Industry Rules for marketing of medicinal products for fish

Adopted by the Pharmaceutical Industry's (LMI) General Assembly on March 23rd2012 and last amended at the General Assembly March 24th2021.

Chapter 1 Purpose and scope

The main task of the pharmaceutical industry is to develop new and effective medicinal products, to improve existing medicinal products, and make them known in such a way that they safeguard fish welfare, as well as public health and benefit the individual patient.

The member company shall provide animal healthcare professionals with relevant, trustworthy, and complete information about the medicinal products the member company markets for the use for fish.

All members of LMI are obliged to comply with these rules. The document summarises regulatory requirements and industry standards related to the marketing of pharmaceuticals.

Chapter 2 Definition of advertising

Advertising of medicinal product:

By the term advertising of medicinal products, means any form of outreach/pro-active informational activities, campaigns, influencing, and other measures intended to promote the prescribing, providing, sales or use of medicinal products.

The definition does not include:

• labelling, package leaflet or summary of product characteristics (SmPC) approved by the issue of a marketing authorization,

• correspondence, including any plainly designed material of non-advertising marketing nature that is needed to answer specific and unsolicited questions from a healthcare professional (HCP) about a particular medicinal product,

• facts and information on changes in package sizes,

• side effects warnings as part of pharmacovigilance,

• sales catalogue and price list, that does not contain any claims about the medicinal product,

• diseases awareness information, provided that neither one nor more medicinal product(s) is directly or indirectly linked to,

• technical instructions for use if it only reproduces the package leaflet,

• execution of vaccine checks.

Chapter 3 General provisions

Advertising for medicinal products must be plain and factual. It must promote rational use according to current prescribing rules. Promotional materials must not give a misleading or exaggerated image of a medicinal product's properties and medicinal value. Promotional materials must not lead to use of the medicinal product that is not medically justified.

The advertisement must correspond with the SmPC approved by the Norwegian Medicines Agency.

Advertising is only permitted for medicinal products that have been approved and for which a marketing authorization has been granted. Advertising for medicinal products that are sold with an approval exemption and advertising for pharmacy-produced medicinal products not included in the approved material, is prohibited.

Advertising must never undermine the public's faith in the pharmaceutical industry.

Information regarding new, serious side effects or contraindications, restrictions regarding indications and decision to deregister due to side effects, delivery problems or changes in retention time, must be sent separately to prescribers and pharmacies. The term "Dear healthcare professional letter" (DHPL) must only be used for such mailings. Deregistration shall, when general considerations require, always be notified to prescribers and pharmacies. All deregistrations must be justified.

All marketed medicinal products must be listed in the Felleskatalogen.

These rules do not prevent a company from obtaining an exemption from the Norwegian Medicines Agency pursuant to Chapter 13 of the regulations, for medicinal products for animals when general considerations or considerations of animal health so require.

Chapter 4 Advertising aimed at the public

Advertising for medicinal products aimed at the public is only permitted for non-prescription medicinal products or medicinal products in packages that are exempted from the prescription requirement, when these are only recommended for diseases, or disease symptoms, that will not normally require examination or treatment by a veterinarian or fisheries biologist.

Such advertising must not contain recommendations from a veterinarian, fisheries biologist, or others who, by virtue of their position, may encourage the use of medicinal products.

Illustrations must only convey information about the medicinal products properties and use in an unbiased way, without overexaggerating its effects. Illustrations must not be misleading or draw upon exaggerated effects.

When advertising to the public, it is not permitted to mention serious illness. It is not permitted to enclose advertising for medicinal products in addition to the approved package leaflet in product packages. It is not permitted to link advertising to items, gifts, prizes, or any other form of reward.

Distribution of free samples to the public is prohibited.

More detailed requirements for content in advertising to the public

Advertising to the public must be designed in such a way that it is obvious that it is advertising, and that the medicinal product being advertised is clearly identified as a medicinal product.

The following information must always be included in advertising to the public:

a) the name of the medicinal product, as well as the name of the active substances,

b) information that is necessary for the correct use of the medicinal product, including the area of use and important precautions and warnings. For medicinal products for animals, it must be stated which animal species are included.

c) encourage user to read the package leaflet and information on the package.

Advertising of medicines to the public must not contain material that:

• gives the impression that it is not necessary to consult a veterinarian or fisheries biologist or other HCPs, or have a surgical procedure performed, by offering a diagnosis or recommending treatment by correspondence,

• imply that the effects of the medicinal product are guaranteed, that it has no side effects or that it is better than or as good as any other treatment or medicinal product,

• imply that the health of an animal can be improved by taking the medicinal product,

• imply that an animal's health may be affected by not taking the medicinal product, except for vaccination campaigns,

• exclusively, or mainly, address children,

• refer to recommendations from researchers, HCPs, or persons who are neither researchers nor healthcare professionals, but by virtue of their reputation can promote the use of a medicinal product,

• imply that the medicinal product is on a par with food, cosmetics, or another commodity,

• imply that the safety of the medicinal product or its effect is based on the product being natural,

• by description or a detailed presentation of a case of illness can lead people to make incorrect diagnoses themselves,

• in an excessive, intimidating, or misleading way refer to claims of healing,

• in an excessive, frightening, or misleading way use visual representations showing changes in the body caused by illness or injury, or of the effect of a medicinal product.

Chapter 5 Advertising aimed at animal healthcare professionals

Advertising for prescription-only medicinal products must only be directed at veterinarians, fisheries biologists, as well as students in these subjects and other subject groups in accordance with the Ministry's further provisions.

The advertisement must contain:

a. relevant information that is complete and that complies with the SmPC approved by the Norwegian Medicines Agency,

b. the dispensing provision of the medicinal product.

The advertisement may alternatively be promoted as a reminder and shall then contain only the name of the medicinal product, active substance, and the name of the marketer.

Further documentation of the medicinal product's properties and effects must be provided by referring to valid scientific references.

Valid references in advertising are package leaflets or scientific works, such as articles in medical journals that are available to the recipient of the advertisement. Scientific works must, in order to be used as a valid reference, be peer-reviewed, and published.

When advertising refers to studies, surveys, articles, etc. which have been published, these must be reproduced correctly, and clear references must be given as to where they can be obtained.

All material used in the marketing of a medicinal product must state the date when it was prepared or last revised.

Guidelines - advertising aimed at animal healthcare professionals

By "relevant" means that the information is adapted to the purpose and target group of the advertisement.

By "adequate" means that the mandatory information must be comprehensive and complete enough for the advertisement to be understood and contribute to the correct use of medicinal products.

"Complies with Summary of Product Characteristics" means that the advertisement must be in accordance with the information in the SmPC.

LMI considers that the industry practice which has been to include the Felleskatalog-text in the advertisement, is no longer necessary.

To ensure balanced advertising, parts of mandatory information, e.g., indication and contraindication, will often be integrated into the key part of the advertisement. Other mandatory information must be placed clearly visible. If one chooses to write mandatory information as a separate text section in the advertisement, it must be ensured that the key message of the advertisement appears balanced. Information that is highlighted elsewhere in the advertisement does not need to be repeated in the text section.

What is to be regarded as mandatory information, and thus be included in the advertisement, must be considered specifically in each individual case. It is recommended that the following is included:

- *Name and active substance of the medicinal product*
- *At least one approved indication. When advertising for specific indication (s), the rest of the mandatory information must relate to this indication (s).*
- *A brief summary of the dosage and usage relevant to the indications included in the advertisement. If it is not obvious, include the form of administration.*
- *A brief description of the most common side effects, as well as relevant, serious side effects.*
- *Warnings / precautions and contraindications relevant to the indications.*
- *Any warnings, such as the black triangle, required to be included in advertisements by national or international authorities.*
- *Prescription group (A, B or C).*
- *If the medicinal product has particular prescribing rules, this should be included.*
- *An encouragement to consult the Felleskatalog-text or the SmPC for more information.*
- *Marketer's name and contact information.*
- *Date of design of the advertisement.*

<u>Dispensing provision</u>

By the term dispensing provision, means that one must include a dispensing provision that is imposed on certain medicines, see information on the Norwegian Medicines Agency's website.

Participation in interdisciplinary meetings with advertising for prescription pharmaceuticals

Other animal healthcare professionals than veterinarians and fisheries biologists may participate in interdisciplinary meetings where prescription medicinal products are being advertised, if (i) a veterinarian or fisheries biologist participates, and (ii) the employer considers that there is a professional need for participation.

Guidelines: Participation at interdisciplinary meetings

By other animal healthcare professionals means personnel who perform independent tasks under the veterinarian's responsibility or personnel who have other tasks within private and public animal healthcare work, such as veterinary assistants, para-veterinary workers ("dyrepleiere"), blood samplers, vaccinators, and inseminators.

Chapter 6 Prohibition of undue influence on animal Healthcare Professionals

Advertising to animal healthcare professionals must not be associated with the distribution of items, gifts, services, prizes, or any other form of benefits of economic value.

This prohibition does not preclude the distribution of objects of insignificant value which are connected to the recipient's professional practice.

Chapter 7 Events and Hospitality

Hospitality offered to animal healthcare professionals must be reasonable in scope and size and a pre-requisite of the professional program. Hospitality must be limited to travel, meals, accommodation, and necessary participation fees.

Hospitality must not exceed what the recipient normally would have paid if the recipient had paid themselves.

The following also applies:

a. For dinner and lunch, the State's representation rates must not be exceeded.

b. Alcohol serving in addition to beer or wine with food is prohibited.

c. It is prohibited to arrange for tickets to be used, in whole or in part, for leisure purposes.

d. Hospitality shall never include sponsorship or organisation of entertainment or social activities.

e. The company is obliged to specify which costs are covered.

f. Companies must complete a protocol of their activities. The protocol must contain all academic and non-academic program and a specification of what is covered. The A protocol template prepared by the Committee for Information on Medicinal Products (The Committee) must be used. This information must be kept with the company for two years after the event. The Committee may require access to the Protocol.

Pharmaceutical companies must not arrange or sponsor an event unless the location of the organizer, expertise and the participants whereabouts justify holding the event at the destination, and that an overall assessment indicates that the destination is considered reasonable and relevant.

The following applies to the use of animal healthcare professionals as consultants and the purchase of exhibition space:

The pharmaceutical company must ensure that there is transparency about activities and consultancy agreements that have been entered into with animal healthcare professionals or groups of animal healthcare professionals. Assignments and agreements for purchase of advertisements, exhibition space, etc. must be agreed in writing.

Chapter 8 Requirements for the distribution of free samples

The following rules apply to distribution of free medical samples:

- Free medical samples must be provided to veterinarians and fisheries biologists only. For prescription-only medicinal products, only free samples of those medicinal product that the individual is entitled to prescribe can be provided.

- Free sample must only be provided after a written and signed request from a veterinarian or fisheries biologist.

- Only one sample of the medicinal product can be dispensed per year per veterinarian or fisheries biologist. If the medicinal product is available in several forms or strengths, one sample of each form and strength can be provided. Each sample shall be identical to the smallest presentation on the market.

- Each sample must be marked: "Free medical sample - not for sale".

- The SmPC must be attached.

- Samples of non-approved medicines must not be provided.

- No samples of prescription group A medicinal products, nor of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, may be provided.

- The member company must keep an overview of the medicinal samples that have been provided. These lists must be stored for two years and submitted to the Norwegian Medicines Authority upon request.

Chapter 9 Employees in the pharmaceutical business

Employees in the pharmaceutical industry must be given adequate training by, or on behalf of, the company where they are employed and must have sufficient professional knowledge to be able to present information about the company's products in an accurate and responsible manner:

a. They must act in accordance with LMI's industry regulations, national rules, and regulations.

b. They must perform their duties ethically and responsibly.

c. During each visit, employees in the pharmaceutical industry must, in accordance with national legislation, make available the SmPC of the medicinal product presented.

d. They must immediately notify their company of any information they may receive in relation to the use of the medicinal product they are presenting, and in particular, information on side effects.

e. Employees in the pharmaceutical industry who supply medicinal products for fish must, always satisfy the current requirements for knowledge and training. The board of the LMI determines the terms.

Chapter 10 Control and sanctions

Marketing of medicinal products to use for fish is subject to control and sanctions by the Committee.