REGULATION

on the advertising of medicinal products.

SECTION I
Definitions, scope and general provisions.

Article 1
Definitions.

For the purposes of this Regulation, the following terms are used as defined below:

a. *Advertising of medicinal products*: Any type of advertising or promotional activity, whether written or oral, in the form of images, the supply of samples, or promotional events and meetings, which is sponsored, directly or indirectly, by the holders of marketing authorisations for the purpose of promoting the prescription, supply, sale or consumption of medicinal products.
b. *Medicinal products subject to medical prescription* (*Prescription-only medicines*): Medicinal products that may only be made available on production of a medical prescription.
c. *Non-prescription medicinal products*: Medicinal products that may be made available without production of a medical prescription.

Article 2
Scope.

This Regulation applies to medicinal product advertisements, their contents and their publication. It applies to medicinal products for both humans and animals unless otherwise stated.

This Regulation does not apply to:

a. labelling on the outer and immediate packaging of medicinal products or their accompanying leaflets,
b. the provision of information necessary to answer questions about a particular medicinal product that does not constitute advertising or promotional activity (cf. point a of the first paragraph of Article 1),
c. announcements and correspondence relating to changes in packaging, warnings about adverse reactions, trade catalogues and price-lists, providing these include no claims regarding the qualities of the product,
d. information about human or animal health or diseases which does not include references (direct or indirect) to medicinal products,
e. announcements by the authorities concerning medicinal products, e.g. those that are published on the homepage of the Icelandic Medicines Agency.

Article 3
Medicinal products that may not be advertised.

The following may not be advertised.

1. Medicinal products for which marketing authorisations have not been granted in Iceland (cf. the first paragraph of Article 7 of the Medicinal Products Act, No. 93/1994, with subsequent amendments).
2. Medicinal products subject to medical prescription for which marketing authorisations have been granted in Iceland but which are not listed in the Medicinal Products Price List and the Proprietary Medicinal Products Register.
3. Specially prepared (‘magistral formula’) medicinal products ordered by physicians and veterinarians (cf. indent 4 of the first paragraph of Article 5 of the Medicinal Products Act, No. 93/1994, with subsequent amendments).
4. Standardised (‘officinal formula’) medicinal products (cf. indent 5 of the first paragraph of Article 5 of the Medicinal Products Act, No. 93/1994, with subsequent amendments).

5. Medicinal products, the importing of which to Iceland has been authorised by the Icelandic Medicines Agency (cf. the seventh paragraph of Article 7 of the Medicinal Products Act, No. 93/1994, with subsequent amendments).

Without prejudice to point 2 of the first paragraph, medicinal products subject to medical prescription for which Icelandic marketing authorisations have been granted and which are not listed in the Medicinal Products Price List and the and the Proprietary Medicinal Products Register may be advertised if a price has been approved for the product under Section XV of the Medicinal Products Act, No. 93/1994, with subsequent amendments and the Icelandic Medicine Pricing and Reimbursement Committee confirms that information about the product will appear in the next edition of the Medicinal Products Price List and the Proprietary Medicinal Products Register.

Article 4

General requirements regarding medicinal product advertisements.

Medicinal product advertisements shall give true and professional information about the products. All information in the advertisement shall be clear and easy to read or hear. All information in a medicinal product advertisement shall furthermore be in accordance with the approved summary of product characteristics (SmPC, SPC).

A medicinal product advertisement shall encourage the sensible use of the product by advertising it in an impartial manner and without undue claims for its properties. Medicinal product advertisements may not be misleading.

All information in a medicinal product advertisement shall be set up or read in such a way that those in the target group for which the advertisement is intended are easily able to read or hear it, or understand the information in another manner.

SECTION II

Advertising of medicinal products to the general public.

Article 5

Advertising of medicinal products to the general public.

Non-prescription medicinal products may be advertised and promoted to the general public.

Medicinal product advertisements to the general public shall be set out in such a way as to make it clear that they are advertisements and that the product being advertised is a medicinal product.

The Icelandic Medicines Agency may authorise medicinal product advertisements concerning vaccination measures that the minister has decided to take (*cf.* Article 12 of the Health Security and Communicable Diseases Act, No. 19/1997, with subsequent amendments).

Article 6

Information in medicinal product advertising to the general public.

Medicinal product advertising for the general public shall contain at least the following information:

1. The name of the medicinal product, together with the common name if the product contains only one active substance.
2. Packaging sizes.
3. One or more indications for the use of the product.
4. Information necessary for the correct use of the product.

In addition to the information required under the first paragraph, the following message shall appear: “Before using this product, read carefully the information in the information leaflet and on the outer packaging. If you need further information about risks and adverse reactions contact a physician or a pharmacist. For further information about this product, see www.serlyfjaskra.is.”

If a medicinal product advertisement for the general public takes the form of a motion picture, and other messages in the advertisement are set forth both in sound and images, then the message as required under the second paragraph shall be set forth visually and read out. If a medicinal product

advertisement for the general public is set forth only aurally, then the message as required under the second paragraph shall be read out.

In cases where veterinary products are approved for use for more than one animal species and a product advertisement intended for the general public only mentions its use for one of these species, the advertisement may contain information on its use for that specific species only.

Article 7

Name advertisements.

An advertisement to the general public (*cf.* Article 5) may contain only the name of the medicinal product if the intention is intended solely to draw attention to the product name.

Article 8

Particular requirements.

Advertising of medicinal products to the general public may not contain any material which

1. gives the impression that it is not necessary to consult a physician or veterinarian;
2. gives the impression that a surgical operation is unnecessary;
3. gives the impression that the effects of the medicinal product are guaranteed, that they will not be accompanied by any adverse reactions or that they are better than, or equivalent to, those of another treatment or medicinal product;
4. suggests that the health of the subject can be enhanced by taking the medicine;
5. suggests that the health of the subject could deteriorate as a result of not taking the medicine;
6. is directed exclusively or principally at children;
7. refers to recommendations by scientists, healthcare professionals or individuals, non-governmental organisations or undertakings which are neither scientists nor professionals but could encourage the use of medicinal products, e.g. through the general recognition or celebrity which they enjoy;
8. suggests that the medicinal product is a food, cosmetic or other consumer product;
9. suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
10. could lead to erroneous self-diagnosis;
11. refers, in improper, alarming or misleading terms, to claims of recovery;
12. uses, in improper, alarming or misleading terms, pictorial representations of changes in the human or animal body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

Point 5 of the first paragraph shall not apply to advertisements of vaccination campaigns (*cf.* the third paragraph of Article 5) approved by the health authorities.

SECTION III

Advertising of medicinal products to healthcare professionals and veterinarians.

Article 9

Advertising of medicinal products to healthcare professionals and veterinarians.

Prescription-only medicinal products may only be advertised and promoted to physicians, dentists, veterinarians, nurses, pharmacologists, pharmacy technicians and students in these disciplines.

The contents and manner of presentation of advertising to physicians, dentists, veterinarians, nurses, pharmacologists, pharmacy technicians and students in these disciplines shall be such that it is unlikely that the advertising will be seen by the general public.

Article 10

Information in advertising of medicinal products to healthcare professionals and veterinarians.

All information in advertising of medicinal products under Article 9 shall be in accordance with the valid summary of product characteristics. The medicinal product advertisement shall contain the following information.

1. The name, strength and pharmaceutical form of the product.
2. The names of all active substances, prominently displayed.
3. The name of the holder of marketing authorisation.
4. Approved indications and contraindications regarding the use of the product.
5. Information on the animal species for which the product is intended and, if appropriate, information on the period by which utilisation must be deferred in the case of advertisements for veterinary medicinal products.
6. The packaging size(s) marketed.
7. The text [in Icelandic] "Information on adverse reactions, interactions, warnings and other important matters can be found in the Proprietary Medicinal Products Register – www.serlyfjaskra.is" shall be prominently displayed.
8. The date of the last approved summary of product characteristics.
9. If appropriate, a clear statement to the effect that marketing authorisation for the product is conditional on the supply of informative material with which any person prescribing the product must have acquainted himself and, if appropriate, made known to the patient, and also by a demand that the patient be provided with certain informative material before use of the product commences. It shall also be stated where the informative material can be obtained from the marketing authorisation holder.
10. Prescription permissions and legal classification of sale and supply.
11. The maximum permitted retail price.
12. The proportion of the cost borne by the health insurance system.
13. Clear directions on how the marketing authorisation holder, or his representative who will give information about the product, can be contacted.

Publication of the information under points 5-13 of the first paragraph may be omitted only if there is a clear and easily legible statement in the medicinal product advertisement to the effect that information about the product, its accompanying leaflet and the valid summary of product characteristics can be found on the website of the Icelandic Medicines Agency, www.serlyfjaskra.is.

If the indications of various pharmaceutical forms of a marketed medicinal product are not the same, and an advertisement intended for physicians, dentists, veterinarians, nurses, pharmacologists, pharmacy technicians and students in these disciplines refers to only one pharmaceutical form of the product, then it shall be permissible to have the advertisement contain information only about the specific pharmaceutical form that is advertised.

Where a veterinary medicinal product is approved for use for more than one animal species and an advertisement intended for veterinarians refers only to its use for one of these species, then it shall be permissible to have the advertisement contain information about use for that one specific animal species only.

Information in a medicinal product advertisement in accordance with the first paragraph shall be set up in such a way that it can be easily read by those who see the advertisement.

Article 11

Informative and promotional materials distributed to healthcare professionals and veterinarians.

All informative and promotional materials concerning medicinal products which are distributed for advertising purposes to physicians, dentists, veterinarians, nurses, pharmacologists, pharmacy technicians and students in these disciplines, shall contain, as a minimum, the information specified in the first paragraph of Article 10 (*cf.*, however, the third and fourth paragraphs of Article 10) in addition to information on when the informative and promotional material was last compiled or revised.

All information in the informative and promotional materials on products (*cf.* the first paragraph) shall be accurate, up-to-date and relevant. It shall be possible to verify the information and it must be

sufficiently detailed to enable the recipient to form an independent opinion on the therapeutic or practical value of the medicinal product in question.

Quotations, tables and other graphic materials which are taken from medical journals or other scientific publications and used as informative and promotional materials concerning medicinal products (*cf.* the first paragraph) shall correspond in every respect with the original sources and include accurate details of the original sources.

The only source materials used in informative and promotional materials on medicinal products (*cf.* the first paragraph), apart from the summary of product characteristics, shall be scientifically-based studies. These studies shall have appeared in recognized and impartial works, professional journals or other comparable publications, Icelandic or foreign. The studies shall have been peer-reviewed by independent parties prior to publication.

Article 12

Advertising of comparisons.

If the information in a medicinal product advertisement includes a comparison between medicinal products, it shall be stated clearly which products are compared. Comparisons may only be made between products which can be compared objectively, i.e. products with the same field of application.

Information in an advertisement containing a comparison in accordance with the first paragraph may only be based on information from the approved summaries of product characteristics pertaining to the products being compared.

Medicinal products may not be compared (*cf.* the first paragraph) in medicinal product advertising intended for the general public.

SECTION IV

Other provisions.

Article 13

Preservation of information on medicinal product advertisements.

Marketing authorisation holders who advertise medicinal products shall maintain records of their advertising and promotional materials (*cf.* Article 18 of the Medicinal Products Act). These records shall be kept for two years and shall be accessible to the Icelandic Medicines Agency. The following information shall be kept in the records:

1. Information on the target group at which the advertisement was aimed.
2. How the advertisement was published and how it was disseminated.
3. A survey of the media in which the advertisement appeared.
4. Information on the period during which the advertisement was published.

Article 14

Presentations by medical sales representatives.

Medical sales representatives shall receive appropriate training from the market authorisation holders for whom they work, and shall possess sufficient professional knowledge to be able to give the most detailed possible information about the medicinal products they promote.

During each visit by medical sales representatives to those who are authorised to prescribe or distribute medicinal products, the representatives shall provide them with written information on the conditions for the registration of the products they are promoting stating details of the characteristics of the products and, as appropriate, the maximum permitted price and participation therein by the health insurance system.

The requirement regarding written information on the conditions for registration of the product under the second paragraph may be waived if clear reference is made to them, with details of where they are to be found.

Medical sales representatives who receive information or notifications from those for whom they promote medicinal products about the products they promote, include as regards adverse reactions,

shall be obliged to transmit such information to the holders of marketing authorisation for the products in question.

Article 15

Gifts, pecuniary advantages, benefits and hospitality.

If a medicinal product promotion is aimed at persons qualified to prescribe or supply the products, then they may not be offered gifts, pecuniary advantages and benefits unless they are of negligible value and the offer is relevant to the practice of medicine or pharmacy.

Hospitality at sales promotion events shall at all times be restricted to the purpose of the promotion may not be extended to persons other than those who are authorised to prescribe and distribute medicinal products.

Persons who are authorised to prescribe or supply medicinal products may not solicit or accept contributions that are prohibited under the first paragraph or contrary to the second paragraph.

Article 16

Samples of medicinal products; delivery of samples.

Free samples of medicinal products may only be given in person to physicians, dentists or veterinarians, providing that they are newly-registered products which are being promoted and that they are not classified as addictive drugs under Regulation No. 233/2001 on addictive drugs and psychotropic substances and other substances subject to supervision.

The persons listed above may only be given samples of medicinal products that they are authorised to prescribe. Furthermore, the following rules apply to the giving of medicinal product samples.

1. Samples may only be given in return for a written, dated and signed request from the physician, dentist or veterinarian in question.
2. Only one sample of a newly-registered medicinal product may be provided each year. If the product is marketed in several pharmaceutical forms and/or strengths, one sample of each pharmaceutical form and strength may be provided.
3. The medicinal product sample shall not be larger than the smallest marketed package of the product.
4. Medicinal product samples shall be marked “Free medicinal product sample – not for sale or use.”
5. Medicinal product samples shall at all times be accompanied by an approved summary of their product characteristics.
6. Samples of non-registered medicinal products may not be supplied.

SECTION V

Monitoring, sanctions and commencement.

Article 17

Monitoring.

The Icelandic Medicines Agency monitors the advertising of medicinal products (*cf.* indent 8 of the first paragraph of Article 3, and the first paragraph of Article 18, of the Medicinal Products Act, No. 93/1994, with subsequent amendments).

The Icelandic Medicines Agency may prohibit the publication of any specific advertisement which infringes the provisions of this Regulation. The Icelandic Medicines Agency may also demand that the advertiser publish a correction or additional explanations in the same manner as the earlier advertisement appeared.

If the Icelandic Medicines Agency considers that a medicinal product advertisement infringes Chapter II of the Commercial Practices and Marketing Act, No. 57/2005, with subsequent amendments, the agency shall report the medicinal product advertisement to the Consumer Agency.

Article 18

Sanctions.

Infringements of the provisions of this Regulation shall be punishable under Articles 48 and 49 of the Medicinal Products Act, No. 93/1994, with subsequent amendments.

Article 19

Commencement.

The provisions of this Regulation are in conformity with those of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive).

This Regulation is issued under the first paragraph of Article 50 of the Medicinal Products Act, No. 93/1994, with subsequent amendments, and takes effect on 1 November 2015. As of the same date, the Regulation on the advertising of medicinal products, No. 328/1995, with subsequent amendments, shall stand repealed.

Ministry of Welfare, xx. xx 2015.

Kristján Þór Júlíusson
Minister of Health

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Margrét Björnsdóttir.