Recommendations for using digital channels:

professional promotion, continuing education and social media

Technology is advancing rapidly and is constantly creating new opportunities and forms of interaction between the pharmaceutical industry and its cooperation partners. In many respects, technological advancement offers opportunities for all stakeholders. The sensible use of technology can improve treatment results for patients, reduce the everyday workload of specialists, and offer pharmaceutical companies new options for targeted communication measures.

These developments are observed and increasingly discussed by the international associations as well as by scienceindustries, particularly because the latest developments can also lead to uncertainty regarding the lawfulness of certain behaviours. The following provides an overview of past and possible future developments as well as proposals for solutions to specific problems that may arise with regard to the use of digital channels. **This document must be interpreted as a recommendation rather than a part of the Pharma Codes.** As it is intended to provide support in dealing with specific issues, it is based on the current legal practice of Swissmedic and – where possible and sensible – the guidelines of international pharmaceutical associations.

This guidance makes no claim to completeness, but serves as an investigation of the digital channels that are used most often and their potential active and reactive applications. Some companies may find it expedient to adapt this document to their specific requirements or needs and are encouraged to investigate additional measures where these seem appropriate.

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A. General guidelines

1. Principles

Please note that the guidelines of Swissmedic for the advertising of medicinal products on the internet dating from 2007/2009 remain valid, which is why reference is made to these guidelines. In this context, the distinction between **medicinal product promotion** and **medicinal product information** is governed by the legal and self-regulation provisions that are currently in force. In line with long-standing practice, a measure is considered promotional if its intention is to promote sales of a specific medicinal product. It is irrelevant whether this objective is actually reached; according to legal practice, its intention as a measure to promote sales is sufficient for its classification as promotion.

The following **principles** must be observed at all times:

- Information about medicinal products must be easy to recognise as such and must meet the requirements of the Pharma Code (PC) (Sections 21 and 26 PC).
- It is **not permitted** to promote **prescription-only** medicinal products to the **public**, and such advertising may only be addressed to specialists (Art. 31 Therapeutic Products Act, TPA and Sections 22 et seq. PC).
- **Promotion** of medicinal products that have **not** been **approved by Swissmedic** is **not permitted** (Sections 23.1, 23.2 PC as well as Art. 32 para. 1 (c) TPA, Art. 5 para. 1 Therapeutic Products Advertising Ordinance, TPAO).

It is the special nature of digital channels that it is **not easy to limit their geographic sphere of influence**, and this can have cross-border legal implications. Even though individual cases have to be investigated in more detail, the general recommendation is to structure such **information or promotional measures to comply with the national regulations for the geographic area that is their primary target**. The established practice at present seems to be that the websites of country organisations focus on a national audience, while the websites of corporate groups address a wider, more international audience. Even though information disseminated via corporate channels often goes beyond the national context, it should still comply with the national laws that apply at the corporation's headquarters. It should, however, be structured so as to ensure that it meets other implicit conditions, which could mean that such measures have to meet the requirements of several legal systems.

2. Responsibility

The signatory companies are **responsible for all medicinal product information and promotion initiated by them**, regardless of the channel that is used.

Depending on the technology that is used, **links** to other websites (in particular in the case of framing, i.e. when internet users are routed to different websites [often those of third parties] without leaving the website that was initially called up) can make the company who installed the link co-responsible for the information presented on the linked website. Relief can be obtained by publishing a disclaimer clause that is displayed automatically as a pop-up when a

user clicks on the link, reminding users that they are leaving the company's own information medium and that the company does not accept any liability for the contents of linked websites. However, as such disclaimers are not suitable for framing and also do not provide any warranties in the event of a dispute, the linked contents should always be carefully examined to ensure their compliance with material and formal quality requirements

When it comes to **interactive communication platforms** (blogs, social media, etc.), the question that is always asked is whether a company is responsible for inappropriate comments to its contributions. The signatory companies should therefore apply a standard internal process for monitoring such comments and deleting them immediately whenever necessary.

Signatory companies are responsible for the activities of their **employees** as well as the employees of third parties who act on behalf of a signatory company. Companies would therefore be well advised to issue clearly formulated guidelines for such activities.

3. Transparency

When using digital channels, the owner or sponsor of the channel **must always be identified by way of its physical and electronic address**.

According to Section 23.7.1 PC, the signatory companies must indicate **who operates or directly or indirectly sponsors the internet site** or other digital channels that are used to promote or disseminate information about medicinal products. For example, if a company appoints someone to write an article for a digital channel, the company's **involvement must be made clear**. In this case the company is also responsible for everything written about the company and/or its products by this person. The contents must comply with the requirements of the PC (see Section 23.7 PC).

4. Security

Companies must ensure that their digital communication channels are **protected by state-of-the-art technology** in order to defend themselves as best as possible against (hacker) attacks by third parties. To avoid errors of content as much as possible and ensure the accuracy of the presentation, a limited number of persons should be able to edit the contents.

Compliance with Swissmedic's practice on access control (see page 3 above) will enhance the **technical security** of professional promotion. Special consideration should be given to the following:

- Distinction between information meant for investors and promotion of medicinal products
- Selection of domain name
- Passwords to control access to professional promotion
- Restrictions on the use of hyperlinks and link lists
- Receiving directory and archiving
- Structure of press releases

5. Data privacy

Insofar as a company collects information about persons and/or processes personal data in the context of a measure or activity in Switzerland, the provisions of the **Federal Act on Data Protection (FADP)** must be observed. For cross-border activities involving persons who are domiciled in the EU, the EU's General Data Protection Regulation (GDPR) may be applicable if goods or services are offered to such persons or their behaviour in the EU is observed. To the extent possible, companies would be well advised not to use these data to try and identify individuals. **Anonymisation** or **pseudonymisation** can serve as adequate measures of protection in this regard. If these measures cannot or should not be implemented, other data privacy tools must be used, among which the **collection of consent** is a method that is frequently used to ensure the secure processing of personal data.

Access to and the use of **Real World Data (RWD) and Real World Evidence (RWE)** in digital format are gaining in importance in the healthcare sector. RWD refers to data that are collected in the context of the clinical exposure gained by a treatment procedure once it is applied in medical practice. As such, these data are collected outside of the strict structures of clinical studies and can usually be allocated to the category of "big data". **The responsible use of quality-controlled RWD/RWE serves the interests of many stakeholder groups and should also be supported and promoted in Switzerland**. The personal data of the affected patients should be protected at all times.

6. Pharmacovigilance

In the context of pharmacovigilance legislation, companies are obliged to report **adverse drug reactions (ADR)** mentioned in relation to their medicinal products to the competent agencies, regardless from whom and how this information came to their attention. Companies would be well advised to issue guidelines about how to handle ADR, in particular if the information about the informants or patients is incomplete. This also applies if a company or its employees receive information about ADR via digital channels/accounts (including social media) that are not directly operated by the company and for which the company is not responsible.

Technological advancement has driven the expansion of communication channels in the past and will likely continue to do so in the future. As a result, the **probability of ADR reports** is increasing and the monitoring of such reports presents companies with a big challenge. At the same time, regulators want to consistently make such information available to a bigger group of persons. Experience has shown that this is a material factor in deciding whether to use digital channels, either for the purpose of providing information or for promotion, as a result of which the pharmaceutical industry is usually **more cautious about using these channels** than other sectors. This is the current state of affairs and companies have to observe the pharmacovigilance rules whenever using expanded communication channels.

7. Technically supported customer care

The administrative capture of customer data and state-of-the-art maintenance of customer databases are standard practice. New technologies are giving birth to ever more precise and more informative customer databases. It is **permitted to establish and proactively use such databases**. When personal data are processed (which presumably is the case quite often), it is imperative to follow the applicable **data privacy regulations**.

Technically supported customer care can also mean that promotional activities are more selective and monitored more strictly, for example by addressing certain measures to a select group of specialists only or by changing the focus placed on certain elements of promotional packages according to the specialist audience. Although such selection processes are permitted, the advertising measure must be structured so as to ensure a more selective communication process while still complying with the rules for advertising and self-regulation. The selection process may in particular not have a **misleading outcome** and must always be **fair**.

Customer-specific promotion measures must always be approved by the **person responsible for advertising**. If the selection process leads to a change in contents or even a reformulation of the message, the relevant promotion measures must be submitted to the person responsible for advertising for approval again and the Code Secretariat must be sent a "specimen copy" (Section 64 PC). If the outcome of the selective promotion measure deviates only marginally from the more comprehensive original measure, it can be considered to be covered by the approval granted to the more comprehensive measure.

8. Archiving

According to Art. 25 para. 3 (e) TPAO, it is the duty of the person responsible for advertising to keep a copy of all **advertisements for medicinal products for six months** after their last publication and to maintain a **list of all recipients**, the medium of dissemination and the date of first publication. As this requirement applies regardless of the advertising channel that was used, companies should observe this minimum standard when organising their archiving systems. Based on current knowledge there is no reason to believe that this rule means that access lists for websites have to be stored, even if such lists should be available for access-controlled professional promotion areas. The **digital storage of information** pursuant to Art. 25 para. 3 (e) TPAO is considered sufficient in the event of a dispute if the information can be physically reproduced and it is technically impossible to change the contents. Companies would also be well advised to consider implications under liability law when drawing up their archiving guidelines, because evidence in legal disputes can often only be presented by taking recourse to documentation. In addition to the **statute of limitations**, companies should also weigh the **legal risks against the efforts required for archiving**.

B. Digital communication channels

1. E-mail correspondence

Instead of the traditional channels for sending out information and advertising materials, these can also be disseminated electronically. This form of communication has become widely used. It is immaterial whether information and advertising materials are disseminated via a physical or a digital channel. The requirements as to form and contents are the same, which is why reference is made here to the rules of Swissmedic (see page 3) and the following comments about websites.

Regarding **promotional mailshots, reference is made to Art. 3 para. 1 (o) of the Federal Act on Unfair Competition** (UCA). According to this provision, mailshots without a direct connection to a requested content that are sent out electronically are only considered fair if the customer's prior consent was obtained, the sender was correctly identified and reference was made to an easy and free option for rejecting the advertising. The latest doctrines about the scope of these provisions differ, and different ways of handling this issue can be observed on the market. It seems to have become established practice to obtain prior permission. As this also complies with the EFPIA HCP Code (Art. 6, Section 6.03), it should become standard practice. If in an exceptional case this is not applied, it must be possible **at first glance to clearly, easily and correctly identify the sender of the mailshot and it must be possible to unsubscribe easily and free of charge (see Sections 29 and 65 PC)**.

2. Websites

Websites are a popular digital channel and are widely considered to be accessible to the public. It is generally recommended that websites be programmed and structured such that only a defined group of persons can make formal and editorial changes to them and that **any and all changes by other third parties are excluded**. Companies should therefore refrain from using applications that allow third-party contributions to websites (also known as "open fields").

If websites are used for the professional promotion of prescription-only medicinal products, **access to this information must be controlled**. Swissmedic has accepted **password protection** as a suitable tool to achieve this. When allocating passwords, companies have to apply a verification process to ensure that passwords are only issued to specialists. In Switzerland, reliable programs are offered by third parties such as DocCheck and swiss-rx-login.

When **choosing the domain name**, we refer to the practice promoted by Swissmedic in the documents mentioned above (see page 3). It is generally permitted to use the names of preparations, companies and diseases as domain names, but a domain name may not be chosen specifically **to get around the advertising restrictions applied by the Therapeutic Products Act**.

Search engines are essential for obtaining an overview of the diversity of contents offered by the world wide web. There are therefore various methods for search optimisation, such as

keyword optimisation (optimised search based on a special selection of keywords) or adwords (contractually agreed priority of hits via certain search engines). **Search optimisation is generally permitted**. However, as websites are deemed to be accessible to the public and search optimisation primarily targets the public, companies are cautioned to exercise **restraint when choosing professional promotion search words**. Aside from this, companies may only make websites accessible to the public that contain general, therapy-focused information or information about over-the-counter medicinal products, which means that the search words are more or less predefined. Search optimisation may also not be used to **get around password protection**, and suitable technical measures must be implemented to ensure this. For over-the-counter medicinal products, the keywords should reflect the SPC contents (summary of product characteristics) whenever possible.

3. Webinars

Webinars have generally increased in importance, in particular in the field of **continuing medical education**, but can also be used for medicinal product promotion and information, among others. Webinars are allowed, but the general rules regarding contents, password protection, etc. must always be observed when they are developed. Experts welcome webinars as a tool for continuing education, but emphasise that their **contents must be valuable** and should not focus on product promotion; indeed, it would be better to stay completely clear of such elements. Experts would expect purely promotional webinars to be identified as such.

Where webinars are used for training purposes, the question that arises in Switzerland is whether the benefiting experts have to **contribute to the costs**. Swissmedic, who seems to be generally positive about such webinars, assumes that the experts have to contribute to the costs if an individual training session lasts longer than half a (work) day. If a series of courses is offered which together will earn the participant training credits, the half-day rule applies to the total duration (see Section 35.3 PC).

Based on past decisions about individual cases by Swissmedic, it makes sense to apply a **differentiated approach** as a cost contribution cannot always be justified. We also believe that the factors influencing prescribing behaviour are weaker for webinars than for physical events since there are usually no opportunities for direct exchange with specialists, and they themselves also cannot engage in more advanced discussions. Furthermore, the administrative expenses for online events are likely to be considerably lower, not least because there is no need for travel. As the webinar concept cannot be directly compared to a physical training event, **it may not always be necessary to require participants to contribute to the costs, even for events that last longer than half a (work) day**. In this case, Swissmedic thus classified such interactive, electronic and audiovisual training courses and access to self-study (e-learning via webinars) as **benefits of monetary value** rather than invitations to conferences. They are then only permitted if they **do not exceed the amount of CHF 300 per specialist, company and year** or if the excess amount is paid by the specialists themselves.

However, it is recommended that cost contributions are made compulsory for the transmission of (international) congresses or similar events. This practice seems justified in view of the considerable costs that would have to be incurred by a specialist for physical

participation in such events and apart from that, a widespread acceptance of this practice can be noted among specialists.

The calculation of the cost contribution is based on the **value of the course for the specialist** (e.g. for the transmission of a series of presentations by a medical faculty, the price of admission), which often cannot be determined or would lead to disproportionate cost contributions in the case of the transmission of international conferences. If this value cannot be determined with proportionate effort or if it seems ridiculously high, the opposite approach can be applied, i.e. the **calculation of the cost contribution can be based on the costs which a company incurred for providing one or more webinars**. The following calculation method is proposed: Total costs for the preparation and dissemination of the webinar, divided by the number of specialists who enrolled for the webinar; one-third of this cost contribution should then be invoiced to the individual specialists.

It is well-known that presentations by specialists at conferences regularly include comments about the **off-label use** of products/therapies. According to the point of view championed here, the transmission of such presentations does not qualify as a promotion measure by the company, and the webinar will still be considered to be a **continuing education measure if the off-label comment is made by an independent speaker at the conference**. It should be remembered that **presentations that are broadcast have the same contents as those presented at a physical event**. Excerpts may not focus on a cluster of statements that will change the communicated contents as this would harbour the risk that such a measure becomes a tool for promoting sales of certain products/therapies and could then qualify as professional promotion. If this should be the case, all comments about off-label use will have to be removed from the webinar and the company may not contribute to any costs.

4. Podcasts

A company can produce one or more own informative or promotional podcasts where the company or an employee is responsible for the contents. Podcasts are subject to the same rules regarding contents and form as websites. If a podcast contains promotional statements and targets specialists, this fact must always be made clear and technical measures must be put in place to ensure that it **can only be downloaded by specialists**. Where podcasts are offered via a specialised merchant, it should be investigated whether the merchant is subject to the prohibition of public advertising. In this case the group of persons who are authorised to access the podcast must be kept as small as possible, and should ideally be limited to a single specialist. Insofar as such podcasts have promotional character, a specimen copy must be sent to the Code Secretariat without being asked (see Section 64 PC).

5. Blogs

It is our understanding that the difference between a text on a website and a blog lies in the fact that blogs are posted by an identifiable and personal sender and new blog entries are published at regular intervals. Bloggers use blogs to voluntarily and spontaneously publish

their personal opinions about certain topics. A distinction can be made between **a company's own blogs** and those of **third parties**.

Currently, the pharmaceutical industry seems to be **very reserved about this communication medium**. When supporting **third-party blogs**, it is very difficult for a company to enforce the statutory and self-regulation rules, and this can lead to liability issues. In case of doubt, it should be assumed that the company is responsible for all contents written by such bloggers, which is why the **contents must comply with all statutory and self-regulation requirements**. Should a company nevertheless consider sponsoring a blog, the third-party blogger must be contractually obliged to observe all statutory and self-regulation rules and the pharma company's support must be clear and transparent. The company then has to strictly monitor compliance with all contractual conditions and take suitable measures without delay in the event of a breach to ensure the immediate restoration of the contractual condition. Consequences under administrative and criminal law should not be excluded.

These issues are likely easier to handle for a **company's own blog**, as the company can actively manage the blog activities. For security reasons it makes sense that a clearly defined group of employees operate the blog. The **provisions of labour law** apply here, and they can be used to ensure compliance with statutory and self-regulation requirements. If a blog is used, its form and contents must comply with statutory and self-regulation requirements; if the blog is used for professional promotion, access to the blog must be controlled as prescribed. Where a company enters into a contractual relationship with a blogger (social influencer) who contributes to the company's own blog, the provisions of advertising law must also be observed when this person writes about prescription-only medicinal products. In this case only a specialist may comment on the products.

6. Apps

Application software made available on the internet for download to smartphones, tablets and PCs is known as apps. A company can develop apps, which have to meet the same conditions as to contents and form as websites.

Apps are already used widely and are becoming more and more common. They can be used to address many topics: Some apps contain **information only**, but others are **promotional** or offer **support** intended to improve treatment **to specialists and patients**. The prescribed access control must be ensured in each individual case. Swissmedic's requirements must be observed for apps providing treatment or diagnostic support, in particular when they qualify as a **medicinal product** and require **certification** before being launched on the market.

If an app has been designed to **monitor therapy**, access must be limited to the person receiving therapy and the competent specialist, if necessary. A **clearly defined identification procedure** must be selected, e.g. the batch number on the packaging of the medicinal product that is used. Another possibility would be to use an access code issued by the HCP when prescribing or issuing the medicinal product. The possible **implications of data privacy and data security** have to be mentioned here: Only the data that are needed to achieve the defined objective should be collected. While consent for the collection and processing of data is a widely used

means of authentication, anonymisation of the data can drastically reduce the risks under data privacy legislation.

7. Social media

The term "social media" is used here to refer to all digital technologies and media that allow users to communicate with one another and to exchange contents. As a rule, social media are used to **reach or interact with the public**. At present, the most important social media include Facebook, Twitter, Snapchat, LinkedIn, Youtube, Instagram and WhatsApp.

It is **generally permitted to use these channels**, but when it comes to the promotion of medicinal products, special care should be taken when addressing the public and compliance with the prohibition of public advertising must be ensured. As these may contradict the statutory and self-regulation requirements, the user guidelines of the individual providers must always be investigated. If there are contradictions, the conflict of standards may mean that these media cannot be used or can only be used to a limited extent.

Social media can be accessed from a transparently named **business account** as well as from the employees' private accounts. Experience has shown that companies mainly use social media at **corporate group level**, and that this channel is used more cautiously at country level. The current trend focuses on Facebook, Twitter and LinkedIn. Given the implications under advertising law, these channels are used more for **information** and less for promotion. Even though it is technically possible to apply access control to some social media channels, an interactive medium seems to have limited use when it comes to the promotion of new products and therapies, particularly because specialists have limited time to spend on this communication medium and would see little added benefit in this.

Companies would be well advised to clearly regulate the **use of private accounts** by employees and define the **rules of conduct** in **internal regulations** (which can be part of the employment conditions). The use of private accounts for business purposes can be completely forbidden, for example. Currently it seems that different rules have been established for the different social media channels, and that the rules for using LinkedIn are more liberal than for the other channels. If employees should be allowed to use their private accounts for business purposes, suitable measures should be implemented (e.g. information and training measures) to ensure that **employees do not violate any statutory and self-regulation provisions**. Such violations could easily establish liability on the part of the company itself. Central factors here are the provisions regarding the **prohibition of public advertising**, observance of the **pharmacovigilance provisions**, and compliance with **transparency requirements**. Finally, it must be possible for a third party to equate the use of the employee's private account with the company's purpose, so that employees must be required to identify themselves as such on their private social media accounts.

When it comes to the use of the "**Like**", "**Share**" and "**Comment**" buttons by employees, companies would be well advised to issue **clear instructions** about what is permitted and what not, as such conduct can under certain circumstances qualify as forbidden advertising measures. In the context of public advertising, Swissmedic refers to Art. 21 (g) TPAO to qualify

the use of "Like", "Share" and "Comment" as forbidden public advertising measures. Companies would be well advised to take account of this when drafting their guidelines.

ADR reports pose a special challenge when operating such channels. If a company actively uses social media, it must **ensure that ADR reported via these channels are actively integrated into the vigilance process** and that follow-up measures are implemented in accordance with the legal provisions.

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