Advertising Order is interpreted broadly. It depends, however, on a specific assessment, whether it is deemed advertising in each case.

Pharmaceutical companies should therefore be aware that **the opinions from independent third parties** might constitute an advertisement. In ENLI's opinion, the company responsible for the website is also responsible for third parties' activities on the site, including third-party opinions, which may constitute advertising, since the site has been set up at the company's initiative. Pharmaceutical companies have a duty to ensure that advertisements on their websites, social media, etc., is in accordance with the rules on advertising, even though the advertisement comes from a third-party activity. This implies an actual commitment for the pharmaceutical company to periodically monitor their webpages, including deleting any illegal statements.

The Danish Medicines Agency has stated that they, as a starting point, do not consider that an independent third-party participation in a debate/chat on the Internet about a medicine is advertising. On the other hand, a pharmaceutical company may be responsible, as the sender of an advertisement, if the company has set up a website or a forum on a website that contains third-party claims/positive mention of the company's medicinal product.

Third-party mention of **competitors' medicinal products** on the pharmaceutical company’s webpage is the pharmaceutical company, in ENLI's opinion, as a starting point, not responsible for. The company should pay special attention to third-party mention of **off-label** use, whether it is regarding the company’s or a competing medicinal product. Thus, ENLI recommends that the post be removed to ensure that the advertising rules are complied with.

It will depend on a specific assessment of the current circumstances, how often a company should monitor its activities on, inter alia, the social media. Thus, both the informative content and policies/guidelines play a role. Webpages on social media change constantly, and it is therefore important that the company often and continuously monitor the site.

For more information on advertising rules, see the Guide to the Promotion Code, www.enli.dk .

Jurisdiction to process cases of advertising on the Internet

ENLI handle cases on advertising of medicinal products to healthcare professionals. Complaint about a possible illegal advertising of a medicinal product to the general public is handled by the Danish Medicines Agency. In accordance with section 9(2) and (3) in the advertising Order, the advertising of medicinal products on the Internet and social media will be regarded as advertising to the general public, unless access to information via demands for personal access code or by other effective means is limited to healthcare professionals. If the information is shared to both healthcare professionals and to the public, it will thus be the Danish Medicines Agency, which handles the complaint. It should be noted that the Danish Medicines Agency also has jurisdiction to deal with cases concerning the advertising of medicinal products to healthcare professionals. This applies, regardless of whether the case in question also falls within the competence of ENLI, cf. the Promotion Code.

Case of procedure at ENLI and the Danish Medicines Agency respectively, regarding postings on social media

ENLI will send a consultation letter to the referred company, in order to clarify whether the company is responsible in relation to the sharing of information, as well as to clarify whether the sharing was done solely to healthcare professionals, or also to the general public.

It should be noted that EFPIA has decided principles for the use of digital channels (see Appendix D), so that pharmaceutical companies can be made responsible for employee sharing of information on employees' private profiles on social media, including: (a) when employees can reasonably be perceived as representing the member company or b) if the employees are instructed, approved or facilitated by the member company to share information on social media. Member companies should therefore have internal guidelines on how their staff should behave on digital media, including on their own personal profile activities. Similar principles are now also included in the joint note for guidance from IFPMA and EFPIA regarding social media and digital channels, cf. appendix E.

In the case of an employee's sharing of information on medicinal products to the public, that may be a case of illegal advertising of a medicinal product, the Danish Medicines Agency will carry out consultation with the company and the employee, who have shared the information.

If an employee of a pharmaceutical company disseminates information on a medicinal product (and it can be considered as unlawful advertising), for example via his LinkedIn profile, the person, as a starting point, will be responsible for this. If it can be demonstrated that the company has asked the employee or otherwise encouraged the employee to share the information, the company may incur responsibility for the illegal advertising. In addition, companies affiliated with ENLI may be liable for an employee's sharing of information about one of the company's medicines on a private profile (in a closed group of healthcare professionals) if the employee can reasonably be perceived as representing the pharmaceutical company on the private profile. It can, for example, be the case on a LinkedIn profile, which clearly states where the employee works. LinkedIn profiles are preferably used professionally for networks, etc. in work context.

The Danish Medicines Agency can refer cases of violation of the rules on advertising to the police with the purpose of criminal prosecution in the courts. If in violation of the advertising rules in the Danish Medicines Act, such as the ban on advertising prescription-only medicines to the general public and the

ban on the advertising of medicinal products which are not marketed or dispensed lawfully in Denmark, the penalty is a fine or jail up to 4 months. A company (legal entity) is punishable by a fine. Violation of the rules on advertising in the Advertising Order can be punished with a fine.

3. Reference guide

Apps/SMS-services

It has previously been accepted by the Danish Medicines Agency that pharmaceutical companies can provide a system of SMS services for patients. This will typically be designed in such a way that a patient receives a reminder to take his medication at a specific point in time. If this is solely a neutral message, without any claim/positive mention of the medicinal product and the doctor assess that the service is suitable for the patient in question, the service will generally not constitute advertising. Such reminders can also be designed as an App, where the same rules will apply.

Patient information leaflets can also be supplied in electronic form, for example, as an App. In that case, it is the pharmacist or doctor, who must provide the code to the App instead of handing over a printed leaflet. Be aware, however, that the App must not contain advertising material, since this is an activity aimed at the general public.

Blog

If a pharmaceutical company creates a live blog for healthcare professionals and has hired a healthcare professional to send updates continuously from a congress etc., the company will be regarded as responsible in the same way as if the company itself hire a speaker in connection with a "physical" event. This means that the company, whether it is a digital presentation, or a presentation, where the presenter stands directly across from the participants, must point out if pre-launch or off-label is being mentioned.

On the other hand, if the company chooses to make the blog available after the event is completed, the starting point will be that the company will be responsible for the full content of the blog. Thus, it is the company's responsibility to ensure that the advertising rules are complied with, including possibly pre-launch or off-label reference to be removed from the blog.

Reference is also made to Annex D, which sets out the principles of EFPIA. Among other things, it states that a blog can be owned by the member company, or the member company can engage (either through sponsorship or consulting fees) the owner to write on a blog (e.g., "social influencers"). In both cases, the blog must clearly state the involvement of the member company. Similar principles are now also included in the joint note for guidance from IFPMA and EFPIA regarding social media and digital channels, cf. appendix E.

Given that a blog itself is intended for contributors to freely and spontaneously express their personal views on a topic, member companies should not sponsor such blogs if they are intended or reasonably expected to promote prescription medicines and their use. The same is also apparent from the joint note for guidance from IFPMA and EFPIA regarding social media and digital channels, cf. appendix E.

Domain names

The use of trade or generic names (of pharmaceuticals) in domains will not in itself be an advertising activity and use of these will not in itself lead to the home page, as the domain refers to, automatically

becomes an advertising activity. ENLI will always carry out a concrete assessment of the relevant website, including the front page and subpages, which the domain leads to and assess whether or not this constitutes a promotional activity. This evaluation will include, inter alia, any information of medicinal products on the domain.

If a company wants to create a website, it is not a requirement that both trade and generic name is part of the domain name. This applies regardless of whether the home page stands out as an advertising activity, or it only contains general disease information. A company can thus choose to create a website where the trade name is the only reference in the domain name, such as www."trade name".com. The company must, however, make sure that the generic name appears somewhere on the website, in the case of advertising activity, cf. the Promotion Code Art. 5 (1)(1).

Effective access restriction

Advertising of medicinal products on the Internet will be treated as advertising to the general public unless access to information via demands for personal access code or by other effective means is limited to healthcare professionals, cf. Advertising Order section 9(2) and (3).

If a company creates a website or a site on social media, the starting point will be that access has been restricted, if a unique user identification in the form of a unique username, authorization number or similar, as well as a related individual password is effectively used.

The following examples will apply (this is not an exhaustive list of examples):

- The HCP is asked to state his/her name, birthday date or authorization ID and work address, and the company shall carry out ex-post controls in the authorization register with the Agency for Patient Safety approval directory on the website www.stps.dk.
- A pharmaceutical consultant (sales rep.) provides, in connection with a visit, a unique username and password for a healthcare professional. This may be combined with a signed receipt for the delivery of username and password.
- A healthcare professional submits a signed sworn statement. The statement may include the individual's name, position/education, work address and telephone number. The information gives the company the opportunity to verify that the individual is a healthcare professional.

The Danish Medicines Agency has confirmed that it will be regarded as effective access restriction to a website targeted healthcare professionals, if access to the website will be sent as a generic link in an e-mail message sent to the HCP's personal mail address. However, this applies only if one at the same time can't search/Google access to the website on the Internet, without using this link.

Facebook and LinkedIn

It follows from the guide to the Advertising Order section 8.1, that it is possible for a pharmaceutical company to create a site on Facebook, where healthcare professionals are given individual access to the information, if the site in question generally is closed for the general public. It is ENLI's view that this applies to similar media such as LinkedIn.

The advertising rules must be complied with, as in all other situations. It is the company's responsibility to ensure that these rules are complied with.

Furthermore, it is a requirement that access to the relevant site in an efficient way is limited to specific groups of people (healthcare professionals). Please refer to the rules above about "Effective access restriction".

The person responsible for the advertisement must also, among other things, pay attention to the rules in section 10 of the Marketing Act regarding unsolicited communication to specific buyers with electronic mail. Reference thereon is made to the Consumer Ombudsman guidance.

External website – link to

If a company wants to refer to an independent website with information about different therapeutic areas, there is nothing immediately to prevent this. The company must be aware; however, that they will be responsible for the website they are referring/linking to, i.e., the front page of that website. The subpages, which one can navigate to from the front page the company, as a starting point, will not be considered responsible for. The company's liability is based, therefore, on an overall assessment of how the company uses the link.

It should be noted that the Promotion Code does not apply for a mere disease informational website. An external link to such a website should, however, be seen in context with the rest of the material referred to. Since the advertising concept is very broad, it does not take much for a link/a reference to be considered advertising.

For rules regarding streaming of congresses, etc., see the section "Live streaming and recorded sessions".

Email addresses

It is ENLI's assessment that the use of trade or generic names in email addresses as a starting point will be perceived as a commercial activity from the company's side. This is because the e-mail is a tool that is used to identify the sender, and that e-mails can be seen as having a "push" functionality. The actual email address will, however, be assessed in relation to the content of the relevant mail.

Emails – sending of

According to the Danish Marketing Act section 10(1), *"a trader must not contact anyone through the use of electronic mail, automated calling system or telefax for the purposes of direct marketing, unless the person concerned has given his or her prior consent. The trader must allow for, easy and free of charge, to revoke consent*". This means that a company cannot send advertising material to an HCP by email, if the company has not prior received acceptance from the healthcare professional.

According to the Danish Marketing Act section 10(2), which is an exception to section 10(1): *"a trader, who from a customer has received his electronic address in connection with the sale of products, notwithstanding paragraph 1, can market own equivalent products to the customer via electronic mail. This pre-*

supposes, however, that the operator provides the customer with clear and unambiguous opportunity, easily and free of charge, to refuse this, both in connection with the issuance of the address to the trader and each subsequent inquiry ". However, it is a prerequisite that the recipient by submitting his or her e-mail address or his mobile number have the opportunity to say no to receive advertising material.

If a company has gained acceptance for the sending of advertising material for a given healthcare professional, and the mail is inserted with links to other websites, it is the company's responsibility to ensure that all websites referenced comply with the advertising rules in relation to the compulsory information, documentation, etc. Thus, the company becomes responsible for all the material that is referenced, directly and indirectly.

Influencers

In accordance with section 10, subsection 1 (7), there is a ban on using persons etc., who has a special reputation, in advertising for medicinal products to the public. According to the Danish Medicines Agency's guidance for the advertising order, the provision covers both persons whose reputation derives from their education, work etc., and persons whose reputation is based on personal characteristics.

It also appears that the term "reputation" also includes fame that has no connection to medicines, health, etc., or a special status that is linked to a certain profession. "*It can either be publicly known persons, e.g., actors, influencers, bloggers, sportsmen and TV hosts, or anonymous persons in particularly prestigious or authoritative professions, e.g., police officers.*"

Note that the joint note for guidance from IFPMA and EFPIA regarding social media and digital channels (Appendix E) has a section on interacting with online influencers and digital opinion leaders, cf. point 4 in Appendix E.

Live streaming and recorded sessions

It is ENLI´s assessment that online transmissions are covered by the Promotion Code Art. 13(1). Thus, the content must be professional and in accordance with the Promotion Code Art. 13(1), and the activity must be notified, cf. Art. 21.

In the case of live transmissions, these can be equated with a professional meeting, where one is physically present. Thus, if a company chooses to provide **live access to the full congress**, it will generally not be considered advertising, but would be considered scientific content (though please see below). However, this applies only for those presentations, which is part of the official congress program. (See Appeal Board's decision, AN-2016-3924, published on ENLI's website).

If a company via its own website, or via a hired third party wants to live stream posts from a congress, the company must make themselves **aware of the program** prior to livestreaming, including assessing whether there are posts which may include mention of the company's medicinal products, which could constitute advertising.

For **material that a company places on its website** and make available on demand, it will also be the company's responsibility to ensure that there is no material that may constitute illegal advertising for the company's medicines, including pre-launch and off-label. It will depend on a specific assessment,

whether or not the material may be considered advertising for the company's medicines, when it is placed/will be livestreamed from a platform/website, owned by the company or one by the company hired third party.

Whether the content of any post can be considered advertising, will, among other things depend on whether it is the company that selects which presentations to be streamed or possibly be included, or whether it is e.g., the congress, which as an independent third party, is making the footage and offers streaming of congressional posts.

As a company, one should therefore be aware of the fact that it **may be considered advertising, if the company selects individual presentations for (live) transmission**, and if selection is not based on objective criteria, e.g., access to a particular day's full program, or a certain number of presentations that is chosen based on the topic. The fact that the company and not the congress, has done the selection, may be an argument that it is advertising. Whether or not this is the case requires, however, that the content of the specific program is known, as it will always depend on a specific assessment, if the contents of the relevant documents, will be considered advertising. The assessment should take the content of the selected post, the background of the selection of posts and possibly additional presentation from the company's side, into consideration.

A session that is recorded, and that a healthcare professional will be shown, or have option to see or revisit (possibly on optional time) can be regarded as promotional material, depending on the specific content.

The pharmaceutical company should also consider the **placement of a link** to the transmission/recordings from professional congresses. In this context, it should be considered to place the link on a separate website that does not contain advertising for the company's medicines. If a link to the post from a professional congress is included as part of e.g., a business website with advertising for medicines, ENLI could, after concrete assessment, asses that the professional presentations (depending on content) from the congress, is used by the company for advertising purposes. Another solution may be that healthcare professionals get a password and can log on to the congress organizer's website, where live transmission/recordings from the congress are accessible.

Podcasts

Of the Danish Medicines Agency's guidance for the advertising order section 5.1. the following appears on the placement of the mandatory text in connection with, among other things, podcasts:

> *"If a podcast contains an advertisement for a medicinal product for healthcare professionals, all mandatory information must be spoken, or the information must otherwise be included as an integrated part of the advertisement. The mandatory information can, for example, be included as an integral part of the advertisement if a podcast is presented on a website for healthcare professionals, and a mandatory text is inserted next to the podcast, which is locked against downloads, so that there is no risk that the podcast and mandatory text can be separated. A similar solution can be used for a video that contains advertising for a medicinal product to healthcare professionals. The video must either contain all mandatory information, or they must in some other way be included as an integral part of the advertisement, and it must*

not be possible to use the video without a mandatory text being included as an integral part of the advertisement."

A podcast that deals only with illness and health information is, in principle, not to be regarded as an advertisement, cf. Art. 2 (2) of the Promotion Code, but the concept of advertising is broad, which is why companies must pay extra attention when disseminating podcasts in connection with a consultant visit, where there will often be mention of medicines regarding the particular disease that the podcast deals with. Therefore, podcasts provided in connection with a consultant visit will often be considered promotional material, which is why the podcast in this case must be notified to ENLI.

Podcasts containing advertisements for the company's medicine must be reported as promotional material, and notification to ENLI must be made no later than the first time password/link to the podcast is provided.

Press releases

Press releases, which are published on a company's website, will not be considered advertising, as a starting point, if:

- It contains brief, objective information on a medicinal product
- It has general news value
- It has the press as target group and
- It is circulated or made available to a multiplicity of journalists or the media for the purpose of journalistic review and processing prior to publication.

A pharmaceutical company can make a press release available to the media in the pressroom of its website for about three weeks. After that, it will no longer be regarded as having general news value and may after a specific assessment be regarded as advertising.

In accordance with the guide to the Advertising Order section 2(a), a "press release", e.g., due to a subjective content, misleading information, excessive information or a highly intrusive manor that looks like advertising, will not be considered as a press release. It will be considered advertising. If a "press release" is published against payment in a media, it is also considered advertising.

An interview with a journalist, possibly on the basis of a press release, may also be advertising.

Example:

In a May 2018 decision, the Danish Medicines Agency concluded that a company's statements to the press were to be regarded as an advertisement for a medicine (the so-called "Kinder Egg" case). At the time of the decision, the medicine was not approved for trade in Denmark.

A pharmaceutical company had been approved for a new medicine for diabetes in the United States, and the company had issued a stock exchange announcement. A news media wanted to follow up with, among other things, a video interview. In the video, the company's research director states, among other things, that the company can offer patients with diabetes, heart disease, obesity, liver disease and perhaps kidney disease the juice and power that

> is in the medicine. The director called the medicine a "Kinder Egg" and stated that it is as if the medicine can go in and say what's wrong in the heart, pancreas, liver, kidneys, and then do the right thing to come as close to the healthy state as possible - without, of course, getting completely healthy.
>
> This, the Danish Medicines Agency considered, was an illegal oral advertisement for the medicine to the journalists to whom the director of research spoke to. The Danish Medicines Agency considered that the company, with opinions and claims about the molecule, promoted the company's medicine, the purpose of the messages being to promote the prescription, distribution, sale and consumption of the medicine. The Danish Medicines Agency stated that the company did not simply state that the molecule had been approved for the treatment of diabetes. The medicine was appraised by the company for patients with diabetes and for other patient groups, including patients with heart disease, obesity, liver disease and kidney disease. It was the opinion of the Danish Medicines Agency that the company's statements were a promotion of the medicine and that it was not appropriate to use the term "Kinder Egg" on a medicine. The Danish Medicines Agency also found that the company's presentation of the medicine was: *"a sales speech without reservation. It is one-sided positive mention of a medicine that can also cause patients side effects and is only approved for treatment of diabetes (type 2 diabetes).*"
>
> It did not change the opinion of the Danish Medicines Agency that the company had not had the opportunity to review the content of the video or edit it.

The pharmaceutical company can create a pressroom on its webpage, where press releases can be made available to the press. If one wants to make the media aware that there is a new press release in the pressroom, the pharmaceutical company can use social media, with clear reference to the press, to make the press aware of the fact that there is new material in the pressroom.

For employee's sharing/liking a press release, please refer to the Guide accordingly in Annex C.

Pre-launch/off-label mention

The company, which is responsible for the website/page on the social media, must ensure that there will not be reference to off-label use of their medicines.

Moreover, reference is made to this guide's Annex B regarding the company's obligations, as well as to ENLI's guide on pre-launch, which is located on ENLI´s website, www.enli.dk .

Push and pull services

If a pharmaceutical company is using push services, where for example pop ups are used, there will be a presumption for this to be a promotional activity. Sharing/liking on social media is also push-information, where you share the information with your network, so that the information will be available, regardless of whether the people in your network have searched for or requested the information.

In contrast to push services, exist the so-called pull services, where one must actively seek information themselves - this information may also be considered advertising, regarding the circumstances. “Pull information” was the case with the website in the “Damgaard-case”, where the interested could gain access to information on the Internet by searching for them.

Please also refer to the ECJ judgment in MSD Sharp & Dohme, C-316/09 that are described under the section "Advertising or health and disease information".

Slides - presentations

If a pharmaceutical company chooses to make presentations/material/slides available on its website, the material could be regarded as advertising. This also applies in cases where the material is prepared and used by a third party in connection with either the company’s own event or a third-party event (congress etc.).

Distribution by request or unsolicited

As a starting point, it will be compliant to distribute slides to participants after the meeting, if these have been requested. If distribution of slides is unsolicited, the distribution of slides could be regarded as an advertising activity, after which the content must be in accordance with the SPC and the Promotion Code.

When slides, etc., are added to/livestreamed from a platform/website, owned by the company or, one of them hired, third party, it will be based on a specific assessment, whether the given material may be considered advertising for the company's medicinal products.

Whether the material, etc., from e.g., streamed posts may be considered advertising, will, among other things, depend on whether it is the company who selects which material/slides that can be downloaded, or whether it is, e.g. an organizer of the congress, who as an independent third party, makes the selection of the slides, which can be downloaded.

Material prepared by a third party, should not be reported to ENLI, unless the company has had an impact on the preparation of these, or when these may be considered advertising.

It appears from the Appeal Board's decision in AN-2012-3824 that:

> *“a pharmaceutical company must in no circumstances exert influence on evaluations made by a healthcare professional or on the scientific documentation that the healthcare professional, employed by the company to give a presentation, finds suited for highlighting the professional health issue concerned, unless the medicinal product is mentioned in contravention of the legislation or the Promotion Code. However, the company has the overall responsibility.”*

Attention is drawn to the fact that if a third party's material only contains **information about disease without specifically mentioning the medicinal product**, the material may be excluded from the rules of the Promotion Code, cf. Art. 2(2)(c).

SMS-services

Look under the section "Apps".

Health and disease information

If a company creates a home page or a page on the social media, containing information only about health and disease, as a starting point, this will be an activity that complies with rules on advertising, see Art. 2(2)(c) in the Promotion Code, as well as the Advertising Order's sec. 2(5). These activities should therefore not be reported to ENLI.

However, this presupposes that specific medicines are not referred to, neither directly nor indirectly. It should be noted that ENLI will do an overall assessment of the webpage, including **the communication and purpose** with that page. ENLI will interpret the exceptions to the Promotion Code restrictively. Based on the purpose of the rules on advertising and by a pharmaceutical company's communication with a healthcare professional, there is not much room before an activity on a social media/blog will be deemed an advertisement. It is presumed that the company's interest in launching the concerned digital activity is likely motivated by a desire to promote the company and its medicines.

As a starting point, a webpage where the following requirements are met will not be regarded as an advertising activity:

- The webpage does not appear to be advertising of a medicinal product, and this is evident on all pages of the website,
- There is no information about medicinal products, either directly or indirectly,
- All product-related posts from any users are removed each day, and
- The company in order to collect and report information about possible adverse reactions, etc., reviews the website daily.

It is important to be aware that a forum that provides information on health and diseases via user interaction may evolve from being legitimate disease information to an advertising of a medicinal product, if users mention specific medicinal products.

Search engines

Generally, the following regarding commercial communications and search engines in relation to e-commerce law is noted[2]:

Commercial communications are defined as any form of communication that, directly or indirectly, is intended to promote the sale of goods or services or to establish an image of a company, an organization or a person who exercises commercial, industrial or craft activity or a regulated profession, cf. the E-Commerce Act sec. 2(6).

[2] The E-Commerce Act includes, inter alia, advertising for medicinal products on the Internet

It states in the E-Commerce Act section 9(1), that all communications that are part of, or constitute, an information society service, shall be designed and presented, so it is clear that it is commercial communication, and it must clearly appear on whose behalf the commercial communication is broadcasted.

Search engines usually consist of several parts that must be assessed individually. Banner ads are covered by the term commercial communications. Regarding the search results, it is noted that it is stated in the comments to the E-Commerce directive, that it does not constitute commercial communications if information is given, is not promotion.

A search result obtained independently of the owner, as this piece of information refers to, will not immediately be covered. If payment has been made for the result to appear on a special priority way, or with a content that is defined by the owner, the search results may fall within the concept of commercial communication, in particular in cases where the recipient experiences that the search results will appear as the "best" result. It is also stated that a distinction between paid inclusions and independent robot-generated results, and that paid recordings, as a starting point, will be covered by section 9[3].

As regards the concept of AdWords[4], it is ENLI's immediate view that it will constitute advertising of a medicinal product, if a pharmaceutical company buys AdWords in order for the name of the medicinal product (trade name and generic name) and possibly therapeutic indication to appear when one is searching on Google, for either their medicinal product, the disease area, which the medicinal product is approved for, or the treatment principles, which deals with the medicinal product.

Videos

The Danish Medicines Agency's guidance for the advertising order section 5.1. states the following on the placement of the mandatory text in connection with, among other things, videos:

> *"If a podcast contains an advertisement for a medicinal product for healthcare professionals, all mandatory information must be spoken, or the information must otherwise be included as an integrated part of the advertisement. The mandatory information can, for example, be included as an integral part of the advertisement if a podcast is presented on a website for healthcare professionals, and a mandatory text is inserted next to the podcast, which is locked against downloads, so that there is no risk that the podcast and mandatory text can be separated. A similar solution can be used for a video that contains advertising for a medicinal product to healthcare professionals. The video must either contain all mandatory information, or they must in some other way be included as an integral part of the advertisement, and it must not be possible to use the video without a mandatory text being included as an integral part of the advertisement."*

If video is used, a dynamic reference display is recommended, where the references are continuously disclosed in the video in connection with the statements to which the references are linked. It can also

[3] The E-Commerce Act with comments by Jacob Plesner Mathiasen, Niels Bo Jørgensen and Johan Schlüter
[4] The definition of AdWords: Google AdWords is Google's online advertising program, which a business can purchases to promote their business, thereby helping to sell products and services, raise awareness and increase traffic on the company's web site. AdWords is thus the ads that appear at the top of the search result, where you buy certain keywords, after which one's link is placed at the top of the search result when searching for a given word.

be considered to create a collective reference collection at the end of the video with clear and concrete reference to which segment in the video the reference relates to, for example by indicating the exact time. A general indication of references at the end without a clear indication of which segment the reference is linked to, is not compliant with the rules.

For further information:

ENLI's website: http://www.enli.dk/

The Danish Medicines Agency's website: http://laegemiddelstyrelsen.dk/

4. Q&A regarding pharmaceutical companies' behaviour on digital media

1. As a pharmaceutical company we are now on Facebook, where we have set up a closed group for healthcare professionals, the purpose of which is to provide information about chronic pain. Now people are beginning to write about our medicines. How does ENLI view these opinions?

Answer: *According to the European Court of Justice decision in C-421/07, a third-party dissemination of information may be considered advertising for a specific medicinal product. An assessment of whether it is an advertisement must be carried out, cf. the Promotion Code. Is this the case, the Promotion Code's rules must be complied with.*

If the company quickly removes a user's posts about specific medicines, it is ENLI's opinion that the company has acted responsibly and taken the necessary steps to maintain the site within the stated purpose. However, it is a prerequisite that the site's purpose and any company policies/guidelines for the site appears sufficiently clear. A pharmaceutical company may refer a healthcare professional to contact the company directly, if the person has specific questions regarding one of the company's medicinal products.

2. We have, as pharmaceutical company, chosen to have a closed LinkedIn group, which is only for oncologists. We mention our own medicinal products as well as the corresponding compulsory information. Now, a longer dialog is running in our group, where our competitors' medicines are mentioned. How does ENLI view these statements about our competitors' medicines?

Answer: *Third-party dissemination of information on specific medicinal products may constitute an advertisement, cf. C-421/07. The purpose of the company's own website will not be to advertise the competitor's medicines. Thus, the company will not be held responsible for third-party mention of competitors' medicinal products on the pharmaceutical company's own webpage. However, one must be cautious, and it is important that the statements of third parties be assessed in the context in which it is presented. If third party claims were included in a debate, this would waive in favour of not assessing it as advertisement.*

The company must also pay attention to whether there is comparative advertising that involves the company's medicinal products, and by doing so, the company must ensure that the rules in the Promotion Code's Art. 8 are complied with.

3. As a pharmaceutical company, we have chosen to create a closed blog, which is only for healthcare professionals who work with rheumatoid arthritis. Here they can discuss various aspects of rheumatoid arthritis as well as exchange experiences. Now they are starting to mention various medicines and use thereof outside the approved indication (off-label). What is ENLI's view on these statements?

Answer: *It is ENLI's recommendation that all off-label posts be removed, and possibly be replaced by a post with an indication of the legal therapeutic area, including adverse reactions, compulsory text, etc. – remember that all the requirements concerning advertising must be complied with, see the rules of the Promotion Code.*

4. Our pharmaceutical company has a Facebook group that is closed and only for physicians, which we have given access. We have noticed that there are many sponsored commercials about medicinal products on the site. Are we responsible for this?

Answer: *In ENLI's opinion, a pharmaceutical company cannot be held responsible for commercial advertisements on various social media, such as Facebook, which is organized and managed through the social media provider, since the company does not have any influence on these.*

5. We have, as a pharmaceutical company, created a closed LinkedIn group for gynaecologists about fertility treatment. Now one of the gynaecologists on the site are asking about specific adverse reactions in connection with one of our fertility products. Can we, in ENLI's opinion, answer the gynaecologist?

Answer: *According to Art. 2(2)(c) in the Promotion Code, cf. sec. 2 of the Advertising Order, individual correspondence, serving to answer a specific question about a particular medicinal product is excepted from the Promotion Code. If a pharmaceutical company replies to a question directly on the website, this is not considered individual correspondence, as the other members of the group also receives the answer. As these did not query the company, the answer in relation to them could be considered advertising for the medicinal product, depending on the content. Answering a question should therefore be done directly to the inquiring gynaecologist, for example, by email. It is important to note that the answer must relate only to the questions asked. Therefore, the company must not provide information on factors others than the asked, since this might otherwise be considered advertising.*

If the other gynaecologists answer the question directly on the site, it is ENLI's view that the pharmaceutical company may be responsible for these statements, if they can be considered advertising. The question itself may also, given the circumstances, constitute an advertisement, depending on the wording therein, and the company should therefore monitor the site for such questions. It is ENLI's recommendation that questions, which might be considered advertising, should be removed; unless it has ensured that, the website complies with the rules in the Promotion Code.

6. We have, as a pharmaceutical company, a closed group on Facebook for healthcare professionals. The doctors, etc., are now writing off-label claims for our medicines. May we correct the information so that it is in accordance with SPC and the Promotion Code?

Answer: *It is recommended that the pharmaceutical company remove such posts. See also the answer to Q3.*

7. As a pharmaceutical company we are now on Facebook – open to the general public. Now people are beginning to write about our own prescription medicines. May third parties mention our medicines, if this is not done in a laudatory manor?

Answer: *No, the company is obliged to remove the post, since it is not allowed to advertise prescription medicinal products to the general public.*

8. Can a company publish that it is participating in a conference or similar with an exhibition stand?

Answer: *Yes, factual information about that one participates at a conference or similar and have an exhibition booth at the conference, shall not be considered as advertising for specific medicinal products.*

9. How does ENLI view the use of hashtags (#)?

Answer: *You should always consider the purpose of the use of hashtags. If the hashtag refers to specific medicinal products (trade or generic name), it will, as a starting point, be perceived as advertising of medicinal products.*

10. Does the rule, that pharmaceutical companies are exclusively responsible for the content of the specific site/the content linked (one click away), and no other content on that website, apply on social media?

Answer: *Yes*

11. Can we as a company share a press release via social media?

Answer: *Please refer to the reference guide's section on press releases as well as to question 2 in the Q&A regarding employee's behaviour on digital media.*

12. In my understanding, you cannot close or delete comments on your twitter profile. This makes it impossible to check the thread for developments after a post by a company has been created. How to deal as a company for this regarding deletion of e.g., the thread, which is in breach of the Promotion Code?

Answer: *You are solely responsible for what you can manage. If you have no option to delete comments/posts on the same tweet, you cannot be held responsible for this as a company. On the other hand, it may be that the person promoting a medicinal product in a comment is responsible for this, if it is covered by the definition of advertising.*

13. Once in a while, we advertise for patients to participate in our clinical trials. The Science Ethics Committee approves the ad text, as well as for it to be announced via Facebook. Can we share such ads on Facebook or other social media in relation to the rules on advertising? There are no

product names mentioned, but it can, for example say that one should currently be in treatment with e.g., metformin (active substance) to be included in the trial.

Answer: *Yes, that is allowed since the intent of the dissemination is not to advertise for a given medicinal product, but to recruit patients for a clinical trial.*

14. One of our employees, on his private LinkedIn profile, shared a press release from our US headquarters about an FDA approval. Can we as a pharmaceutical company be made responsible for this?

Answer: *In principle, the employee is responsible for his or her activities on social media. In a 2018 case from the Danish Medicines Agency, the agency found that an employee of a pharmaceutical company who shared a US press release on its private LinkedIn profile was responsible for the illegal advertising that the press release was. On the other hand, the Danish Medicines Agency did not find that the pharmaceutical company could be made responsible.*

It should be noted that if the sharing had occurred today (after June 2020) and only for healthcare professionals in a closed group, the company (if complaint filed to ENLI) could be at risk of liability, cf. Annex D regarding EFPIA principles on the use of digital channels. Companies affiliated with ENLI could thus be responsible for an employee's sharing of information about one of the company's medicines on a private profile if the employee can reasonably be regarded as representing the pharmaceutical company. It can, for example, be the case on a LinkedIn profile, which clearly states where the employee works. LinkedIn profiles are preferably used professionally for networks, etc. in a work context.

15. I have come to know that my employee has shared an article on study results on one of our medicines on his Facebook profile. It does not appear from the Facebook profile that he works in our pharmaceutical company. As a pharmaceutical company, can we be made responsible for the employee's sharing of any illegal advertising of medicines?

Answer: *In principle, the employee is responsible for his or her activities on social media. If it can be shown that the company has asked the employee or otherwise encouraged the employee to share the information, the company will be liable for the illegal advertising. There may be a co-responsibility for the company if you are aware that employees are acting in violation of advertising law without doing anything about it. It thus becomes a question of whether the company can accept responsibility for complicity in the offense by passivity.*

Annex A

Rules to remember

Remembering the following rules will help to ensure that a website or a page on a social media are in accordance with the Promotion Code. The following rules must, however, not be considered an exhaustive list of conditions to ensure compliance with the rules.

1) When a pharmaceutical company creates a webpage on a social media, as a starting point, the company will be responsible for the activities on this site, including the users' activities.
2) The advertising concept is broad, cf. the Promotion Code and Advertising Order.
3) Make it clear what the purpose of the company's action on the selected webpage is, for example, health education information or advertising of a medicinal product.
4) The purpose of the messages/information on the website, is decisive for whether the site will be deemed advertisement, see definition of advertising; "any kind of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products". Purpose of the messages are viewed on an overall assessment of the page's form and content.
5) User's opinions about specific medicinal products may constitute advertising.
6) Health and disease information with reference to medicinal products may be considered advertising, particularly if information from the approved summary of product characteristics, which are selected and/or reworded, are mentioned.
7) Monitor the user activity that occurs on your website or page on the social media often and continuously. Pay attention to whether the dialogue goes in a unilateral direction and/or reference to specific medicinal products is made.
8) By activities exclusively targeted healthcare professionals, it is important to make sure that there actually is a closed group, which has an effective access control. If advertising for a specific medicinal product occurs, the rules of the Promotion Code must be complied with.

See also Annex B.

Annex B

Pharmaceutical companies' obligations on social media

Where is the activity taking place	Third party actions	The company's duty
The company's own webpage	Third party mentions the company's medicines.	The company must ensure that all activity is in compliance with the rules of the Promotion Code and the legislation
The company's own webpage	Third party refers to off-label use of the company's medicinal product.	The company must remove the post and possibly replace it with a post stating the legal scope. Advertising of a medicinal product must only contain information on approved indications contained in the approved summary of product characteristics. As a starting point, it will be marketing of off-label use, if the company does not remove the mention of off-label use from its own website. In addition, the company must ensure compliance with the rules on advertising.
The company's own webpage	Third party mentions other companies' medicinal products.	As a starting point, the company cannot be held responsible for third party mention of competitors' medicinal products.
External website where the company cannot edit	Third party mentions the company's medicinal products but has no financial interest in promoting the sale of pharmaceutical products.	Third party dissemination of information about a medicinal product might be considered advertising, even if the third party is acting on its own initiative and independently, de jure and de facto, of the manufacturer/seller of such medicinal product. As a starting point, the company cannot be held responsible for third-party mention of the company's medicines when this occurs on an external website.

Annex C

Employees' behavior on social media

General comments on advertising on social media

The advertising concept, applicable to pharmaceuticals, is very broad, as reviewed above. However, there are situations that are not covered by the definition of advertising, for example the presentation of oneself on a LinkedIn profile, which for example shows which tasks one has in the company concerned or have had in other companies, one have previously been employed in, or participation in debates and chats about disease-related topics, etc.

One especially needs to be aware of the rules on advertising, if one, as a person/employee in a pharmaceutical company share/"likes" product-related information, such as that one of the company's medicinal products have obtained approval for a new indication, results from a phase 3 study, information about a medicinal product that is not approved for marketing in Denmark, information on prescription-only medicinal products, etc.

Responsibility for the sharing of information on social media

The case from the European Court of Justice with Frede Damgaard (see the section regarding the scope of the advertising concept) shows that even a person without any ties to the pharmaceutical company may be considered to advertise for a given medicinal product, and in that case, it ended with a fine of DKK 10,000 kroner to the third party.

It should be noted that as an employee of a pharmaceutical company, one would not be an "independent third party".

If an employee of a pharmaceutical company disseminates information on a medicinal product (and it can be considered as unlawful advertising) for example via his LinkedIn profile, the person will, as a starting point, be responsible for this. If there is proof, that the company has asked the employee, or otherwise encouraged his/her, to share information, the company will also incur liability for the illegal advertising. In addition, companies affiliated with ENLI may be liable for an employee's sharing of information about one of the company’s medicines on a private profile (in a closed group of healthcare professionals) if the employee can reasonably be perceived as representing the pharmaceutical company on the private profile. It can, for example, be the case on a LinkedIn profile, which clearly states where the employee works. LinkedIn profiles are preferably used professionally for networks, etc. in work context.

It should be noted that ENLI solely controls and sanctions the pharmaceutical companies' activities towards healthcare professionals. If, for example, an employee, in a forum that only consists of healthcare

professionals, shares information that may constitute illegal advertising, ENLI will only be able to proceed with the case, if the company in question may have a responsibility in relation to the sharing of information.

In case of sharing information that may constitute illegal advertising to the general public, the Danish Medicines Agency will send a consultation letter to both the company and the employee in order to get information when proceeding the case.

ENLI may solely control and sanction pharmaceutical companies, which are affiliated with the pharmaceutical industry's self-regulation system at ENLI. If an employee shares information about, e.g., a prescription medicine in a closed group of healthcare professionals (and sharing may constitute illegal advertising), ENLI, as mentioned above, only proceeds with the case, when the company in question may have a responsibility in relation to the sharing of the information.

Advertising of prescription medicines to the general public is a matter for the Danish Medicines Agency. The Danish Medicines Agency will then send a consultation letter to both the company and the employee. The employee is responsible, as a starting point, for posts, etc., on his private profile on social media. If it can be demonstrated that the company has asked the employee, or otherwise encouraged the employee to share information, the company could incur responsibility for the illegal advertising.

The employees' behaviour on social media

As evidenced in the Damgaard-case referenced above, an independent third party (Frede Damgaard) may be regarded as responsible for advertising for a pharmaceutical company's medicine. It should be noted that an employee of a pharmaceutical company, as a starting point, would not be regarded as an independent third party, since by virtue of the employee's employment he/her will be related to the company.

If an employee of a pharmaceutical company "likes" or shares a post, which in itself may constitute advertising or if they write an update about new medicinal products, it could constitute advertising, and, as appropriate, also constitute illegal advertising to the general public.

Since the vast majority of employees have profiles on LinkedIn, Facebook, etc., it is recommended that each pharmaceutical company draws up guidelines for employees' statements and behaviour on these media as regards posts/shares/likes, etc., which may be related to the company's medicines, etc.

ENLI is aware that some companies instruct their personnel in only sharing approved posts from the company.

ENLI is also aware that certain companies have linked annual training in compliance, including the rules on advertising, up to a bonus system. This approach can thus help to ensure that all staff keep abreast of current regulations, and that they thereby get their knowledge on the rules refreshed minimum once a year.

Q&A regarding employees' behaviour on social media

General on the definition of advertising

4. How do you know if what you share, etc., can be perceived as advertising?

Answer: *First, one should ask themselves: Why do you choose, as an employee of the company, which the post is concerning, to share/like this post – and would you share a similar post if it referred to a competitor? Based on the broad interpretation of the definition of advertising in the Damgaard-case, a like, a share or a comment to a post, may be covered by the definition of advertising.*

2. May I share a press release from the company, I'm employed in?

Answer: *It depends on the content of the press release and the purpose of sharing the press release.*

The Promotion Code Art. 2(2)(c), and the Advertising Order's sec. 2(7) states that the rules on advertising of medicinal products does not apply to press releases that contain factual and concise information about a medicinal product, have general news value, ***have the press as audience,*** *and is circulated to or made available for a plurality of journalists or media for the purposes of journalistic review and processing before publication.*

If an employee shares a press release to healthcare professionals/general public on social media, it is not covered by the provision in Art. 2(2)(c) in the Promotion Code, respectively sec. 2(7) in the Advertising Order. The post should then be regarded like any other post on a medicinal product - which may be advertising, including possibly illegal advertising.

If the article, which has been drawn up based on a press release, is shared, the specific purpose of sharing will be, as with any other posting, assessed. As reviewed above, it can be regarded as an advertising activity, although the employee on his or her own initiative carries out the sharing.

3. Is distinction made, between which type of post is being shared/liked? Would it play a role whether you share a post that stems from a "neutral" party, for example an authority, journals, etc.?

Answer: *What determines whether there is a violation of the rules is the purpose of the sharing, including the content of what is shared/liked. In this context, it is subordinate who the original author of the article/statement is. Sharing can thus be considered advertising, and possibly illegal advertising, if the post, for example contains information about off-label use, pre-launch, etc. The crucial factor in this context is the form, content and context.*

4. How is a situation assessed in which an employee has liked or shared e.g., a disease awareness campaign, which is subsequently commentated by others with claims regarding medicines?

Answer: *The employee will not be responsible for any subsequent comments on a sharing of information about health/disease information. On the other hand, there may be a case of advertising for the person who is commenting on a post with claims such as, e.g. "You should use medicine X, it has worked well for me" or the like, that can be held liable in accordance with the rules on advertising in the pharmaceutical legislation.*

5. Can one share/like information about clinical trials?

Answer: *This is based on a specific assessment. There may be a case of advertising, for example if you are promoting an upcoming medicinal product that is not approved for marketing in Denmark, share information about a non-approved indication, or share/likes information about positive results from a phase 3 study. For further, please see ENLI's guide on pre-launch.*

6. Can we avoid responsibility of the advertising rules, if we write a disclaimer on our profile, for example "the views and opinions expressed are my own", so that it is clear that the post is not done on behalf of the pharmaceutical company, one is employed in?

Answer: *No, a disclaimer does not mean that one may be exempt from liability. One is always responsible for what one posts/share/"likes" on social media. If the post, etc., can be considered an illegal advertisement, the individual is responsible in accordance with the provisions of the pharmaceutical legislation, which is enforced by the Danish Medicines Agency.*

The company may incur a liability/responsibility, if the company has asked the employee, or otherwise encouraged the employee to carry out the respective sharing of information on a medicinal product. However, a disclaimer from the individual may indicate that the company has nothing to do with the post, and thus are not jointly responsible for the post.

In addition, companies affiliated with ENLI may be liable for an employee's sharing of information about one of the company's medicines on a private profile (in a closed group of healthcare professionals) if the employee can reasonably be perceived as representing the pharmaceutical company on the private profile. It can, for example, be the case on a LinkedIn profile, which clearly states where the employee works. LinkedIn profiles are preferably used professionally for networks, etc. in work context.

Health/disease-related information (without information on specific medicinal products)

7. Can we as employees "like"/share/comment company-related posts regarding disease information within the therapeutic areas the company is working for (not product related posts). This could be generally disease-related or, for example World Arthritis Day.

Answer: *Yes, you are welcome to comment on the information about the diseases within the company's therapeutic areas (without product mention). It states in the Promotion Code Art. 2(2)I, and section 2(5) in the Advertising Order that the rules on advertising of medicinal products does not apply to information on health and illness, provided that specific medicines are not referred to, either directly or indirectly.*

8. Can we as employees like/share posts from our own Facebook pages — regardless of the source of the information? (Disease-related information – does not contain information on medicines).

Answer: *Yes, as a starting point. See also Q3 and Q7.*

9. Can one, as an employee, share company produced material or links one's own private profile on social media? For example, information from "The World vs. "MS"

Answer: *Yes, if the material does not contain information about specific medicinal products, and if the purpose of sharing information is not to advertise medicines, you will be able to share information from, e.g., the pharmaceutical company where you are employed.*

Information about specific medicines

10. May I share a call to be vaccinated, if a pharmaceutical company that has vaccines in its portfolio employs me?

Answer: *Yes, a general call, without mention of specific medicinal products, to be vaccinated, shall not be considered in itself as an advertisement for vaccines. See also the answer to Q13.*

11. Where is the limit on social media – what if you or a family member suffer from the disease?

Answer: *It is subordinate whether you, a family member or an acquaintance suffers from the disease. If that post, etc. constitutes advertising, and the purpose of posting this is advertising, for example to recommend a medicinal product, that one themselves or ones nearest has benefited from, it falls within the definition of advertising. If you promote e.g., prescription medicines, as you*

yourself have benefited from during the treatment of a disease, it can thus be regarded advertising according to the rules in the Advertising Order.

Information about the company

12. Is it advertising, if you as an employe "like" a post regarding our company's investments in production facilities for new medicines?

Answer: *Such a post would be deemed general business advertising, and not regarded as advertising specific medicinal products.*

Information regarding own opinions

13. Can one in response to an article about e.g., measles epidemic on social media, share the article and for example, type: "Get those kids vaccinated now!"? It is, of course, my personal opinion. In addition, does it matter if I work at a pharmaceutical company, which has medicines within the area I comment on?

Answer: *Yes, you are welcome to participate in the debate – be it in a factual debate or with posts as part of a general societal debate – and sharing your personal views as part of the debate; even if the pharmaceutical company you work for, have medicines within the disease area, as the debate regards.*

If, however, in the context of the debate, you are promoting specific medicinal products, it may be covered by the definition of advertising, if the purpose of the claim is to advertise the medicinal product.

See also the answer to Q10.

14. In my optics, my personal freedom of expression is taken away from me. Moreover, this in an area that I know some about. I would like to be allowed to like and comment on the debates about pro/con therapy on Facebook.

Answer: *The European Court of Justice dealt with the issue of freedom of expression in the mentioned "Damgaard case" (C-421/07). Here, the Court of Justice ruled that if the communication has a purpose, which is covered by the definition of advertising, the communication is considered advertising, which is not a violation of freedom of expression in relation to The European Convention on human rights. The European Court of Justice noted in the judgment that freedom of expression may be restricted, if the terms of the public interest requires it. It follows from the ECHR article 10(2) that freedom of expression may be subject to limitations, restrictions and criminal provisions that are prescribed by law and are necessary in a democratic society, inter alia in order to protect public health. The rules on advertising of medicinal products aims to protect public health. The European Court of Justice noted, therefore, that if the information, which Damgaard disseminated*

on the Internet, should be considered advertising, his conviction could be regarded as reasonable and proportionate in view of the legitimate aim pursued, namely the protection of public health.

Miscellaneous regarding social media

15. Is it always the company's responsibility, if an employee shares information on social media, which can be considered illegal advertising of a medicinal product?

Answer: *No, not if the company have not requested the employee - or otherwise encouraged the employee to share information on social media, and it has not occurred as part of the terms of employment. However, please note that if the company is affiliated with ENLI, the company may be liable for an employee's sharing of information about one of the company's medicines on a private profile (in a closed group of healthcare professionals) if the employee can reasonably be perceived as representing the pharmaceutical company on the private profile. It can, for example, be the case on a LinkedIn profile, which clearly states where the employee works. LinkedIn profiles are preferably used professionally for networks, etc. in work context.*

16. Is there a difference between liking and sharing a post in relation to the definition of advertising?

Answer: *No, not immediately. When you "like" a post, this will be shared with your network in the same way as when you share a post.*

It should be noted in this context that the Damgaard-case concerned information on a website - so-called "pull" information", where the interested could get access to information on the Internet by searching for this, whereas sharing/liking is "push information", where you share the information with your network, so this information is available regardless of whether the people in your network have searched for or requested the information.

17. Is it regarded as advertising to the general public, if an employee writes something product related in his Facebook profile which is closed to the 150 friends the person has? I.e., should all be considered public or is there a limit, for example "closed" groups (where only one's friends have access).

Answer: *"General public" is defined in advertising contexts as anyone who is not a "healthcare professional". Thus, it is not essential that the information be shared only with one's friends. However, you will always have to look at the purpose of the sharing of information, and if that does not take place with a purpose, covered by the advertising definition, it will not be deemed advertising.*

Jurisdiction

18. Does the employee's location mean anything? For example, how to assess it, if a Danish employee works temporarily for the company's American Division and the post/potential advertising is done in the United States and has nothing to do with DK?

Answer: *It is the employee's physical location, which is decisive for whether a situation is covered by Danish rules. Posts made by a Danish employee hired and placed in the company in the United States, are thus not subject to the Danish legislation, and ENLI's Promotion Code, with regard to companies' advertising to healthcare professionals.*

19. How does ENLI in general view its jurisdiction in cases concerning the use of social media?

Answer: *ENLI may solely control and sanction pharmaceutical companies, which are affiliated with the pharmaceutical industry's self-regulation system at ENLI. If an employee shares information about, e.g., a prescription medicine in a closed group of healthcare professionals (and sharing may constitute illegal advertising), ENLI, as mentioned above, only proceeds with the case, when the company in question may have a responsibility in relation to the sharing of the information.*

Advertising of prescription medicines to the public is a matter for the Danish Medicines Agency. The Danish Medicines Agency will then send a consultation letter to both the company and the employee. The employee is responsible, as a starting point, for posts, etc. on his private profile on social media. If it can be demonstrated that the company has asked the employee, or otherwise encouraged the employee to share information, the company could incur responsibility for the illegal advertising.

ANNEX D

Principles for the use of digital channels (Annex II of the EFPIA Code of practice)

This document is intended as a supplement to the provisions of the EFPIA Code of Practice that apply to all types of communication including via digital channels.

As this document is non-binding, Member Companies and Associations may need to adapt it to meet their particular requirements and are encouraged to adopt additional measures which extend further than the provisions in this document.

This document describes the most commonly used digital channels and what to be aware of, when communicating to and with the public and/or HCPs.

1. Principles applicable to all types of communication

Compliance with laws, regulations and codes of practice

A digital channel is only a platform for communicating. Laws and regulations applicable to other platforms and media also apply to digital media. The content, target group and use of the platform are relevant factors to determine applicable rules, not the media as such.

Therefore, the provisions of the Directive 2001/83/EC related to the Medicinal Products' advertising and of the EFPIA Code of Practice apply to digital communication.

The processing of personal data must comply with applicable data protection regulations.

Responsibility

Member Companies are responsible for all material disseminated via any digital channel that is initiated, branded and/or sponsored by Member Companies, or any Third Party acting on their behalf, including promotion of Medicinal Products.

A Member Company owning the social media page or site is responsible for the content. E.g. any mention of a Prescription-Only Medicine is likely to be considered promotion of that medicine to the public and prohibited. Another example might be the use of social media directed to the public to alert HCPs about the publication of a study on a Medicinal Product which is also likely to be considered promotion of that Medicinal Product and therefore prohibited.

Member Companies may also have responsibilities when interacting on digital channels owned by other companies or organisations.

Member Companies are also responsible for information disseminated by Member Company staff who do so via their private social media channel including, a) when they can reasonably be perceived as representing the Member Company, or b) if they are instructed, approved or facilitated by the Member Company to do so. The Member Company should have internal guidelines in place on how its staff should behave on digital channels including their own personal account activities.

For digital channels owned by the Member Company, processes should be established to monitor, moderate and/or delete any inappropriate comments in a timely manner to the extent permitted by the data protection regulations and applicable laws and codes.

Member Companies may need to have similar processes when using digital channels owned by other companies or organisations.

Pharmacovigilance

Member Companies should consider developing specific guidance for digital channels and contacting their pharmacovigilance experts for specific projects in order to meet their pharmacovigilance responsibilities including the obligation to record and report any adverse effects that are discussed about their Medicinal Products.

Transparency

Section 7.04 of the EFPIA Code of Practice requires Member Companies to clearly indicate when they have sponsored a communication. Whenever a Member Company or an individual or entity acting on behalf of a Member Company provides information on a digital channel, it should clearly state the involvement of the Member Company, including but not limited to defining content, funding in part or in totality.

In addition, the transfers of values to HCPs, HCOs and POs are reportable under the disclosure obligations as described in the EFPIA Code of Practice (Chapter 5).

When possible, the target audience of the channel should be clearly identified (e.g., HCPs and the public, or a combination thereof).

2. How to identify the allowed information for the different digital channels

It is important that the Member Company understands what content is appropriate for the different digital channels and the respective audience. All laws and regulations in this regard must be complied with in the same way as for other media.

Information included on a digital channel should be regularly updated and should clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.

The following questions can be useful to assess risks associated with digital communication and appropriateness of digital channel content, access, set-up and maintenance:

- What is the objective of the communication (promote, inform, exchange)?

- What content will be made available on the digital channel?
  - Is the content related to Medicinal Products?
  - Is the content promotional or non-promotional?
  - Is the content related to disease awareness?
  - Is the content related to healthcare information e.g., in connection with diagnosis, treatment education, dietary support
  - Is the role of the Member Company providing/developing the content clear?

- Who is the intended audience? e.g., public, HCPs or both
  - Is verification of audience required?
  - If yes, how?

- What is the channel standard set-up?
  - Is the digital channel open to audience reaction such as sharing, commenting, exchanging?
  - How is the information cascaded across the digital channels?
  - Is the digital channel an open platform or for a closed audience?
  - Are there limitations in content size? e.g., Twitter
  - Are there any community guidelines applicable? e.g., Facebook, YouTube
  - How is the information about the channel audience processed?

- How is the content reviewed, approved and maintained including by the Member Company?

3. EFPIA guidance for members for various digital channels

Below is a short description of the general use of different types of digital channels. When deciding which digital channel to use and how to develop it, the principles set out above should be taken into account.

The content published by a Member Company on each channel must be appropriate and aligned with relevant regulations, laws and codes including the EFPIA Code of Practice.

Websites

Websites are classified as a channel that reaches the public, unless verification (e.g., pop-up for identification, or password) is required to access the website e.g., to HCPs. Some websites may include forums where the public can exchange or discuss topics.

Since many website visits are a result of using a search engine, keyword optimization has become an important tool. Member Companies can use appropriate search optimization to ensure that their websites are displayed high on the list of search results for relevant key words.

However, Member Companies need to ensure that the use of keyword optimization is appropriate for the intended audience. For example, optimized search through use of key words directed to websites with therapy-oriented information for the public or websites aimed at HCPs, where such websites can only be accessed by the authorized individuals.

Member Companies may sponsor website material to be produced by a Third Party in which the role of the Member Company must be made clear. If the Member Company i) is initiating the material, or the concept for it; ii) is influencing the content of the material in any way; iii) is selecting or directly paying the authors; then the Member Company is very likely to be liable for the contents of the website. If the reverse is true, and there is a strictly arm's length arrangement with the Member Company just providing a grant, then the Member Company may not be liable.

Member Companies should be confident about the choice of linked websites and that these do not promote Prescription-Only Medicines to the public. If a Member Company includes website addresses in an advertisement of a Prescription-Only Medicines to HCPs, the core principles apply, of ensuring the content of those websites is appropriate.

Social media

In general, social media are digital channels that are considered to be aimed at the public.

Social media are websites or applications on which people can interact in social networks (e.g., Facebook, Twitter, Snapchat, LinkedIn, YouTube, Instagram). In most cases social media are used to reach or interact with the public. A social media platform can be an open channel for the public or a closed channel for a targeted audience where verification of the audience is required before providing access.

Blogs

The difference between a text on a website and on a blog is that a blog is usually owned and updated by a person or a group of people who posts on the blog regularly.

A blog can be owned by the Member Company, or the Member Company may engage (either through sponsorship or consultancy fees) the owner to write on a blog (such as "social influencers"). In both cases, the blog should clearly state the involvement of the Member Company.

Given that, by its very nature, a blog is for contributors to freely and spontaneously express their personal views on a subject, Member Companies should not sponsor such blogs if they were intended, or could reasonably be expected, to promote Prescription-Only Medicines and their uses.

Podcasts

A Member Company can have its own podcast which should follow the same rules as for websites.

A podcast can be downloaded from any podcast distributor. Core principles apply, of ensuring the recipient is well defined and targeted and that content is appropriate. E.g., a podcast promoting Prescription-Only Medicines should only be accessed by HCPs.

Applications (Apps)

An application, usually referred to as an "app", is to be downloaded on an electronic device (e.g., smartphone, computer or tablet).

A Member Company can develop apps for the use of external stakeholders (e.g., HCPs, HCOs, patients, payers), provided that they follow the same rules as for websites. Also, they should consider potential regulatory requirements if the app fulfils the requirements for a medical device. Core principles apply, including ensuring the audience is well defined and targeted.

An app can also be developed to improve compliance with a treatment method. If an app targets a specific group (e.g., HCPs, patients, caregivers), it is important that only this group is offered access to the app content.

Webinars

A webinar is an on-line event conducted via the internet and it can be either performed as a live streaming event or as an on-demand service.

A Member Company can be the direct organizer of a webinar and/or use a Third-Party facilitator to run the event. The Member Company is responsible for these webinars including the content and ensuring that the audience is well defined and targeted. Similar arrangements apply to Third Party webinars sponsored by Member Companies Such webinars can be for the communication with external stakeholders (e.g., HCPs, HCOs, patients, payers) provided, that they follow the same rules as for websites.

Direct channels

These are one-to-one or one-to-many channels, which are targeting selected recipients; these are most commonly private, not visible to non-selected recipients; they could be replies on social media channels to an individual.

Member Companies should ensure they have the consent of the recipients to be in contact with them, and the recipients should be able to stop receiving messages easily. Appropriateness of the frequency of contact should be borne in mind.

Discussion forums

If a Member Company facilitates a discussion forum on either a Third-Party platform, or hosts a forum on its own platform, the Member Company must be confident that they can moderate the site such that the content complies with relevant regulations, laws and codes including the EFPIA Code of Practice. The intended audience should be identified so that relevant requirements are complied with. If discussion forums are used for market research, Member Companies should ensure these are compliant with relevant legal and ethical guidelines.

ANNEX E

Joint note for guidance on social media and digital channels

by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA)

September 2022

This global guidance serves as a non-binding and evolving resource for IFPMA members when considering their activities on social media and digital channels. It identifies the most used social media and digital channels and describes what members should be aware of when communicating with the public, Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), Patient Organizations (POs)*, and/or other stakeholders. The guidance describes principles applicable to communications on social media and digital channels, helps members identify appropriate information to share across different digital channels while measuring the risk, describes the general use of different types of digital channels, and provides specific guidelines when engaging with online influencers and digital opinion leaders.*

Introduction

The Ethos of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is centered on trust to "act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients, and other stakeholders."

The purpose of this Note for Guidance is to serve as a non-binding and evolving resource for IFPMA members[5] when considering their activities on social media and digital channels. The Guidance should be read with the spirit of the IFPMA Code of Practice (the "IFPMA Code") in mind and always in accordance with applicable laws, regulations, and industry codes.

The EFPIA Code, as well as other member associations' codes, reflect the principles and rules of the IFPMA Code and should be considered in conjunction with the IFPMA Code and this Note for Guidance, where applicable.

The overall intention of this Note for Guidance is to support and guide members in always basing their cooperation with Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), Patient Organizations (POs), and other stakeholders on the highest ethical standards and the clear goal to benefit patients.

[5] IFPMA member companies and member associations

In countries where Direct to Consumer (DTC) promotion of prescription-only products is allowed, company policies on promotion to the general public may follow the laws, regulations, and codes applicable in that country.[6]

Acknowledgment: This Note for Guidance is inspired by existing guidance in this field. Many elements of the EFPIA Code of Practice, Annex 2 Principles for the use of digital channels are reflected in its text (https://www.efpia.eu/media/676434/220718-efpia-code.pdf).

This document identifies the most commonly used social media and digital channels and describes what members should be aware of when communicating with the general public, HCPs, HCOs, POs, and/or other stakeholders.

The continuous development of the "Information Society" has made available to our members new media, new means of delivery and channels of communication about pharmaceutical products and therapeutical areas, and interaction across various stakeholders (HCPs, HCOs, POs, the general public, etc.). Due to the global nature of these channels, any information shared through such social media and digital channels may potentially be accessed from anywhere in the world, which generates risk and uncertainty for our members. Irrespective of the medium used, pharmaceutical companies and anyone acting on their behalf shall follow their obligation to consistently comply with the terms, conditions, and the spirit of the IFPMA Code and applicable laws, regulations, and local/regional codes.

Social media is accessible to the public and, as such, this Note for Guidance sets principles to help the industry manage one of the highest risks when using social media: unauthorized promotion to the general public. Except where otherwise permitted by law, promotion of pharmaceutical products via social media to the public may run counter to prohibitions on DTC advertising of prescription drugs.

This guidance recognizes that the definition and uses of social media and digital channels are continually evolving. IFPMA will monitor developments and recommends that members take a pragmatic and vigilant approach and apply this guidance in a way that is consistent with IFPMA principles and industry practices.

Key Definitions

In this Note for Guidance,

- **Digital channels** are platforms for electronic communication through transmission of digital content over the internet or computer networks. Digital Channels include but are not limited to social media.

- **Social media platforms** are digital channels for interaction in social networks. This includes websites or applications such as Facebook, Twitter, LinkedIn, YouTube, Instagram, chat rooms, blogs, and other online forums. Social media allows users to interact in real time, including posting, liking, commenting, and sharing. Often, social media channels are used to reach or interact with the public. A social media channel can be an "open" channel with unrestricted access for

[6] See IFPMA Code of Practice 2019 1.1 Scope

the general public, or a "closed" channel for a specific audience and with access control (i.e., where verification of the credentials of the participants is required before granting access). Examples of a closed social media channel are:
    - A social media channel on a company's intranet where access is restricted to the company's own employees, or
    - A social media channel created or supported by a member company where access is restricted to selected third party stakeholders (e.g., only selected HCPs or patients interested in a particular subject).
- **Pharmaceutical product** means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) that are intended to be used on the prescription of, or under the supervision of, a HCP, and that are intended for use in the diagnosis, treatment, or prevention of disease in humans, or to affect the structure or any function of the human body.[7]

- **Promotion of pharmaceutical products** means any activity, including advertising, undertaken, organized, or sponsored by a member company that is directed at HCPs specifically to promote the prescription, recommendation, supply, administration, or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.[8]

Scope

Activities: This Note for Guidance includes general principles applicable to all members' activities on social media and digital channels directed to/intended for third parties, conducted either by the member company itself or a third party acting on its behalf. The internal closed-loop digital communication does not fall within the scope of this Note for Guidance.

Products: This Note for Guidance applies to both pharmaceutical-products-related activities as well as therapeutic-area-related activities (including disease awareness programs, scientific communications, etc.). Over-the-counter (OTC) products and non-medical products as well as medical devices not mentioning, displaying, or branded with pharmaceutical products are not within the scope of this Note for Guidance.

1. Principles applicable to communications on social media and digital channels

General applicability of laws, regulations, and codes

The provisions of the national and international legislation and guidelines on the promotion and advertising of pharmaceutical products and of the IFPMA Code apply to communications on social media and digital channels. This includes:

[7] See IFPMA Code of Practice 2019 1.2 Definitions
[8] See IFPMA Code of Practice 2019 1.2 Definitions

- *Promotional rules*: To the extent required by applicable laws, regulations, and codes, member companies are prohibited from advertising pharmaceutical products or indications of such that do not have a valid marketing authorization (ban on off-label advertising).[9] A member company must not use social media or digital channels to engage in improper promotion of pharmaceutical products.

- *Direct-to-consumer (DTC) advertising*: DTC advertising of prescription pharmaceutical products is prohibited in most countries. Companies must comply with applicable laws/guidelines to restrict access to promotional content/materials to the appropriate audience (e.g., HCPs only).[10]

- *Balanced content*: Member company generated or sponsored content on social media and digital channels must be truthful, non-misleading, balanced, current, and accurate.[11]

- *Transparency*: Member companies should be transparent about the materials they produce, publish, sponsor, fund, or support on social media and digital channels. Whenever a member company or a third party acting on its behalf provides content on social media, it should clearly state the involvement of the company.[12]

- *Personal data*: The processing of personal data must comply with applicable national and international data protection regulations, such as the EU General Data Protection Regulation (GDPR), and similar local and regional legislations.

Responsibilities specific to social media and digital channels

Member companies are responsible for all content disseminated via a digital channel including social media when the content is initiated, branded, and/or sponsored by the member company or a third party acting on its behalf.

- *IT security*: Member companies should ensure measures are in place to assess and verify adequate IT security of social media and digital channels.

- *Adequate monitoring*: Member companies should establish procedures to review and monitor their activities, content, and materials on social media and digital channels to ensure compliance with relevant codes and applicable laws.[13] Processes should be established to monitor, moderate, and/or, where appropriate and possible, delete any inappropriate comments in a timely manner to the extent permitted by the data protection regulations and applicable laws and codes.

[9] See IFPMA Code of Practice 2019 Article 3.
[10] See IFPMA Code of Practice 2019 Article 6.
[11] See IFPMA Code of Practice 2019 Article 4.2
[12] Transparency is a requirement. When there is a single sponsor, it should be mentioned. In co-sponsored events, transparency should be provided according to applicable rules in the local jurisdiction. See also IFPMA Code of Practice 2019 Article 2.2 and Q&A 7.
[13] See IFPMA Code of Practice 2019 Article 12.1.

- Member companies are not expected to generally monitor or police independent third-party activity on non-company social media and digital channels. This means where the member company has not initiated or sponsored the activity and/or the member company (or a third party acting on its behalf) does not own or control the digital channel on which the activity occurs. This is without prejudice to any duty of diligence and correction that exists under applicable laws, regulations, and local/regional codes.

- *Employee activities*: Member companies may be held responsible for engagement with or dissemination of information disseminated by company employees who do so via their private social media channels including a) if the employee can reasonably be perceived as representing the company and b) if the employee is instructed, approved, or facilitated by the company to do so. Companies should ensure that relevant employees receive training appropriate to their roles for responsible conduct on social media and digital channels.[14]

- *Pharmacovigilance*: Member companies should implement policies or procedures and/or employee trainings on social media and digital channels to allow them to meet their pharmacovigilance responsibilities including applicable monitoring, reporting, and recordkeeping requirements.

2. How to identify the allowed information for the different digital channels: risk considerations

It is important to understand what content is appropriate for the different digital channels and the respective audience. All laws and regulations in this regard must be compliant in the same way as for other media.

Member companies should ensure that information on their digital channels is up-to-date and should clearly display, for each page and/or item, as applicable, the date when the information was posted or updated.

The following questions can be useful to assess risks associated with digital communication and appropriateness of digital channel content, access, set-up, and maintenance:

- What is the objective of the communication (promote, inform, exchange)?

- What content will be made available on the digital channel?
  - Is the content related to pharmaceutical products?
  - Is the content promotional or non-promotional?
  - Is the content related to disease awareness?
  - Is the content related to healthcare information, e.g. in connection with diagnosis, treatment education, dietary support?
  - Is the role of the company providing/developing the content clear?

- Who is the intended audience? e.g. employees, the general public, HCPs or a combination?

[14] See IFPMA Code of Practice 2019 Article 12.2.

  - Is verification of the audience required?
  - If yes, how is it done?
  - Are there other access controls in place?
  - Has the company added a statement about the intended audience (e.g., "This site is intended for U.S. Audience only")?

- What is the digital channel standard set-up?
  - Is the digital channel open to audience reaction such as sharing, commenting, exchanging?
  - How is the information cascaded across the digital channels (company sourced, medical journals, news, blogs)?
  - Is the digital channel an open platform or the platform has the feature to create closed audiences? - Are there limitations in content size (e.g. Twitter)?
  - Are there any community guidelines applicable (e.g. Facebook, YouTube)? - How is the information about the channel audience processed?

- How is the content reviewed, approved, maintained, and monitored including by the company?
- Who controls, owns, or operates the digital channel?
- What are the potential limitations of each channel and the caveats to add for the users (for example, geo-targeting, addressing online influencer interactions)?
- What is the company's role and responsibility in cases where the content on digital channels is accessible in countries where such content is not permitted (for instance, DTC advertising permitted in one country but not in others, differences in approval status, etc.)?

3. IFPMA guidance for members for various digital channels

Below is a short description of the general use of different types of digital channels. When deciding which digital channel to use and how to develop it, the principles set out in Section 1 above should be considered.

The content published by a member company on every channel must be appropriate and aligned with relevant regulations, laws, and codes including, as applicable, the IFPMA Code and the EFPIA Code.

Websites

Websites are classified as a channel that reaches the public, unless verification (e.g., pop-up for identification, password protection, professional self-declaration button etc., as consistent with local laws/regulations) is required to restrict access to the website, e.g., to HCPs. Some websites may include forums where the public can exchange or discuss topics.

Since many website visits are because of using a search engine, keyword optimization has become an important tool. Member companies can use appropriate search engine optimization and marketing tools to ensure that their websites are displayed high on the list of search results for relevant keywords while

ensuring that the use of keyword optimization is appropriate for the intended audience and that unauthorized promotion to the public is avoided.

Member companies may sponsor website content to be produced by a third party. In such cases, the role of the member company should be made clear. If the member company i) is initiating the content, or the concept for it; ii) is influencing the content; or iii) is selecting or directly paying the authors, then the member company may be held accountable under relevant law/codes for the content.

In countries where DTC advertising is not allowed by law, member companies should be confident about the choice of linked websites and that these do not promote prescription pharmaceutical products to the public. However, member companies may include promotional website addresses in advertisements of their pharmaceutical products to HCPs as long as access to the website is appropriately verified to ensure only the intended audience (HCPs) can access.[15]

Social media platforms

Social media platforms are websites or applications on which people can interact in social networks (e.g. Facebook, LinkedIn, Twitter, YouTube, Instagram). In most cases social media platforms are used to reach or interact with the public. However, a social media platform can be either an open channel for the public or a closed channel for a targeted audience (HCPs, patients with specific diseases, etc.) where verification/disclosure of the audience status or credentials is possible and can be required before providing access.

Member companies should take particular care when using platforms that limit or restrict their ability to monitor or access comments, such as ephemeral and encrypted apps.

Member companies are reminded that, in case of activity carried out by a third party on behalf of the company, according to the IFPMA Code of Practice, the member company may be held responsible for the content published by a third party.

Blogs

The difference between a text on a website and on a blog is that a blog is usually owned and updated by a person or a group of people who posts on the blog regularly.

A blog can be owned by a member company or a member company may engage (either through sponsorship or consultancy fees) the blog owner to write on a blog (such as “online influencers”). In both cases, the blog should clearly state the involvement of the member company.

Member companies should not sponsor blogs that are promoting, or could reasonably be expected to promote, pharmaceutical products and their uses in countries where DTC advertising is not allowed by law.[16]

[15] See also Annex 3 Principles for the use of digital channels, EFPIA Code, p60
[16] See also Annex 3 Principles for the use of digital channels, EFPIA Code, p61

Podcasts

A podcast is defined as an audio (music or talk) or video program made available in digital format for automatic download over the Internet and is typically available as a series that can be received by subscribers automatically.

A member company can have its own or can support a podcast, which should follow the same rules as for websites.[17] Core principles apply, as that of ensuring the audience is well defined and targeted and that content is appropriate, e.g., a podcast promoting pharmaceutical products should only be accessed by HCPs in countries where DTC advertising is not allowed by law.

Webinars

A webinar is an online event conducted via the Internet and it can be either performed as a live streaming event or as an on-demand service. Such webinars can be for the communication with external stakeholders (e.g. HCPs, HCOs, Pos etc.) provided that they follow the same rules as for websites. A member company can be the direct organizer of a webinar and/or use a third-party facilitator to run the event on behalf of a member company and/or sponsor a webinar organized by a third party. The member company is responsible for these webinars, including the content and taking reasonable steps to ensure that the audience is well defined and targeted. Nevertheless, if there is a strictly arm's length arrangement with the member company just providing financial support, then the member company may not be responsible.

Direct channels

These are one-to-one or one-to-many communication channels, which may or may not be private, such as emails, texts, direct messages, private messages, etc. Such direct channels can be used for communication with external stakeholders (e.g., HCPs, HCOs, patients, payers) subject to the same guidance as for websites (e.g., having appropriate content for the targeted audience) and the principles in Section 1.

Member companies should ensure they comply with applicable laws and regulations, specifically on data privacy and electronic communications, when they use direct channels to communicate with their intended audience, e.g., member companies should ensure they have a legal basis for conducting such electronic communications with individuals and/or provide individuals a right to opt-out from receiving such communications, as applicable.

[17] See also Annex 3 Principles for the use of digital channels, EFPIA Code, p61

Discussion forums

If a member company facilitates a discussion forum on either a third-party platform, or hosts a forum on its own platform, it should be confident that the site can be moderated such that the content complies with relevant regulations, laws, and codes, including the IFPMA Code. The intended audience should be identified so that relevant requirements are compliant. If discussion forums are used for market research, member company should ensure these are compliant with relevant legal and ethical guidelines.[18]

4. Specific guidelines when engaging with online influencers and digital opinion leaders

Online Influencers and digital opinion leaders may be experts on specific issues or may be media figures within an area or sector. Some examples of online influencers and digital opinion leaders include, but are not limited to, HCPs, patients, patient advocates, celebrities, or TV personalities.

Because of their expertise in reaching people, online influencers and digital opinion leaders may be engaged as consultants and advisors for services, including creation and co-creation and posting of digital content, as allowed by local regulations. Engagements with online influencers and digital opinion leaders may take various forms, including but not limited to, consultancies, collaborations, and partnerships.

Engaging with online influencers requires subtle and careful evaluation, including assessment of the risks of undue influence towards HCPs or patients or vulnerable groups, or risks that such digital content could be perceived as improper promotion of pharmaceutical products. Member companies should evaluate the context of each engagement with potential online influencers and ensure that their interactions comply with the provisions and spirit of the IFPMA Code and applicable laws and regulations. Member companies should follow key principles when engaging with online influencers, including:

- *Compliance with promotional rules*: Promotion of pharmaceutical products to the public, including via online influencers, is prohibited unless it is permitted under local law. Promotion of products for any uses outside the approved label or inconsistent with the product label (off-label promotion) is prohibited.

- *Risk of undue influence*: The rationale for engaging with specific online influencers and digital opinion leaders (HCPs and non-HCPs) should be considered and documented to avoid the perception of improper promotion or perception of improper reward for past decisions, or as undue influence on future healthcare or other business-related decisions.

- *Fair remuneration*: Engagements with online influencers and digital opinion leaders (HCPs and non-HCPs) should be carefully assessed to ensure that the services provided constitute bona fide services or serve a legitimate need and that any compensation or remuneration provided is appropriate and reasonable. Member companies are encouraged to establish a methodology for calculating FMV rates to ensure transparency and consistency.

[18] See also Annex 3 Principles for the use of digital channels, EFPIA Code, p62.

- *Transparency*: Full transparency of relationships with online influencers should be ensured and such relationships should be disclosed according to local regulation (e.g. via disclaimers attached to the materials/post).[19] Any transfer of value to online influencer must be disclosed, where required by law or codes.

- *Compliance with relevant laws*: Compliance with other applicable laws and obligations, including GDPR and pharmacovigilance obligations, must be ensured when engaging with online influencers.

- *Internal guidelines*: It should be evaluated if implementing written guidelines or rules governing engagements with online influencers may be helpful to ensure such engagements are appropriate and comply with applicable law or rules.

[19] See Article 2.2 - Transparency of Promotion, IFPMA Code of Practice 2019. EFPIA members have to follow Section 7.04 of the EFPIA Code of Practice.