



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)

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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 <u>Ethos</u> 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 members¹ when considering their activities on social media and digital channels. The Guidance should be read with the spirit of the IFPMA Code") in mind and always in accordance with applicable laws, regulations, and industry codes.

¹ IFPMA member companies and member associations

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.

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.²

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.

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² See IFPMA Code of Practice 2019 1.1 Scope

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 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.³
- → 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.⁴

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.

³ See IFPMA Code of Practice 2019 1.2 Definitions

⁴ See IFPMA Code of Practice 2019 1.2 Definitions

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:

- → 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).⁵ 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).⁶
- → Balanced content: Member company generated or sponsored content on social media and digital channels must be truthful, non-misleading, balanced, current, and accurate.⁷
- → **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.⁸
- → 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.⁹ 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.

⁵ See IFPMA Code of Practice 2019 Article 3.

⁶ See IFPMA Code of Practice 2019 Article 6.

⁷ See IFPMA Code of Practice 2019 Article 4.2.

⁸ 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.

⁹ 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.¹⁰
- → 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 consideration

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?

¹⁰ See IFPMA Code of Practice 2019 Article 12.2.

- → Who is the intended audience? e.g. employees, the general public, HCPs or a combination?
 - · 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, geotargeting, 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 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.¹¹

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.¹²

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.

¹¹ See also Annex 3 Principles for the use of digital channels, EFPIA Code, p60.

 $^{^{12}}$ See also Annex 3 Principles for the use of digital channels, EFPIA Code, p61.

A member company can have its own or can support a podcast, which should follow the same rules as for websites. ¹³ 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.

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.¹⁴

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.

¹³ See also Annex 3 Principles for the use of digital channels, EFPIA Code, p61.

¹⁴ See also Annex 3 Principles for the use of digital channels, EFPIA Code, p62.

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 businessrelated 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.
- → **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). ¹⁵ 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.

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¹⁵ 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.