## PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

**Authors:** Marie Vaale-Hallberg

### 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 advertisement of pharmaceuticals are regulated in the Medicines Act (LOV-1992-12-04-132) (the 'Medicines Act') and the Regulation on Pharmaceuticals for Humans (FOR-2009-12-18-1839) (the 'Regulation on Pharmaceuticals').

The promotion and advertisement of medical devices are regulated in the Act on Medical Devices (LOV-1995-01-12-6) (the 'MDR Act') and the Regulation on Medical Devices (FOR-2021-05-09-1476) ('MDR Regulation'). Norway is a party to the European Economic Area (EEA) Agreement, and the two European Union regulations for medical devices: Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) are both incorporated into the MDR Act and MDR Regulation.

Furthermore, the Marketing Control Act (LOV-2009-01-09-2, the 'Marketing Control Act') applies to all marketing, regardless of product category, and is also applicable to pharmaceuticals and medical devices. The Marketing Control Act sets out the general principles, such as prohibitions against unfair commercial practices, misleading marketing and aggressive commercial practices, and also a documentation requirement for any claims made.

In addition, the Association of the Pharmaceutical Industry in Norway (Legemiddelindustrien or LMI) has adopted rules regarding advertising for pharmaceuticals; how to provide information about pharmaceuticals, health and disease; and how the industry may interact with health professionals and patient organisations (the 'LMI Code') (2023 version). The LMI Code is based on the regulations made by the European Federation of Pharmaceutical Industries and Associations. As for medical devices, Melanor (the Norwegian trade organisation for developers and suppliers of medical devices) has adopted a similar code of ethics applicable to its members (the 'Melanor Code').

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

It follows from the Marketing Control Act that an advertisement is commercial communication made by a trader and is directly connected to the promotion, sale or supply of a product to consumers.

A specific definition applies to 'advertising of pharmaceuticals' in the Regulation on Pharmaceuticals, section 13-1, in which 'advertising of pharmaceuticals' is defined as any form of outreach information activities, campaigns, influencing activities/incentivising and other measures intended to promote the prescription, dispensing, sale or use of pharmaceuticals. This is based on the definition of 'commercial practices' in Directive 2005/29/EC, Article 2 (d).

Further, the LMI Code provides examples of what is deemed 'promotional material' pursuant to the LMI Code.

There is no legal distinction in Norway between the terms 'promotion' and 'advertisement' of pharmaceuticals and medical devices. Both terms cover activities and measures that are initiated to market one's product or service.

**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 Norwegian Medical Products Agency (Direktoratet for medisinske produkter) enforces the rules on the advertisements of pharmaceuticals and medical devices. The Norwegian Medical Products Agency is an agency under the Ministry of Health and Care Services. The Marketing Control Act is enforced by the Consumer Authority.

Within the limitations following Norway's obligations to incorporate EEA-relevant legislation, the legislative power vests in Parliament or may be delegated by law to the Ministry of Health and Care Services (further delegation is also possible under the circumstances).

The supervisory and enforcement function of the Norwegian Medical Products Agency is independent from the industry associations, Melanor and LMI. Hence, the self-regulatory process outlined in the codes is only enforced by Melanor and LMI.

**4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?**

It follows from the Medicines Act, section 20, that expressing that a substance, drug or preparation that is not a pharmaceutical is recommended as a means to prevent, cure or alleviate diseases, disease symptoms or pain, or affect physiological functions in humans or animals is prohibited in advertising or similar contexts, through text or images, directly or indirectly. Other products, such as food supplements, food-bearing health and nutrition claims and/or food for special nutritional purposes are defined as food and regulated by other acts and regulations.

**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 (advertisements) in your country and, if so, which ones?**

For pharmaceuticals, there is a distinction between advertising to the general public and advertising to healthcare professionals. Marketing prescription-only drugs to the public is prohibited.

Advertising over-the-counter (OTC) drugs to the general public is allowed, but it must meet certain requirements. First, advertising should be moderate and truthful. Second, an advertisement is only allowed for pharmaceuticals recommended for diseases or disease symptoms that do not require examination or treatment by a doctor or dentist. Furthermore, it is explicitly prohibited to mention serious diseases, such as tuberculosis; sexually transmitted diseases, cancer or other tumour diseases; chronic insomnia; diabetes; or other metabolic disorders, in advertisements. Giveaways of pharmaceuticals to the public are also illegal. There are some exemptions, such as vaccination campaigns launched by the pharmaceutical industry that are approved by the authorities.

As for the more detailed requirements, we mention that advertising to the general public must be designed in a way that clearly indicates that it is an advertisement and that the promoted product is a pharmaceutical. The advertisement must not, for example, suggest that the effects of the pharmaceutical are guaranteed, that it is without side effects, or that it is better than or equally effective as other treatments or pharmaceuticals.

The rules on the advertisement of pharmaceuticals to healthcare personnel are different from the above, and it is generally legal to advertise both OTC and prescription drugs on the condition that certain legal requirements are met; see the response to Question 10.

The promotion and advertising of all forms of medical devices directly to the public (including healthcare professionals) is allowed. For medical devices, there is, as opposed to the advertisement of pharmaceuticals, no distinction between advertising to the general public and advertising to healthcare professionals.

However, any trader must adhere to the general principles that follow from the Marketing Control Act (eg, unfair commercial practices, misleading marketing, aggressive commercial practices and documentation requirements for any claims made).

In addition, any marketing of medical devices must be in accordance with Article 7 of the Regulation (EU) 2017/745 on medical devices (MDR), which has been implemented in Norwegian law. It is thus prohibited to present any claims that may:

- attribute features and characteristics to the equipment that it does not have;
- create a false impression of the treatment or diagnosis, features or characteristics that the equipment does not have;

- fail to disclose a probable risk when using the equipment for its intended purpose; and
- propose a different use of the equipment other than that specified as part of the intended purpose covered by the conformity assessment.

**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?**

There are no rules that specifically target promotion (and advertising) through the internet and social media. Accordingly, the main principles presented in the previous answers also apply to activities carried out on such mediums. The main point is that, any promotional activities are always clearly presented as such (and not disguised as something else, eg, as 'information' or 'a recommendation'). Reference is made to the Norwegian Consumer Authority's guidelines on marketing in social media.

**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 prior approvals from regulators are needed for promotions and/or advertisements as such. However, applicable marking requirements (eg, CE marking) and general requirements for the approval of products must be complied with before the products are marketed to the public.

Further, the holder of the marketing authorisation for pharmaceuticals shall provide (or make available) a copy of any advertisements for pharmaceuticals to the Council for Medicines Information before the use of the advertisement. In practice, any advertisements shall be uploaded to the council's electronic archive.

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

No. According to the Regulation on Pharmaceuticals section 13-3, advertising is only allowed for pharmaceuticals with marketing authorisation in Norway. Any advertising for authorised pharmaceuticals products must comply with the information included in the Summary of Product Characteristics (SmPC) approved by the Norwegian Medical Products Agency. Thus, off-label information cannot be advertised.

**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 Norwegian Regulation on Comparative Advertisements governs comparative advertisements. This regulation implements the requirements in EU Directive 2006/114/EC.

Comparative advertising, including the use of another company's name (and/or brand name) as part of such a comparison is permitted, provided it satisfies the criteria laid down in the regulation. Specifically, as for the use of another company's name and/or brand, one must, for example, ensure that no unfair advantage is taken ('free-riding') and that such names or brands are not discredited or denigrated.

Please note that more restrictive standards are included in the LMI Code in relation to pharmaceuticals. For advertisements aimed at the public, it is not permitted to claim that a pharmaceutical is as good as, or better than, another treatment or pharmaceutical. In addition, indirect comparisons are prohibited (eg, statements such as 'Norway's best-selling drug').

As for comparative advertisement towards healthcare professionals, the LMI Code stipulates that such comparative advertisement must be designed in accordance with the regulations mentioned above.

There are no explicit rules on references to a competitor's product or indication that has not yet been authorised. However, based on the fact that (1) any comparisons made must not be misleading and must compare products available for the same purpose or products that have similar attributes; and (2) advertising is only allowed for pharmaceuticals with marketing authorisation in Norway, we find it generally to be high risk to refer to a product or indication that is not allowed or authorised in Norway. However, this should be assessed on a case-by-case basis.

**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?**

Healthcare professionals are defined in the Health Personnel Act (Act of 2 July 1999 number 64) as follows:

- personnel with specific authorisation or a licence as outlined in the act; and
- personnel in health and care services or in pharmacies who are engaged in any treatment that has a preventive, diagnostic, therapeutic, health-preserving, rehabilitating, or nursing or care-purpose. In addition, students and trainees who, in connection with health-related education, carry out the same actions, fall within the definition.

Chapter 13 of the Regulation on Pharmaceuticals, which is about the marketing of pharmaceuticals, includes a slightly more restricted definition of healthcare personnel. In this chapter, health personnel are defined as physicians, dentists, publicly approved nurses, pharmacists, optometrists and dental hygienists, as well as students in these fields and other professionals appointed by the ministry.

The marketing of pharmaceuticals to this group of health personnel must contain:

- information that is relevant and corresponds to the approved SmPC, as well as dispensing, price and reimbursement;
- the date of creation of the ad or last revision must be indicated;
- information that is accurate, up-to-date, verifiable and sufficiently detailed to allow recipients to form their own opinion on the therapeutic value; and
- when using quotes, tables or other illustrations from medical journals or scientific works, the source must be faithfully cited. Medical journals should undergo peer review, and scientific works should have undergone peer review and publication.

Marketing pharmaceuticals towards other categories of health personnel is not allowed, but, under certain conditions, other health personnel may participate in interdisciplinary meetings where marketing is presented.

Furthermore, the LMI Code, chapter 7, provides detailed requirements for the marketing of pharmaceuticals to healthcare professionals. All marketing should be plain and factual, and promote sensible use in accordance with prescription regulations. The communication must not be misleading or exaggerated. It should be dated and correspond to the SmPC. It must include some mandatory information and be accurate, balanced, honest and objective, as well as sufficiently complete. It should be based on and reflect the most recent evaluation of scientific material and should not be misleading in any way. It must not be claimed that the product has no side effects or carries no risk of creating dependency. The word safe or any other word to that effect may not be used without proper qualification. The word new must not be used for products that have been available for more than one year.

**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 rules that specifically target the promotion (and advertising) conducted virtually. Accordingly, the main principles presented in the previous answers also apply for activities carried out virtually. The main point is that any promotional activities should always be clearly presented as such (and not disguised as something else, eg, as ‘information’ or ‘a recommendation’).

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

It is illegal to include endorsements from healthcare professionals in the marketing of pharmaceuticals towards the public.

The same prohibition does not apply when marketing is directed at healthcare professionals or for the marketing of medical devices (compare above), but the LMI Code, Melanor Code and Norwegian Health Personnel Act may hinder the inclusion of endorsements. In addition, the Medical Association’s Code of Ethics (which must be complied with by doctors) states that a doctor must not enter into commercial relationships with the pharmaceutical industry and/or suppliers of medical devices that could lead to a weakening of confidence in the doctor’s professional assessments. Furthermore, and specifically in relation to a doctor’s involvement in marketing activities, the Code of Ethics states that a doctor must not

advertise or market drugs, medical supplies or other health-related products (however, statements in a professional context, eg, in articles and lectures, and for non-profit purposes, is not regarded as marketing). The Nurses' Association's Code of Ethics has similar provisions, namely that the nurse must not be involved in marketing and commercial activities that weaken the patients' and society's trust in the profession. Violation may lead to sanctions against the clinic and/or the healthcare personnel by the relevant association.

**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.**

According to section 13-11 in the Regulation on Pharmaceuticals and Chapter 21 of the LMI Code, free samples to health personnel may only be provided on the following conditions:

- Samples of prescription drugs may only be provided to healthcare professionals who are qualified to prescribe the product in question.
- Only one sample of the smallest package in each form and strength may be provided per recipient per year.
- Samples may be provided only in response to a written, dated and signed request from the healthcare professional.
- The company must keep a record of recipients of free medical samples, which shall be stored for two years and available for pharmaceutical authorities on request.
- Each sample must be labelled 'Free medical sample – not for resale'.
- The samples must be accompanied by the SmPC.
- Samples of unauthorised pharmaceuticals, products in prescription group A and products containing substances classified as psychotropic and narcotic substances may not be provided.
- Samples of pharmaceuticals may only be provided for the purpose to allow healthcare personnel to familiarise themselves with the product.
- Samples may not be provided later than two years after the product was launched on the Norwegian market.
- Samples may not be provided to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer the product.

According to the Melanor Code, a reasonable number of samples of medical devices may be provided at no charge to healthcare professionals in order to enable them to evaluate and/or familiarise themselves with the product, and help them assess and decide whether to use, order, purchase and/or recommend such a product. Samples of multiple-use products can only be provided for a limited trial period.

Further, the provision of samples of medical devices must not improperly reward, induce and/or encourage healthcare professionals to purchase, lease, recommend, prescribe, use, supply or procure the company's products or services. The company shall maintain appropriate records for samples provided. Samples may also be provided to healthcare professionals for the purpose of the third-party evaluation of medical devices under a written contract.

When marketing pharmaceuticals to health personnel giving, offering or promising gifts, financial benefits or benefits in kind are prohibited, unless they are of negligible value and connected to the relevant health personnel's business (compare section 13-10 of the Regulation on Pharmaceuticals).

More strict rules follow from the LMI Code, chapter 11, in which it is stated that to give, offer or promise gifts, personal favours or pecuniary advantages to healthcare professionals is not allowed. This also includes inexpensive promotional items. Information and educational material may be distributed to healthcare professionals if the material is of low value and of direct significance for treatment. The same applies for medical utilities.

There are also limitations in the Norwegian Health Personnel Act, section 9 and the Norwegian Regulation on Limitations for healthcare personnel to receive gifts, commission or similar services and/or payments. The main rule is that health personnel shall not receive gifts, commission or other services that are eligible to affect the health personnel acting in a professional capacity in an undue or improper way.

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

It follows from the Regulation on Pharmaceuticals section 13-10 that representation in connection with advertising activities for pharmaceuticals must be kept at a reasonable level and be strictly subordinate to

the main purpose of the meeting and must not include persons other than the healthcare personnel.

LMI Code section 16.2 states that hospitality offered by pharmaceutical companies is only allowed in connection with events organised by the company. Such events should be held at an appropriate venue and destination (as a main rule in Norway), and not at destinations associated with leisure and sporting activities or which have a reputation for being extravagant.

Hospitality must be limited to travel, meals and accommodation. Hospitality offered must be reasonable in scope and size and a prerequisite for the professional programme. Special rates apply for meals. The professional programme must be of a certain duration and there are limitations as to the type of activity. Hospitality must not be given or offered in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a pharmaceutical.

According to the Melanor Code, medical device companies may provide reasonable hospitality to healthcare professionals in the context of company events and third-party organised events when they are attending the event in person, but any hospitality must be subordinate in time and focus to the event purpose. No home delivery, for example, is permitted. Accommodation should not be at the top category or luxury hotels and not for a period of stay beyond the duration of the event.

**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?**

Yes, there are rules on donations from pharmaceutical companies in LMI's rules chapter 17. Donations may only be made to healthcare organisations where the purpose is to contribute to medical research or improved patient treatment. Donations to individual persons are not permitted, however, a pharmaceutical company may pay for, or contribute to, grants and prizes that will be granted to individuals if certain conditions are met.

The donation must be made for a clearly defined purpose and not for the general operation of the healthcare organisation. It may only be given after an application from the healthcare organisation and must be governed by a written agreement, clearly stating what the donation comprises, as well as the donation and other non-financial contributions, before it is granted.

Documentation of the donation must be kept by the company for a minimum of five years and the company must publish any financial contributions made.

Donations may not be granted in order to unduly influence a decision to recommend, prescribe, purchase, supply, sell or administer a pharmaceutical.

Rules regarding donations from medical device companies are found in the Melanor Code, chapter 4. Donations shall not be contingent on any purchase, recommendation, prescription, use or supply of the medical device company's products. Donations may not be granted to individual healthcare professionals; they must be granted directly to the healthcare organisation. The decision or approval of donations shall not be made by the sales and/or commercial function of the company. Prior to any decision to provide a donation, the company shall evaluate the appropriateness of the donation. The evaluation shall be documented.

All donations must be documented. Donations may only be granted in response to a written request. There are detailed requirements regarding the content of the request and the agreement.

**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?**

According to the LMI Code, chapter 15, courses and professional meetings organised by health authorities should be arranged without contributions from pharmaceutical companies. However, pharmaceutical companies may contribute to lectures at internal courses organised by health authorities. Pharmaceutical companies may also, with some exceptions and provided that some requirements are fulfilled, be co-organisers together with health authorities of professional meetings, courses, congresses or similar.

According to the Melanor Code, medical device companies may invite and, in some cases, pay the costs of attendance of healthcare professionals at company events, such as product and procedure training, and education events and sales, promotional and other business meetings, provided the event complies with some general criteria for events.

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

According to the LMI Code, collaboration between pharmaceutical companies and patient organisations may take place provided that: (i) the patient organisation maintains its independence; (ii) the collaboration is based on mutual respect; (iii) the company must not collaborate with a motivation to unduly promote sales, or use or promote a product; (iv) the purpose of the collaboration must be publicly available; (v) the company must encourage the organisation to seek multiple sources of income; and (vi) collaborations must be in agreement with chapter 11 on gift prohibition and chapter 12 on information and education materials and aids.

All companies must have an internal approval process for collaborations with patient organisations.

There are three different forms of approved collaborations: (1) collaboration on patient-related projects; (2) a pharmaceutical company may advertise (at market value) in the organisation's magazine or website; and (3) the pharmaceutical company can purchase a stand at a patient organisation event. Exclusive deals are prohibited. Profit from such collaborations may not exceed certain limits related to the organisation's budget.

**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?**

There are no specific rules governing access to delegate such activities. The general rules referred to in the previous answers apply.

According to the Regulation on Pharmaceuticals, the Norwegian Medical Products Agency shall not prohibit co-promotion of a pharmaceutical by those who hold the marketing authorisation and one or more partner companies.

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

Yes, according to an agreement between the LMI and the Norwegian Medical Association (NMA), all transfers of value from pharmaceutical companies to healthcare professionals must be made public by the company. The companies must follow the European Federation of Pharmaceutical Industries and Associations' rules, Code of Practice, chapter 5.

**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 violation of the provisions of the MDR Act and MDR Regulation, and the Medicines Act and Regulation on Pharmaceuticals, as well as the Marketing Control Act, may be sanctioned (civil or criminal), and illegal advertising can thus result in compulsory fines and penalty fees, either as:

- daily fines until correction (civil);
- one-time fine (civil); and
- criminal fine or imprisonment (up to three months).

The Norwegian Medical Products Agency can impose penalty fees of up to 2G for private individuals (which amounts to NOK 237,240 as of May 2023) and 15G for businesses (equivalent to NOK 1,779,300 as of May 2023). The penalty will depend on the assessed severability of the offence.

Daily fines should be set to an amount that encourages the entity's adherence to any decision made. We are not aware of cases of daily fines imposed based on the medical device regulation. The violation of the advertising ban for pharmaceuticals has, in 2023, been met with daily fines in the amount of NOK 2,000–10,000 each day until correction.

Further, the Norwegian Consumer Authority can issue fines for violation of the Marketing Control Act, either as daily fines until correction or a one-time fine. One-time fines can amount to up to four per cent of the annual turnover or up to 24m (whichever is the highest).

**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 Norwegian Medical Products Agency is responsible for enforcement of the rules governing medical devices and pharmaceuticals. The Norwegian Consumer Authority is responsible for the enforcement of general rules on advertising and promotional activities pursuant to the Marketing Control Act (and affixed regulations).

Provisions protecting the interest of traders are included in the Marketing Control Act. According to these provisions, no act shall be performed in the course of trade that conflicts with good business practice among traders, and misleading representations are prohibited. Any trader (competitor) can bring before the courts a case against another trader concerning the violation of these provisions.

Finally, any complaints on violations of the LMI Code and Melanor Code can be submitted to the Council for Medicines Information and Melanor's Ethical Council, respectively. Through the companies' membership in these organisations, the companies have also accepted that the organisations have the authority to issue sanctions (eg, warnings, order on correction, economic fines and, ultimately, exclusion).

**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?**

The reform of EU pharmaceutical legislation that is currently ongoing is also expected to affect Norway to the extent that it is considered EEA relevant.