

# ETHICAL RULES FOR THE PHARMACEUTICAL INDUSTRY IN SWEDEN

**Revised and valid from 1 February 2026**

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# Ethical rules for the pharmaceutical industry in Sweden

## Background, purpose, scope, and applicability

### Background and purpose

#### **LER includes only human medicinal products.**

Since they were originally adopted in 1969 by the Swedish Association of the Pharmaceutical Industry (Lif) and the Association of Representatives of Foreign Pharmaceutical Industries (RUF), the Rules governing medicinal product information have been the primary document for specifying in greater detail the responsibility of pharmaceutical companies as regards information about medicinal products. In recent years, the Lif has, in part through its membership of the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) been covered by these organisations' regulations. In addition, Lif has entered several agreements regarding forms of co-operation between the pharmaceutical industry and healthcare etc. In addition, rules for non- interventional studies, rules for forms of co-operation with organisations/interest associations, rules for interaction between pharmaceutical companies and pharmacy employees as well as rules for interaction between companies and politicians have been issued.

Lif's Board of Directors has decided to gather the national and international regulations in a single code. On 13 June 2007, Lif's Board of Directors decided to adopt the new regulation specified in the Ethical rules for the pharmaceutical industry. The regulations entered into force on 1 October 2007. The ethical rules for the pharmaceutical industry shall be regarded as a complement to current legislation, regulations and code of statutes issued by governmental bodies, and applicable codes, e.g. anti-bribery legislation, the Code to prevent Corruption in Business issued by the Swedish Anti-Corruption Institute and rules on procurement. On the 1 January 2018 a Nordic association for veterinary medicinal products was formed that will inter alia be responsible for market surveillance of veterinary medicinal products. In connection with the revision of LER in February 2018 it was therefore decided to remove the parts in LER that specifically related to veterinary medicinal products. As of this date, the scope of application of other parts in LER no longer applies to veterinary medicinal products or veterinary medicinal companies.

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**Scope and applicability**

The member companies of Lif, ASCRO and Föreningen för Generiska Läkemedel (FGL) follow the Ethical rules. These are collectively referred to as “member companies” in this regulation.

In the event of conflict between applicable provisions according to law, the Swedish Ethical rules for the pharmaceutical industry, the EFPIA Code of Practice, or the IFPMA Code of Practice, the most restrictive provision shall apply.

It is up to the Swedish pharmaceutical companies to ensure that the Ethical rules for the pharmaceutical industry are also observed by parent companies and sister companies in the event of activities on the Swedish market or targeted at the Swedish market. It is also the duty of such companies, in license agreements or similar with business partners, to enjoin them to comply with the Ethical rules for the pharmaceutical industry, even when such business partners do not act on behalf of the pharmaceutical company.

A pharmaceutical company is responsible for all activities conducted on its behalf by an intermediary.

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# **CHAPTER 1 – Rules governing information of medical products**

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## Background and purpose

To ensure that the pharmaceutical industry performs its task of developing, manufacturing and marketing medicinal products correctly, the industry is obliged by law and by well-established legal principles to provide information, in connection with its marketing operations, about the properties, effects and appropriate applications of the medicinal products concerned. By supplying such information, the industry performs the important task of making the medicinal products known and permitting them to be used in a proper way. The information must conform to good business practice and must be presented in such a way that it gains credibility and a good reputation.

The rules are divided into two sections. The **first section** regulates medicinal product information that is addressed to physicians and other healthcare personnel. As has been the case to date, the rules indirectly express the responsibility that the pharmaceutical industry has towards the general public as consumers of medicinal products.

The **second section** regulates medicinal product information that is targeted to the general public. The underlying principle is that the function of such information – like that of information addressed to healthcare personnel, allows for the correct use of medicinal products. This information must also be compatible with good business practice and must be presented in such a way that it gains credibility and a good reputation.

The rules are based on applicable codified law – the Marketing Act and case law, as well as the provisions regarding medicinal product information and medicinal product advertising contained in domestic and EU pharmaceutical legislation and other enactments or in directives issued by government agencies. In addition, the information rules are based on non-judicial standards such as the Code of Advertising Practice drawn up by the International Chamber of Commerce and the EFPIA Code of Practice adopted by the European Federation of Pharmaceutical Industries and Associations (EFPIA). The regulations are concordant with WHO's ethical rules for marketing medicinal products and the IFPMA and the EFPIA Code Practice. An important part of the international regulations is that each national industry organisation must have a Compliance Officer who is responsible for the preventive work, e.g. providing advice and training.

The concept of good business practice in the area of medicinal product information is also clarified by other non-statutory provisions, such as the ICC/ESOMAR:s Code on Market and Social Research.

Compliance with the rules is kept under constant scrutiny by the Swedish Pharmaceutical Industry's Information Examiner Committee (IGN).

Questions as to whether the information supplied by the pharmaceutical industry and the marketing measures adopted by it are compatible with the rules and with good business practice are examined by the IGN and the Information Practices Committee (NBL). NBL also has the ongoing task of establishing further standards in this area.

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## **Section 1 - Information that, in connection with marketing medicinal products, is targeted at physicians, dentists, pharmacists or other personnel within Swedish healthcare or distribution of medicinal products.**

### **Area of application, Section 1**

The rules in Section 1 apply to the information provided by the pharmaceutical industry that, in connection with the marketing the medicinal products, is targeted at or otherwise may reach physicians, dentists, pharmacists or other personnel within Swedish healthcare or distribution of medicinal products.

The rules are applicable to any media used by the pharmaceutical industry in such marketing.

### **Rules regarding the content and form of information Objectivity**

#### **Article 1**

Medicinal product information must include accurate, objective, meaningful and balanced particulars dealing adequately with the favourable and unfavourable properties of the medicinal product.

This fundamental principle is further defined in the following rules.

#### **Article 2**

The information may only refer to medicinal products that have received marketing approval in Sweden.

The summary of product characteristics (SPC) that has been adopted for a medicinal product constitutes the factual basis for information about the medicinal product. In addition to information directly taken from the SPC, or which can be derived from it, other information may be used. This is under the condition that such information supplements the SPC, by confirming or specifying information in it, and that such supplementary information is in conformity with the information in the SPC.

The information may not contain indications or dosages other than those approved of for the medicinal product, unless otherwise permitted by the Medical Products Agency.

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### **Article 3**

Pharmaceutical companies must always maintain a high ethical standard.

Information about medicinal products must conform to good practice and good taste. Offensive presentations are not permitted.

### **Truthful presentation**

#### **Article 4**

Medicinal product information must be truthful and may not contain any presentation in words or pictures that directly or indirectly – by implication, omission, distortion, exaggeration or ambiguity – is intended to mislead.

The requirement for truthful presentation entails e.g.

- 4.1 that information regarding the composition, active ingredients, properties and effects of a medicinal product may not be incorrect, misleading or unverified,
- 4.2 that information regarding a medicinal product may not be so brief or incomplete that it could be misunderstood,
- 4.3 that exaggerated claims about a medicinal product's properties or effects may not be made.
- 4.4 that it may not be implied that a medicinal product or an active substance has any special benefit, quality or property if this cannot be verified,
- 4.5 that the presentation may not be deceptive or suggestively misleading,
- 4.6 that expressions such as "better", "more effective", "cheaper", or similar may not be used unless it is made clear what is being compared, and if the claim has been substantiated in a qualified manner.
- 4.7 that expressions such as "safe" may not be used unless the claim has been substantiated in a qualified manner.
- 4.8 that the word "new", or other expressions for novelty, may not be used to describe a product or packaging that has been generally available for more than one year or that has a therapeutic indication that has been marketed generally for more than one year,
- 4.9 that the medicinal product may be described as "medicinal product of choice", "routine preparation" or the like only if the majority of specialists within the relevant therapeutic area consider the medicinal product to be a first-line choice,
- 4.10 that it may not be claimed that a product does not have any side-effects, toxic risks or risk of misuse or dependence.
- 4.11 that images that are included in the information are neither misleading as regards the nature of a medicinal product (e.g. whether it is appropriate to give the medicinal product to a child) nor contain misleading assertions or comparisons (e.g. using incomplete or statistically irrelevant information or uncommon scales).

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## **Identification**

### **Article 5**

Medicinal product information must be easy to recognise as such; this applies irrespective of the form of the information and the medium used. Medicinal product information must not be disguised.

Clinical evaluations, other investigations as well as studies following approval (also including retrospective investigations and studies) may not be used as disguised marketing measures. Such assessments, programs and studies must be implemented with a primarily scientific purpose.

Information disseminated through media also containing scientific or other editorial material must be presented in such a way that it will be readily recognised as a marketing activity.

If the information material concerning medicinal products and their use, regardless of whether it is of a commercial nature or not, is financed by a company, this must be clear in the material.

Written medicinal product information must clearly show the name of the manufacturer concerned or of his representative who is responsible for the medicinal product information in Sweden. The written medicinal product information shall, in addition to the name of the manufacturer or representative, contain clearly visible information on the manufacturer's or the representative's address or telephone number or web address. Information about medicinal products on websites must also clearly show to whom the information is addressed as well as that the presentation (content, links, etc.) is adapted for the intended target group.

### **Article 6**

Medicinal product information must contain a clear statement about the year of publication or, in the case of Internet information, the date when the site was most recently updated, as well as a designation that makes it possible to identify the information without difficulty. However, this does not apply if the year of publication and the identity are apparent in some other way, e.g. as in an advertisement appearing in a journal.

## **Current knowledge**

### **Article 7**

Medicinal product information must be up to date. This implies for example that any information given about therapeutic results, side-effects and contra-indications must reflect up-to-date scientific views.

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## **Documentation and references**

### **Article 8**

Information as to the quality and efficacy of a medicinal product shall be capable of substantiation by means of documentation. In this context, documentation is understood to mean any written or visual presentation containing reports on scientific facts and discoveries. Documentation to which reference is made in medicinal product information shall be of a high scientific standard. It shall have been published or accepted for publication in a scientific journal or made public or accepted for public presentation at a scientific congress or symposium. Other documentation may be cited in exceptional cases, however only on the condition that it may be considered to be of great value to those to whom it is addressed. Unpublished documentation must meet the same quality requirements as published documentation in both contents and form and must be dated and signed by the investigator in charge.

Testimonials from individual patients may not be cited as documentation. Case studies shall be formulated as typical cases so that the identity of the individual patient is kept anonymous and the studies shall remain free from subjective evaluations from the patient.

Healthcare personnel may not, on behalf of a pharmaceutical company, offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment. Healthcare personnel may, however, be engaged as lecturers provided that the information is objective, balanced, and fair as regards content and presentation. The company is responsible for the information being compliant with the Ethical Rules for the Pharmaceutical Industry (LER).

### **Article 9**

Documentation that has been compiled for a particular medicinal product may be cited in support of information about another medicinal product only on the condition that the documentation is obviously applicable to the latter medicinal product as well. The citation shall then be expressed in such a way that it does not give the incorrect impression that the documentation was compiled for the medicinal product being marketed. If necessary to avoid misunderstanding, the name of the medicinal product to which the documentation refers shall be stated clearly in the information.

### **Article 10**

Medicinal product information that contains quotations, numerical data, diagrams, images, including graphics, illustrations, photographs or tables taken from a scientific study or deals with a comparison between medicinal products that is based on such a study, must clearly contain information about relevant sources and references to the documentation.

As to other cases, it is not normally necessary for reference to be made in the information to documentation that supports statements contained in the information. However, the pharmaceutical company shall always provide such reference(s) promptly on request.

Reference to documentation shall be made in the generally accepted form, thus ensuring that the source can be identified without difficulty.

Documentation not generally available shall, without delay and free of charge, be provided by the pharmaceutical company upon request.

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## Article 11

Documentation must be cited in a balanced and fair way.

The requirement for a fair and balanced presentation means e.g.:

- 11.1 that the results of a study, which are contradicted by another study, may not be cited without reservation and that results that have been refuted must not be used,
- 11.2 that a study may not be cited in such a way that it could convey an incorrect or misleading impression of the nature, scope, implementation or importance of the study,
- 11.3 that a study performed in vitro or a study based on animal tests should not be cited in such a way that it could give an incorrect or misleading impression of the clinical value of the study,
- 11.4 that statements of comparisons between different medicinal products or alternative treatments should be expressed in such a way as to make clearly their statistical validity evident,
- 11.5 that the report of a study should not be cited or abstracted in such a way that the citation or abstract gives an inaccurate or misleading impression of the contents of the report and the conclusions stated therein.
- 11.6 that information containing such details referred to in article 10, first sentence in paragraph 1, be correctly reproduced (except when adaptation or alteration is required in order to satisfy applicable rules, in which case it must be clearly evident that adaptation or alteration has been made).

## Comparisons

### Article 12

Medicinal product information that includes comparisons between effects, active ingredients, costs of treatment, etc., must be presented in such a way that the comparison as a whole is fair. The object(s) included in the comparison must be selected in a fair way, must be relevant and must be presented objectively and truthfully.

The requirement for a fair comparison means e.g.:

- 12.1 that the objects included in the comparison should always be clearly specified; thus, if required for sake of clarity, the complete name and generic designation of the compared medicinal products should be stated,
- 12.2 that the facts which the comparison is intended to clarify and the limitations inherent in the comparison must be stated in such a way that the comparison is not likely to mislead,
- 12.3 that comparison of properties of synonymous medicinal products, or of medicinal products with the same indications, shall give a comprehensive and fair picture of the properties compared,
- 12.4 that comparison of certain properties should not induce incorrect or misleading conclusions regarding properties not covered by the comparison.

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## **Discreditation**

### **Article 13**

#### **Medicinal product information**

- 13.1 may not contain presentations in words or images that are likely to be perceived as denigratory to another pharmaceutical company or the pharmaceutical industry,
- 13.2 may not contain presentations likely to bring another medicinal product into contempt or lay it open to ridicule, and
- 13.3 must be of such nature that it respects the special nature of the medicinal product as well as the professional standing of the recipient.

## **Rules on disseminating information**

### **Article 14**

- 14.1 Medicinal product information shall be distributed selectively and should only be directed towards those who may be presumed to be in need of, or have an interest in, the information in question, unless otherwise indicated in the ethical agreements that the concerned associations for pharmaceutical companies have entered into. Recipients that may be eligible in the context of this article are those who prescribe, recommend, prepare, administer or hand over medicinal products.
- 14.2 Mailing lists must be kept up to date. Requests from healthcare personnel to be removed from promotional mailing lists must be complied with.

### **Article 15**

Information on new findings regarding serious side effects, contra-indications, limitations applying to indications or decisions concerning recall of manufacturing batches or medicinal products shall be sent out in the form of separate communication. The term “Important Message” or similar expressions may only be used for such dispatches.

As regards regulations for the inclusion of warning statements in information, such regulations are contained in the Product Safety Act (SFS 2004:451).

## **Specific rules regarding the form of the information**

### **Article 16**

Written medicinal product information refers to information that is conveyed in words, pictures or sound, in all media regardless of the channel.

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#### Article 17

Information concerning medicinal products for which the relevant SPC is available at any time via Fass.se must, in the event the SPC is not reproduced, contain at least the following particulars:

- 17.1 the name of the medicinal product,
- 17.2 its dosage form and, if required, its strength,
- 17.3 its active ingredients, specified by generic name which must be positioned close to the name of the medicinal product where this first appears as a headline or eyecatcher,
- 17.4 a balanced statement of product characteristics; this description shall contain required particulars about pharmacological group or other accepted group affiliation, together with indication or area of indications,
- 17.5 required warnings or restrictions as regards the use of the medicinal product,
- 17.6 such details of company name and contact information referred to in article 5,
- 17.7 such details referred to in article 6, and
- 17.8 information about the date on which the summary of product characteristics was compiled or reviewed,
- 17.9 product status, specify **Rx** or prescription alternatively **OTC** or over-the-counter medicine
- 17.10 the status of the product in relation to the pharmaceutical benefit, state **EF** or "not reimbursed" alternatively **F** or "reimbursed". If TLV has decided that the medicinal product shall be part of the benefits system; the sales price for the subsidized packages (which may be stated by a reference to fass.se according to 17.11 below), as well as explicit statement of any restrictions in the benefits system.
- 17.11 a reference to fass.se for further information.

#### Article 18

In the event the current SPC for a medicinal product is not available at any time via Fass.se, written information concerning the medicinal product must contain the adopted SPC in full.

#### Article 19

SPCs that are reproduced in written medicinal product information must, as with the rest of the text, be easily legible. It must be positioned so that it is readily observed.

#### Article 20

Printed matter, advertisements or other informational material should not be larger in format or bulk than is required by nature and content of the information. Directly distributed informational material shall be easy to handle and shall be dispatched in such a way as not to cause any unnecessary inconvenience to the addressees.

#### Article 21

Verbal medicinal product information refers to information that is conveyed in person by representatives of pharmaceutical companies. Such information may be given in conjunction with personal visits, visits to clinics, training seminars, symposia, conferences and meetings of other kinds.

Meetings for conveying verbal information shall be aimed at presenting facts and objective data. Such meetings shall be arranged so as to fit in usefully and naturally with the execution of the recipients' duties.

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**Article 22**

Verbal medicinal product information is conveyed by pharmaceutical representatives and other authorised pharmaceutical advisers. In addition to such advisers, people with specialised knowledge may also be engaged in the provision of such information.

Representatives who convey verbal medicinal product information must comply with and be well acquainted with all relevant requirements according to applicable rules, laws and provisions, and the companies are responsible for ensuring compliance with these. The same applies to personnel who are involved in the preparation or approval of promotional material or activities.

The tasks must be carried out in a responsible and ethical manner.

Pharmaceutical representatives are trained and authorised in accordance with criteria that Lif has established or that apply according to regulations. Individuals undergoing training as pharmaceutical representatives may, in accordance with these norms, convey verbal medicinal product information under the supervision of an authorised pharmaceutical representative.

**Article 23**

When a verbal information activity is planned, the pharmaceutical company shall properly notify the person(s) concerned well in advance. (See further the relevant sections in chapter 2 regarding inter alia agreement with the healthcare management and to whom an invitation may be sent.)

A notification of verbal information shall be formulated in such a way that it is instantly evident that it is a question of announcing such information as well as what the information is intended to comprise. If the notification contains a product logotype or any other graphic design that is associated with the brand, it must include the minimum information required according to article 17. In other cases, it is permitted that the notification contains such minimum information.

If the information applies to medicinal products that have not yet been granted marketing authorisation at the time when the notification is dispatched, but that are expected to have received such authorisation by the time the information is issued, this must be explicitly stated in the notification. Such a notification may neither bear either any product logotype or other graphic design that is associated with the brand, nor may it be made more comprehensive than is necessary to present the intended information.

If the information applies to a new indication or dosage only, that has not yet been authorised at the time when the notification is dispatched, but that is expected to have received such authorisation by the time the information is issued, this must be explicitly stated in the notification. Such a notification may bear a product logotype or any other graphic design that is associated with the brand (in which case the notification must also contain the minimum information required according to article 17), but it may not be made more comprehensive than is necessary to present the intended information.

**Article 24**

Entertainment and other benefits offered to those to whom verbal information is addressed may not be of a kind or on such a scale that there is a risk that the recipients will let themselves be influenced thereby in the execution of their professional duties.

The pharmaceutical company must not offer or promise any compensation to recipients of information.

See also what is specified in the relevant sections in chapter 2.

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**Article 25**

- 25.1 In the course of verbal information, and according to applicable laws and directives, the pharmaceutical company's representatives must provide the addressees who are visited with a copy of the SPC for each medicinal product that is presented or have such information available.
- 25.2 In the course of verbal information, the addressees must be given an opportunity to report their experiences and views related to the medicinal product under discussion to the representatives of the pharmaceutical company. The representatives must forward these reports to the company.

**Medical samples****Article 26**

Medical samples must be distributed in a very restricted manner, at most one per product per year to one and the same person. Medical samples of prescription medicinal products for human use may only be regarded as new products. In this context a new product refers to a product that has been publicly available for less than two years. New strength or dosage form without new indication is not considered to be a new product. Further, samples shall be offered in conformity with those prescribed by the Medical Products Agency and specified in regulations. Medical samples may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

**Rules on responsibility****Article 27**

The responsibility for medicinal product information extends to the information, its content as well as its form, including any statements of opinion therein, any clinical reports or any reprints of published articles. The fact that the content and form of the information originate from other sources is irrelevant from the point of view of responsibility.

**Bearer of responsibility****Article 28**

Responsibility for observance of the Rules Governing Medicinal Product Information rests with the pharmaceutical company concerned or its representative in Sweden. The representative is also responsible for information administered directly by the foreign principal.

**Article 29**

Within every pharmaceutical company, there shall be appointed a competent person from among the executive staff who shall be responsible for consultation with other people concerned in the company, for ensuring that relevant regulatory requirements are satisfied and for supervising the company's external information and its marketing practices. The person shall be the company's.

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liaison officer in ethical matters related to informational and marketing activities (Information Officer in marketing ethics).

Pharmaceutical companies must also appoint a body that shall approve and monitor non-interventional studies. The body that is appointed should include a physician, or where appropriate a pharmacist, to be responsible for monitoring the non-interventional studies (also including reviewing liability for such studies, in particular those for which pharmaceutical representatives are responsible). The executive responsible must certify that he or she has examined the report/publication and that it is compatible with the applicable laws and provisions.

The information officer must approve all marketing material before it is taken into use. The person must certify that he or she has studied the final marketing material and that it satisfies the requirements in the applicable rules on information and applicable laws and regulations, that it corresponds with the SPC as well as decisions and recommendations by the Dental and Pharmaceutical Benefits Agency (TLV), and that it is a true and impartial presentation of the facts.

The information officer must have completed training in marketing law (IMA training) arranged by Lif.

When appropriate in view of its size, organisation or product range, the pharmaceutical company may appoint more than one person, having the status and functions stated in the first paragraph, with responsibility for information. A clearly defined area of responsibility shall then be assigned to each of these people.

In December each year, every pharmaceutical company shall inform the Lif secretariat, in writing, of the name(s) of the person(s) who will be responsible for informational matters during the coming year. If more than one such person has been appointed, the area of responsibility of each person must be indicated. If a person is appointed with responsibility for informational matters in the course of a year, or if the area of responsibility of such a person is changed, the Lif secretariat shall be informed of this immediately in writing.

### **Burden of proof**

#### **Article 30**

A pharmaceutical company should be able to substantiate any facts, statements, claims, and other presentations in words or pictures contained in its medicinal product information. The company shall be prepared, upon request by IGN or the NBL, to fulfill its obligation to produce supporting evidence without delay. Specific rules on documentation of statements of properties and effects of medicinal products are included in articles 8-11.

### **Statutory copies**

#### **Article 31**

The market surveillance shall, according to the statutes of IGN and NBL, be managed by IGN. For IGN to be able to fulfill this task, pharmaceutical companies must send new marketing materials (such as brochures, advertisements, invitations, mailings, commercial films, or information on websites) or already submitted marketing materials with significant updates, to IGN. This should be done within a reasonable time after the material has been put into use, but no later than within three months.

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## **Section 2 - Information that, in connection with the marketing of medicinal products on the Swedish market, is targeted at the public.**

### **Area of application, section 2**

The rules in Section II apply to the information provided by the pharmaceutical industry that, in connection with the marketing of the medicinal products, is targeted at the general public.

The rules are applicable to any media used by the pharmaceutical industry in such marketing.

### **Rules regarding the content and form of information Objectivity**

#### **Article 101**

Medicinal product information must include accurate, objective, meaningful and balanced particulars dealing adequately with the favorable and unfavourable properties of the medicinal products.

This fundamental principle is further defined in the following rules.

When compiling medicinal product information concerning medicinal products for human use, special attention shall be paid to the general public's need for factual information for guidance in the area of self-medication.

The information shall be supplied in a form easily accessible to the general public.

#### **Instructions**

Application of the overall principles in article 101 to the provision of information to the general public shall be based on the general principle of market law that advertising measures shall be judged – and, consequently, also be devised – with reference to the effect they may be presumed to have on the target group. Thus, in devising and assessing the measures, it is important to consider the fact that different target categories, as well as partly different market conditions, are involved here as compared with those governing the application of rules for medicinal product information to healthcare personnel – for example, different media or different technical solutions may be involved.

#### **Article 102**

The summary of product characteristics (SPC) that has been adopted for a medicinal product constitutes the factual basis for information about the medicinal product.

The information may only refer to medicinal products that have received marketing approval in

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Sweden. It may not contain indications or dosages other than those approved of for the medicinal product, unless otherwise permitted by the Medical Products Agency.

Information regarding pharmaceuticals may not be directed towards children under the age of 18.

Information to the general public regarding prescription medicinal products shall be supplied only to the extent permitted in the Medical Products Agency's provisions and that which applies according to laws and regulations. Information to the general public regarding prescription of medicinal products may be done through Fass.se or such aids from the pharmaceutical industry that are intended to be handed to patients by physicians or other healthcare personnel to facilitate the correct use of their medicinal products.

In addition to what is stated in the previous paragraph, for the purpose of ensuring the public access to requested and easily comprehensible information on prescription medicinal products, information which fulfils the requirements below may also be provided on websites established and administered by pharmaceutical companies. The information may be provided solely on condition that pre-examination has taken place and resulted in approval in accordance with the requirements below. Said pre-examined and approved information regarding certain medicinal product(s) is, for the purpose of these ethical rules, defined as "*pre-approved website*", and shall, in all aspects, have as its factual basis what is stated on Fass.se and the summary of product characteristics as approved from time to time by the Medical Products Agency for the medicinal product at issue. A *pre-approved website* may not in any part contradict the content of said information. There is however no requirement that this information be reproduced word by word or in its entirety on the *pre-approved website*. The content of the *pre-approved website* shall provide the public, access to patient suited information regarding the medicinal product to facilitate the correct use of the same. The name of the medicinal product may be used in a domain name and may be mentioned on but may not dominate or constitute a major part of the *pre-approved website*.

#### **Article 102 a**

In respect of campaigns in radio, TV and in other advertisements for vaccination of humans against one or more infectious diseases, the purpose of such campaigns shall be to provide the general public with necessary information regarding protection against infectious diseases through vaccination. Product name, product logotype, the generic name of the pharmaceutical or similar distinctive marks or features such as administration method or pharmaceutical form, may thus not appear. Such campaigns shall not be regarded as constituting marketing of a certain pharmaceutical, regardless of whether, at the time of the campaign, there is one or several, in Sweden, approved of pharmaceuticals for vaccination against the infectious disease or diseases that the campaign concerns.

#### **Article 103**

Pharmaceutical companies must always maintain a high ethical standard.

Information about medicinal products must conform to good practice and good taste. Offensive presentations are not permitted.

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## Truthful presentation

### Article 104

Medicinal product information must be truthful and may not contain any presentation in words or pictures that directly or indirectly – by implication, omission, distortion, exaggeration, or ambiguity – is intended to mislead.

The requirement for truthful presentation entails e.g.

- 104.1 that information regarding the composition, active ingredients, properties, and effects of a medicinal product may not be incorrect, misleading, or unverified,
- 104.2 that information regarding a medicinal product may not be so brief or incomplete that it could be misunderstood,
- 104.3 that exaggerated claims about a medicinal product's properties or effects may not be made,
- 104.4 that it may not be implied that a medicinal product or an active substance has any special benefit, quality or property if this cannot be verified,
- 104.5 that the presentation may not be deceptive or suggestively misleading,
- 104.6 that expressions such as "better," "more effective," "cheaper," or similar may not be used unless it is made clear what is being compared, and if the claim has been substantiated in a qualified manner.
- 104.7 that expressions such as "safe" may not be used unless the claim has been substantiated in a qualified manner.
- 104.8 that the word "new," or other expressions for novelty, may not be used to describe a product or packaging that has been generally available for more than one year or that has a therapeutic indication that has been marketed generally for more than one year,
- 104.9 that the medicinal product may be described as "medicinal product of choice," "routine preparation" or the like only if most specialists within the relevant therapeutic area consider the medicinal product to be a first-line choice,
- 104.10 that it may not be claimed that a product does not have any side-effects, toxic risks or risk of misuse or dependence.
- 104.11 that images that are included in the information are neither misleading as regards the nature of a medicinal product (e.g. whether it is appropriate to give the medicinal product to a child) nor contain misleading assertions or comparisons (e.g. through the use of incomplete or statistically irrelevant information or uncommon scales).

The content of the medicinal product information may not be formulated in such a way that it may have as an effect that the medicinal product is used in a way which may result in damages or which is otherwise not appropriate or formulated in such a way that it may lead to people not seeking the appropriate care.

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## **Identification**

### **Article 105**

Medicinal product information must be easy to recognise as such; this applies irrespective of the form of the information and the medium used. Medicinal product information must not be disguised.

Clinical evaluations, other investigations as well as studies following approval (also including retrospective investigations and studies) may not be used as disguised marketing measures. Such assessments, programs and studies must be implemented with a primarily scientific purpose.

Information disseminated through media also containing scientific or other editorial material must be presented in such a way that it will be readily recognised as a marketing activity.

If the information material concerning medicinal products and their use, regardless of whether it is of a commercial nature or not, is financed by a company, this must be clear in the material.

Written medicinal product information must clearly show the name of the manufacturer concerned or of his representative who is responsible for the medicinal product information in Sweden. The written medicinal product information shall, in addition to the name of the manufacturer or representative, contain clearly visible information on the manufacturer's or the representative's address or telephone number or web address. Information about medicinal products on websites must also clearly show to whom the information is addressed as well as that the presentation (content, links, etc.) is adapted for the intended target group.

Referral to Fass.se may not occur in a vaccination campaign.

Information regarding human medicinal products shall be presented in such a way that it is clear that the product is a medicinal product.

### **Instructions**

The requirements laid down in paragraph 5 cannot, for practical reasons, be applied to certain media used for advertising to the general public, for example certain types of advertising signs, however the company responsible must always be specified in the information.

### **Article 106**

Medicinal product information must contain a clear statement about the year of publication or, in the case of Internet information, the date when the site was most recently updated, as well as a designation that makes it possible to identify the information without difficulty. However, this does not apply if the year of publication and the identity are apparent in some other way, e.g., as in an advertisement appearing in a journal.

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## **Current knowledge**

### **Article 107**

Medicinal product information must be up to date. This implies for example that any information given about therapeutic results, side-effects and contra-indications must reflect up-to-date scientific views.

## **Documentation and references**

### **Article 108**

Information as to the quality and efficacy of a medicinal product shall be capable of substantiation by means of documentation. In this context, documentation is understood to mean any written or visual presentation containing reports on scientific facts and discoveries. Documentation to which reference is made in medicinal product information shall be of a high scientific standard. It shall have been published or accepted for publication in a scientific journal or made public or accepted for public presentation at a scientific congress or symposium. Other documentation may be cited in exceptional cases, however only on the condition that it may be considered to be of great value to those to whom it is addressed. Unpublished documentation must meet the same quality requirements as published documentation in both contents and form and must be dated and signed by the investigator in charge.

Testimonials from individual patients may not be cited as documentation. Case studies shall be formulated as typical cases so that the identity of the individual patient is kept anonymous and the studies shall remain free from subjective evaluations from the patient.

Healthcare personnel may not, on behalf of a pharmaceutical company, offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment. Healthcare personnel may, however, be engaged as lecturers provided that the information is objective, balanced, and fair as regards content and presentation. The company is responsible for the information being compliant with the Ethical Rules for the Pharmaceutical Industry (LER).

### **Article 109**

Documentation that has been compiled for a particular medicinal product may be cited in support of information about another medicinal product only on the condition that the documentation is obviously applicable to the latter medicinal product as well. The citation shall then be expressed in such a way that it does not give the incorrect impression that the documentation was compiled for the medicinal product being marketed. If necessary to avoid misunderstanding, the name of the medicinal product to which the documentation refers shall be stated clearly in the information.

### **Article 110**

It is not required to refer to the information to supporting documentation. A pharmaceutical company must, however, upon request, immediately provide documentation supporting data supplied therein.

Reference to documentation shall be made in the generally accepted form, thus ensuring that the source can be identified without difficulty.

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Documentation not generally available shall, without delay and free of charge, be provided by the pharmaceutical company upon request.

#### **Article 111**

Documentation must be cited in a balanced and fair way.

The requirement for a fair and balanced presentation means e.g.:

- 111.1 that the results of a study, which are contradicted by another study, may not be cited without reservation and that results that have been refuted must not be used,
- 111.2 that a study may not be cited in such a way that it could convey an incorrect or misleading impression of the nature, scope, implementation, or importance of the study,
- 111.3 that a study performed in vitro or a study based on animal tests should not be cited in such a way that it could give an incorrect or misleading impression of the clinical value of the study,
- 111.4 that statements of comparisons between different medicinal products or alternative treatments should be expressed in such a way as to make clearly their statistical validity evident,
- 111.5 that the report of a study should not be cited or abstracted in such a way that the citation or abstract gives an inaccurate or misleading impression of the contents of the report and the conclusions stated therein.
- 111.6 that information containing quotations, numerical data, diagrams, images, including graphics, illustrations, photographs or tables taken from a scientific study be correctly reproduced (except when adaptation or alteration is required in order to satisfy applicable rules, in which case it must be clearly evident that adaptation or alteration has been made).

#### **Comparisons**

##### **Article 112**

Medicinal product information that includes comparisons between effects, active ingredients, costs of treatment, etc., must be presented in such a way that the comparison is fair. The object(s) included in the comparison must be selected in a fair way, must be relevant, and must be presented objectively and truthfully.

The requirement for a fair comparison means e.g.:

- 112.1 that the objects included in the comparison should always be clearly specified; thus, if required for sake of clarity, the complete name and generic designation of the compared medicinal products should be stated,
- 112.2 that the facts which the comparison is intended to clarify and the limitations inherent in the comparison must be stated in such a way that the comparison is not likely to mislead,
- 112.3 that comparison of properties of synonymous medicinal products, or of medicinal products with the same indications, shall give a comprehensive and fair picture of the properties compared,

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- 112.4 that comparison of certain properties should not induce incorrect or misleading conclusions regarding properties not covered by the comparison.

Comparisons between specific medicinal products or groups of medicinal products may not occur on a *pre-approved website*.

## **Discreditation**

### **Article 113**

Medicinal product information

- 113.1 may not contain presentations in words or images that are likely to be perceived as denigratory to another pharmaceutical company or the pharmaceutical industry,
- 113.2 may not contain presentations likely to bring another medicinal product into contempt or lay it open to ridicule, and
- 113.3 must be of such nature that it respects the special nature of the medicinal product.

## **Rules on disseminating information**

### **Article 114**

- 114.1 Medicinal product information should be distributed selectively and should only be directed towards those who may be presumed to be in need of, or have an interest in, the information in question.
- 114.2 Mailing lists must be kept up to date. Requests to be removed from promotional mailing lists must be complied with.

In the event of enquiries which are made by individuals from the general public for advice regarding personal medical issues, the enquirer must be advised to consult a physician or other healthcare personnel.

Pharmaceutical companies may not actively disseminate information about prescription medicinal products on *pre-approved websites* to the general public. This includes, among other things, that pharmaceutical companies may not sponsor links to such websites or in any other way actively promote such websites. Supplying requested information, publishing a link to a *pre-approved website* on Fass.se, publishing a *pre-approved website's* address on such aids provided by the pharmaceutical industry as referred to in article 102 and other such corresponding measures, shall not constitute an active promotional activity. Publishing links on Fass.se shall be in compliance with the rules on additional information which Lif Service AB applies from time to time.

Dissemination through directly distributed informational material, addressed or non-addressed, is not allowed in a vaccination campaign.

### **Article 115**

Information on new findings regarding serious side-effects, contra-indications, limitations applying to indications or decisions concerning recall of manufacturing batches or medicinal products shall.

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be sent out in the form of a separate communication. The term “Important Message” or similar expressions may only be used for such dispatches.

As regards regulations for the inclusion of warning statements in information, such regulations are contained in the Product Safety Act.

### **Specific rules regarding the form of the information**

#### **Article 116**

Written medicinal product information refers to information that is conveyed in words, pictures, or sound, in all media regardless of the channel.

#### **Article 117**

Advertising for over-the-counter medications to the public shall include, as a minimum, the following particulars:

- 117.1 the name of the medicinal product,
- 117.2 its dosage form,
- 117.3 its active ingredients specified by generic name or in some other suitable way,
- 117.4 the use of the medicinal product to which the information relates, as well as statement of any necessary warning or limitations that are applicable to its use,
- 117.5 such details of company name and contact information referred to in article 105,
- 117.6 date of publication see also article 106,
- 117.7 an explicit and easily legible invitation to carefully study the information contained in the leaflet or, as applicable, on the outer packaging
- 117.8 If the medicine is used for a disease or a symptom that requires medical consultation for diagnosis or treatment, the information to the public must clearly encourage consulting a doctor before using the medicine.

The regulations in this article shall not be applied to information provided on *pre-approved websites*.

#### **Instructions**

1. In general, it should be possible to fulfill the minimum requirements laid down in article 117.1-117.8. However, in exceptional cases the chosen medium of information may be such that, for practical or other reasons, it is not possible to fulfill a particular requirement, such as stating information about use of the medicinal product. The lack of such information must then be accepted. As stated in the instructions for article 105, it must correspondingly be accepted that certain kinds of written information cannot include the name of the manufacturer concerned, etc. However, the company responsible must always be specified in the information.
2. When judging which information should be considered necessary in a warning statement or a statement about limitations on use, the general principles stated in article 101 and the instructions provided for this article shall be considered.

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**Article 117 a**

Information to the general public on *pre-approved websites* shall include the following particulars:

- 117a.1 information that the medicinal product is a prescription medicinal product;
- 117a.2 the medicinal product's active ingredients specified by generic name or in some other suitable way;
- 117a.3 overview regarding the relevant area of therapy, that is, the use of the medicinal product to which the information relates, as well as necessary warnings and limitations that are applicable to its use;
- 117a.4 such details of company name and contact information referred to in Article 105;
- 117a.5 such details referred to in article 106;
- 117a.6 information about the date on which the summary of product characteristics was compiled or reviewed;
- 117a.7 a clear reference to the summary of product characteristics as approved from time to time by the Medical Products Agency as well as a clear reference to complete information regarding the medicinal product on Fass.se; and
- 117a.8 information that the website has been pre-examined and approved.

**Article 118**

*The regulation corresponding to article 18 in Chapter 1, Section 1 is not applicable to information to the general public.*

**Article 119**

Text that is reproduced in written medicinal product information must be easily legible. It must be positioned so that it is readily observed.

**Article 120**

Printed matter, advertisements, or other informational material should not be larger in format or bulk than is required by nature and content of the information. Directly distributed informational material shall be easy to manage and shall be dispatched in such a way as not to cause any unnecessary inconvenience to the addressees.

**Article 121**

*The regulation corresponding to article 21, in Chapter 1, Section 1 is not applicable to information to the general public. Regarding verbal information provided to the general public, the same rules apply as to any other form of distributing information to the general public.*

**Article 122**

*The regulation corresponding to article 22 in Chapter 1, Section 1 is not applicable to information to the general public. The fact that high standards of training and good factual knowledge must be imposed on the representatives engaged in the provision of verbal information to the general public follows from the rules applying to the content of the information and from general principles of market law, in particular the requirement of good business practice.*

**Article 123-126**

*The regulation corresponding to article 23-26 in Chapter 1, Section 1 is not applicable to information to the general public.*

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## **Rules on responsibility**

### **Article 127**

The responsibility for medicinal product information extends to the information as a whole, its content as well as its form, including any statements of opinion therein, any clinical reports or any reprints of published articles. The fact that the content and form of the information originate from other sources is irrelevant from the point of view of responsibility.

### **Bearer of responsibility**

#### **Article 128**

Responsibility for observance of the Rules Governing Medicinal Product Information rests with the pharmaceutical company concerned or its representative in Sweden. The representative is also responsible for information administered directly by the foreign principal.

#### **Article 129**

Within every pharmaceutical company, there shall be appointed a competent person from among the executive staff who shall be responsible for consultation with other people concerned in the company, for ensuring that relevant regulatory requirements are satisfied and for supervising the company's external information and its marketing practices. The person shall be the company's liaison officer in ethical matters related to informational and marketing activities (Information Officer in marketing ethics).

Pharmaceutical companies must also appoint a body that shall approve and monitor non-interventional studies. The body that is appointed should include a physician, or where appropriate a pharmacist, to be responsible for monitoring the non-interventional studies (also including reviewing liability for such studies, particularly those for which pharmaceutical representatives are responsible). The executive responsible must certify that he or she has examined the report/publication and that it is compatible with the applicable laws and provisions.

The information officer must approve all marketing material before it is taken into use. The person must certify that he or she has studied the final marketing material and that it satisfies the requirements in the applicable rules on information and applicable laws and regulations, that it corresponds with the SPC as well as decisions and recommendations by the Dental and Pharmaceutical Benefits Agency (TLV), and that it is a true and impartial presentation of the facts.

The information officer must have completed training in marketing law (IMA training) arranged by Lif.

When appropriate in view of its size, organisation or product range, the pharmaceutical company may appoint more than one person, having the status and functions stated in the first paragraph, with responsibility for information. A clearly defined area of responsibility shall then be assigned to each of these people.

In December of each year, every pharmaceutical company shall inform the Lif secretariat, in writing, of the name(s) of the person(s) who will be responsible for informational matters during the coming

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year. If more than one such person has been appointed, the area of responsibility of each person must be indicated. If a person is appointed with responsibility for informational matters in the course of a year, or if the area of responsibility of such a person is changed, the Lif secretariat shall be informed of this immediately in writing.

### **Burden of proof**

#### **Article 130**

A pharmaceutical company should be able to substantiate any facts, statements, claims, and other presentations in words or pictures contained in its medicinal product information. The company shall be prepared, upon request by IGN or NBL, to fulfill its obligation to produce supporting evidence without delay. Specific rules on documentation of statements of properties and effects of medicinal products are included in articles 108-111.

### **Statutory copies**

#### **Article 131**

The market surveillance shall, according to the statutes of IGN and NBL, be managed by IGN. For IGN to be able to fulfill this task, pharmaceutical companies must send new marketing materials (such as brochures, advertisements, invitations, mailings, commercial films, or information on websites) or already submitted marketing materials with significant updates, to IGN. This should be done within a reasonable time after the material has been put into use, but no later than within three months.

The regulation in this article does not apply to *pre-approved websites*.

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## **CHAPTER 2 – Rules of cooperation: the profession**

## **Division 1 – Agreement on forms of collaboration with healthcare**

### **Background and purpose**

The Swedish Association of Local Authorities and Regions (Sw. Sveriges Kommuner och Regioner, SKR), the Swedish Association of the Pharmaceutical Industry, Swedish Medtech, Swedish Labtech and SwedenBio have agreed on common rules for how employees and managers in healthcare and industry should collaborate and interact with each other.

The parties believe that collaboration between health care and industry is an important part of the development of both healthcare and business, and with this agreement they want to ensure that the cooperation can continue to develop in a trusting manner.

The agreement has been jointly developed based on the outside world's demands for increased transparency, moderation in collaboration and the need for a clear division of responsibilities between health care and industry, e.g. that the health care authority's responsibility for the continuing education of healthcare personnel.

The agreement on collaboration rules consists of two parts and both are governing:

- One part, the agreement, consists of fundamental principles and rules of a long-term nature, which constitute the basic prerequisites for collaboration (see Articles 1-2 below). An insightful application of these can be quite sufficient for collaboration to take place in a trusting manner.
- The second part, the specification, consists of concrete collaboration situations, which are intended to support collaboration, which the parties can update more continuously for the greatest possible timeliness (see Articles 3-10 below).

It is the responsibility of the parties to work to ensure that each party's members have a well-functioning self-action system in order to maintain good compliance with the collaboration rules and that their employees and managers have good knowledge of them.

## Definitions

Secondary employment	Any activity, temporary or permanent, which is carried out in addition to employment, and which is not related to private life.
Healthcare	All publicly funded healthcare in county councils, municipalities and private businesses with care agreements or according to LOV (the Act on Freedom of Choice Systems).
Industry	All companies in the pharmaceutical, medical technology and laboratory technology industries that operate in or are aimed at the Swedish market.
Employees	Employee, student in education or traineeship, contractor or consultant.
Regular activities	Refers to the existing working methods, tasks and activities that form part of the day-to-day operations within a unit in healthcare, and which the unit has decided to perform. The concept also includes statutory duties but is limited to activities that fall outside what is normally included in the healthcare provider's decided assignments or commitments.
Healthcare principal	Region or municipality responsible for healthcare.
Operations Manager	All operations in healthcare must have an operations manager. The operations manager is the one who has overall responsibility for the activities.
Product information	Gathering organised for marketing purposes to provide information on the characteristics and operation of a product.
Sponsorship	Financial or other support for specific activities, gatherings or materials that include a market-based quid pro quo. Such a quid pro quo may consist of, for example, an exhibition space, the opportunity for a product demonstration or some other form of exposure of the company/product. Sponsorship is different from a donation, where there is no quid pro quo.
Gathering	All forms of meetings where healthcare employees and managers and industry interact with each other. A gathering can also take place remotely.
Consultation	Healthcare professionals hired by companies for various assignments. These may include assignments in areas such as research, education, conferences, product development or participation in advisory boards.

## General conditions

In Sweden, collaboration between health care, research and industry has long been important for the development of new methods and treatments. Effective product development requires close and trusting collaboration between industry and healthcare. Collaboration can take different forms and have different purposes.

Good collaboration creates mutual commitment that provides faster knowledge collection, evaluation and introduction of new treatment methods as well as phasing out older treatment methods. The goal is to provide patients with appropriate, evidence-based, cost-effective and safe care, and to continuously improve healthcare, which is of great importance to society.

Collaboration with industry can be an important part of the continuing education and skills development of healthcare professionals, which in itself is necessary to be able to improve methods and treatment and to ensure a high level of patient and user safety.

The healthcare system is undergoing continuous change, while the demand for safer and more effective treatments is increasing. The parties must therefore update the collaboration rules regularly so that they adapt to their times.

Healthcare will move closer to patients, which means that it will take place to a greater extent in primary care, at home or remotely. Healthcare is also being digitalised at a rapid pace. New ways of meeting or monitoring the patient are being developed. Pharmaceuticals, medical and laboratory technologies are also becoming increasingly integrated, including through the development of new diagnostic methods, software and apps to support medical treatment.

The healthcare sector's need for skills supply and knowledge support requires new ways of working, where digitalisation and knowledge management provide opportunities for other types of meeting places. Where time or finances are an obstacle, digital meetings at a distance can enable knowledge acquisition or dialogue. Regions and municipalities' joint systems for knowledge management can contribute to the dissemination of information.

Regardless of the form of collaboration, it is of the utmost importance that healthcare employees and representatives of the industry maintain an independent approach to each other and in accordance with applicable regulations, for example in procurement.

## Scope of the collaboration rules

### Article 1

- These rules apply to all employees and managers in both healthcare and industry (including parent companies and sister companies in collaboration with Swedish healthcare).
- Regardless of whether a company belongs to a trade association or not, the healthcare sector must apply the rules when collaborating with companies in the pharmaceuticals, medical technology and laboratory technology sectors that operate on the Swedish market.
- In addition to this, employees and managers in healthcare and industry must also comply with their employers' rules for travel, representation, secondary occupations and other policies and codes.

## Fundamental principles and rules

### Article 2

The starting point is that all collaboration must be documented, open to scrutiny, reasonable and bring benefits to all parties involved. In the event that the collusion entails a transfer of value, the rules in Chapter 2, Title 3 shall apply.

#### **The following principles apply to all forms of collaboration**

### Article 2a

#### *The principle of trust*

A prerequisite for healthy collaboration is good compliance with current legislation, for example regarding bribery, procurement and taxation. This ensures that tax money is used correctly, that patients and users receive the best possible healthcare, and that public trust is maintained. Collaboration must withstand scrutiny and scrutiny without the risk of compromising trust.

Collaboration between healthcare and industry shall not entail undue influence and must not jeopardise or be perceived to jeopardise the independence of healthcare.

#### *The utility principle*

Collaboration between healthcare and industry shall be based on health care operations and the patient's needs and be clearly linked to the company's operations. There must therefore be a mutual benefit perspective.

*The principle of transparency* Collaboration between healthcare and industry must be open and transparently and in accordance with these rules, statutes, business and codes of conduct and policies.

For pharmaceutical companies, there are additional requirements for transparency via the European Federation of the Pharmaceutical Industry (EFPIA). Value transfers to both individual employees and activities in the healthcare sector must be openly reported annually in the Swedish Association of the Pharmaceutical Industry's collaborative database.

*The proportionality principle* In collaboration between healthcare and industry, commitments of the parties shall be in reasonable proportion to each other. All forms of remuneration must be reasonable, proportionate to the scope of the assignment, and correspond to the market value of the service performed.

*The moderation principle* Events that are in any way supported or arranged by the industry must be permeated by moderation and must not appear to be behavioural to the recipient.

*The Documentation principle* All forms of collaboration between healthcare and industry regardless of compensation or cost coverage must be documented in writing, for example via an agreement or another type of agreement. Relevant documentation such as agreements and invoices must be saved at least 3 years after the collaboration has been carried out. This applies to both individual employees and businesses.

## **The following rules apply to all forms of collaboration**

### **Article 2b**

*Basic rule* The industry may not make, promise or offer, and employees and managers in the health care sector may not accept, accept a promise of, or request benefits or compensation that violate these rules.

*Acceptance of participation* The person who participates in a meeting is responsible for obtaining the employer's approval.

*Meals* At gatherings arranged by or in cooperation with industry, the industry may offer a moderate meal in connection with the gathering. In the case of remote participation, meals may not be offered. A free meal may, depending on the nature and frequency of the gathering, constitute a taxable benefit. For meals in Sweden, the value may not exceed the value per participant determined by Lif at any given time. For

	meals abroad, local rules must be followed, in the absence of these, the Swedish rules must be applied as far as possible.
<i>Alcohol</i>	To be offered only moderately and only with meals. Spirits must never be offered, and non-alcoholic alternatives must always be available.
Social activities	Must not be financed by industry or requested by employees in the health care sector, whether at gatherings or in other contexts.
<i>Travel</i>	Trips must be planned so that arrival and departure take place as close to the assignment as practically possible. For air travel, economy class must be chosen, well-justified exceptions can be made for trips (> 6 hours) outside Europe.
<i>Included</i>	Only people who have been invited to an event are eligible to participate. Accompanying people to invited participants are not allowed to participate.
Sponsorship	The industry can, in return for a reasonable consideration, sponsor professional parts of specific gatherings that have a connection to its own field of activity. Sponsorship may only relate to the actual costs of a specific and clearly defined gathering/activity. Sponsorship of regular activities, participation fees, travel and accommodation, etc. is not allowed.

*Choice of location and venue*

The industry may only arrange or sponsor gatherings outside Sweden or the Öresund region if the majority of the participants are not from Sweden or if equivalent knowledge or experience cannot be gained here. The choice of location and venue for the implementation of the event must be reasonable in relation to the purpose of the event. Seasonal leisure resorts and places known for their exclusivity should be avoided, such as winter sports resorts during the ski season. The same applies to locations where major international events are taking place at the same time or in connection with the event, such as sports competitions.

## **Risk minimisation information (RMI) - specific information and measures to ensure correct and safe operation and functioning**

### **Article 3**

Risk minimisation information (RMI) means the information that marketing authorisation holders are required to communicate to healthcare professionals (or to patients via healthcare professionals) under specific conditions in the product's authorisation (2001/83/EC) or imposed after authorisation due to a safety signal that has arisen.

RMI is intended to ensure the correct and safe use of medicine and is described in the product's risk management plan.

RMI is based on patient safety aspects and is given to those employees who need to take part in it for safety or management reasons. The information is provided during working hours and at the workplace. Deviations from this must be well-justified and reportable.

Companies may not, in connection with a visit or gathering classified as RMI, market the product in question and/or other products. Nor may RMI involve the financing of other collaborations or gatherings. This is particularly important to consider if the information is provided outside the workplace.

In addition to what is stated in any procurement contracts, the provider of the information may bear all relevant costs for the implementation of the RMI, however, in accordance with the fundamental principles of this regulatory framework.

The provision of RMI is not affected by the ongoing purchasing process.

## **Product information**

### **Article 4**

A product information gathering shall provide participants with up-to-date and relevant information on the characteristics, functions and handling of specific medicinal products or medical and laboratory devices.

For medical and laboratory devices, product information is provided when it refers to products that have not been procured or are included in the pharmaceutical benefit and that are not yet used in healthcare, i.e. an activity for marketing purposes.

Product information should preferably be provided to a group of employees at the recipient's workplace and during working hours.

The invitation must state the following:

- Purpose and content
- Target group
- Temporal scope
- If possible, time and place

The title must state that it is about product information.

The invitation is sent to relevant employees, i.e. the main target group for the gathering, with a copy to the operations manager or the person he or she has appointed or the operation's functional mailbox (e-mail).

The operations manager decides who can participate in the product information session. However, participation should be limited to those who are directly affected/those who have direct benefit from the information in their daily work.

## **Other gatherings**

### **General for all meeting categories**

### **Article 5**

Other gatherings refer to various forms of competence development, e.g. therapy-oriented training, seminars, scientific gatherings, congresses and symposia.

The employer is responsible for the employees' continuing education and skills development and must bear any costs for participation in such activities.

The industry may only offer gatherings and sponsorship of events that are linked to the company's own areas of activity. The scientific and vocational program shall constitute the dominant part and be the purpose of the meeting in question.

The industry may contribute to the costs of premises, lecturers, study materials, moderate meals and the like that are necessary for the implementation of the gathering.

Travel may not be paid for by industry or requested by individual participants. The exception is shorter joint ground transport for participants between points A and B, for example, from a collection point to the meeting room, which may be arranged and paid for by the industry for practical, logistical reasons. This applies to meetings according to 5a and 5b below.

Accommodation and any registration fees may not be paid for by the industry or requested by individual participants in gatherings.

Booking of travel and accommodation may only be arranged by the industry for meetings in accordance with 5a and 5b below. If booking and payment are made by the industry, the companies must invoice the participants in full.

Participants in gatherings may not be offered a fee by companies and participants are not entitled to receive or request a fee for their participation.

Participants in a gathering are responsible for obtaining the employer's approval.

The three main types of gatherings are described below and the rules that apply to each of them (see 5a, 5b and 5c below).

## **a) Meetings arranged by the industry**

### **Article 5a**

The industry itself can arrange, pay for and be the sender of gatherings aimed mainly at employees in the health care sector.

The meeting shall normally be held at or as close to the participant's workplace as possible, unless special circumstances exist.

The invitation must state the following:

- Purpose and content
- Target group
- Temporal scope
- Location
- Costs covered by industry

If product information is available, it must be stated in the invitation or program.

The invitation is sent to relevant employees, i.e. the main target group for the meeting, with a copy to the operations manager or to a functional mailbox (e-mail). Additional copies should be sent to the relevant pharmaceutical committees for information, or alternatively to a functional mailbox (e-mail). Medical device companies shall, if relevant, send a copy to the relevant medical device managers.

In the case of open advertising for gatherings in print or web-based media aimed at the majority of a specific target group, the invitation procedure as mentioned above (in Article 5a), does not need to be followed. The same applies to remote participation for such gatherings or remote participation for other gatherings aimed at a specific target group. This can be used, for example, at major training sessions, congresses or symposiums that are advertised in medical journals and to which the majority of all concerned can be assumed to have access.

## **b) Meetings jointly arranged by healthcare and industry**

### **Article 5b**

In collaboration with the health care system, the industry can share responsibility, act as the sender and partly pay for meetings aimed mainly at employees in the health care sector.

All parties are expected to contribute to the implementation of the meeting, for example by covering costs for the meeting or for materials and/or contributing working hours. The meeting and how to contribute are carried out in the way agreed by the parties. The healthcare system covers the costs of its own staff, such as lecturers, course secretaries or similar.

The meeting shall normally be held at or as close to the participant's workplace as possible, unless special circumstances exist.

The invitation to the meeting must state at least the following:

- Purpose and content
- Target group
- Time
- Location
- Costs covered by industry

If product information is available, it must be stated in the invitation or program.

The invitation is sent to relevant employees, i.e. the main target group for the meeting, with a copy to the operations manager or to a functional mailbox (e-mail). Additional copies should be sent to the relevant pharmaceutical committees for information, or alternatively to a functional mailbox (e-mail). Medical device companies shall, if relevant, send a copy to the relevant medical device managers.

In the case of open advertising of gatherings in print or web-based media aimed at the majority of a specific target group, the invitation procedure as mentioned above (in Article 5b), does not need to be followed. The same applies to remote participation for such gatherings or remote participation for other gatherings aimed at a specific target group. This can be used, for example, at major training sessions, congresses or symposiums that are advertised in medical journals and to which the majority of all concerned can be assumed to have access.

There is no sponsorship situation since all the parties are organizers.

## **c) Gatherings arranged by healthcare or third parties**

### **Article 5c**

The health care system or an interest association that organizes employees in the health care sector can itself arrange and act as a sender for gatherings aimed at employees in the health care sector where the industry can be a sponsor.

Sponsorship means financial or other support that includes a reasonable quid pro quo, corresponding to the market value, such as e.g. exhibition space, opportunity for product demonstration, time in the program or other form of exposure of the company/product.

When requesting sponsorship, the organizer must provide a complete budget for the activity as a basis for decision-making, where all income and costs are specified.

Income from sponsorship may only cover actual, documented, reasonable and direct costs. Who are the sponsors must be communicated well in advance of the gathering.

Sponsorship of gatherings where the meal is the only actual cost may not be requested or offered.

Sponsorship of the internal activities of healthcare must not occur, for example, individual activities' training, planning conferences or staff parties. Nor may such sponsorship be requested or offered.

The healthcare system covers the costs of its own staff, such as lecturers, course secretaries or similar.

Within three months of the end of the activity, a follow-up of the budget must take place where the financial outcome is reported to the sponsors concerned. When sponsorship income is equal to costs, simple written communication is enough to ensure that this is the case. If the sponsorship income generates a surplus, repayment must be made to the sponsors.

## **Consulting assignments for the industry**

### **Article 6**

Employees and managers in the healthcare sector are often an important element in various activities, such as research, education, conferences, product development and advisory boards.

It is always the employer who decides whether the assignment is a secondary occupation or whether it is an assignment in the course of the service. Assignments should normally be carried out in the course of the service. It is the employee in the health care sector (the consultant) who is responsible for informing and agreeing with the employer whether the assignment is to be carried out as an assignment in the service or if it is a secondary occupation.

Compensation for work performed must be reasonable in relation to the content of the work and time spent. Apart from compensation for work performed and any cost coverage for travel, board and lodging, no other compensation, benefits, or gifts may occur.

For assignments in the position, a written agreement is drawn up between the employee (consultant), the employee's employer and the company. At a public employer, the agreement constitutes a public document. Compensation for assignments in the service must be paid to the employer.

If the assignment is conducted outside of work, it is to be regarded as secondary employment and the applicable provisions on secondary employment in the Public Employment Act (LOA) and collective agreements must be applied.

- For assignments that constitute secondary employment, a written agreement is drawn up between the employee (consultant) and the company.
- The employee (consultant) must always inform their employer of the nature, scope of time and remuneration of the assignment in order to ensure that it complies with the employer's secondary employment rules. It is the employer who assesses whether the secondary occupation may be harmful to trust, work hindering or competing, in accordance with the LOA and the applicable collective agreement.

Collaboration between companies and healthcare must be open and transparent in accordance with the principle of transparency. This means, among other things, that:

- Employees and managers in the healthcare sector must be open with assignments for the industry. This applies, for example, to assignments for authorities or expert bodies and to contact with the media in relevant situations. Assignments must always be included in the current declaration of conflict of interest to enable an assessment of any conflict of interest.

Value transfers in the form of, for example, consultancy fees from pharmaceutical companies to healthcare professionals or other healthcare professionals must be public and published in the Swedish Association of the Pharmaceutical Industry's collaborative database. The publication of information on transfers of value involves the processing of personal data. Companies can support this processing either on a balance of interests on a legal basis or on the consent of the individual consultant. If consent is used as a legal basis, both employers and companies must encourage consultants to provide such consent. Please note, however, that such consent must always be given voluntarily and can never be mandatory on the part of the company. Consultants who do not provide consent should not be hired.

## **Advisory board**

Participating in an advisory board is an assignment where the industry engages and remunerates employees in the healthcare sector to provide independent advice and contribute knowledge in a particular area where the knowledge cannot be obtained within the company. The Company intends to act based on the information obtained.

An advisory board must constitute a small group, and the number of employees engaged must not exceed what is necessary to achieve the stated purpose.

The selection criteria for selecting employees shall be based on the identified need, and responsible persons from the industry shall have the experience required to be able to evaluate whether a particular person in the healthcare sector meets these requirements.

An advisory board must not aim to influence the participants.

## **Scholarships**

### **Article 7**

The industry may finance scholarships aimed at the health care sector.

A scholarship is awarded after nomination to people to promote a specific cause.

Companies may only award scholarships in an area that is linked to the company's own areas of activity.

The scholarship must be of a professional nature, such as future education and research or similar, and must provide added value to the healthcare system. Selection criteria, purpose, scholarship committee, reasons for choosing scholarship recipients and scholarship donors must be public and transparent.

The donor of the scholarship must obtain the approval of the scholarship recipient's employer. A scholarship may not constitute compensation for work on behalf of the employer.

Scholarships where the sole purpose is to finance travel, accommodation and/or participation fees for e.g., education or congress are not allowed.

## **Donations**

### **Article 8**

Donations to healthcare may only be made if the purpose is research and development (R&D).

Donations to health care may not be made if the purpose is to finance:

- Internal activities
- Regular activities
- Social activities

Donations must be transparent, well-documented, and in accordance with the agreement on collaboration and its intentions.

Donations may not be linked in any way to the past, present, or potential future use, recommendation, sale, or prescription of the donor's products or services.

## **Development projects where healthcare and pharmaceutical companies collaborate**

### **Article 9**

Development projects refer to collaboration in project form on areas and topics that are naturally linked to the constituent parties' areas of activity.

Development projects may not be started with the aim of financing or otherwise supporting the existing working methods of healthcare in ordinary activities.

There must be a detailed project plan that will regulate the purpose and goals of the project, how the project will be evaluated and the experiences will be utilised and disseminated/published. A budget should also always be budgeted.

Project proposals for development projects must be sent to the operations manager, who informs any relevant bodies. An agreement must always be signed that regulates the content and scope of the project.

A development project may not constitute a personal assignment with an individual employee, but an agreement must be signed between the pharmaceutical company and a unit in the health care sector.

The agreement must not entail exclusivity for the pharmaceutical company to enter into agreements on collaborations with one or more units in the healthcare sector. The agreement must clarify the roles and responsibilities of healthcare and industry, e.g. regarding the handling of personal data, patient responsibility and how the results of a development project may be used.

Both the health care system and the company must contribute to the project with resources

such as financial resources, materials and/or working hours. The distribution between the parties' contributions must be perceived as reasonable by all parties and be reported in the project plan. The health care system must always bear its own administrative costs associated with the project, such as employees' time or travel carried out within the framework of the development project.

The project must be limited in time based on what is reasonable in relation to the objectives of the project and must not be longer or more extensive than is justified in order to achieve the purpose of the project. The project must be completed after the project period.

The project must be reported openly, for pharmaceutical companies this means that they must be made available in the Swedish Association of the Pharmaceutical Industry's collaborative database.

Activities that are not defined as development projects in these rules are:

- Collaboration to develop commercial products for companies, such projects must be carried out within the framework of consultancy agreements.
- Offers of treatment linked to a company's medicines through agreements or procurements that are regulated within the framework of ordinary business activities. Examples of areas that may be relevant are orderly introduction and examples of products and services that may be covered are tests, diagnostics or patient support programs.

## **Patient support programs**

### **Article 9a**

Patient support programs (PSPs) are activities or offers designed to support patients in their treatment and/or management of their disease.

A patient support program should always be offered through the healthcare system and not directly from a company.

After the patient has received information about a patient support program from the health care system, additional information may be provided to the patient by the company.

## **Market research**

### **Article 10**

Market research is surveys, interviews and focus groups with different goals and set-up and may only have the purpose of gathering information, opinions and attitudes.

Surveys must not influence the respondent or mediate sales-promoting contacts.

When companies covered by these collusion rules commission market research to be carried out, the person conducting the survey must comply with the ethical guidelines for market research according to ICC/ESOMAR.

Requests to participate in market research may only be made by e-mail or letter, unless otherwise agreed in the individual case.

The proportion of respondents shall not exceed the number necessary to achieve reasonable certainty in the results.

Respondents' responses shall be treated as strictly confidential and in accordance with the data protection law in force at any given time.

Compensation for participation must not exceed what is reasonable in relation to the time input. For swiftly completed market research by telephone or survey, no or only symbolic remuneration shall be paid. For more time-consuming market research, for example with in-depth interviews, compensation may be paid corresponding to the time required, but not more than 2.5 per cent of the applicable price base amount/CPI.

The respondent is responsible for obtaining the employer's consent if necessary. In the case of financial compensation for participation in market research related to the practice of the profession, the employer's consent should always be obtained.

## **Information- and educational material and medical utility items**

### **Article 11**

Gifts may not be supplied, offered or promised to healthcare or its employees except for what follows below.

Information- and educational material may be provided under the condition that the material is (i) of low value, (ii) directly relevant to the practice of the recipient and (iii) directly beneficial to the care of patients.

Items of medical utility may be provided for purposes of educating employees and for the care of patients under the condition that the item is (i) of low value and (ii) not such which is routinely used in the recipient's business. The definition of "low value" refers to no higher amount than at any time is determined by Lif's Board.

Information- and educational material and items of medical utility may not be supplied, offered or promised to healthcare personnel as an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products.

Information- or educational materials and items of medical utility can include the company name, but must not be product branded, unless the medicinal product's name is essential for the correct use of the material or item by the patient.

## **Clinical Trials**

### **Article 12**

A separate agreement has been concluded between the Association of Local Authorities and Regions and the Association of the Pharmaceutical Industry (Lif) regarding clinical trials; according to which agreements must be entered into between affected healthcare managements, investigators and pharmaceutical companies. The agreement has a standardised agreement form. The pharmaceutical companies must also comply with the publication of information on clinical trials databases and in scientific literature. See "Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases" respectively "Joint Position on the Publication of Clinical Trial Results in the Scientific Literature"

## Section 2 – Ethical rules for interaction between pharmaceutical companies and pharmacy employees

### Area of application Background and

#### purpose

The pharmaceutical industry and the pharmacies have a long history of cooperation in many different areas. This is important to both parties alike and valuable for patients at large.

Under various statutory provisions and best business practice, the pharmaceutical industry is obliged to provide complete and accurate information about its products, including properties, effects and appropriate fields of application as well as possible side effects. Pharmacy employees have a corresponding need for such information to enable them to give good advice on the proper use of medicinal products.

Pharmacy employees also come to develop a broad knowledge base concerning the properties and the use of various medicinal products, which knowledge must be fed back to the pharmaceutical companies to provide a basis for development, both to existing medicinal products and new applications.

The purpose of these rules is to present rules promoting collaborations to be carried out in an ethical way, with good judgment and maintenance of credibility and in accordance with ruling laws. However, good compliance with the rules does not exempt pharmaceutical companies and pharmacy employees from possible accusations of corruption and bribery. Such responsibility must always be examined individually, based on the importance of the connection between the advantages, the exercise of duties and the extent of influence.

#### Definitions

<i>Pharmacy</i>	A single sales outlet with a license from the Medical Products Agency to operate retail of pharmaceuticals. Includes pharmacies (sw. <i>öppenvårdsapotek</i> ) and hospital pharmacies.
<i>Pharmacy company</i>	The legal person which operates pharmacy business acting on or directed to the Swedish market.
<i>Pharmacy manager</i>	Appointed person by the pharmacy/pharmacy company who is responsible for the operation and has the general management responsibility.
<i>Secondary employment</i>	Any temporary or permanent employment or assignment which is carried out as a sideline activity and not related to private life.
<i>Pharmaceutical company</i>	All companies within the pharmaceutical industry that act on or is directed to the Swedish market.

<i>Employee</i>	An employed person, student under education or training, contractor or consultant.
<i>Product information</i>	Product information meetings aiming to inform attendees of the specific properties or handling of a given medicinal product.
<i>Sponsorship</i>	Sponsorship entails financial or other support, and it includes a market-based return, such as exhibit space, the opportunity to demonstrate a product, or other forms of exposure.
<i>Other meetings</i>	Other meetings can concern various forms of training and development of skills other than those pertaining to product information, e.g. therapy-oriented training, seminars, scientific meetings, congresses and symposia.
Market research	Market research comprises questionnaires, interviews and focus groups with different goals and structures, and may only have the purpose of obtaining information, opinions and attitudes, it must not influence the respondent or supply sales promotional contacts.
<i>Consultation</i>	Employees at pharmacies or pharmacy companies are often an important part of various activities, such as research, training, conferences, product development, and advising bodies, referred to as advisory boards.
<i>Advisory board</i>	An appointment that entails a pharmaceutical company engaging and compensating pharmacy or pharmacy company employees who provide independent advice and contribute knowledge in a particular area where such knowledge cannot be obtained within the company, and where resulting information is instrumental to subsequent activities. An advisory board is an activity that may not have the purpose of influencing the participants

## **1. Basic principles and rules**

The basis for all cooperation is documentation, transparency, reasonability and shall be of benefit to all parties.

### **The following basic principles shall always apply:**

<i>The principle of trust</i>	Cooperation between pharmacy companies, pharmacies and industry shall not entail an undue influence and may not jeopardize or be perceived as jeopardizing the independence of healthcare. The prerequisite for a sound cooperation is compliance with applicable legislation, such as legislation regarding bribery, procurement and tax. This is to ensure that tax revenue is used correctly, that patients and users can be assured of getting the best possible healthcare and that cooperation upholds the trust of the public. The cooperation must withstand examination and scrutiny with regard to the risk of jeopardizing trust.
<i>The benefit principle</i>	The cooperation between pharmacy, pharmacy company and industry should be based on the activities of a pharmacy and on the needs of patients and shall be clearly linked to the company's business. A mutual benefit perspective shall be applied.
<i>The transparency principle</i>	Cooperation between pharmacy, pharmacy company and industry shall be open and transparent and in accordance with these rules and with applicable laws, regulations, good business practice codes and ethical codes and policies. In case the cooperation entails a transfer of values, as defined in chapter 2, section 3 of the Ethical rules for the pharmaceutical industry, the rules in chapter 2, section 3 shall be applied on such transfer of value.
<i>The proportionality principle</i>	Throughout cooperation between pharmacy, pharmacy company and industry, the obligations of each respective party shall be reasonable as seen in relation to the obligations of the other party. In addition, all kinds of remuneration shall be proportional, reasonable and shall correspond to the fair market value of the service provided.
<i>The moderation principle</i>	A meeting which is in any way sponsored or arranged by a pharmaceutical company shall be permeated by moderation. The requirement for moderation means that the privilege may not appear as influencing the behaviour of the recipient.
<i>The documentation principle</i>	All forms of cooperation between pharmacy, pharmacy company and industry where any form of remuneration or recovery of costs occurs, whether involving single employees, groups of employees or a pharmacy unit, shall be documented in writing, e.g. in the case of a decision or an agreement. Relevant documentation such as agreements, related reports, invoices, etc. shall be archived.

**The following basic rules shall apply for all cooperation:**

<i>The basic rule</i>	Participants in meetings may not be offered remuneration from pharmaceutical companies and participants are not entitled to accept or demand remuneration for their participation. Pharmaceutical companies are not permitted to offer, and pharmacy employees are not permitted to ask for or receive benefits or other types of remuneration, or request actions which are in breach of these rules or the intentions thereof.
<i>Participation</i>	Product information or other meetings shall normally be carried out at participants' place of work or in the same town or city or as near as possible, if not particular circumstances motivate otherwise. The participating employees are responsible for ensuring that the employer has given its consent to the participation.
<i>Meals</i>	At meetings arranged by or in collaboration with pharmaceutical companies, the pharmaceutical companies may offer a moderate meal in connection with the meeting, although this is not the case at remote participation. For meals in Sweden, the value of a lunch or a dinner should not exceed the amount per participant stipulated by Lif at the time. For meals abroad, local rules take precedence. In the absence of local rules or guidance the Swedish levels apply.
<i>Alcohol</i>	Hospitality including alcohol in form of wine and beer in connection with a meeting shall be restrictive and only occur at meals. Spirits may never be offered. Non-alcoholic alternatives should always be made available.
<i>Recreational activities</i>	No stand-alone social activities or recreational activities in connection with meetings or other forms of interaction may be financed by a pharmaceutical company or be requested by employees. However, simpler social activities, such as background music or local performances, in conjunction with meetings shall not be deemed offered by the pharmaceutical company as long as they neither have been arranged, required or paid for by the pharmaceutical company.
<i>Travel participant</i>	Pharmaceutical companies must not pay for the cost of travel or accommodation for participants in a meeting. Neither conference fees for pharmacy's nor third party's meeting.
<i>Travel contractor</i>	When it is possible, travel shall be arranged in economy class. If possible, travel time may not exceed the total length of the meeting, including potential side event.
<i>Accompanying individuals</i>	Only participants in the meeting may be invited. Accompanying

individuals may not participate.

*Selection of location and venue* The selection of location and venue for a meeting shall be reasonable in relation to the purpose of the meeting. Leisure resorts during season and places known for their exclusivity shall be avoided, e.g. locations for winter sports during ski season. The same applies to locations at which major international events are being staged at the same time as or in connection with the meeting, e.g. motor races and golf tournaments. Neither shall companies contribute financially to meetings held at such locations.

## **2. Product information**

The invitation shall include information about content, duration and, if possible, time and venue.

Visits that do not include product information may be carried out on each pharmacy's terms.

The same conditions as described in chapter 2, section 1, article 4, applies for product information that is presented in exhibition stands or that is distributed at international scientific conferences or symposia

## **3. Other meetings**

Regulated under corresponding conditions as provided in the Ethical Rules for the Pharmaceutical Industry chapter 2, section 1, article 5/5 a/5 b/5 c.

## **4. Consulting and assignments**

The assignment shall be agreed upon in writing between the employee and the pharmaceutical company. The participation may be an assignment that falls under normal work duties or be of a consulting nature and this be regard as secondary employment.

Remuneration for work carried out shall be regulated in the agreement. Remuneration for work shall be reasonable in relation to the content of the task and the time spent. No other benefits, remuneration or gifts may occur. Compensation for work carried out as a part of normal work duties shall be paid to the employer.

Before an assignment is initiated, a legitimate need for carrying out such assignment must be established. The selection criteria for pharmacy employees must be based on the identified need, and responsible individuals at the pharmaceutical companies must have the experience that is required in order to evaluate whether a particular person within the healthcare sector/pharmacy satisfies these requirements.

The pharmaceutical company is recommended to indicate, in the written agreement, that there is an obligation for the employee to declare that he or she is a consultant for, or a part-time employee of, the company when he or she expresses an opinion in public, verbally or in writing, on the topic covered by the assignment.

The consultant shall also in the agreement be urged to be transparent with the assignment in relevant situations as for example, assignments on behalf of authorities of expert bodies and

include this in relevant declaration of challenge.

Hiring pharmacy personnel for the execution of a particular assignment may not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products or to otherwise influence the participants.

## **5. Market research**

When pharmaceutical companies conduct market research, the person performing the research shall abide by the ethical guidelines for market research in accordance with ICC/ESOMAR.

The number of respondents may not exceed the number necessary to provide reasonable assurance of the outcome. The respondents' answers should be treated in strict confidence and in accordance with the applicable data protection legislation in force at any time.

Compensation for participation shall not exceed what is reasonable in relation to the time committed. For market research completed via telephone or a questionnaire in a timely manner, no payment other than symbolic compensation shall be issued. For more time-consuming market research, e.g. an in-depth interview, compensation can be paid which relates to the time committed, but no more than 2.5 % of the current base amount/KPI.

## **6. Information- and educational material and medical utility items**

Gifts may not be supplied, offered or promised to pharmacy companies, pharmacies or their employees except for what follows below.

Information- and educational material may be provided under the condition that the material is (i) of low value, (ii) directly relevant to the practice of the recipient and (iii) directly beneficial to the care of patients.

Items of medical utility may be provided for purposes of educating employees and for the care of patients under the condition that the item is (i) of low value and (ii) not such which is routinely used in the recipient's business.

The definition of "low value" refers to no higher amount than at any time is determined by Lif's Board. Information- and educational material and items of medical utility may not be supplied or offered as an incentive to recommend, prescribe, purchase, supply, sell or administer medicinal products.

Information- or educational materials and items of medical utility can include the company name, but must not be product branded, unless the medicinal product's name is essential for the correct use of the material or item by the patient.

## **7. Development projects**

Development projects between pharmaceutical companies and pharmacies may occur under equivalent conditions as mentioned in LER chapter 2, section 1, article 9.

The pharmacy manager and the pharmacy company shall assess the appropriateness on the pharmacy's side.

## Section 3 – Disclosure of transfers of value

### Definitions

#### Article 1

In chapter 2, section 3, the following terms shall have the following definitions:

- **Healthcare** shall mean any legal person or sole trader which performs healthcare services or research or educational services within this field, or an organization with a medical or scientific purpose, with the exception of such organizations which fall within the scope of chapter 3.
- **Healthcare personnel** shall mean a physician, dentist, pharmacist, nurse or any other natural person within healthcare or a government agency who has a right to prescribe, purchase, supply, recommend or administer a medicinal product, including employees of a pharmaceutical company whose primary occupation is that of a practicing healthcare personnel. All other employees of a pharmaceutical company or employees of a distributor of medicinal products are excluded from the definition of healthcare personnel.
- **Recipient** shall mean healthcare or healthcare personnel.
- **Reporting period** shall mean a full calendar year, starting with the calendar year 2015.
- **Transfer of value** shall mean direct and indirect transfers of value, whether in cash or in kind, which takes place in connection with the development or sale of medicinal products exclusively for human use, irrespective of whether or not the purpose is promotional. Direct transfers of value are those made directly by a pharmaceutical company to or for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company by a third party (e.g., a subcontractor, a cooperation partner or affiliate) to or for the benefit of a recipient, provided that the pharmaceutical company knows or can identify the recipient.
- **Transfer of value for research or development** shall mean transfers of value to recipients related to the planning or conduct of (i) non-clinical studies (as defined in OECD:s Principles for Good Laboratory Practice), (ii) clinical studies or (iii) prospective non-interventional studies which include the collection of patient data from or on behalf of healthcare personnel.

### Scope of duty of report

#### Article 2

2.1 Direct and indirect transfers of value which are made to or for the benefit of a recipient shall be documented and publicly disclosed by the pharmaceutical company as further described in chapter 2, section 3.

2.2 Transfers of value which (i) fall outside the scope of what is stated in article 4 below in this section or (ii) are made within the framework of an ordinary purchase or sale of medicinal products for human use, are not comprised by the duty of disclosure.

#### **When disclosures shall be made**

##### **Article 3**

3.1 Disclosures of transfers of value shall be made annually and shall comprise a full calendar year. The first reporting period is the year 2015.

3.2 Companies are strongly recommended to report transfers of values on the last weekday in May. If this is not possible for some reason, as soon as possible thereafter, and by the latest 30 June. The details shall be disclosed publicly and shall remain public during a period of three years calculated from the time when the details were made public.

#### **How disclosure shall be made**

##### **Article 4**

4.1 Disclosure of transfer of value shall be made in accordance with the template in Appendix 1 to the ethical rules.

4.2 The report shall, at minimum, be searchable by recipient name, and downloadable; this is mandatory from the publication in 2027 disclosure of transfer of values from 2026.

4.3 The publication shall also include a summary of the methods used to do the report.

It is mandatory to use the structure in EFPIA's "Template of the methodological note structure" in the EFPIA code of practice, Annex B. It must be implemented at the latest for the 2026 disclosure of transfer of values from 2025.

#### **Platform for disclosure**

##### **Article 5**

5.1 Disclosure shall either be done

- (i) in Lif's co-operation database; or
- (ii) on the pharmaceutical company's website.

If disclosure is made on the pharmaceutical company's website, a link to the report shall be placed in Lif's co-operation database.

#### **Applicable rules**

##### **Article 6**

6.1 Disclosures shall be made in accordance with the rules of the national code which apply in the country where the recipient has its principal place of business or its seat. If the recipient has its principal place of business or seat in another European country than Sweden, and if the pharmaceutical company cannot disclose the transfer of values through a member of its group of

companies in the country of the recipient, the pharmaceutical company shall disclose the transfer of value according to the rules in this code.

## **Language**

### **Article 7**

7.1 The transfers of value shall be disclosed in Swedish. The pharmaceutical companies are encouraged to also disclose the information in English.

## **Documentation and retention of records**

### **Article 8**

8.1 Details on transfers of value shall be documented by the pharmaceutical company and be maintained for a period of at least 5 years following the expiry of each reporting period.

## **Individual disclosure**

### **Article 9**

9.1 If nothing else is explicitly stated in this chapter 2, section 3, transfers of value in each reporting period shall be disclosed on an individual basis for each identifiable recipient where the transfer of value can be reasonably allocated to one of the categories set out below in article 9.1.1 – 9.1.2. Such transfers of value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to (i) the relevant recipient, and/or (ii) the relevant authorities.

9.1.1 For transfers of value to healthcare, disclosure shall be made of an amount related to any of the categories set forth below:

- (a) donations referred to in chapter 2, section 1, article 8.
- (b) financial support to such arrangements referred to in chapter 2, section 1, article 5 c, which pharmaceutical companies may sponsor through sponsorship agreements with healthcare or with a third party who has been appointed by healthcare to arrange the arrangement.
- (c) remuneration for consultation and assignments referred to in chapter 2, section 1, article 6.

9.1.2 For healthcare personnel, disclosure shall be made for transfers of value which relate to consultation and assignments referred to in chapter 2, section 1, article 6. Reimbursement for expenses (if any) shall be disclosed separately.

## **Aggregated disclosure**

### **Article 10**

10.1 For transfers of value which can be allocated to one of the categories set forth in article 9.1.1 – 9.1.2 above but where the information cannot be disclosed on an individual basis due to legislation, the details on transfers of value shall instead be disclosed on an aggregate level for each reporting period. The aggregated details shall, for each category, include (i) the number of recipients which are comprised by the details, expressed as a number and a percentage of the total number of recipients, and (ii) the aggregated amount for the transfer of value which is not disclosed on an individual level.

## **Indirect transfers of value to health care personnel**

### **Article 11**

11.1 When transfers of value are made indirectly to healthcare personnel through the employer, the transfer of value shall only be disclosed once. To the extent possible, such disclosure shall be made in accordance with article 9.1.2.

## **Transfers of value for research and development**

### **Article 12**

12.1 Transfers of value for research and development shall be disclosed on an aggregate level. Costs related to such activities shall be included in this category.

## **Additional guidance (EFPIA Code of Practice)**

For further guidance see Appendix B EFPIA Code of Practice.

## **CHAPTER 3 – Rules of interaction: organisations and politicians**

## **Section 1 – Ethical rules as to collaboration between pharmaceutical companies and user organisations/interest groups/the general public**

### **Background and purpose**

There has long been an important partnership and exchange of experience between pharmaceutical companies and various organisations. The pharmaceutical companies should maintain close contact with organisations. The co-operation between the parties is all the more important since pharmaceutical companies need to exchange knowledge and experience with those suffering from a specific disease or using pharmaceutical products so that the use and development of pharmaceutical products can be optimised and to be able to develop information and services that support the patient in his/her everyday life. Pharmaceutical companies often possess knowledge and resources which can help to develop or support the organisation's work to improve the members' management of their disease or pharmaceutical care. There might also be a need to conduct projects together to jointly improve the conditions for living with a particular disease. All collaboration should take place within the constraints of these ethical rules, and other parts of the ethical rules.

The purpose of these ethical rules is to ensure that the co-operation takes place in a responsible and meaningful manner, and that it is conducted in such a manner that the parties' independence from one another is not jeopardised or questioned from either legal or ethical standpoints. This means that the collaborative projects may not form a dominant part of the organisation's activity and/or economy.

### **Scope**

The ethical rules are applicable to the pharmaceutical companies in its collaboration and communication with Swedish organisations or its members. Certain organisations and companies have set their own rules regarding collaboration. Such rules are to be seen as complementary to these ethical rules.

In this document, organisations mean interest organisations such as disability organisations, patient associations, relatives' associations and other patient networks/associations. Also included are other interest organisations which form opinion within the healthcare sector, such as pensioners' organisations, the 1.6 Million Club, the Swedish Cancer Society, the Swedish Heart-Lung Foundation etc.

If relevant, an organisation should be contacted or involved as a first step in a collaboration. The rules are also applicable when collaborating with patients who are not members of an organisation or who do not represent an organisation. This also applies to collaboration with patients' caregivers. In these terms, the term caregiver refers to both people from the patient's family, relatives, partner, close friend etc., and other people supporting the patient, for example a voluntary support person (excluding health care workers in their role as service providers).

If international activities or activities are arranged by the company's foreign principal in Sweden, or is aimed at the Swedish market, it shall be incumbent upon the subsidiary in Sweden to ensure that the principal also respects the rules which apply in Sweden.

The rules also apply if a company itself or in collaboration with an organisation hires a third party (e.g. a communications agency or advertising agency) to carry out all or part of the activity, i.e. the pharmaceutical companies responsible for ensuring that the external consultant complies with the rules.

## **Fundamental principles**

The following principles serve as guidance for all collaboration between pharmaceutical companies and various organisations:

- *Respect for each other and each other's roles*
- *Reciprocity in relationships*
- *Openness and transparency to the outside world*
- *Restriction of the choice of collaborative fields*
- *The independence of the collaboration partners shall be safeguarded*

### **Respect for each other and each other's roles**

The organisations, whether they are referred to as disability organisations, patient organisations, organisations for relatives etc. have as their mission to represent their members or equivalent.

The pharmaceutical companies are companies that conduct research and development, manufacturing and/or marketing and sales of medicinal products.

In an exchange of experience, the members of the organisations can contribute, for example, with their knowledge and experience of living with various diseases and ill-health conditions. The organisations also communicate requirements and requests for improvements to the companies, and the feedback can strengthen the user perspective when designing packaging, information in package leaflets, information about and organisation of clinical research studies.

Companies, on their part, need information and information on how it is to live with different ill-health conditions, and how society and healthcare work for them. Companies can also contribute to disease awareness material or similar to the members of the organisations.

It is important that the parties jointly discuss what they want to achieve and what it is appropriate to collaborate on. To avoid conflicts, should objectives, roles, responsibilities and rules for collaboration be clear from the start.

### **Reciprocity in relationships**

The choice of activities and projects must be in the interest of all parties involved. When planning activities, it is important to discuss what common interests the parties have, what they want to achieve together and what areas they can collaborate on.

The objective is to jointly plan and execute projects or activities for which all parties can take responsibility.

### **Openness and transparency to the outside world**

It is important to ensure openness and transparency in all collaborations. Information on collaboration shall be available in Lif's Collaboration Database, [www.lif.se](http://www.lif.se), no later than three months after the start of the activity/collaboration and for a period of three years.

### **Restriction of the choice of collaborative fields**

Collaboration must be chosen with care, and collaborations shall be conducted on correct grounds and be transparent to the outside world. Collaboration shall be conducted in fields with a natural link to the interests of the parties involved.

### **The independence of the parties is the basis for all collaboration**

It can sometimes be an advantage that several companies and possible other appropriate actors are involved in collaborations with one or more organisations. To ensure an independent position, collaboration and the industry's sponsorship of activities must not become a dominant part of the organisation's economy and operations.

### **The following basic rules shall always apply**

**Marketing of prescription-only medicinal products** – pharmaceutical companies may not market prescription-only medicinal products to the public (see LER Chapter 1, Section 2), either directly or indirectly. Members of organisations as well as their officials and elected representatives etc. are to be considered as public.

**Patient testimonials** – medicinal product information must not contain testimonials from individual patients/the public or close relatives etc. (LER, Chapter 1, section 1 and 2, Article 8/108). However, the patient may, e.g. describe his/her illness and what it is like to live with the disease but must never point out individual medicinal products or specific treatments in such a way that it directly or indirectly points out individual medicinal products.

**Meals** – at meetings arranged by or in collaboration with pharmaceutical companies, the pharmaceutical companies may offer a moderate meal in connection with the meeting. For meals in Sweden, the value may not exceed the amount established by Lif per participant at any given time. For meals abroad, local regulations should be followed, and in the absence of such, Swedish regulations should be applied as far as possible. Hospitality, including alcohol in connection with a meeting shall be restrictive and only occur at meals. Spirits may never be offered. Nonalcoholic alternatives shall always be made available.

**Social activities** – Neither in connection with meetings nor collaboration in general may

separate social activities be offered or paid for by pharmaceutical companies. In conjunction with meals or receptions may, however, a simpler social activity such as music entertainment be arranged if it is secondary to the activity as well as the meal or reception.

**Health-promoting activities** – in connection with gatherings, there may be health-promoting activities which are relevant to the patient group, which aim to inform and to create interest in lifestyle changes, e.g. exercise and movement, and which has a positive impact on the disease. The health-promoting activities should not be the main purpose but should be secondary to the gathering.

**Donations** – are only allowed if dedicated to research, and that it can be ensured that these funds go to research and are not used for other ordinary activities, which can be assured via e.g., a 90-account. Donations to beneficiaries who are covered in this chapter shall be published in the Pharmaceutical Industry Association's cooperation database (see below under "Transparency and agreements"/Article 1). A donation must never constitute compensation for or be linked to a return.

**Travel, accommodation, and registration fees** – may only be paid in connection with a consultancy assignment. Travel should be planned so that arrival and departure are as close to the assignment as reasonably practicable. For air travel, economy class should be selected. Duly justified exceptions may be made for travel (> 6h) outside of Europe.

**Accompanying individuals** – only participants in the meeting may be invited. Accompanying individuals may not participate. When it comes to hiring consultants, pharmaceutical companies may, in exceptional cases, pay for travel, food and lodging for accompanying individuals as assistant/escort to a consultant. Escorts may not be reimbursed by pharmaceutical companies.

**Selection of location and venue** – Companies may arrange or sponsor meetings outside of Sweden or the Öresund region only if the majority of the participants come from countries other than Sweden or if corresponding knowledge or experience cannot be provided there. The selection of location and venue for the meeting shall be reasonable in relation to the purpose of the meeting. Leisure resorts during season and places known for their exclusivity shall be avoided, e.g. locations for winter sports during ski season. The same applies to locations at which major international events are being staged at the same time as or in connection with the meeting - e.g., sports events. Neither shall companies contribute financially to meetings held at such locations. Lif's Compliance Officer decides whether a place is acceptable. A decision by the Compliance Officer can be appealed.

**Benefits** – Pharmaceutical companies may not offer benefits or other compensation, and organisations and their members, employees or elected representatives may not claim or receive benefits or other compensation or require measures that violate these rules or its intentions.

**Fees and reimbursements** – Pharmaceutical companies may only pay fees and reimbursements according to market conditions and what other actors may pay, e.g. member fees, participant fees advertising costs, exhibition space or fees. Market-based compensation for customary advertisements in e.g. a patient association's membership journal is not covered by this chapter, and does not need to be

reported in the collaboration database. The reason for this is that compensation for customary advertisements at market price is not considered to be sponsorship or collaboration.

**Ordinary activities** – Pharmaceutical companies should not support organisations' ordinary activities. Ordinary activities mean e.g. board meetings, rents, internal administration and communication or similar. Advocacy activities and opinion-forming are considered ordinary activities in so far as it is not a joint and limited activity. Media training and social media strategies etc. are also considered ordinary activities.

**Area of business** – Pharmaceutical companies can only collaborate on activities or gatherings within their own business area.

### **Transparency and agreements**

#### **Article 1**

- 1.1 Consultancy assignment, sponsorship, donation or collaboration projects, regardless of whether a transfer of value takes place or not, between pharmaceutical companies and organisations/patients/caregivers shall, as a general rule, be regulated in written agreements and be signed by both parties before the collaboration/activity is performed. In exceptional cases, the collaboration may be documented in another appropriate way (e.g. via a written decision, minutes, an invitation to the company activity etc.)
- 1.2 Agreements shall contain a clear description of the purpose, information about its financing and clearly state the rights and obligations of each party and the duration of the project/activity.
- 1.3 When using an organisation's logos and name in information etc., the pharmaceutical company shall obtain the organisation's consent thereto prior to such use. When acquiring such consent, it shall be stated for which specific purposes and in which way the logo and name shall be used. The same applies to organisations who wish to use the pharmaceutical company's logo and name in information etc.
- 1.4 Contracts and agreements between organisations and pharmaceutical companies shall also be kept available for third parties. Openness relates to all agreements, whether ongoing, concluded or regarding future projects.
- 1.5 Information about the consultancy assignment, sponsorship, donation or collaboration project shall be available in Lif's Collaboration Database after the agreement has been signed by all parties and no later than three months after the start of the activity/collaboration. It will be published for a period of three years, after that they are automatically unpublished. The relevant member company is responsible for entering the information into the correct section in accordance with the headings used at the time of publication. Information can be found on [www.lif.se](http://www.lif.se). All consultancy assignments with an individual patient or a caregiver, e.g., for a lecture, advisory board or other consultation, in its role as a patient or a caregiver, are published in the same manner without personal data.
- 1.6 Lif's Compliance Officer is responsible for quality control of the Co-operation Database with

the aim of working preventatively and supportively to the parties, so that the database is kept up to date and current.

## **Meetings and activities arranged by pharmaceutical companies**

### **Article 2 Meetings arranged by companies**

Pharmaceutical companies themselves can arrange, pay for and be the sender of meetings or activities aimed at members of the organization, patients or the general public.

If the activity concerns an education in a certain area, the program should be focused on the disease and e.g., aim to improve the patient's own ability to manage his/her illness, for example through increased motivation to complete treatment through lifestyle changes, knowledge of the disease and similar. The content of the disease-oriented program must be adapted to the target group and shall form the dominant part and purpose of the meeting.

Pharmaceutical companies may only offer meetings that are linked to the pharmaceutical company's area of business.

- 2.1 Pharmaceutical companies may finance the venue, speakers, study materials, meals and similar as is necessary to carry out the meeting. Travel, accommodation, and any applicable registration fees for individual participants may not be paid for by pharmaceutical companies or requested by individual participants or organisations. Participants in meetings may not be offered a fee by pharmaceutical companies and participants do not have the right to receive or request a fee for his/her participation. Companies may also charge a fee corresponding to the company's costs for the arrangement.
- 2.2 When physicians are invited to an activity, e.g., in the capacity of a lecturer, and if the company is to be regarded as arranger or co-arranger, what is mentioned in Article 6, LER, Chapter 2, Section 1, regarding agreement on cooperation with healthcare, shall also apply.
- 2.3 An invitation to a planned activity shall be sent to the responsible within the organisation concerned (who decides if and how the invitation should be distributed to its members). If the target group for the meeting is patients, relatives etc. who are not members of or represent a specific organisation, the invitation shall be advertised or disseminated in another reasonable and appropriate manner. The invitation shall state (i) purpose and content, (ii) the duration of the planned meeting, (iii) time and place, (iv) the costs that the pharmaceutical company may intend to bear. The invitation must clearly state who is the organizer of the meeting.

## Consultation

### Article 3

- 3.1 Members of organisations are important experts for pharmaceutical companies in various activities regarding highlighting the perspective of the patient, such as in product development, research, education, lectures, advisory boards or in development of informational material, articles etc.

Where appropriate, an individual patient or representative from the general public (e.g., a caregiver) may be engaged for a specific consultancy assignment.

The purpose shall be knowledge-and experience exchange, for example that a personal disease story is shared by a patient and/or a caregiver, that users who have been testing a specific item of medical utility (app. etc.) or other patient support, provides feedback to the company about its functionality. The independence of the organisation, the patient and the representative must be considered in all communication and contact. See the section on Transparency and agreements above.

- 3.2 The following must be considered when a consultant is hired for a specific assignment:

- There shall be a legitimate need for the assignment before it is requested or initiated. The criteria for selecting consultancy assignments shall be based upon identified needs.
- The duration of the assignment shall not be greater than what is necessary to achieve the identified need.
- The number of consultants that are engaged for the assignment must not be higher than what is necessary to achieve the identified purpose.
- The purpose of a consultancy assignment must not be to influence or train the consultant.
- The hiring of a consultant may not constitute an incentive to recommend a specific medicinal product, product or pharmaceutical company.
- If the person is a member of an organisation, the request for the assignment shall be made to the person responsible within that organisation. The organisation decides if the request should be accepted or not. If the assignment is to be performed by an individual patient or representative from the general public who does not represent an organisation, the initial contact can be made via e.g., healthcare.
- All assignments (whether a transfer of value takes place or not) between pharmaceutical companies and organisations, or an individual if an individual patient or representative from the general public (e.g., a relative) is to be engaged, shall be agreed in writing between both parties before the assignment is performed, in accordance with article 1 in this section.

- In the written agreement it is recommended to include an obligation for the organization/the individual consultant to disclose, when making public statements about a topic that is related to the assignment, that the consultant has performed consultancy assignments for the company.
- Remuneration for work carried out must be reasonable in relation to the scope of the assignment. The written agreement shall stipulate the time to be spent, the amount of remuneration and how remuneration shall be paid. The pharmaceutical company may pay for travel, accommodation and lodging provided that the costs are moderate and necessary for the execution of the assignment. No other fringe benefits, remuneration, or gifts may be provided. Remuneration to representatives of an organisation is to be paid to the organisation, not to the individual.
- If the assignment is to provide a lecture/patient story to healthcare or the general public, the consultant may only lecture/talk about his/her own or a related's disease and possible care and not about specific medicinal products, treatments or vaccinations, i.e., may not be a patient testimonial.
- When the assignment consists of participating in an advisory board, pharmaceutical companies engage and remunerate a small group of consultants to provide independent advice and knowledge in a specific field which cannot be obtained within the company. The company shall document and use the information and the documentation provided by an advisory board in an appropriate manner and shall also intend to take actions based on the information obtained. At advisory board meetings, it is important that everyone who participates as a consultant has a clear task and actively contributes to the meeting.

#### **Information- and educational material, items of medical utility and patient support programs**

##### **Article 4**

- 4.1 Gifts may not be supplied, offered or promised to organisations and their representatives or to patients/representatives, except for what follows below.
- 4.2 Product-neutral information- and educational material and items of medical utility may be provided under the condition that the material is (i) of low value, and (ii) constitutes relevant information to the public/patient about e.g., a disease.
- 4.3 Pharmaceutical companies may provide different kinds of product-neutral patient support programs to patients, e.g., materials, applications, lectures, support etc. The primary purpose of a product-neutral patient support program shall be to safeguard patient safety and improve the patient's ability to handle his/her illness.
- 4.4 A product-specific patient support program for prescription-only medicinal products may only be provided to patients who have been prescribed the product, which is ensured e.g. by health care providing information about the patient support program.
- 4.5 The definition of "low value" refers to no higher amount than at any time is determined by

Lif's Board. For Informational- and educational materials and Items of Medical Utility, also refer to the rules stipulated in Article 11, LER, Chapter 2, Section 1.

## **Meetings and activities arranged by pharmaceutical companies in collaboration with an organisation**

### **Article 5      Collaboration projects**

Collaborations can evolve around e.g. joint disease awareness activities (meetings, development of patient support programs or information material etc.), joint opinion-forming and impact work within the framework of a limited activity.

5.1 A basis for the collaboration is that it should be in the common and legitimate interest of both parties. A collaboration shall be jointly planned and implemented, and both parties shall contribute, and it shall be conducted in a manner agreed by the parties. The parties shall bear their own administrative costs. Everyone who participates in and develops an activity or project plan must agree on the plan and have information about the timetable, the objectives and the respective party's interest in the project. Travel, accommodation, and registration fees for individual participants may not be paid for by pharmaceutical companies or requested by individual participants.

5.2 A collaboration shall be a delimited project. The time schedule should include continuous reconciliation and evaluation to ensure that the project proceeds as agreed by the parties. After the project has been completed, the parties should evaluate the activity.

5.3 Collaborations shall always take place openly, in a manner transparent to the public. Informational material and invitations shall for example clearly state that it is a collaborative project and all activities shall be accounted for in the co-operation database.

5.4 When physicians are invited to an activity, such as in the capacity as lecturers, and if the company is to be regarded as arranger or co-arranger, what is mentioned in Article 6, LER, Chapter 2, Section 1, shall also apply.

5.5 A collaboration project may comprise more than one company and/or include public bodies. Choosing a primary partner is permissible in a collaboration. A collaboration shall be documented in a joint written agreement.

5.6 At a joint meeting, the rules of Article 2 shall also be complied with, with the exception that the meeting is conducted in accordance with the principles of cooperation in this article.

## **Meetings and activities arranged by or on behalf of an organisation**

### **Article 6      Sponsorship**

Organisations arrange activities or meetings themselves or through third parties that address its members or the general public.

Sponsorship refers to financial or other support which includes a market-based return, such as exhibit space, be a part of the program or other forms of exposure of the company.

6.1 Pharmaceutical companies may provide sponsorships only under certain conditions:

- the organisation shall provide a budget for the meeting/activity/material, specifying revenues and the costs.
- Pharmaceutical companies may only offer sponsorships to organisations to cover actual, documented, reasonable and direct costs which are necessary for a meeting/activity/material to be conducted, e.g. costs for lecturers, venues, health-promoting activities, or meals in connection with the scientific part of the meeting or costs for educational material. A health-promoting activity may only be financed if the activity is of reasonable proportion in relation to the rest of the meeting/activity and is not central to the meeting/activity. Travel, accommodation and registration fees for individual participants may not be paid for by pharmaceutical companies or requested by individual participants.
- Fees and remuneration may not exceed the actual costs for what is intended.

**Monitoring IGN and NBL**

The Swedish Pharmaceutical Industry's Information Examiner Committee (IGN) and the Information Practices Committee (NBL) have the task of auditing and assessing any pharmaceutical company's violation of these rules.

## **Section 2 – Ethical rules for interaction between pharmaceutical companies and politicians**

### **Background and purpose**

Pharmaceutical companies and politicians conduct an on-going dialogue with the purpose of optimizing shared interests and creating a basis for increasing access to the best possible medical preventive measures and treatments for patients and other citizens. The ethical rules provide a framework for the dialogue between pharmaceutical companies and politicians, so as to ensure that the dialogue is always conducted with good judgement, maintained credibility and high ethical standard.

In applying this appendix, the word "politician" shall mean elected representatives, e.g. members of parliament and members of local governments and county council's decision-making bodies. "Politician" also refers to ministers, county commissioners, local government commissioners, members and alternate members of boards and committees, and politically appointed officials e.g. secretary of State, political experts and political secretaries.

### **Consultation and assignment**

#### **Article 1**

A pharmaceutical company may not remunerate politicians for services to the company. This, however, does not apply for remuneration to:

- a politician who is a permanent employee of the pharmaceutical company and the remuneration exclusively relates to the employment and the employment is not in any way related to the employee's political office, or
- a politician who performs a consultation assignment for the pharmaceutical company and in his or her assignment is not acting in his capacity as politician.

A pharmaceutical company may, within the scope of a specific and limited assignment, assign politicians to perform teaching, lectures or the like. No remuneration or reimbursement shall be paid for such assignment.

### **Events**

#### **Article 2**

Politicians may be invited to scientific meetings, conferences, symposiums and other similar events.

## **Refreshments, expenses and remuneration**

### **Article 3**

Pharmaceutical companies may not cover travel expenses, overnight accommodation or conference fees for politicians who attend an event or offer politicians remuneration or any other form of compensation for the attendance. Pharmaceutical companies may, however, pay the costs for conference facilities, speakers, study materials and similar that are necessary in order to carry out an event that is wholly or partially targeting politicians. As regards meals and social or leisure activities, pharmaceutical companies shall apply article 2b of Chapter 2 Section 1, regarding forms of collaboration with healthcare professionals and others, correspondingly.

## **Gifts**

### **Article 4**

Gifts to politicians may not be distributed.

## **Campaign contributions, other benefits etc.**

### **Article 5**

Pharmaceutical companies may not offer politicians benefits, remuneration or gifts other than what is allowed under this appendix. Pharmaceutical companies may not offer campaign contributions to individual politicians.

If a pharmaceutical company makes a campaign contribution to a political party, this shall be made public on the company's website.<sup>1</sup>

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<sup>1</sup> For example UK Bribery Act and The American "Foreign Corrupt Practices Act" (FCPA) as well as pharmaceutical companies' internal codes of conduct may contain provisions which constitute a more stringent regulation than what is stated here. The fact that the content of LER in this respect has a lesser strict content does obviously not mean that departure from other applicable and more stringent regulations may be made.

## **CHAPTER 4 – Non-interventional studies and National Quality Registers within the health service**

## Section 1 – Rules for non-interventional studies

### Background and purpose

Non-interventional studies mean all studies and projects which are not clinical trials according to the Swedish Medical Products Agency. The concept of non-interventional studies thus includes quality projects, follow-up studies, prescription studies etc. The rules given below also apply to participation in or support for the establishment or operation of various registers (e.g. quality registers). For those studies and projects covered by rules on non-interventional studies, agreements must be signed by all relevant responsible authorities, if staff in the public health service are participating, or where it concerns private healthcare if the study or project may entail costs to the responsible authority (i.e. in the form of prescribing medicinal products).

Studies are currently performed in the healthcare sector, which are not clinical trials, but which may be supported by pharmaceutical companies in some way. This might involve the mapping of therapeutic practice or costs, quality assurance of whether given guidelines are being followed, or a follow-up of how a medicinal product is being used or the health economics impact of a given medicinal product therapy. The need for information provided by such studies is considerable and is growing at both regional and national level. The Medical Products Agency may require pharmaceutical companies to follow up medicinal product use, and the formula committees may have wishes concerning the mapping of experience of medicinal products in an everyday clinical context.

### Difference between non-interventional studies and clinical trials

The design of the study determines whether it is a clinical trial or a non-interventional study.

A clinical trial generally studies a selected group of patients (patients chosen based on various exclusion and inclusion criteria) in a controlled manner. Patients are normally randomised to one or more treatments. These studies are always prospective and often take quite a long time to perform.

A non-interventional study includes patients based on one or more selection criteria, e.g. by diagnosis or treatment received. Data is then collected retrospectively or prospectively using forms or obtained from existing databases or medical records. In a cross-sectional study, information is obtained about the situation at a particular point in time. No study-related intervention is made.

### When are non-interventional studies performed?

Which type of study should be chosen – clinical trial or non-interventional study – depends on its aim. Non-interventional studies are never a substitute for clinical trials but may be a complement. We need the knowledge that is generated by both clinical trials and non-interventional studies. For example, epidemiological data cannot be studied in a clinical trial. Internationally Sweden has the advantage of being able to draw on national health data registers for epidemiological data. One example is the National Board of Health and Welfare's Prescribed Medicinal Product Register, which

collects medicinal product data from pharmacies.

Besides providing greater knowledge about medicinal product effects, non-interventional studies can also be a good way of further mapping risks in the real world. Post-marketing surveillance (PMS) studies can in some cases be important in studying adverse effects after the introduction of a new pharmacological therapeutic principle.

Non-interventional studies allow information to be collected on the actual use of a particular medicinal product. These studies can also provide epidemiological information about a particular disease or even identify an unfulfilled medical need.

#### **Criteria for non-interventional studies:**

### **The study must be performed during standard healthcare provision**

#### **Article 1**

- The prescription of any medicinal products being studied must be clearly separated from the decision to include the patient in the study.
- The medicinal product must be prescribed in the normal manner and in accordance with the terms of the marketing authorisation. The contribution of the medical representative may only be administrative in character and under the supervision of the medical department, which should also ensure that the representative has the relevant training. The representative's contribution may not be associated with the prescribing of medicinal products. For further information on the role of representative, see what is stated in article 22 of Chapter 1, Section 1.
- The study is to be conducted so that the parties maintain full confidence and an independent standing in relation to one another. The study should not result in undertakings or expectations concerning prescribing or use of the pharmaceutical company's products.
- Financial compensation for extra resources for implementation of non-interventional studies should only be paid in cases where the workload within the framework of the study obviously exceeds the staff's ordinary daily operational responsibility/work duties.

#### **Responsible health authority**

#### **Article 2**

The study must be approved by responsible health authority. An agreement must be reached between the healthcare provider, the responsible investigator and the pharmaceutical company. This also applies to studies which the investigator carries out in his/her "spare time", i.e. outside paid working hours for the healthcare provider or private healthcare subcontractor. Where financial remuneration is payable, this must be reasonable in relation to the amount of work involved and specified in the agreement.

## **Regional ethical vetting board**

### **Article 3**

An application must be submitted to the regional ethical vetting board for assessment. The study must not be performed if the regional ethical vetting board is opposed to this.

## **Study plan/protocol**

### **Article 4**

There must be a study plan/protocol which approved and monitored by the pharmaceutical company's medical department and which contains:

- (i) *Background.* Motivation for performing the study.
- (ii) *Aim.* Description of what is to be studied (the scientific purpose).
- (iii) *Motivation for number of patients.* Total number of patients and number of patients per investigator.
- (iv) *Data collection.* How data is to be collected, patient information, questionnaires, etc.
- (v) *Data processing and collation.* Who is responsible for data processing, how it will happen, and when.
- (vi) *Adverse event reporting.* Reporting to the Medical Products Agency/company.
- (vii) *Study reporting.*

A summary of the report/publication should be analysed and, within a reasonable time, communicated to the pharmaceutical company's medical department. The medical department should keep a list of such reports which should be kept for a reasonable time. The report/publication is to be completed within 12 months of the end of the study and distributed to the participating clinics and, where necessary, the authority concerned. If the study indicates a result which is important from a risk or utility point of view, the summary of the report/publication should immediately be sent to the relevant authority.

Both the study plan/protocol and study report should be made available on demand to the Pharmaceutical Industry's Information Examiner (IGN) and the Information Practices Committee (NBL) as well as Lif's Compliance Officer.

## **The General Data Protection Regulation (GDPR)**

### **Article 5**

Regulations in the GDPR must be complied with and consent from the patient for their participation must be obtained according to applicable rules.

## **Ownership of data**

### **Article 6**

The agreement between the parties must cover issues such as who owns the database and who holds the publication rights.

## **The company's internal process**

### **Article 7**

The company must have guidelines which describe the internal process for the performance of non-interventional studies. The company's medical department must approve these studies.

## **Quality assurance**

### **Article 8**

ICH Good Clinical Practice must be applied where applicable and standard scientific methodology must be used. Monitoring (verification of source data) or auditing need not normally be performed, but there must be a process for quality assurance.

## **The Swedish Medical Products Agency**

### **Article 9**

An application need not normally be submitted to the Medical Products Agency. In case of uncertainty, the Medical Products Agency must be contacted.

## **Announcement**

### **Article 10**

As with clinical trials, pharmaceutical companies must publish the information given in the summary of the report/publication for non-interventional studies.

## Section 2 – Financial support for National Quality Registers within the health service

### Background and purpose

The National Healthcare Quality Registries hold data collected by healthcare personnel from clinics across Sweden. The registries contain individualised data on problems or diagnoses, treatments and outcomes. The fact that these registries are national means that data for all patients can be aggregated and analysed at patient, unit and national level. The health authorities have the main responsibility for the development, operation and funding of the registries, and for compliance with the Personal Data Act and Patient Data Act.

The Swedish Association of Local Authorities and Regions (SALAR) collaborate with the National Board of Health and Welfare at central level and provides financial and other support for the use of the National Healthcare Quality Registries. The registries are subject to a quality assurance system which requires annual reports, including a review of operations describing, among other things, how the registry's operations have contributed to local quality improvements.

The majority of National Healthcare Quality Registries currently receive financial support from pharmaceutical companies. All in all, support from the industry accounts for around a fifth of total funding for the registries. One recommendation is that the supporting pharmaceutical company should have access to anonymised, aggregated data from the registry in question on that company's own products.

On 9 March 2012, Lif entered into a collaboration agreement with SALAR, Swedish Medtech and Sweden BIO regarding cooperation between SALAR and the representatives of the industry concerning the National Healthcare Quality Registries. The agreement comprises the Swedish local authorities and regions (principals) represented by SALAR, and the industry, represented by the trade associations Lif, Swedish Medtech and SwedenBio.

The purpose of the agreement is to provide guidelines for the ethical, legal and financial considerations necessary for good cooperation between the principals and the industry regarding the National Healthcare Quality Registries. The aim is to achieve proper transparency regarding agreements and forms of cooperation pursuant to applicable legislation. Whenever personal data from health-, medical- or dental care is used in connection with any other form of collaboration with the industry, applicable parts of the agreement should be applied to the extent possible.

It is important that the collaboration between the parties is open, and one option is to register collaboration in Lif's collaboration database in the Healthcare Personnel section. To register, visit [www.lif.se](http://www.lif.se).

## Criteria for providing financial support to National Quality Registers

### Article 1

- (i) The cooperation regarding the National Healthcare Quality Registries shall be executed under such forms which enable the parties to maintain full credibility and independence in relation to each other. Cooperation may not be an incentive to recommend, prescribe, buy, provide, sell or administer specific medicinal products.
- (ii) Sponsoring of the National Healthcare Quality Registries is prohibited.
- (iii) There shall be a written collaboration agreement between the parties (central authority acting as data controllers (*centralt personuppgiftsansvarig myndighet*) and company) stating the parties' rights and liabilities as well as the duration of the partnership. Whenever the collaboration agreement comprises research cooperation, a three-party agreement shall be drafted, in which the university/college shall be included as a party. The managing group of each National Healthcare Quality Registry and the principal shall approve of all such cooperation.
- (iv) If the cooperation is carried out as a service, the agreement shall contain details about the service and the payment for it. Access to raw data from the National Healthcare Quality Registries, publication policy and any intellectual properties shall be settled in the agreement. Data which has been disclosed from the National Healthcare Quality Registries may be subject to mandatory reporting to the authorities, which if applicable shall be agreed upon in the agreement.
- (v) In relation to cooperation regarding the development of a product, service or innovation as well as research studies, the agreement shall be supplemented with a project plan containing details on how the project shall be executed and evaluated. The contributions of any party to the project, such as financial means, material and hours of work, shall also be regulated in the agreement. Pilot studies may be conducted at separate healthcare authorities within the scope of a National Healthcare Quality Registry; however, the intention is that the project can be nationally scalable.
- (vi) The contents of the collaboration agreement shall be open and clarified in all contexts where the register is presented, e.g. via websites, and publications of annual reports. The company may not inappropriately influence the interpretation of analyses, final drafting of reports and publications.
- (vii) Financial remuneration for a service from the National Healthcare Quality Registries may comprise remuneration for registering data, data quality work, statistical analysis, reporting as well as product- and service development. In addition, education sessions for supporting proper implementation of new business intelligence or follow-up tools which support the National Healthcare Quality Registries may be included in the service. In addition to the remuneration for the actual service, the parties to the collaboration agreement shall agree to pay an

additional cost to cover expenses for describing the service and signing the agreement, payments made for infrastructure and development of the registry.

- (viii) Payment shall be made to the central authority responsible for personal data. All costs shall be accounted for in an understandable and transparent way.

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# Appendices

## Appendix 1 – Template for disclosure of transfers of value

Article number relates to Ethical Rules of the Pharmaceutical Industry (LER) (Chapter 2, section 3)

TEMPLATE													
												Date of publication:	
	Full name  (article 2)	HCPs: City of Principal Practice HCOs: city of practice (registered address)  (article 9)	Country of principal practice  (article 1)	Principal practice address (e.g. clinic/office/healthcare unit/department)  (article 9)	Unique identifier - OPTIONAL  (article 9)	Donations to HCOs (article 9)	Contribution to costs of events (article 9)			Fee for service and consultancy (article 9)			TOTAL OPTIONAL
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event	Registration fees	Travel and accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel and accommodation		
HCPs	INDIVIDUAL NAMED DISCLOSURE - one line per HCP (i.e. all transfers of value during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate).												
						N/A	N/A	N/A	N/A				
						N/A	N/A	N/A	N/A				
						N/A	N/A	N/A	N/A				
						N/A	N/A	N/A	N/A				
	OTHER, not included above - where information cannot be disclosed on an individual basis with regard to the General Data Protection Regulation												
	Aggregate amount attributable to transfers of value to such Recipients - article 10						N/A	N/A	Aggregate	Aggregate	Aggregate	Aggregate	
	Number of Recipients						N/A	N/A	number	number	number	number	
% of total number of recipients of individual HCPs						N/A	N/A	%	%	%	%	N/A	
HCOs	INDIVIDUAL NAMED DISCLOSURE - one line per HCO (i.e. all transfers of value during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate).												
								N/A	N/A				
								N/A	N/A				
								N/A	N/A				
								N/A	N/A				
	OTHER, not included above - where information cannot be disclosed per HCO for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients - article 10						N/A	N/A	N/A	N/A	Aggregate	Aggregate	
	Number of Recipients						N/A	N/A	N/A	N/A	number	number	
% of total number of recipients of individual HCOs - article 10						N/A	N/A	N/A	N/A	%	%	N/A	
	Not: N/A = Not Applicable												
R&D	AGGREGATE DISCLOSURE												
	Transfers of value re Research & Development (as defined) (article 12 and article 1)											TOTAL AMOUNT SHALL BE GIVEN	OPTIONAL

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## **Appendix 2 - Statutes of and rules of procedure for IGN and NBL**

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# Statutes of the Swedish Pharmaceutical Industry's Information Examiner Committee (IGN) and the Information Practices Committee (NBL)

## Governing bodies and areas of activity

- § 1.1. The IGN and NBL are engaged in the system of self-regulation, which the Association of the Pharmaceutical Industry (Lif) has maintained in the pharmaceutical sector since 1969 for the purpose of realising the industry's aim of ensuring that the information supplied by pharmaceutical companies follows the Ethical rules for the pharmaceutical industry.
- § 1.2. Lif is the governing body of the two agencies.
- § 2. The IGN and NBL perform their duties independently and separately. The distribution of work between and within the IGN and NBL is regulated in these statutes and by the rules of procedure established by the governing bodies.

## Duties

- § 3 The task of the IGN and NBL is, in the forms stated in § 4 and on the basis of the work distribution between them stated in § 5, to endeavour to ensure that the pharmaceutical companies follow the Ethical rules for the pharmaceutical industry, observe legal statutory provisions and general non-statutory criteria for good business practice in industry, and otherwise comply with good industrial practice.

## Nature of activity

- § 4.1. The overall activity assigned to the IGN and NBL consists primarily of monitoring the market, assessing cases and pre-examination according to article 102 of Chapter 1, Section 2.
- § 4.2. In addition, the NBL may issue advisory statements, i.e. explain what is or should be considered as good industry practice in any particular case.
- § 4.3. **Monitoring the market** entails first and foremost an ongoing monitoring of the product information provided by pharmaceutical companies, in respect of medicinal products. This task is performed by IGN.
- § 4.4. **Assessment of cases** includes preparing and considering, and making decisions in, cases taken up for consideration in connection with monitoring the market or on receipt of a report. The assessment is performed by the IGN and/or the NBL. It focuses on whether

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a certain measure taken by a pharmaceutical company is objectively compatible with what is or should be considered as good industrial practice. The intention behind the measure is not examined.

§ 4.5. Pre-examination includes examination of and making a decision regarding applications for pre-approval according to article 102 of Chapter 1, Section 2.

§ 4.6 Lif's Compliance Officer decides on his/her own initiative or upon notification or enquiry, if the location of the planned arrangement is acceptable.

### **Distribution of cases**

§ 5 Assessment of cases is distributed between the IGN and NBL, primarily as follows.

#### **IGN**

§ 5.1 The IGN's task is to try/examine:

- 1) Measures that the IGN finds cause to question in the course of monitoring the market,
- 2) Measures that, in a report to the IGN, are questioned by a party that is entitled to take legal action in accordance with § 18,
- 3) Applications for pre-examination according to article 102 of Chapter 1, Section 2, submitted by a pharmaceutical company.

#### **NBL**

§ 5.2. The NBL's task is to try/examine:

- 1) Measures that the IGN, without taking a decision on its own, passes on to the NBL or which are reported by a public authority,
- 2) Measures that, in a report to the NBL, are questioned by a party with the right to take legal action in accordance with § 19,
- 3) Appeals against decisions taken by the IGN or Lif's Compliance Officer (cf. § 36).

§ 6. The NBL can issue advisory statements on issues of major importance, either in connection with consideration of a certain case, at the request of a party named in § 20 or at its own initiative, or when the NBL finds it necessary to make such a statement.

### **Rules of procedure**

§ 7 Detailed regulations concerning the IGN's and NBL's methods or working and the division of work between them can be found in the Rules of Procedure (cf. § 2).

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## **Organisation**

### **IGN**

- § 8.1           The IGN comprises a chairman and at least two and at most four members.
- § 8.2           At least one member shall represent medical expertise; he or she must be a qualified physician, have a clinical specialty or corresponding expertise and have clinical experience.
- § 8.3           At least one member shall have a qualified education within healthcare with significant and comprehensive experience as well as a sound knowledge of market law.
- § 9.            The IGN has its disposal the assistance required for carrying out its activities effectively.
- § 10.           The chairman and members of IGN is/are appointed by Lif's Board of Directors for a period of three calendar years; however, the first term may be of a shorter duration. The election takes place not later than the month of November before the start of the term. Re-election is permitted. Lif's Board of Directors may appoint a deputy chairman. Lif's Board of Directors may also appoint at most two deputies to the members of IGN. The same qualification requirements apply to the deputies as those that apply to the members they are to replace.

### **NBL**

- § 11.1.        The NBL comprises a chairman and eleven members.
- § 11.2.        The chairman must be an experienced lawyer with certified expertise and must not be engaged in the pharmaceutical sector.
- § 11.3.        Six members must hold executive positions associated with pharmaceutical companies, and at least one of them must have specific experience in the area of self-medication products. All these members should possess knowledge of market law.
- § 11.4.        Two members must represent medical expertise; they must be qualified physicians, have a clinical specialty or corresponding expertise and have clinical experience.
- § 11.5.        Three members must represent public interests, one of them in particular consumer interests.
- § 12.1.        There must be an alternate for the chairman – the deputy chairman.
- § 12.2.        There must be three deputies for those members with corporate affiliations; there must also be one deputy for the medical experts and two for the members representing public interests.

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- § 12.3. The same skills requirements apply to the deputy chairman and the deputies as those that apply to the chairman and the members they are to replace.
- § 13.1. Lif's Board of Directors elects the members with corporate affiliations and their deputies, as well as the chairman, deputy chairman and other members and deputies.
- § 13.2. The members with medical expertise and their deputy are appointed after consultation with the Swedish Medical Association.
- § 13.3. The representatives of public interests and their deputies are appointed in a corresponding manner following consultation with an appropriate body or authority.
- § 14. Members are elected for two calendar years, although the first term may be shorter. The election takes place not later than the month of November before the start of the term. Re-election is permitted.
- § 15.1. The NBL has one or more secretaries. Secretaries must be lawyers with a sound knowledge of market law.
- § 15.2. The secretary has the required assistance at his disposal.
- § 16. Secretaries are appointed by Lif's Board of Directors, in consultation with the chairman and deputy chairman, for two years at a time. Any other necessary assistance is arranged for a specific duration, for a specific task or until further notice.
- § 17. The NBL may co-opt members following consultation with Lif. The NBL may also co-opt experts if this is required for a particular case.

### **Entitlement to take legal action**

#### **IGN**

- § 18 The right to complain to the IGN regarding measures that a pharmaceutical company itself has adopted, or that some other party has adopted on its behalf, lies with
- 1) a private individual,
  - 2) a pharmaceutical company which is member of Lif, ASCRO or FGL or which has, in writing, accepted to be bound by the Ethical rules
  - 3) a pharmaceutical company which has signed an undertaking to adhere to the provisions in these statutes regarding IGN-fees and NBL-fees (§§42.1-44.5 and 46) for the measure in question
  - 4) another company than a pharmaceutical company or association (a public authority files complaints regarding such measures directly to the NBL, see § 19.1),
  - 3) Lif's Compliance Officer (regarding transgressions of decisions according to § 4.7).

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## NBL

§ 19.1. The right to complain to the NBL about adopted measures lies with

- 1) The IGN,
- 2) A private individual (appeal),
- 3) A pharmaceutical company which is member of Lif, ASCRO or FGL or which has, in writing, accepted to be bound by the Ethical rules (appeal),
- 4) a pharmaceutical company which has signed an undertaking to adhere to the provisions in these statutes regarding IGN-fees and NBL-fees (§§42.1-44.5 and 46) for the measure in question (appeal),
- 5) Another company than a pharmaceutical company or association (appeal),
- 6) A public authority.

The right to complain to the NBL regarding an adopted measure concerning a *pre-approved website* according to article 102 lies with

- 1) A private individual,
- 2) A pharmaceutical company which is member of Lif, ASCRO or FGL or which has, in writing, accepted to be bound by the Ethical rules,
- 3) a pharmaceutical company which has signed an undertaking to adhere to the provisions in these statutes regarding IGN-fees and NBL-fees (§§42.1-44.5 and 46) for the measure in question,
- 4) Another company than a pharmaceutical company or association,
- 3) A public authority.

§ 19.2. The right to appeal to the NBL against a decision issued by the IGN lies with the defendant in a case that has been brought up by the IGN himself and with the parties in cases that have been reported to the IGN. For pharmaceutical companies which have reported a case with the IGN and which are not members of Lif, ASCRO or FGL or which has not undertaken to comply with the Ethical rules, an undertaking to adhere to the provisions in these Statutes regarding IGN-fees and NBL-fees (§§ 42.1-44.5 and 46) for the applicable matter must have been signed and submitted in order to appeal a decision to the NBL. In matters regarding pre-examination according to article 102 of Chapter 1, Section 2, the right to appeal to the NBL against a decision issued by the IGN lies with the applicant.

§ 20. The right to request an advisory statement from the NBL lies with

- 1) Lif, Föreningen för Generiska Läkemedel (FGL), ASCRO, the IGN, the chairman of IGN and pharmaceutical companies that are members of LIF, ASCRO or FGL
- 2) Apoteket AB and associations of people working in the medical field,
- 3) Courts of law and other public authorities.

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## **Request for termination of a measure**

- § 21. Competing pharmaceutical companies that submit a report to the IGN or NBL must enclose evidence that the company or companies against whom the representation is made has been encouraged to terminate or change the criticised measure but has failed to observe such request within two weeks of receiving it. In cases where the company against which the request for termination of a measure has been directed has contested that the criticised measure conflicts with the Ethical Rules, the company which has sent the request for termination of a measure can submit a report to IGN or NBL not later than within a month from receiving the contest.

The IGN and NBL may respectively permit an exception to the requirement of the request for termination of a measure if the measure constitutes a serious disregard of good industrial practice or if a prompt intervention is required to prevent further damage caused by the measure.

## **Quorum in final decisions and issuing of warnings**

### **IGN**

- § 22.1 The IGN constitute a quorum when the chairman and at least two members are present. Decisions are taken by vote. The opinion shared by the majority constitutes the decision. In the event of an equal numbers of votes, the chairman has the casting vote.
- § 22.2 The IGN is free to engage in confidential consultations with other experts when the IGN considers this appropriate.
- § 22.3 In cases within the monitoring of the market, where the violation can be regarded as minor, a warning shall be issued, and the pharmaceutical company be given the opportunity to comply before the matter is taken up for final decision. Warning is issued by IGN or IGN:s chairman.
- § 22.4. The IGN or IGN:s chairman may, without issuing a decision, dismiss a case from further handling if the case is of minor importance and the pharmaceutical company concerned has already terminated the measure when contacted by the IGN or if the company after receiving a warning cease with the measure or rectifies the matter in an acceptable way. If the matter is a result of a complaint, it is a precondition that the complaint is withdrawn by the complainant. The IGN or IGN:s chairman may also remove a case from the case list if a complaint to the IGN regards a matter which the NBL is simultaneously trying or has previously tried on the same grounds.

### **NBL**

- § 23.1. The NBL constitute a quorum when the chairman or deputy chairman and at least five members are present. At least three of these members must have corporate affiliations, at least one must be a medical expert and at least one must represent public interests.
- § 23.2. In dealing with cases concerning self-medication products, at least one member with corporate affiliation, with special experience in this area, shall be present.

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- § 24. Cases that are reported to the NBL and that the chairman judges to be simple in nature – in particular cases where the facts are unambiguous from a medical point of view where clear practice exists – may be settled by the chairman and one member with medical expertise.
- § 25. In cases relating to advisory statements, the NBL constitutes a quorum when the chairman or deputy chairman and at least seven members are present and take part in the decision. At least four members must have corporate affiliations and at least one must be a medical expert or represent public interests. If only one member with medical expertise can be present, this person must have consulted with either of the other two medical experts regarding the matter.
- § 26. At meetings of the NBL, all those who are not challengeable may participate in the deliberations (cf. § 32.3). Deputies for members who are present do not have voting rights. According to § 17, co-opted members or experts do not have the right to vote either.
- § 27. Decisions are taken by vote. The opinion shared by the majority constitutes the decision. In the event of an equal numbers of votes, the chairman has the casting vote.

#### **Interim decisions**

- § 28. If, at an early stage, when a case is being prepared at the NBL, it is clear that a measure is obviously and seriously in conflict with good industrial practice, the NBL or the chairman acting on the NBL's behalf may urge the pharmaceutical company concerned through an interim decision to desist from the criticised measure until the NBL, at a meeting with the composition stated in § 23, has delivered a final decision in the case.
- § 29. The NBL can revoke an interim decision whenever it finds cause to do so.
- § 30. If, while dealing with a case, the IGN finds that the circumstances call for an interim decision, the IGN shall immediately pass the case on to the NBL.

#### **Decisions in dealing with a case**

- § 31.1. A decision during the handling of a case by the NBL or the IGN, shall be taken by the chairman or the person appointed by the chairman.
- § 31.2. If a complaint to the IGN or the NBL or an appeal against a decision made by the IGN is withdrawn, the matter is to be dismissed from further handling. The decision to dismiss is taken by the chairman or the person appointed by the chairman.

#### **Challenge**

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- § 32.1. In case of a challenge to the chairman, deputy chairman, member, deputy member or an expert of the IGN, to the chairman of the NBL, deputy chairman, members and deputies, a co-opted member or expert, or the secretary, the challenge regulations in the Swedish Arbitration Act shall apply.
- § 32.2. In case of a challenge to the IGN in such an extent that the IGN does not constitute a quorum, the case shall be transferred to the NBL.
- § 32.3. A person who is challengeable in a case may not be present when the case is considered.

### **Final decisions and advisory statements**

#### **IGN**

- § 33.1. The IGN's final decision shall be stated in writing and be accompanied by the grounds for such decision and contain information about any charges payable according to §§ 42-44 and, where appropriate, a request to the company concerned to desist from repeating the measure after a certain date.
- § 33.2. Irrespective of whether an appeal has been lodged in accordance with § 36, the IGN's request shall be complied with until the NBL decides otherwise.

#### **NBL**

- § 34. The NBL's final decision shall be given in writing and contain
- 1) A description of the questioned or criticised measure,
  - 2) The criticisms and the grounds on which they are based,
  - 3) The objections of the defendant companies and the reasons for these,
  - 4) The NBL's assessment of the measure, with reasons,
  - 5) The NBL's conclusion,
  - 6) Information about any charges payable in accordance with §§ 42-44,
  - 7) Where appropriate, a request for the company to desist from repeating the measure after a certain date,
  - 8) The names of those who took part in the decision and any dissenting opinions.

This paragraph shall not apply to decisions regarding pre-examination according to article 102 of Chapter 1, Section 2.

- § 35. The NBL itself decides on the form of its advisory statements and decisions regarding pre-examination according to article 102 of Chapter 1, Section 2.

### **Appeals to the NBL**

- § 36. An appeal against a decision taken by the IGN or Lif's Compliance Officer may be lodged with the NBL within three weeks of the date of the decision. Appeals that are received too late shall be dismissed by the NBL.

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## **Minutes and annual reports**

### **IGN**

- § 37.1. The IGN shall make appropriate notes of measures adopted. Minutes shall be kept by the chairman or by the one appointed by the chairman and shall be approved by one member. The names of those present and which cases have been dealt with shall be noted therein. The decisions taken shall be appended to the minutes.
- § 37.2. The IGN shall no later than 1 April of each year submit a brief report to Lif and the NBL about the operation during the preceding calendar year.

### **NBL**

- § 38.1. Minutes shall be kept at NBL meetings and shall be approved by the chairman. The names of those present and which cases have been dealt with shall be noted therein. The decisions taken shall be appended to the minutes.
- § 38.2. No later than 1 April each year, the NBL shall issue an annual report of operations for the preceding calendar year.

## **Openness, confidentiality and professional secrecy**

- § 39. The IGN's and NBL's final decisions, the NBL's advisory statements and the IGN's and NBL's annual reports are accessible to the public.
- Regarding matters of pre-approval, only such decisions which result in an approval are public. Such decisions will become public at such time that the IGN or the NBL decides. When deciding on the time for making such decisions public, consideration shall be paid to the applicant's interest for protection of non-available information and to the industry's interest in having an approved decision made public as soon as possible.
- § 40. In addition to that stated in § 39, documents in the possession of the IGN or NBL may not be handed over to outside parties without the permission of the IGN and NBL respectively. Nor may information in such documents be disclosed in any other way to outside parties without permission.
- § 41. A person who has taken part in dealing with a case at the IGN or NBL may not disclose to outside parties what has taken place during discussions regarding the case, nor the content of a decision not yet announced.

## **Fees**

### **IGN and NBL fees**

- § 42.1 In those cases specified in §§ 43-44 below, the IGN and NBL are entitled to determine fees for pharmaceutical companies.

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- § 42.2 Fees determined by the IGN and NBL may not exceed SEK 500,000. In special circumstances, the IGN and NBL can refrain from setting a fee.
- § 42.3 When determining the size of a fee in individual cases, all circumstances must be taken into consideration. When good industry practice has been disregarded, particular consideration should be taken to whether the infringement is to be considered minor or serious. As regards pharmaceutical companies with an annual turnover of less than SEK 40,000,000 for the previous year according to "InformX Sellout National, Sellout OTC (Massmarket) and Vaccine", the fee is to be reduced to half the fee that would otherwise have been determined. However, this does not apply to late payment fees. In addition to this, the IGN and NBL can determine late payment fees in accordance with § 45 below.
- § 43.1 If, in its final decision, the IGN determines that the pharmaceutical company in question has implemented a measure that is incompatible with good industry practice, the company must pay a fee determined by the IGN.
- § 43.2 If, in the final decision regarding a reported case, the IGN determines that complaints brought against the contested initiative are not justified, the complainant, if the complainant is or represents a pharmaceutical company, must pay a fee determined by the IGN.
- § 43.3 A pharmaceutical company's obligation to pay a fee determined by the IGN is cancelled if the NBL, after an appeal in accordance with § 36, finds in a final decision that the appeal is justified and the IGN's decision is overturned.
- § 43.4 If the IGN, in accordance with § 22.4, concludes a case by dismissing it from further handling, no fee is payable.
- § 44.1 If, after an appeal has been lodged, the NBL confirms the IGN's decision in accordance with § 43.1, the pharmaceutical company must pay a fee determined by the NBL in addition to the fee determined by the IGN. Similarly, if the NBL confirms a decision by the IGN in accordance with § 43.2, the complainant must pay a fee determined by the NBL in addition to the fee determined by the IGN.
- § 44.2 If, in an appeal case, the obligation to pay a fee determined by the IGN is cancelled in accordance with § 43.3, the opposite party, if the party is a pharmaceutical company, must instead pay a fee determined by the NBL.
- § 44.3 If a party submits an appeal regarding part of the IGN's decision, or if both parties submit an appeal, the NBL will reach a decision, impartially with regard to the outcome, as to whether the fee determined by the IGN is to be cancelled and whether and to what extent a fee is to be determined by the NBL.
- § 44.4 If the NBL, in a case other than one involving an appeal, finds that the measures undertaken are not in accordance with good industry practice, the pharmaceutical company concerned must pay a fee determined by the NBL.

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- § 44.5 If the NBL, in a case other than one involving an appeal, finds that complaints made against the measures undertaken are unjustified, the pharmaceutical company making the complaint is to pay a fee determined by the NBL.

#### **Late payment fees**

- § 45 Should a pharmaceutical company exceed the prescribed period determined by the IGN or the NBL to reply to a charge, retort or other statements in the case, the company must pay a late payment fee for each instance of an amount not exceeding SEK 10,000. From the rules of procedure, it is made clear that cases may be determined even if a party has not complied with a request from the IGN or NBL.

#### **Payment**

- § 46 The fees must be paid to Läkemedelsindustriföreningens Service AB as a contribution to the self-regulatory system.

#### **Advertising**

##### **Corrective advertisements**

- § 47 If the IGN or NBL finds that a pharmaceutical company has implemented a measure that is incompatible with good industry practice and that can be viewed as serious, the IGN or NBL is entitled, in addition to the fee, to request that the pharmaceutical company place a corrective advertisement in the media determined by the IGN or NBL. The corrective advertisement may include a summary of the implemented measure.

##### **Disciplinary measures**

- § 48 If a pharmaceutical company refuses to comply with the IGN's or NBL's decision, the IGN or NBL shall report this to Lif, and, as applicable, to the concerned industry association. It is dependent on Lif's Board of Directors to decide on any necessary disciplinary measures. The same applies if it has not been possible to persuade the pharmaceutical company to participate loyally in the preparation of the case.

##### **Administrative regulations**

- § 49 The funds required for the IGN's and NBL's activities are supplied by Läkemedelsindustriföreningens Service AB.

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- § 50.        Remuneration is payable to the members of the IGN. ~~Remuneration is payable to the following NBL members: the chairman, deputy chairman, the members with medical expertise and their deputy, the representatives of public interests and their deputy, as well as the secretary and co-opted members or experts. The members with corporate affiliations and their deputies do not receive any remuneration.~~

**Adoption and amendments of statutes**

- § 51        These statutes have been adopted by Lif's Board of Directors and came into effect on 1 July 2022. They will then replace the previously established statutes.
- § 52        Decisions on amendments to statutes follow the same rules as those applying to the adoption of statutes.

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## Rules of procedure for the IGN and the NBL

- p.1 These rules of procedure have been adopted by Lif's Board of Directors with the support of § 2 in the Statutes of the IGN and NBL (referred to here as "the Statutes"). The mode of operation of the two agencies – particularly the procedure to be followed in matters regarding pre-approval according to article 102 of Chapter 1, Section 2, monitoring the market and dealing with cases – is determined in detail by these rules in the light of the regulations contained in the Statutes concerning the nature of activities and distribution of duties (§§ 4-7).

### Terminology

- p.2 In the rules of procedure, the following definitions are assumed
- application for pre-approval, such an application which is submitted to the IGN by a pharmaceutical company regarding a decision for pre-approval in accordance with article 102 of Chapter 1, Section 2.
- cases examined on own initiative: such cases that the IGN tries for examination in connection with its ongoing monitoring of the market.
- reported cases: such cases that the IGN or NBL tries after notification in accordance with § 18 or § 19 of the Statutes.
- cases referred by public authorities: those cases that the NBL takes up at the request of a court of law or other public authority or at the instance of another public authority.

### Pre-approval

- p.3 An application for pre-approval regarding such a website referred to in article 102 of the Ethical rules for the pharmaceutical industry is handled by the IGN. The assessment shall primarily aim at the measure's compliance with articles 102, 112 and 117a of Chapter 1, Section 2. The measure's compliance with other rules in the Ethical rules for the pharmaceutical industry shall however also be observed. The recipients' interest and need for guidance shall be especially observed.

### Monitoring the market

- p.4 The task of monitoring the market is handled by the IGN. The chairman of the IGN is responsible for cases within the monitoring of the market where the infringement is to be considered minor. The monitoring of the market shall first and foremost be aimed towards commercial information about medicinal products for human use. Monitoring shall

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primarily focused on the accuracy and reliability of the informational measures. Special attention should be paid to the interests of the recipients and their need for guidance. Secondly, the monitoring of the market should be aimed at complying with any other regulations pursuant to the Ethical rules for the pharmaceutical industry.

- p.5 Product information in FASS, FASS VET, and Fass.se are not covered by the IGN's monitoring of the market.

#### **Assessment of cases by the IGN Pre-approval**

- p.6 An application for pre-approval is made in writing to the IGN. Complete material shall be submitted with the application.
- p.7 The IGN may reject an application for pre-approval if it is so incomplete that a consideration of the application cannot be based on it. The IGN may however allow the applicant to supplement the application.
- p.8 The IGN shall decide on the matter as soon as possible upon receipt of the application.
- p.9 If the IGN finds that the application for pre-approval does not give rise to any criticism, the IGN shall grant the application for pre-approval. The pharmaceutical company shall be notified thereof in writing.
- p. 10 If the IGN finds cause for criticism to the application for pre-approval, the IGN issues a written final decision in accordance with § 33 of the Statutes.

#### **Cases examined on own initiatives**

- p. 11 If, when monitoring the market, the IGN finds cause to question the compatibility of an adopted measure with the Ethical rules for the pharmaceutical industry, the IGN may try the case on its own initiative.
- p. 12 Following registration, the IGN shall, as promptly as possible, communicate its inquiry with the liaison officer of the pharmaceutical company responsible for matters related to information and market ethics.
- p. 13 Issuing of warnings Issuing of warnings in accordance with § 22.3 in the Statutes shall be in writing in the form decided by the IGN and shall include a required statement of reasons and a request to the company to take corrective actions. If a measure is ceased or rectified as a result of the warning, as applicable within the given time limit, or if the IGN finds that

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no criticism should be directed at the questioned measure, the IGN or the chairman of the IGN respectively shall dismiss the case from further handling.

- p. 14 If a warning does not result in the measure being ceased or corrected within the given time limit, the IGN shall, after handling the case in accordance with p. 15-18 below make a final decision on the case where after required statement of reasons, also information on fees in accordance with §§ 42-44 shall be included.
- p. 15 In other cases examined on own initiatives than those which are mentioned in p. 13, the communication shall take place in writing in the form decided by the IGN. It must be clear from the communication what is being criticised and on what grounds. In the communication, the IGN shall state a fixed time-limit, normally a maximum of two weeks, within which the pharmaceutical company is required to submit a complete defence.
- p. 16 The IGN shall take a decision in the case as soon as possible after receipt of the defence, normally not more than two weeks after expiry of the time-limit. The IGN is entitled to take a decision even if no defence has been received in the prescribed way.
- p. 17 If the IGN finds that no criticism should be levelled against the measure in question, the IGN dismisses the case, normally without providing reasons for its decision. The pharmaceutical company must be notified of this in writing.
- p. 18 If the IGN finds cause for criticism of the measure, the IGN issues a written final decision in accordance with § 33 of the Statutes. A form shall be appended to the decision urging the pharmaceutical company to confirm that it undertakes, after a certain date, to desist from repeating the criticised measure. The form, bearing confirmation of compliance, shall be returned to the IGN within a week of the date on which the company received the decision.

#### **Reported cases**

- p. 19 A report to the IGN with a request to consider and act against a measure is to be made in writing. The report should clearly state what is being criticised and the circumstances on which the claim is based. The required investigative material must accompany the report.
- p. 20 The IGN deals with reported complaints which, in accordance with § 18 of the Statutes, have been initiated by a party other than a competing pharmaceutical company, in the same way as cases undertaken on its own initiative, in accordance with p. 15-18. In reported cases, the IGN shall not supplement the comments made in the report with its own comments. These shall instead be taken up in a separate case undertaken on its own initiative. As soon as a statement in a reported case has reached IGN it shall be sent to the respective opposite party for its information.
- p. 21 The IGN tries a reported case initiated by a competing pharmaceutical company only when the company has shown that a notice of termination of the criticised measure has been

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served in accordance with § 21 of the Statutes, unless the IGN has made an exception to this requirement in accordance with the same section of the Statutes. The case is then dealt with in the same way as other reported cases in accordance with point 20.

In addition to providing proof of notice of termination in accordance with the preceding section, a reported case which has been initiated by a competing pharmaceutical company which is not a member of Lif, ASCRO or FGL or which has not in writing undertaken to follow the Ethical rules, will be tried by the IGN only after an undertaking to adhere to the provisions in the Statutes regarding IGN-fees and NBL-fees (§§ 42.1-44.5 and 46) has been signed and submitted by the company for the applicable matter.

As soon as a statement in a reported case has reached IGN it shall be sent to respective opposite party for its information.

- p. 22.1 The IGN may reject a report if it is obviously groundless or if it is so incomplete that consideration of the case cannot be based on it or if the required investigative material or notice of termination has not accompanied the report. However, the IGN may grant the complainant an extension to supplement the report. The IGN shall reject a report if the undertaking stated in p. 21, second paragraph, as requested, has not been submitted. The report may also be rejected by the IGN if it has reached the IGN later than one month after receiving such contest as mentioned in § 21 in the Statutes for IGN and NBL.
- p. 22.2 The IGN shall reject a report if, at the time of reporting, three years have elapsed since the alleged breach occurred.

#### **Referral to the NBL**

- p. 23 If the IGN finds, immediately or at a later stage when dealing with an application for pre-approval or with a case that the case is complicated or difficult to assess or is important in principle or otherwise of great significance, the IGN shall refer the case to the NBL as soon as possible, without taking a decision.
- p. 24 The IGN may proceed, in the same way as stated in p. 23, in a case to be tried on its own initiative where the pharmaceutical company contests, in a reasoned defence, that there is cause for finding fault against the measure criticised by the IGN, and the IGN does not accept the company's standpoint and, for special reasons, finds that the case should be referred to the NBL.
- p. 25 That stated in p. 23 regarding the IGN's obligation and in p. 24 regarding the potential for IGN to refer a case to the NBL also applies with regard to reported cases.
- p. 26 If a report to the IGN concerns a measure that the IGN has already tried on its own initiative and that are based on the same grounds the case shall be referred to the NBL. The same applies if the previous examination of the IGN regards case reported by another complainant. If the report is submitted by the same complainant as previously, it shall be rejected. If different grounds are cited in the report, the IGN may try the case.

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## **Assessment of cases by the NBL Institution of**

### **proceedings**

- p. 27 A report filed with the NBL containing a request to try a measure must be submitted in writing. As regards a report to the NBL, that stated in p. 19 shall apply, as well as that stated in p. 21, p. 22.1 and p. 22.2 concerning a report to the IGN.
- p. 28 If, without taking a decision of its own, the IGN refers an application for preapproval or a case to be tried on its own initiative to the NBL in accordance with p. 23 and p. 24, the IGN shall, if so required, state the reasons for the measure and also append the relevant documents in the case.
- p. 29 Appeals must be submitted in writing to the NBL. The appeal shall clearly state the reasons for the appeal and the investigative material cited. Material not cited when the IGN considered the case may be cited before the NBL only if specific reasons are present. Regarding appeals on the IGNs decisions regarding an approved application for pre-approval to the NBL, that which is stated in p. 19 and p. 22.1 regarding a report to the IGN applies.

### **Preparation of cases**

- p. 30 In reported cases in accordance with p. 27 and in cases that have been referred to the NBL by the IGN in accordance with p. 28, the NBL must communicate all documents to the pharmaceutical company as soon as possible for written statements. This shall not apply to an application regarding pre-approval.
- p. 31 In cases where a party lodges an appeal against the IGN's decision, the NBL shall notify the IGN and any possible opponents about the appeal and shall give them the opportunity to submit their comments on the matter. In cases where a party lodges an appeal against a decision made by Lif's Compliance Officer, the NBL shall notify Lif's Compliance Officer of the appeal and shall give that person the opportunity to submit comments.
- p. 32 When sending information for a statement in accordance with p. 30 and p. 31, a certain time limit shall be set for a reply, normally not more than two weeks. Extension of the time limit may not be permitted unless there are special reasons present. The NBL is entitled to determine the case even if no response has been received in the prescribed way.
- p. 33 As soon as a statement in accordance with p. 30 and p. 31 has reached the NBL, it shall be sent to the complainant or when applicable to the IGN or to Lif's Compliance Officer and the party lodging the appeal, as information. The preparation of the case is thereby

normally complete.

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**Consideration of cases and decision**

- p. 34 When the preparation of a case is complete or the time-limit for a statement set in accordance with p. 30 has expired, the NBL shall consider the case and take a decision on the first suitable occasion.
- p. 35 The NBL's decision, where appropriate taken in accordance with § 34 of the Statutes, should be forwarded promptly to the parties and should normally reach them within three weeks of the day of the meeting on which the NBL took a decision in the case.

**Advisory statements**

- p. 36 If a request for an advisory statement in accordance with § 20 of the Statutes is presented in connection with a certain criticised measure, that stated in p. 27 and pp. 30-34 regarding the institution of proceedings, the preparation of cases and the consideration of cases and decisions shall apply where appropriate.
- p. 37 If a request for an advisory statement is not connected to a particular criticised measure, the NBL shall, when required, itself attend to the investigation. The same applies if the NBL decides to issue an advisory statement on its own initiative.

**Cases referred by public authorities**

- p. 38 Cases referred by public authorities are dealt with, where appropriate, in the same way as reports with a request for an advisory statement. See pp. 36-37.

**Non-affiliated companies**

- p. 39 If a pharmaceutical company that is not a member of Lif refuses to file a defence or to loyally assist in the consideration of a case by the IGN or the NBL, this shall promptly be reported by the IGN or the NBL to Lif.

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These rules of procedure came into effect on 1 July 2021.

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### **Appendix 3 – Guideline for promotion of non- prescription medicines on mobile phones and tablets**

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# Guideline for promotion of non-prescription medicines on mobile phones and tablets

## Background

The purpose of this guideline is to adapt and improve advertisements on digital platforms to make the information available for the recipient (the general public as consumer) in an appropriate manner. To achieve this purpose the industry needs to apply a set of common principles, by adhering to this guideline.

Apart from what is stipulated in this guideline, promotion of non-prescription medicines in digital platforms with limited field of view must adhere to the applicable parts of LER, Chapter 1, section 2, and in particular with regards to the content of the "compulsory information" (see below) and its readability, what is stipulated in Article 117 and Article 11, respectively.

## Article 1. Compulsory information ("minimi-information")

Advertisements for non-prescription medicines on smart phones, tablets etcetera, i.e. digital platforms with limited field of view, shall contain the following compulsory information:

- a) to read the patient leaflet,
- b) indication, and
- c) there shall be a reference to finding the additional compulsory information in an expandable field.

What is considered as compulsory information will vary. A concrete assessment must be conducted in each specific case. The requirements concerning the content of the information, and the readability of it, as stipulated in Article 117 and Article 119 respectively, must be fulfilled.

## Article 2. The configuration of the advertisement

To fulfill the requirements in Article 1 above, the advertisement shall be configured as follows:

The advertisement shall be marked with a green bar across the entire width of the advertisement, which should constitute at least 1/5 of the total area of the advertisement. The green bar shall be marked with a standardised symbol, of a white-coloured cross inside a white circle, followed by the heading «Non-prescription medicine», and the text «Read the patient leaflet before use».

The green bar shall contain a clickable field, or the option to scroll further to the rest of the compulsory information, that is marked with e.g. the text «read more here».

The advertisement and the compulsory information must appear together in a uniform manner and all text that is included in the advertisement must be easily readable.