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 promotion and advertising of pharmaceuticals and medical devices in Denmark are governed by the following:

- Consolidated act no 339 of 15 March 2023 on Medicinal Products, Chapter 7;
- Consolidated act no 682 of 29 May 2023 on Medical Devices etc;
- Executive Order no 849 of 29 April 2021 on Advertisement etc for Medicinal Products (the 'Advertising Order');
- Executive Order no 715 of 24 May 2022 on Advertisement etc for Medical Devices (the 'MD Advertising Order');
- Guideline no 9400 of 20 April 2022 on advertising etc of Medicinal Products;
- Guideline no 10357 of 29 December 2014 on Advertising for Medical Devices;
- Guidance no 9840 of 18 October 2021 on labelling and instruction manuals for Medical Devices;
- Consolidated Act on Danish Marketing Practices no 866 of 15 June 2022;
- the Ethical Committee for the Pharmaceutical Industry (ENLI) is the self-regulatory body within the pharmaceutical industry in Denmark, which regulates the relationship between the pharmaceutical industry and healthcare professionals. ENLI has issued:
    - the Pharmaceutical Industry's Code of Practice on Advertising, etc of Medicinal Products aimed at Healthcare Professionals (the 'Promotion Code'). The provisions in the Promotion Code are generally in line with relevant legislation, although the Promotion Code in some cases provides for stricter requirements;
    - the Donation Code;
    - guidance documents covering specific elements of the Promotion Code, including, inter alia: digital media; sponsorships; prelaunch activities; and market research;
- Medicoindustrien is the self-regulatory body for medical devices in Denmark. Medicoindustrien has implemented MedTech Europe's Code of Ethical Business Practice, except for the rules on transparency and economic advantages for healthcare professionals, which is subject to National regulation in the MD Advertising Order.

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

The term 'advertising' in the context of the pharmaceutical legislation is defined in section 1(1) of the Advertising Order: advertising of medicinal products means any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of pharmaceuticals. The term is interpreted broadly.

The term 'advertising' in the context of medical devices mirrors that of pharmaceuticals.

The Danish laws and industry codes listed under Question 1 do not distinguish advertisement from promotion.

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?

The Danish Medicines Agency (DKMA) is the authority regulating and enforcing the promotion and advertisement of pharmaceuticals and medical devices.

The policing of advertising activities by the DKMA is supplemented by trade specific self-regulatory bodies.

There are six self-regulatory bodies:

- the Ethical Committee for the Pharmaceutical Industry (Etisk Nævn for Lægemiddelindustrien, ENLI);

- the Marketing Board of the Danish Association of the Veterinary Pharmaceutical Industry (VIF's Markedsføringsnævn);
- the Danish Pharmacy Committee (Apotekernævnet);
- the DMA Ethical Council (Lægeetisk Nævn);
- the Ethical Board of the Danish Association of Suppliers to the Health Industry (Helsebranchens Leverandørforenings Etiske Nævn); and
- the Medicoindustry (Medicoindustrien).

While a complaint regarding an advertisement towards a healthcare professional (HCP) typically falls within the purview of a self-regulatory body, a complaint can also be lodged directly with the DKMA. When the DKMA assesses a complaint, it may seek input from the relevant self-regulatory body. It is important to note that a decision rendered by a self-regulatory body cannot automatically be appealed to the DKMA. However, a dissatisfied complainant retains the right to bring the complaint to the DKMA, even if it has already undergone examination by a self-regulatory body. In such a situation, the DKMA's review will encompass the decision made by the self-regulatory body. In general, ENLI forwards complaints to the DKMA, if they fall outside the mandate of ENLI.

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?

A 'pharmaceutical product' is defined as a product that:

- is *presented* as being suitable for the treatment or prevention of human disease; or
- may be *used* in or administered to human beings either to restore, modify or modify physiological functions by exerting a pharmacological, immunological or metabolic action or to make a medical diagnosis.

The advertising regulations encompass all categories of pharmaceuticals for both humans and animals, such as herbal medicinal products, traditional herbal medicinal products, homeopathic medicinal products, and certain strong vitamins and minerals.

Other product types, for example food supplements, special nutritional, etc, are separately regulated, provided they do not fall under the above definition.

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?

In general, the following categories pharmaceuticals cannot be promoted to the public:

- pharmaceuticals that cannot be sold in Denmark, for instance, pharmaceuticals which do not have: (1) a marketing authorisation; and/or (2) a list price notified to Medicinpriser;
- magistral pharmaceuticals;
- pharmaceuticals for non-clinical trials and clinical trials when a marketing authorisation has not been issued for said pharmaceutical;
- pharmaceuticals sold or dispensed according to a special compassionate use permit;
- sera, vaccines, specific immune globulins and other immunological investigational products not covered by a marketing authorisation, and which are sold or supplied by the SSI (Statens Serum Institut) or the National Veterinary Institute, Technical University of Denmark;
- prescription only pharmaceuticals;
- pharmaceuticals that are not suited for use without the patient having been diagnosed or surveyed by a physician; and
- pharmaceuticals that are covered by the Act on controlled substances.

Medical devices intended for exclusive use of doctors or dentists in their treatment of patients must not be promoted to anyone other than doctors, dentists and persons who in a professional capacity purchase medical devices.

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?

Yes, the Advertising Order provides that all internet advertising is considered aimed at the public, unless there is an effective access restriction, meaning that only healthcare professionals (HCPs) can access the site. As such, advertising of pharmaceuticals and medical devices on the internet must adhere to the same requirements and restrictions as advertisements via traditional channels. However, it is essential to interpret and apply the rules with consideration for the unique features of the internet. The rules apply to banner ads, internet advertising and the like which clearly take the form of advertising and to the mention of medicinal products on, for example, pharmaceutical company websites when such mention must otherwise be considered to fall under the definition of advertising, see Question 2 above 'Definition of advertising and scope of rules'.

Advertisements for pharmaceuticals are required to include specific compulsory information as outlined in sections 5 and 11 of the Advertising Order. On the internet, where multiple pages can be linked, the requirement for posting mandatory information may be satisfied by including a link in the advertisement to a separate page containing the necessary information.

ENLI's Digital Media Guide furthermore provides further guidance on the use of social media in marketing activities for pharmaceuticals.

We note that generally, the DKMA and ENLI are known to be very strict in respect of SoMe enforcement.

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)?

No. Promotional materials are not required to receive prior approvals from regulators. A pharmaceutical company that is a member of ENLI, may, however, apply for a (non-binding) pre-approval of material. The pre-approval is subject to a fee. All promotional material must be notified to ENLI before being used and provided to HCPs.

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

No. The information contained in promotional material must comply with the approved summary of product characteristics (SPC) for the pharmaceutical.

In relation to unauthorised pharmaceuticals, see the answer to Question 5 above, namely that pharmaceuticals that cannot be sold in Denmark cannot be promoted. A new pharmaceutical can only be sold lawfully from the time it has been approved by means of a marketing authorisation and the price has been notified to Medicinpriser (public registry of prices on medicinal products).

ENLI has issued a Guide on Pre-launch, in which it is stated as a general principle that the mentioning or scientific reference of studies and data related to phases I and II of a development program for potential future pharmaceuticals to HCPs, falls outside the scope of the Promotion Code.

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?

The Advertising Orders stipulate restrictions and requirements on comparative advertisements.

If an advertisement involves comparing multiple medicinal products or medical devices, it must clearly specify the products/devices under comparison. Comparisons are permissible only if made with pharmaceuticals that are objectively relevant due to sharing the same indication(s) or with medical devices having the same scope of use.

A company may use another company's brand name as part of comparative advertisements of pharmaceuticals. While there is no comparative administrative case law affirming that this is also the case for comparative advertisements of medical devices, the same must be assumed to apply.

The preparation of comparative advertising should be based on information derived from the Summary of Product Characteristics (SPCs) of the products being compared, to the extent that the SPC contains relevant details.

It is strictly prohibited to convey the impression to the public that the effectiveness of one pharmaceutical is superior or equivalent to another. Therefore, advertisements targeting the public must refrain from comparing the effects of various medicinal products.

The specific information about another company that can be utilised in a comparative advertisement is not explicitly outlined; however, in general, comparisons should not be made with pharmaceuticals that are not legally tradable in Denmark. Consequently, unauthorised pharmaceuticals should generally not be included in comparative advertisements.

As a general rule, comparative advertisements of pharmaceuticals should comprise all pharmaceuticals with the same pharmaceutical form and strength and insignificant deviations in pack size. Comparative advertisements of medical devices should comprise all medical devices with the same scope of use. For both product types, comparative products with a market share below two to three per cent may be excluded from the comparative advertisement.

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?

HCPs are defined as doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaconomists, midwives, bioanalysts, clinical dietitians, radiographers, social and healthcare assistants or students within these fields.

The Advertising Orders regulate promotional communications directed to HCPs.

Advertising directed at HCPs must include compulsory information. Material sent or provided to HCPs must also carry the date the material was prepared or last modified.

However, advertisements of pharmaceuticals that are directed only at HCPs may be limited solely to the name and common name of the pharmaceutical. If further information is included in the communication, it falls outside the scope of the exception, and thus all information must be included.

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?

No. In general, the advertising rules apply to both virtual and physical meetings, including congresses and symposia. Companies must therefore comply with Danish regulation with the modification that companies established in other EU/EEA countries are generally not obliged to comply with Danish advertising rules which are stricter than those of the country where the company is established.

ENLI has drafted a Guide regarding the participation of pharmaceutical companies in international congresses, in which also virtual meetings and congresses are encompassed.

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?

An advertisement for either a pharmaceutical or a medical device towards the public must not include recommendations by HCPs, scientists or other persons, associations of persons, institutions, companies, etc, which/who, by virtue of their prestige etc, could encourage the consumption of pharmaceuticals.

This includes both persons and organisations and covers furthermore the mere presence of a such person/organisation by, for example, a picture of a person appearing to be an HCP.

According to the Medical Association's ethical principles, a doctor must not, in his or her medical role, advertise medicines or products that are claimed to have a curative or preventive effect.

Danish affiliation rules must be considered when engaging doctors, dentists, nurses, or pharmacists. The rules require the individual to obtain prior permission from the DKMA before a professional relation is established and the company must notify the DKMA of the relation. The affiliation rules apply to the following companies:

- companies with a marketing authorisation valid for Denmark;
- companies with an import or wholesale distribution authorisation from the DKMA;
- authorised representatives of the above; and
- companies established in Denmark that manufacture, import or distribute medical devices in risk class IIa, IIb or III, or in vitro diagnostic medical devices, and representatives of such companies.

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.

Samples of medicinal products

Free samples of medicinal products may by supplied on the following terms:

- Medicinal product samples may be supplied only to doctors, dentists and veterinarians and only to the extent that these persons are entitled to prescribe the medicinal product, and its use is permitted in the course of the activities pursued by them in their capacity as a doctor, dentist or veterinarian.
- Only one sample of each medicinal product must be supplied in any one year to any one doctor, dentist or veterinarian. If the medicinal product is available in several pharmaceutical forms and strengths, one sample of each form and strength may be supplied.
- The medicinal product sample must be no larger than the smallest pack size available on the market.
- The pack must be labelled 'Free medicinal product sample – not for resale'.
- Medicinal product samples must be supplied only in response to a written request, signed and dated, from the recipient.
- Medicinal product samples may only be supplied by the marketing authorisation holder or a representative. Samples must not be supplied from a pharmacy.
- Every medicinal product sample must be accompanied by the medicine's summary of product characteristics.
- Samples of medicinal products covered by the Danish Act on Euphoriant Substances must not be supplied.

A sample can be supplied only in response to a written request from a doctor. The request must be dated and signed by the doctor. A signature by the doctor's secretary would not be sufficient.

Gifts or monetary donations to HCPs

The Advertising Order prohibits the provision of economic benefits to HCPs for promotional purposes or otherwise to promote a pharmaceutical product or medical device.

The prohibition does not apply to

- Gifts of professional utility and insignificant value (approximately DKK 300 in aggregate annual value per calendar year is generally considered insignificant value). A gift includes loan of a medical device free of charge with the exception that a medical device may be provided for demonstration for up to two months. Discounts on purchase of medical devices are not considered an economic benefit when the discount is agreed upfront.
- Remuneration for professional services performed by HCPs is allowed if the payment is reasonably proportionate to the service. The payment should be direct and not through reimbursement, payment in kind, or other indirect means. If a company pays an HCP for a service, both the company and the HCP must notify the DKMA of the affiliation.
- Hospitality is permitted concerning the payment of direct expenses for meals, travel, accommodation, etc, related to the advertising or professional information about medicinal products or medical devices. However, expenses for activities with purely entertainment purposes, such as purely social or cultural events, are not allowed.
- Professional information and education, including payment of direct expenses for relevant conferences, courses, and supplementary education attended or conducted by HCPs, are permissible. The activities must provide information on medicinal products, medical devices or other content professionally relevant to HCPs.

In general, any transfer of value must be reasonable in level and strictly limited to the main purpose of the activity.

The rules on economic benefits to HCPs also apply to owners and managerial staff in the business of selling, offering advice about, and purchasing, pharmaceutical products or medical devices.

MedTech Europe's Code of Ethical Business Practice at Chapter 9 regarding Demonstration Products and Samples applies. Further, Chapter 8 of the Code regarding Educational Items and Gifts applies.

We note that the ENLI Promotion Code has stricter rules, with respect to gifts meals and permitted venues, than Danish legislation. According to the Promotion Code, it is not allowed to supply, offer or promise HCPs

gifts or financial benefits, either in the form of cash, cash equivalents, personal services or benefits. The prohibition is subject to exceptions in articles 13 to 15, regarding professional events, sponsorships, hospitality, information and educational material, medical equipment and the use of professional services.

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

See Question 13 above.

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?

Donations may be considered a promotional tool, depending on the subject matter of the donation agreement, whether the donation was provided following an unsolicited request and the extent of the pharmaceutical company's influence on the project for which the donation was made.

Donations are regulated in the ENLI's Donation Code.

Further, MedTech Europe's Code on Ethical Business Practice Chapter 4 regarding Grants and Charitable Donations applies in regard to medical devices.

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?

The below assumes 'pharmaceutical laboratories' refers to manufacturers of pharmaceutical products.

Pharmaceutical manufacturers and medical device manufacturers and their licensees may support HCPs' scientific or educational meetings, by either sponsorships or by providing the education:

- representation in the form of payment of the direct costs of meals, travel, accommodation, etc, in connection with advertising and professional information about medicinal products or medical devices and other professionally relevant information; and
- professional information and training, in the form of payment of the direct costs of professionally relevant courses, conferences, continuing education, etc, in which HCPs participate or organise. These activities must include pharmaceutical information or other professional information that is professionally relevant to the participants.

The support must be notified to the DKMA, by both the company and the HCP, if the support is provided by one of the following companies:

- companies with a marketing authorisation valid for Denmark;
- companies with an import or wholesale distribution authorisation from the DKMA;
- authorized representatives of the above;
- companies established in Denmark that manufacture, import or distribute medical devices in risk class IIa, IIb or III, or in vitro diagnostic medical devices, and representatives of such companies.

Pharmaceutical manufacturers and medical device manufacturers and their licensees may furthermore sponsor meetings with relevant professional information and activities, hosted by HCPs for the benefit of the general public.

The support is furthermore subject to the rules laid down in MedTech Europe's Code on Ethical Business Practice Chapters 1 to 3.

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

A patient organisation must publish financial benefits, including sponsorships, payments in kind, funding, etc, received from the industry on their website. The amount must be specified in each amount and contributor. The information must be available on the website no later than one month after having received the advantage and be available for at least two years. This applies to both pharmaceutical companies and medical device companies.

The relationship between industry and patient organisations is regulated in the Advertising Order, the MD Advertising Order and ENLI's Patient Organisation Code.

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?

Promotional activities targeting HCPs and involving the engagement of healthcare and patient organisations may be delegated through service agreements to third parties, such as consultancy, advertising, or communication agencies.

Third parties like consultancy service companies acting on behalf of the pharmaceutical companies are also defined as 'Pharmaceutical companies' in the Promotion Code, and thus the relevant rules apply.

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

Yes. Beyond transfers of value such as fees for consultancy services, HCPs and companies must report to the DKMA, when a company has paid hospitality expenses in connection with the HCP's participation in a professional activity or congress, whether in Denmark or abroad. This applies to the following companies:

- companies with a marketing authorisation valid for Denmark;
- companies with an import or wholesale distribution authorisation from the DKMA;
- authorised representatives of the above; and
- companies established in Denmark that manufacture, import or distribute medical devices in risk class IIa, IIb or III, or in vitro diagnostic medical devices, and representatives of such companies.

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 public authorities can order the company to cease the advertisement or report an infringement to the police, which can then propose the company to settle the offence by payment of a fine. If the company refuses the fine, the state prosecutor will initiate enforcement at the city court. The public authorities actively impose penalties and other sanctions. These penalties and sanctions are not publicly announced but may be disclosed following successful freedom-of-information requests.

ENLI can sanction members following ENLI's Penalties and Fees Regulations.

ENLI may sanction the companies by a fine (in the range of DKK 30,000–300,000), a warning or by issuing a public reprimand to a company for breaches of the rules.

ENLI also has the authority to instruct affiliated pharmaceutical companies to correct inaccurate information, withdraw illegal advertising material, issue a corrective statement or cancel a planned event.

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?

The DKMA is responsible for the enforcement of rules governing the advertising of pharmaceuticals and medical devices. ENLI is responsible for the enforcement of ENLI's codes governing the advertising of pharmaceuticals targeting HCPs. ENLI only has competence when companies have acceded to ENLI jurisdiction. The rules are generally strictly enforced by both DKMA and ENLI.

Competitors may also take direct action by filing a complaint on infringement to DKMA, to the national courts or at ENLI.

Medicoindustrien has also established a Report Panel, to which members can complain about other members' potential infringement of the codes. The decisions by the Panel are publicly available.

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?

In general, there has been an increased public attention on the pharmaceutical sector, which has, among others, resulted in increased press attention. Besides an increased activity from the press, ENLI has also experienced an increased number of anonymous complaints from member companies, which ENLI has taken into considerations.