PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The most important sector-specific laws governing the promotion and advertising of pharmaceuticals and medical aids (*gyógyászati segédeszköz*)[1] are as follows:

- Act No XCVIII of 2006 on general rules for the safe and economical supply and distribution of pharmaceutical products and medical aids (the 'Medicinal Act'); and
- Healthcare Decree No 3/2009 on detailed rules concerning the promotion of pharmaceutical products for human use and medical aids, the registration of persons responsible for promotion of pharmaceutical products and medical aids, and the rules on commercial practices towards consumers in relation to pharmaceutical products and medical aids (the 'Promotion Decree').

There are no sector-specific laws governing the promotion and advertising of 'medical devices' (*orvostechnikai eszköz*).[2]

The most relevant code of ethics concerning pharmaceutical product promotion is the Code of Ethics for Pharmaceutical Communication (the 'Code of Ethics') available via the following link: **https://etikusgyogyszer.hu/images/download/GYKEK_egysges_szerkezetben_2022.pdf**.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

The notion of 'advertising' is defined in Act No XLVIII of 2008 on advertising activities (the 'Advertising Act'). The Advertising Act defines 'advertising' as follows: 'Advertising' means any form of communication, information or the making of a representation in any form with the aim or having the direct or indirect effect of promoting the supply of certain products (goods of a fungible nature that are capable of being delivered, including natural resources that can be utilised as capital goods, including money, securities and financial instruments), and services, immovable property, rights and obligations (collectively referred to as 'goods'), or in connection with this objective, the representation of the name, the trademark or the activities of a producer of goods or a provider of services.

The definition of 'advertising' applies to all goods.

Promotional activities related to pharmaceutical products, dietary supplements and medical aids fall under the definition of 'commercial practice' included in the Medicinal Act. Commercial practice means professional, scientific communication or any information, action, representation, commercial communication, including marketing, directly connected with or capable of promoting the prescription, procurement, sale or supply of a pharmaceutical product, dietary supplement or medical aid.

Commercial practice covers both: (1) promotional activities towards the general public; and (2) promotional activities towards healthcare professionals (HCPs).

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

In the case of pharmaceutical products and medical aid-related promotional activities towards HCPs, the relevant supervisory authority is the Nemzeti Népegészségügyi és Gyógyszerészeti Központ (the 'NNGYK').

In the case of pharmaceutical products and medical aid-related advertising activities towards consumers the NNGYK, Hungarian Competition Authority or Consumer Protection Authority may have competence, depending on the type of breach.

As a general rule, self-regulatory processes based on the Code of Ethics and authority proceedings can be launched independently.

4. Are there other product types that fall under the same regulations on promotion (and

advertisement) as pharmaceuticals for example, food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

In addition to pharmaceutical products, medical aids and dietary supplements are covered by the rules on commercial practice laid down in the Medicinal Act. This means that specific rules govern: (1) the advertising of medical aids and dietary supplements towards the general public; and (2) promotional activities of medical aids and dietary supplements towards HCPs.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

As a rule, only over-the-counter (OTC) medicinal products may be advertised to the general public. Advertising prescription-only products and reimbursed pharmaceutical products to the general public is prohibited.

'Medical devices' and non-reimbursed 'medical aids' may be advertised to the general public.

As a main rule, advertising reimbursed medical aids to the general public is prohibited.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

The online promotion and advertising of pharmaceuticals and medical devices are not specifically regulated in Hungary.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

There is no mandatory approval process regarding promotional materials and advertisements. Companies may make a request to the NNGYK to provide its comments regarding their promotional materials and advertisement in the framework of NNGYK's consultancy proceedings in exchange for a certain service fee.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

Unauthorised pharmaceuticals and off-label information cannot be promoted (advertised) in Hungary.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

With regard to the comparative advertising of pharmaceuticals, medical devices and medical aids, the below rules laid down in Act No LVII of 1996 on the Prohibition of Unfair Trading Practices and Unfair Competition may apply.

For comparative advertising:

- only goods that are intended for the same purpose or satisfy the same needs may be compared;
- the comparison must relate to a relevant, significant, typical and verifiable characteristic of the goods, and the price, where it is also the subject of the comparison, must be objective; and
- comparisons of products with a designation of origin must involve only products with the same designation of origin.

Using another company's information (including brand name) is not prohibited per se.

Comparative advertising is prohibited if:

- naming the competitor or its name, goods, trademark or other designation may give rise to an unfair advantage as a result of the competitor's reputation;
- the reputation of a competitor or the name, goods, trademark or other designation of a competitor may be damaged;

- it presents the goods as imitations or replicas of other goods bearing a trademark or other protected sign; or
- as a result of comparative advertising, market participants may confuse the given company with a competitor or the name, goods, trademark or other designation of the company with that of a competitor.

Referring to any unauthorised product or unauthorised indication of a competitor is not permitted.

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

In the context of promotional activities, HCPs fall under the definition of 'persons qualified to prescribe or supply pharmaceutical products and medical aids', which means: (1) physicians; (2) pharmacists; and (3) producers and traders of pharmaceutical products and medical aids, holding the appropriate licence, being engaged in the commercial distribution of pharmaceutical products and medical aids.

Promotional activities regarding pharmaceutical products and medical aids towards HCPs may only be carried out by medical sales representatives registered by the NNGYK.

Medical sales representatives must not hinder the professional activities of the relevant HCP and patient care. Medical sales representatives may only visit HCPs for promotional purposes using pre-agreed appointments, which must take place when the HCP is not engaged in the provision of healthcare services, according to the treatment plan of the relevant healthcare provider. Product promotion must not interfere with the therapeutic activity provided by the healthcare provider.

Medical sales representatives must provide information and documents regarding the relevant product in sufficient detail to enable the given HCP to form an opinion on the use of the given product. All information and documentation conveyed to the given HCP in the course of promotional activities must be accurate, verifiable and up-to-date. All documents must include the date of the finalisation or last update of the given document.

In the course of promotional activities, quotations, tables and other illustrative materials from medical journals or other scientific sources must be presented in accordance with the original source; the exact source and date of publication must be indicated.

If the given pharmaceutical product or medical aid is reimbursable, then the amount of the produce price, the reimbursement and the consumer price of the given product must be indicated in the document provided to the HCP in the course of the promotional activities.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

There are no specific legal provisions governing online interactions with HCPs. General legal provisions governing interactions with HCPs also apply to online interactions.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

HCP recommendations cannot be included in pharmaceutical advertisements and medical aid advertisements.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

Product samples of pharmaceutical products and medical aids[3]

In the case of pharmaceutical products and single-use medical aids, free product samples may be provided to HCPs in line with the below-specified rules.

As a general rule, a maximum of two pieces of the smallest distributed unit may be provided to each HCP entitled to prescribe the given pharmaceutical product/medical aid per year following the launch of the given product in Hungary. In the case of reimbursed products, product samples can only be given until the end of the year following the year in which the given product has been first launched in Hungary.

The provision of product samples of 'medical devices' to HCPs is not regulated in Hungary.

Gifts

As a rule, companies carrying out promotional activities related to pharmaceutical products and/or medical aids must not provide, offer or promise any gifts, monetary benefits or advantage to HCPs directly or indirectly.

As an exception, gifts can be provided to HCPs, provided that the below criteria are fulfilled:

- the gift is related to the healthcare activities of the given HCP;
- the individual amount of each gift's value cannot exceed five per cent of the monthly minimum wage in Hungary (currently HUF 266,800), that is, the individual amount of each gift's value cannot exceed HUF 13,340 (approximately €35);
- the yearly aggregate value amount of all gifts provided to an HCP cannot exceed 60 per cent of the monthly minimum wage in Hungary, that is, the yearly aggregate value amount of all gifts provided to a HCP cannot exceed HUF 160,080 (approximately €415); and
- the gift needs to be provided to the given HCP by medical sales representatives in the course of product promotional activities.

14. What rules govern the offering of hospitality to healthcare professionals?

As a main rule, companies carrying out promotional activities related to pharmaceutical products and/or medical aids may not provide, offer or promise any benefit to HCPs directly or indirectly.

As an exception, hospitality may be provided to HCPs, provided that the below criteria are fulfilled:

- in the case of professional events organised by pharmaceutical companies carrying out promotional activities intended for HCPs, the total organisation cost of the given event/person cannot exceed five per cent of the monthly minimum wage in Hungary/person, that is, it must not exceed HUF 13,340 (approximately €35/person);
- hospitality must be secondary to the main purpose of the professional event; and
- hospitality can only be provided to HCPs in the course of professional events, as according to the NNGYK's interpretation, hospitality outside of such professional programmes (eg, business launches) is regarded as an unlawful gift.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

The donation of pharmaceutical products and medical aids is regarded as promotional activity and is subject to specific regulations.

Pharmaceutical products and medical aids may only be donated for charitable purposes and only to healthcare institutions, social institutions and charity organisations where the professional conditions for the use of the given pharmaceutical products and/or medical aids and the control of their use are ensured.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

Scientific and educational meetings can be supported in Hungary.

If companies carrying out promotional activities regarding pharmaceutical products and medical aids in Hungary support scientific and educational meetings, a specific regulatory regime applies.

Most importantly, pharmaceutical product and medical aid product promotion may only be carried out at such scientific and educational meetings if the promotional activities can be clearly distinguished from the scientific and educational part of the programme.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

The relationship between the industry and patient organisations is not regulated in Hungary. Although the term 'patient organisation' is used in some legal provisions, this term is not defined under Hungarian law.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

It is possible to delegate promotional (advertising) activities to a third party through a service agreement. There are no specific legal provisions applicable to such a service agreement. Co-promotion is not regulated in Hungary.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

When a company carrying out promotional activities related to a pharmaceutical product or medical aid is planning to support professional, educational, or promotional conferences or meetings, such a company must notify the NNGYK electronically 15 days before the start of the meeting.

More specifically, the electronic notification must include, among others, the names of the involved HCPs, the amount of support to be provided to the HCPs and the amount of the organisation's cost for the meeting (including hospitality). The relevant agreements related to holding presentations at such conferences and meetings must also be attached to the notifications.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

The application of specific sanctions for the violation of the applicable rules on the promotion of pharmaceutical products or medical aids depends primarily on the specific violations found by the NNGYK.

If the NNGYK finds a breach of the rules on pharmaceutical/medical aid product promotion, it usually imposes a fine on the pharmaceutical company carrying out the promotional activities.

The fine imposed on pharmaceutical companies carrying out promotional activities may range from HUF 500,000 (approximately €1,300) to HUF 500m (approximately €1.3m). In practice, fines imposed by the NNGYK tend to be under HUF 100m (approximately €260,000).

According to the relevant laws, medical sales representatives can also be fined for breaching their respective obligations regarding the promotion of pharmaceutical products. The potential fine on medical sales representatives may range from HUF 500,000 (approximately €1,300) to HUF 5m (approximately

€13,000).

As a main rule, the NNGYK publishes: (1) its decisions establishing a breach of product promotion where the imposed fine exceeds HUF 1m (approximately €2,600); and (2) related final and binding court decisions.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

In the case of pharmaceutical/medical aid product promotional activities towards HCPs, the NNGYK is the relevant authority.

The NNGYK tends to initiate proceedings in relation to pharmaceutical/medical aid product promotion frequently and enforces applicable laws strictly.

It is not common for competitors to take direct legal action against each other in relation to pharmaceutical/medical aid product promotion. It is more common for competitors to try to solve their promotional-related concerns in an amicable manner and, if not successful, to refer such concerns to the Ethics Committee operating on the basis of the Code of Ethics.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

We are not aware of any future significant developments in the field of pharmaceutical and medical aid-related promotional activities.

The NNGYK tends to actively enforce legal provisions governing pharmaceutical and medical aid-related promotional activities. In practice, the biggest challenge for market players is probably the interpretation of applicable promotion-related laws, which are sometimes ambiguous. Ensuring compliance with pharmaceutical and medical aid-related promotional rules requires an understanding of the NNGYK's relevant guidelines and applicable case law.

Notes

[1] The notion of a 'medical aid' shall be distinguished from the notion of a 'medical device'. The main concept of the distinction is as follows:

- Medical devices qualify as medical aids if the following conjunctive criteria are met:
  - the given device is made available for personal use to patients suffering in a temporary or persistent health impairment or disability; and
  - the given device is designed for use without the continuous presence of healthcare professionals.
- There are certain 'technical devices for nursing and caring purposes' (*ápolási technikai eszköz*) that do not fall under the category of medical devices, but qualify as medical aids, provided that the above conjunctive criteria are met.

[2] Please refer to footnote 1.
[3] For the distinction between 'medical device' and 'medical aid', please refer to footnote 1.