

ETHICAL RULES FOR THE PHARMACEUTICAL INDUSTRY IN SWEDEN

Revised 12 February 2018, valid from 12 February 2018



Ethical rules for the pharmaceutical industry in Sweden

Background and purpose

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 into a number of 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.

It is up to the Swedish marketing 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.

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 and were revised in February 2018. 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 on Gifts, Rewards and other Benefits 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 does no longer apply to veterinary medicinal products or veterinary medicinal companies.

The member companies of LIF, Föreningen Innovativa Mindre Life Science Bolag (IML), ASCRO and Föreningen för Generiska Läkemedel (FGL) follow the Ethical rules.

Contents

CHAPTER 1 – Rules governing information of medical products	8
Background and purpose	9
<i>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.</i>	10
Area of application, Section 1	10
Rules regarding the content and form of the information	10
Objectivity	10
Truthful presentation	11
Identification	12
Current knowledge.....	12
Documentation and references	13
Comparisons.....	14
Discreditation	15
Rules on disseminating information	15
Specific rules regarding the form of the information	15
Medical samples.....	18
Rules on responsibility	18
Bearer of responsibility	18
Burden of proof.....	19
Statutory copies	19
<i>Section 2 - Information that, in connection with the marketing of medicinal products on the Swedish market, is targeted at the general public.</i>	21
Area of application, section 2	21
Rules regarding the content and form of the information	21
Objectivity	21
Truthful presentation.....	23
Identification	24
Current knowledge.....	25
Documentation and references	25
Comparisons.....	26
Discreditation	27
Rules on disseminating information	27
Specific rules regarding the form of the information	28
Rules on responsibility	31
Bearer of responsibility	31
Burden of proof.....	32
Statutory copies	32
CHAPTER 2 – Rules of cooperation: the profession	33

Section 1 – Agreement on cooperation with healthcare.....	34
Background and purpose	34
Terms and definitions	35
Scope of the cooperation rules	36
Basic principles and rules	36
Product information.....	38
Other meetings	39
Meetings arranged by or in cooperation with pharmaceutical companies.....	39
Meetings arranged by or on behalf of healthcare or an economic association	40
Consultation and assignments	41
Collaborative projects	42
Market research.....	43
Public procurement.....	43
Scholarships	44
Donations and grants	44
Information- and educational material and items of medical utility.....	45
Clinical Trials.....	45
Section 2 – Ethical rules for interaction between pharmaceutical companies and pharmacy employees.....	46
Area of application	46
Background and purpose	46
Definitions	46
1. Basic principles and rules	47
2. Product information.....	49
3. Other meetings	50
4. Consulting and assignments.....	50
5. Market research	51
6. Information- and educational material and items of medical utility.....	51
7. Collaborative projects	52
Section 3 – Disclosure of transfers of value	53
Definitions	53
Scope of duty of report	53
When disclosures shall be made.....	54
How disclosure shall be made.....	54
Platform for disclosure.....	54
Applicable rules.....	54
Language	55
Documentation and retention of records	55
Individual disclosure.....	55
Aggregated disclosure	56
Indirect transfers of value to health care personnel	56
Transfers of value for research and development.....	56
Methods of disclosure.....	56
CHAPTER 3 – Rules of interaction: organisations and politicians	58
Section 1 – Ethical rules as to co-operation between pharmaceutical companies and user	

organisations/interest groups	59
Background and purpose	59
Ethical rules	60
Transparency and contract	60
Economic and other support.....	60
Consultation	62
Rules for co-operation	63
Monitoring IGN and NBL.....	64
Section 2 – Ethical rules for interaction between pharmaceutical companies and politicians ..	65
Background and purpose	65
Consultation and assignment.....	65
Events.....	65
Refreshments, expenses and remuneration.....	66
Gifts	66
Campaign contributions, other benefits etc.	66
CHAPTER 4 – Non-interventional studies and National Quality Registers within the health service	67
.....	67
Section 1 – Rules for non-interventional studies	68
Background and purpose	68
Difference between non-interventional studies and clinical trials	68
When are non-interventional studies performed?.....	68
Criteria for non-interventional studies:	69
The study must be performed in the course of standard healthcare provision	69
Responsible health authority	69
Regional ethical vetting board	70
Study plan/protocol	70
The Swedish Data Protection Act (PUL)	70
Ownership of data.....	71
The company’s internal process	71
Quality assurance	71
The Swedish Medical Products Agency.....	71
Announcement.....	71
Section 2 – Financial support for National Quality Registers within the health service	72
Background and purpose	72
Criteria for providing financial support to National Quality Registers.....	73
CHAPTER 5 – Regarding bribes	75
Regarding bribes	76
Chapter 10 of the Penal Code (SFS 2012:301)	76
Appendices	77
Appendix 1 – Template for disclosure of transfers of value	79
Appendix 2 - Statutes of and rules of procedure for IGN and NBL	82
Statutes of the Swedish Pharmaceutical Industry’s Information Examiner Committee (IGN) and the Information Practices Committee (NBL)	83

Governing bodies and area of activity	83
Duties	83
Nature of activity.....	83
Distribution of cases.....	84
Rules of procedure	84
Organisation	85
Entitlement to take legal action	86
Request for termination of a measure.....	88
Quorum in final decisions and issuing of warnings.....	88
Interim decisions.....	89
Decisions in dealing with a case	89
Challenge.....	90
Final decisions and advisory statements.....	90
Appeals to the NBL.....	91
Minutes and annual reports.....	91
Openness, confidentiality and professional secrecy.....	91
Fees	92
Late payment fees.....	93
Payment	93
Advertising	93
Corrective advertisements.....	93
Disciplinary measures	93
Administrative regulations.....	94
Adoption and amendments of statutes	94
Rules of procedure for the IGN and the NBL.....	95
Terminology	95
Pre-approval.....	95
Monitoring the market.....	95
Assessment of cases.....	96
Assessment of cases by the IGN.....	96
Pre-approval.....	96
Cases examined on own initiatives	96
Reported cases	97
Referral to the NBL.....	98
Assessment of cases by the NBL	99
Institution of proceedings.....	99
Preparation of cases.....	99
Consideration of cases and decision	100
Advisory statements	100
Cases referred by public authorities	100
Non-affiliated companies.....	100



CHAPTER 1 – Rules governing information of medical products

Background and purpose

In order 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 HCP Code 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 Compliance Officer is also the contact person for IFPMA's Code Compliance Network.

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.

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

If an SPC has not yet been set, the applicable catalogue text according to Fass.se shall constitute the factual basis for information about the medicinal product instead.

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

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. 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,
- 4.4 that the presentation may not be deceptive or suggestively misleading,
- 4.5 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.
- 4.6 that expressions such as "safe" may not be used unless the claim has been substantiated in a qualified manner.
- 4.7 that the word "new" 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,
- 4.8 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,
- 4.9 that it may not be claimed that a product does not have any side-effects, toxic risks or risk of misuse or dependence.
- 4.10 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).

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, programmes 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 clearly evident 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.

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, participate in medicinal product information and offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment.

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.

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 evident their statistical validity,
- 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.

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 a 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.
- 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 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 (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.

Article 17

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

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- 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 the status of the product (e.g. R_x or OTC),
 - 17.10 the status of the product regarding the benefits system (e.g. EF or F). 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 catalogue text for a medicinal product is not available at any time via Fass.se, written information concerning the medicinal product must contain the applicable catalogue text in full, or the adopted SPC.

Article 19

Catalogue text or SPCs that are reproduced in written medicinal product information must, as 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 the 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.

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 representative 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. The notification may not be made more comprehensive than is necessary to present the intended information. The notification may however include the minimum information required according to article 17. 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. The same applies to indications or dosages that have not yet been approved at the time of the notification, but that are expected to have been approved before the date when the information is issued.

Article 24

Entertainment and other benefits offered to those to whom verbal information is addressed may not be of such 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.

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 relative 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 regard 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 that 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 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 originates 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 in consultation with other persons 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, in particular those for which pharmaceutical representatives are responsible). The responsible executive 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 persons.

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 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 on pictures contained in its medicinal product information. The company shall be prepared, upon request by the 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

According to the statutes for the IGN and NBL, the IGN is responsible for monitoring the market. In order for the IGN to be able to carry out this task, the pharmaceutical companies must send new, up-to-date medicinal product information to the IGN, such as publications, advertisements, invitations, mailings, commercial films or information on websites. On request, the IGN may provide general advice on measures that have not yet been implemented. Such advice constitutes non-binding advance decisions.



Section 2 - Information that, in connection with the marketing of medicinal products on the Swedish market, is targeted at the general 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 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 the information

Objectivity

Article 101

Medicinal product information must include accurate, objective, meaningful and balanced particulars dealing adequately with the favourable 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 take into account 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.

If an SPC has not yet been set, the applicable catalogue text according to Fass.se shall constitute the factual basis for information about the medicinal product instead.

The information may only refer to medicinal products that have received marketing approval in 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 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 in order 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 an 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 to the public, access to patient suited information regarding the medicinal product in order 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.

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. 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,
- 104.4 that the presentation may not be deceptive or suggestively misleading,
- 104.5 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.
- 104.6 that expressions such as "safe" may not be used unless the claim has been substantiated in a qualified manner.
- 104.7 that the word "new" 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,
- 104.8 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,
- 104.9 that it may not be claimed that a product does not have any side-effects, toxic risks or risk of misuse or dependence.
- 104.10 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.

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, programmes 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 clearly evident 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 responsible company 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.

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, participate in medicinal product information and offer their opinion as a guarantor for a particular medicinal product or recommend a particular treatment.

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 make reference in 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.

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 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 evident their statistical validity,
- 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 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.:

- 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,
- 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 a nature that it respects the special nature of the medicinal product.

Rules on disseminating information

Article 114

- 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.
- 14.2 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 website or in any other way actively promote such website. 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 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 (SFS 2004:451).

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

Information to the general public shall normally, and when permitted by the chosen medium of information, 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 the details which are referred to in article 106,
- 117.7 if the information regards human medicinal products, an explicit and easily legible invitation to carefully study the information contained in the leaflet or, as applicable, on the outer packaging
- 117.8 as regards non-prescription medicinal products that are effective against a disease or symptoms of a disease that require contact with a physician for diagnosis or treatment, the medicinal product information to the general public must include a clear recommendation to consult a physician before using the medicinal product.

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 responsible company 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 taken into account.

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 the 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 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 for 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.

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 originates 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 in consultation with other persons 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, in particular those for which pharmaceutical representatives are responsible). The responsible executive 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 persons.

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 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 the 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 108-111.

Statutory copies

Article 131

According to the statutes for the IGN and NBL, the IGN is responsible for monitoring the market. In order for the IGN to be able to carry out this task, the pharmaceutical companies must send new, up-to-date medicinal product information to the IGN, such as publications, advertisements, invitations, mailings, commercial films or information on websites. On request, the IGN may provide general advice on measures that have not yet been implemented. Such advice constitutes non-binding advance decisions.

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

CHAPTER 2 – Rules of cooperation: the profession

Section 1 – Agreement on cooperation with healthcare

Background and purpose

The Swedish Association of Local Authorities and Regions (Sw. *Sveriges Kommuner och Landsting*, SKL), Läkemedelsindustriföreningens Service AB, Swedish Medtech and Swedish Labtech have agreed on common rules for how employees and senior management in healthcare and pharmaceutical companies shall cooperate and interact with each other.

It is the view of the parties that collaboration between healthcare and pharmaceutical companies is an important part of the development of healthcare as well as pharmaceutical companies. With these rules, the parties wish to safeguard a continued development of collaboration in a trustful manner.

The rules have been jointly developed in response to external demands for increased transparency, moderation in all collaboration, and the need for a clearer allocation of responsibilities between healthcare and pharmaceutical companies, such as the responsibility of healthcare authorities for the training of employees.

In the agreement, the group to which these rules apply is described and certain terms and definitions are provided.

The parties shall work to ensure that the members of each party, respectively, have a properly functioning self-regulatory system for the purpose of maintaining a good level of compliance to these rules.

The parties agree to collectively reevaluate the rules once a year, in order to adjust as needed.

In Sweden, healthcare and pharmaceutical companies have had a valuable collaboration for many years, providing important developments to healthcare. A close collaboration between healthcare and pharmaceutical companies has been a prerequisite for developing and evaluating new methods and treatments.

An efficient form of cooperation between healthcare, research, and pharmaceutical companies creates a mutual commitment to effective gathering of knowledge, structured introduction, and evaluation of treatments. In this way, conditions required for continuous improvements of healthcare are provided, which is of great importance to patients, as well as to the healthcare and pharmaceutical companies sectors. The basis for all efficient forms of cooperation is to provide patients with appropriate, evidence-based, cost-efficient and secure care. The pharmaceutical companies are a knowledge-intensive sector of major importance for Sweden. To effectively develop methods and products, close and trustful cooperation is needed between companies in this sector and healthcare.

Collaboration with the pharmaceutical companies is an important part of the training and development of skills which are necessary to enable healthcare employees to enhance methods and treatments and to ensure a high level of patient and user security. The employer is responsible for its employees' training and development of skills and carries the responsibility for related costs.

Terms and definitions

<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>Senior management</i>	Director, medical director, head of section/ division /operations, or any other official in a principal position.
<i>Healthcare</i>	Healthcare financed by public funding in county councils, regions or local authorities, and by private entities.
<i>Employee</i>	All healthcare professionals, such as persons employed by healthcare, students under education or training, contractors or consultants.
<i>Meeting</i>	A meeting regarding product information, therapy-oriented training, a scientific meeting, or other related types of meetings or gatherings where healthcare professionals and senior management interact with the pharmaceutical companies.
<i>Healthcare authority</i>	County council, region or municipality responsible for healthcare.
<i>Contracting authority</i>	Governmental, regional or local authority as defined in the Swedish Act on Public Procurement (LOU) Chapter 2 Section 19.
<i>Operations manager</i>	Within all healthcare, an operations manager shall carry the general management responsibility and be responsible for the operations.

Scope of the cooperation rules

Article 1

All employees including senior management in healthcare and pharmaceutical companies are subject to these rules.

The healthcare shall apply these rules in dealings with all companies within the pharmaceutical industry that act on or target the Swedish market, whether or not these companies are members of a trade organization.

The members of LIF shall apply these rules throughout on all collaboration with employees and senior management within healthcare.

Employees and senior management within the healthcare and the pharmaceutical companies shall, in addition to these rules and applicable laws, apply any rules, codes or policies that their respective employers have established for their own operations regarding travel, hospitality, secondary employment, and good business and ethical conduct.

Basic principles and rules

Article 2

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

In the event the cooperation involves a transfer of value, as defined in chapter 2, section 3, the rules in chapter 2, section 3 shall be applied to the transfer of value.

Article 2a

The following basic principles shall always apply to all cooperation:

The benefit principle

The cooperation between healthcare and pharmaceutical companies shall be based on the activities of healthcare and on the needs of patients, and shall be clearly linked to the company's business. A mutual benefit perspective shall be applied.

The transparency principle

Cooperation between healthcare and pharmaceutical companies 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.

The proportionality principle

Throughout the cooperation between healthcare and

pharmaceutical companies, 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.

The moderation principle

A meeting which is in any way sponsored or arranged by pharmaceutical companies shall be permeated by moderation. The requirement for moderation means that the privilege may not appear as influencing the behavior of the recipient. Collaboration between healthcare and pharmaceutical companies shall not constitute undue influence and may not jeopardize or be perceived as jeopardizing the independence of healthcare.

The documentation principle

All forms of cooperation between healthcare and pharmaceutical companies where any form of remuneration or recovery of costs occurs, whether involving single employees, groups of employees or a healthcare 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.

Article 2b

The following basic rules shall always apply:

The basic rule

Companies are not permitted to offer and healthcare 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.

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, lunch and dinner expenses shall amount at most to the value per participant laid down by LIF at that time. For meals abroad, local rules must be followed where applicable. In the absence of such rules, the Swedish rules must be applied as far as possible.

Alcohol

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.

Recreational activities

Recreational activities, including various forms of entertainment, may neither be financed by pharmaceutical

companies nor requested by healthcare employees in connection with meetings or other forms of interaction. Simple social activities, such as background music or local performances, playing at the venue in connection with the meeting shall not be considered as offered by pharmaceutical companies provided that it has neither been organized, requested nor paid for by the pharmaceutical company.

Travel

When it is possible, travel shall be arranged in economy class. Additionally, travel time may not exceed the length of the meeting, including potential side events.

Accompanying individuals

Only participants in the meeting may be invited. Accompanying individuals may not participate.

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.

Product information

Article 3

A product information meeting entails a meeting where information is provided about the specific properties, functions and handling of a pharmaceutical or a medical technology product. The content shall provide the participants with current up-to-date and relevant information.

An invitation to a meeting shall always be sent to the operations manager or the person he/she has appointed. Copies of the invitation may be sent to relevant employees, i.e. the main target group of the meeting. The operations manager shall, in such case, be informed that a copy of the invitation has been sent and the individuals or groups which are the recipients.

The invitation shall include information about

- (i) content,
- (ii) duration and,
- (iii) if possible, time and venue.

In the heading of the invitation, it shall be stated that the meeting concerns product information. The invitation shall be designed to clearly indicate that the information is not product-neutral. (See also article 23 of chapter 1, section 1 regarding the form and content of booking letter/notification of verbal information.)

Any healthcare professional who participates in a product information meeting is responsible for obtaining his/her employer's approval for participation.

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

Product information that is presented in exhibition stands or that is distributed at international scientific conferences or symposia may refer to medicinal products that are not registered in the country where the event is taking place, or that are registered in a different way, on the condition that:

- (i) The event is an international scientific meeting with a majority of participants from countries other than the country where the event is taking place.
- (ii) Marketing material containing information about a medicinal product that has not been granted marketing authorisation in the country where the meeting is taking place includes details about the countries in which the medicinal product has received marketing authorisation, as well as the fact that it has not been granted such authorisation in the country where the event is taking place.
- (iii) Marketing material that refers to prescribing information (indication, warning texts, etc.) that has been approved in a country or countries, although not in the country where the event is taking place, but where the medicinal product is registered, is followed by information that the registration terms may differ internationally.
- (iv) Information indicates the countries in which the medicinal product has been approved, and specifies that the medicinal product has not been approved locally.

Other meetings

Article 4

Meetings other than those pertaining to product information can concern various forms of training and development of skills, e.g. therapy-oriented training, seminars, scientific meeting, congresses and symposia.

Meetings arranged by or in cooperation with pharmaceutical companies

Article 4 a

Pharmaceutical companies may independently, or in collaboration with healthcare or a third party,

arrange, pay for and be the sender of invitations to meetings aimed at healthcare employees. The scientific and professional program should be the dominant element and the purpose of the meeting. Pharmaceutical companies may only invite to meetings where the program has a connection to the pharmaceutical company's own business areas.

An invitation to a meeting shall always be sent to the operations manager or the person designated by him/her. "Invitation" may also refer to an advance invitation. A copy of the invitation may be sent to relevant employees, i.e. the main target group of the meeting. The operations manager shall, in such case be informed that a copy of the invitation has been sent and the individuals or groups which are the recipients. Pharmaceutical companies shall also send a copy of the invitation for the attention of relevant pharmaceutical committees.

The invitation shall specify

- (i) purpose and content,
- (ii) the duration of the planned meeting,
- (iii) time and place,
- (iv) the costs that the company intends to finance, and any additional arrangements.

It shall be clear from the program and the invitation whether product information will occur.

As a rule, the meeting shall be held at the participants' workplace, or in the vicinity of the participant's workplace, or as close to such locality as possible, unless special circumstances warrant otherwise.

The employee participating in a meeting is responsible for obtaining the employer's approval for participation.

Pharmaceutical companies may finance the venue, speakers, study materials, meals and similar as is necessary to carry out the meeting. Travel and accommodation for individual participants may not be paid for by pharmaceutical companies or requested by individual participants.

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 participating.

Meetings arranged by or on behalf of healthcare or an economic association

Article 4 b

Sponsorship entails financial or other support that includes a market-based return, such as exhibit space, the opportunity to demonstrate a product, or other forms of exposure. Sponsorship differs from a donation, where no return exists.

At a meeting arranged by or on behalf of healthcare or an association that organizes employees in the healthcare sector, the scientific and professional program shall be the dominant element and the purpose of the meeting, to render it possible for pharmaceutical companies to participate as sponsor.

Pharmaceutical companies may only offer sponsorship to meetings that have a connection to the company's own business areas.

Sponsorship of the ordinary activities and internal activities of healthcare or associations may not occur, such as training for an individual clinic, planning conferences, or staff parties, neither may such sponsorship be requested or offered.

The party arranging the meeting shall well before the meeting, communicate the names of the sponsor.

The income generated to healthcare or an association generated by sponsorships may only cover actual, documented, reasonable and direct costs that are necessary in order to carry out the professional parts of a meeting. Examples of such costs are expenses for speakers, venues, moderate meals in connection with the scientific part of the meeting, or the cost for training materials. Sponsorship of meetings where the meal is the only actual cost may not be requested or offered.

Travel, accommodation, and participation fees may not be paid for by pharmaceutical companies or requested by individual participants. Booking of travel and accommodation may not be provided by pharmaceutical companies.

If the pharmaceutical company is not provided with a complete budget for the meeting which has been arranged by or on behalf of healthcare or an association that organizes employees in the healthcare sector as a basis for decision, where am where e.g. the aforementioned costs are specified, the pharmaceutical company shall request such.

The financial outcome of the meeting which has been arranged by or on behalf of healthcare or an association that organizes employees in the healthcare sector shall be reported to the pharmaceutical company within six months after the activity is completed. If the revenues from all sponsors generate a surplus to the organizer, a refund shall, as a rule, be made to the companies that have participated as sponsors.

Consultation and assignments

Article 5

Employees and senior management within healthcare are often an important part of various activities, such as research, training, conferences, product development, and advising bodies, referred to as advisory boards.

Participation should generally entail an assignment that falls under normal work duties. If the participation is of a consulting nature, it shall be regarded as secondary employment. In such cases, the employer's rules on secondary employment shall be applied.

There must be a legitimate need for the assignment before it is requested or initiated with the potential employee within healthcare. The selection criteria for 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 assignment shall be agreed upon in writing between the employee, the employer and the company. With a public employer, the agreement constitutes a public document. Remuneration for work shall be reasonable in relation to the content of the task and the time spent. Where applicable, reimbursement of expenses shall be paid in accordance with the employer's rules for travel and expenses. The agreement shall stipulate which tasks shall be performed and how remuneration is regulated. 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.

In the written agreement between the employee, the healthcare management/the pharmacy company and the pharmaceutical company, the pharmaceutical company shall indicate 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 a topic related to the assignment.

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

Hiring healthcare personnel/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.

Pharmaceutical companies' appointment of an advisory board entails engaging and compensating healthcare 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. Thus, an advisory board is a small group with a limited number of participants, and the number of employees that are engaged should not be higher than what is necessary in order to achieve the identified purpose.

Collaborative projects

Article 6

Collaboration between healthcare and the pharmaceutical companies can have various features and different aims and purposes. In respect of clinical trials, for example, separate agreements have been concluded, and the conditions for those trials are regulated separately. (See article 12 in this section.)

Collaborative projects between pharmaceutical companies and healthcare shall be understood in these rules as cooperation in projects with the aim of improving support to patients, enhancing quality of care, or otherwise contributing to increased patient benefit.

Proposals for collaborative projects shall be sent to the operations manager, who shall subsequently inform any relevant organizational levels.

An agreement regarding a collaborative project may not constitute an assignment to an individual. The agreement shall be concluded by the pharmaceutical company and a unit within healthcare. The agreement may not imply exclusivity for the pharmaceutical company to provide certain kinds of services to one or more healthcare providers.

Both the healthcare and the company shall contribute to the collaborative project with resources such as funds, materials and working time. A project plan shall exist, which, for example, shall regulate how the project shall be evaluated. The collaborative project shall be reported to the public and be available in LIF's cooperation database.

Market research

Article 7

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. Market research must not have the purpose of influencing the respondent, or to supply sales promotional contacts. When companies subject to these cooperation rules conduct market research, the person performing the research shall abide by the ethical guidelines for market research in accordance with ICC/ESOMAR.

A request for participation in market research can only be made by e-mail, SMS, letter or fax, unless otherwise agreed upon in the particular case.

The number of respondents may not exceed the number necessary to provide reasonable assurance of the outcome. The respondents' answers shall be treated in strict confidence and in accordance with the Personal Data Act (PUL).

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 a 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.

The respondent is responsible for obtaining the employer's consent, where necessary. In case of financial compensation for participation in market research that is linked to professional tasks, the employer's consent should always be obtained.

The participation of individual healthcare employees in market researches should not be viewed as "consultation" in accordance with article 5 above, if the above criteria for the market research are satisfied.

Public procurement

Article 8

A large part of the cooperation between healthcare and pharmaceutical companies relates to individual products that are, or may become, subject to public procurement. In such situations, it is of particular importance that healthcare employees and the companies maintain an independent attitude towards each other and in accordance with rules under law.

Communication before, during and after the procurement between pharmaceutical companies and the contracting authority promotes good business. It is the responsibility of the contracting authority to inform healthcare and companies that public procurement is on-going.

When a group of products is subject to a public procurement process, it is important that participants from healthcare/purchase departments and companies communicate in a manner that is consistent with the public procurement process applicable at such time.

Scholarships

Article 9

Pharmaceutical companies may fund scholarships directed towards healthcare. A scholarship may be awarded, following the nomination of persons, for the promotion of a certain purpose.

Awarding a scholarship is only permitted if:

- (i) the scholarship shall, in essence provide professional improvement, e.g. in regard to future education and research or similar, and shall add value to healthcare,
- (ii) selection criteria, purpose, scholarship committee, statement of reasons for the selection of the scholarship candidate, and the scholarship donor shall be open and transparent,
- (iii) the scholarship is related to an area which is linked to the company's own areas of business, and
- (iv) the scholarship is not be awarded to healthcare employees for the purpose of circumventing the intentions of these collaboration rules.

Scholarships may not be connected to previous, ongoing or potentially future use, recommendation, prescription, purchase, supply, selling or administration of the donor's product or services and may not either constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Donations and grants

Article 10

Donations and grants to healthcare are only allowed if made to support research and development (R&D). The donor shall keep a register of the donations and grants given and the donation or grant shall be given transparently and be well documented.

Donations and grants may never be offered or requested to fund healthcare's internal or regular activities. Pharmaceutical companies' donations and grants may not be requested or offered to finance of recreational activities.

Donations and grants to healthcare shall not be connected to past, present or potential future use, recommendation, sale or prescription of the donor's products or services, and may not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Information- and educational material and items of medical utility

Article 11

Gifts may not be supplied, offered or promised to healthcare or its employees with the exception of 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.

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 in order 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 advantage, 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 meeting, 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:

The benefit principle The cooperation between pharmacy, pharmacy company and industry shall 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. Collaboration between pharmacy, pharmacy company and industry shall not constitute undue influence and may not jeopardize or be perceived as jeopardizing the independence of pharmacies.
<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 motivates otherwise. The participating employees are responsible to ensure 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. 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 shall always be made available.
<i>Recreational activities</i>	No stand-alone social activities or recreational activities may occur in connection with meetings or other forms of interaction. 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 or 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.
<i>Selection of location and venue</i>	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 3, applies for product information that is presented in exhibition stands or that is distributed at international scientific conferences or symposia

3. Other meetings

a. Meetings arranged by or in cooperation with pharmaceutical companies

Pharmaceutical companies may independently, or in collaboration with pharmacies or a third party, arrange, pay for and be the sender of invitations to meetings aimed at pharmacy or pharmacy company employees.

The scientific and professional program should be the dominant element and the purpose of the meeting.

The invitation shall specify purpose and content, the duration of the planned meeting, time and venue.

It shall be clear from the program or the invitation whether product information will occur.

Pharmaceutical companies may finance the venue, speakers, study materials, meals and similar as is necessary to carry out the meeting.

b. Meetings arranged by pharmacy, pharmacy company or a third party

At a meeting arranged by or on behalf of a pharmacy, pharmacy company or an association that organizes employees in the pharmacy sector, the scientific and professional program shall be the dominant element and the purpose of the meeting, to render it possible for pharmaceutical companies to participate as sponsor. The names of the sponsors shall be communicated well before the meeting.

The income generated to pharmacies, pharmacy companies or an association generated by sponsorships may only cover reasonable and direct costs that are necessary in order to carry out the professional parts of a meeting. Examples of such costs are expenses for speakers, venues, moderate meals in connection with the scientific part of the meeting, or the cost for training materials.

Upon request for sponsorship, the organizer shall provide a complete budget for the activity as a basis for decision, where *inter alia* all revenue and costs are specified. It is desirable that the financial outcome of the meeting is accounted for after the activity is completed.

Sponsorship of the ordinary activities and internal activities of pharmacies or pharmacy companies may not occur.

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 regarding 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.

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 shall be treated in strict confidence and in accordance with the Personal Data Act (PUL).

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 a 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 items of medical utility

Gifts may not be supplied, offered or promised to pharmacy companies, pharmacies or its employees with the exception of 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.

7. Collaborative projects

Collaborative projects between pharmaceutical companies and pharmacies may occur under equivalent conditions as mentioned in LER chapter 2, section 1, article 6.

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

- **healthcare** shall mean any legal person 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 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) 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 this 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 shall be made in accordance with the template in Appendix 1 to the ethical rules.

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 applies 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 for an amount related to any of the categories set forth below:

- (a) donations referred to in chapter 2, section 1, article 10 as well as sponsorships referred to in chapter 2, section 1, article 4b.
- (b) financial support to such arrangements referred to in chapter 2, section 1, article 4, 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 5.

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 5. 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.

Methods of disclosure

Article 13

13.1 Pharmaceutical companies shall make public a summary of the methods used for the disclosure. The summary shall describe which disclosure methods have been used and may include details regarding accrual of the amounts made under agreements which cover more than one reporting period, long contractual terms, VAT and other tax related aspects, currency aspects and other questions related to the timing and the amount of the transfer of value.



CHAPTER 3 – Rules of interaction: organisations and politicians

Section 1 – Ethical rules as to co-operation between pharmaceutical companies and user organisations/interest groups

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 contacts with organisations. The co-operation between the parties is all the more important since the pharmaceutical companies need to exchange knowledge and experience with those using pharmaceutical products so that the use and development of pharmaceutical products can be optimised. For their part, pharmaceutical companies possess knowledge which must be passed on to patients. All collaboration should take place within the constraints of these ethical rules.

The purpose of these ethical rules is to ensure that the co-operation between organisations and the pharmaceutical companies takes place in a responsible and meaningful manner, and that the co-operation, information and training are also 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 chosen collaborative projects may not comprise an overwhelming share of the organisation's activity and/or economy.

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*
- *Common responsibility for planning and implementation*
- *Openness and transparency to the outside world*
- *Restriction of the choice of collaborative fields*

The ethical rules are applicable to the pharmaceutical companies. Certain organisations and companies have set their own rules as to collaboration. Such rules are to be seen as complementary to these ethical rules.

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

Ethical rules

Transparency and contract

Article 1

- 1.1 The co-operation between pharmaceutical companies and organisations should be regulated in written agreements.
- 1.2 Agreements should contain a project description, information about its financing and clearly state the rights and obligations of each party and the duration of the project. When using 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 shall apply to organisations who wish to use the pharmaceutical company's logo and name in information etc.
- 1.3 Contracts and agreements between organisations and pharmaceutical companies should also be kept available to third parties. Openness relates to all agreements, whether ongoing, concluded or regarding future projects.
- 1.4 Short versions of all contracts and agreements should also be available in the LIF Co-operation Database when activity is ongoing and at least for one month after the project is concluded. It is the responsibility of member companies to enter information into the Co-operation Database in accordance with current headings in the database. Information can be found on www.lif.se.
- 1.5 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 updated and current.
- 1.6 If international co-operation is 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.

Economic and other support

Article 2

- 2.1 Economic or other support shall only be given to the specified collaborative projects or activities. The pharmaceutical companies may not supply economic funds or other support which:
 - are intended to finance a user organisation's regular operations, or
 - mean that a user organisation's operations cannot survive when the co-operative agreement ends, or
 - mean that a dependency relationship arises between the parties, or
 - exceeds the costs of the activity/conference

2.2 Companies may give economic support for personnel costs only in cases where the personnel costs are included in a temporary project. However, this does not mean that the company takes on employer's liabilities. This should be evident from the agreement made between the parties.

2.3 The pharmaceutical companies may pay the costs of such things as conference and educational activities as well as for travel, food and accommodation and educational materials necessary to conduct a joint activity in Sweden. Companies may also charge a fee corresponding to the company's costs for the arrangement. The choice of location for an event must be reasonable in relation to the purpose of the event. Locations at which major international events are being staged at the same time as, or in connection with, the arrangement shall be avoided. Neither should companies contribute financially to events that are located in such places. LIF's Compliance Officer decides whether a location is acceptable or not. A decision made by the Compliance Officer can be appealed.

If the collaboration relates to financing of the organization's participation in a meeting, activity or congress abroad, reference is made to what applies according to article 2.5 in this section.

2.4 When a physician is invited to an activity, such as a lecture, and if the company is to be regarded as arranger or co-arranger, what is mentioned in article 5 of Chapter 2, Section 1, regarding the interaction between the health care and representatives of the pharmaceutical industry, is also applicable. In this case, a contract is required with both the physician/his or her employer, as well as with the interest group concerned. Merely supplying a contribution for a specific project does not mean that the company is to be regarded as co-arranger.

2.5 If the collaboration relates to financing of the organization's participation in a meeting, activity or congress abroad, invitations should be addressed to the management of the organisation. It is then the organisation which determines first whether there is a need to participate, and secondly who from that organisation that will take part. Subsequently, provided there is participation, an agreement is made between the company and the organisation. However, the pharmaceutical company, or several companies part-financing the activity, may not be responsible for more than 50% of the total cost to the participant. As for the choice of location for events abroad, reference is made to what applies according to article 2.3 in this section.

Companies may not arrange or provide financial support for arrangements that are held outside of their home country unless:

- (i) the majority of those invited come from countries other than the home country and, bearing in mind the origins of most of those invited, it is reasonable from a logistical or security perspective to organise the arrangement abroad, or

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- (ii) bearing in mind the relevant resources or experts who are the subjects of the arrangement, it is rational to organise the arrangement in another country (“international arrangement”).
- 2.6 A company may not pay fees which differ significantly from what other players must pay, e.g. membership dues, advertising costs, exhibitions or remunerations.
- 2.7 Travel should be planned so that the participants/consultant arrive(s) at and depart(s) from the conference/assignment as close to the opening and closing times of the arrangement as practically possible.
- 2.8 The activity as well as travel, food and accommodation shall be moderate and must be strictly related to the purpose of the activity.
- 2.9 Pharmaceutical companies may in exceptional cases, in cases of medical reasons, pay for conference fee, travel, food and accommodation for an accompanying person to a participant in connection with activities or congresses. If the activity or congress is held abroad, article 2.5 in this section shall be complied with as regards the extent of the financing.
- 2.10 Neither in connection with activities nor collaboration in general may separate social activities or leisure events be offered by pharmaceutical companies. In conjunction with meals or receptions may, however, a simpler social activity such as music entertainment be arranged as long as it is secondary to the activity as well as the meal or reception.

Consultation

Article 3

- 3.1 Representatives of organisations often form an important part of various activities to highlight the perspective of the patient, such as research, training, conferences, market studies, advisory boards or in product development of information material, articles etc.

The following must be taken into consideration when pharmaceutical companies wish to engage representatives of organisations for various assignments:

- The number of representatives that are hired must not be higher than what is necessary to achieve the identified purpose.
- There shall be a legitimate need for the assignment before it is inquired or initiated. The criteria for selecting consultation assignment shall be based upon identified needs. The inquiry regarding the assignment shall be made to the responsible persons within the organisation. The organisation decides if the inquiry shall be accepted or not. The extent of the assignment shall not be greater than is necessary in order to achieve the identified need. Before the assignment is initiated, it shall be agreed in writing between the organization that the representative represents and the

pharmaceutical company in accordance with article 1 in this section.

- The pharmaceutical company shall appropriately make use of the information and the records that is provided through the assignment. The pharmaceutical company shall make known that the representative is a consultant for the company when the company expresses an opinion in public, verbally or in writing, on the topic covered by the assignment. In the written agreement it is recommended to indicate that an obligation for the organisation to declare that the representative is a consultant for the company when he or she expresses an opinion in public, verbally or in writing, on the topic covered by the assignment.
- Hiring representatives for the execution of a particular assignment may not constitute an incentive to recommend a specific medicinal product, product or pharmaceutical company.
- Remuneration for work carried out must be reasonable in relation to the content of the work and the time spent. The above agreement shall stipulate how remuneration is regulated. The pharmaceutical company may pay for travel, board and lodging for the representative when performing the assignment under the condition that the costs are moderate. No other fringe benefits, remuneration, or gifts may be provided.

Rules for co-operation

Article 4

- 4.1 A basis for collaboration is that it should be in the interest of both parties. Collaboration should be jointly planned and implemented in a manner agreed by the parties. This should always take place openly, in a manner transparent to the public. Furthermore, it should always be clearly evident from any informational material and invitations that this is a collaborative project, so that the recipient understands who or which parties stands behind the material. The pharmaceutical companies are liable to observe the information rules and other applicable standards within what is known as the industry's self-regulatory system.
- 4.2 These rules are applicable to the pharmaceutical company even if a company in collaboration with an organisation hires an external consultant (such as an advertising or PR agency).
- 4.3 A collaborative project may comprise more than one company and/or include public bodies. Choosing a primary partner is permissible in collaboration and in specific projects an exclusive right can be agreed. However, an exclusive right should not be included in any general contracts and/or agreements.

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 government's 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 also politically appointed officials, e.g. under-secretaries 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.¹

¹ 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 guide-lines 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 every-day 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 on the basis of 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 on the basis of 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 in the course of 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 concluded 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 Swedish Data Protection Act (PUL)

Article 5

Patients must receive, where applicable, written information (including relevant provisions of the Personal Data Act) and give their written consent to take part in the study unless the regional ethical vetting board has permitted otherwise. In some cases the regional ethical vetting board may agree that consent need not be obtained from patients with reference to section 19 of the Personal

Data Act.

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) collaborates 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. In 2012, a total of 100 registries received financial support from SALAR (figures obtained from www.kvalitetsregister.se) and in 2011 the companies' financial support amounted to SEK 12,4 million which can be compared to SALAR's support of SEK 61,4 million (figures obtained from LIF's annual FoU-report). 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 a 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.

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. The 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 controller (*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, publications 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.

CHAPTER 5 – Regarding bribes

Regarding bribes

Chapter 10 of the Penal Code (SFS 2012:301)

5 a § A person who is an employee or is performing a duty and receives, accepts a promise of or demands an improper reward for the performance of the employment or the duty shall be sentenced for *taking a bribe* to a fine or imprisonment for at most two years. The same shall apply to a person who is a participant in or an official at a competition which is subject to betting arranged for the public and the improper reward is related to his or her fulfillment of the duties at the competition.

The provisions of the first paragraph shall also apply if the person committed the act before obtaining such a position referred to therein or after leaving it.

A person who receives, accepts a promise of or demands an improper reward pursuant to the first or second paragraph on behalf of another person shall also be sentenced for taking a bribe.

5 b § A person who gives, promises or offers an improper reward in cases indicated in 5 a § shall be sentenced for *bribery* to a fine or imprisonment for at most two years.

5 c § If the crime in 5 a or 5 b § is gross, a person shall be sentenced for *gross taking of bribe* or *gross bribery* to imprisonment for at least six months and at most six years. In assessing whether the crime is gross, special consideration shall be given to whether the act involved misuse of or assault towards an especially responsible position, concerned a substantial value or was a part of criminality which is conducted systematically or to a large extent or otherwise was of especially dangerous nature.

5 d § A person shall be sentenced for *trading with influence* to a fine or imprisonment for at most two years in cases other than those indicated in 5 a or 5 b § if that person

1. receives, accepts a promise of or demands an improper reward to influence another persons' decision or action in exercising public authority or public procurement,
or
2. gives, promises or offers an improper reward to someone in order for that person to influence another persons' decision or action in exercising public authority or public procurement.

5 e § A person carrying on business activities who supplies another person, who is representing the person carrying on business activities in a certain matter, with money or other assets and by gross negligence thereby promotes bribery, gross bribery or trading with influence according to 5 d § 2 in relation to that matter is sentenced for *negligent financing of bribery* to a fine or imprisonment for at most two years.

Appendices



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

TEMPLATE													
											Date of publication:		
	Full name	HCPs: City of Principal Practice HCOs: city of practice (registered address)	Country of principal practice	Principal practice address (e.g. clinic/office/healthcare unit/department)	Unique identifier - OPTIONAL	Donations to HCOs (article 9)	Contribution to costs of events (article 9)			Fee for service and consultancy (article 9)			TOTAL OPTIONAL
	(article 2)	(article 9)	(article 1)	(article 9)	(article 9)		Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an event	Registration fees	Travel and accomodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel and accomodation		
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				
						N/A	N/A	N/A	N/A				
HCOs	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	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 HCPs					N/A	N/A	N/A	N/A	%	%		N/A
	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				
R&D	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

Healthcare (HCO) shall mean any legal person 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 (HCP) shall mean a physician, dentist, pharmacist, nurse or any other natural person within healthcare 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.

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

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

Governing bodies and area 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 for human. This task is performed by the 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 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 At the request of a pharmaceutical company, the chairman of IGN may provide general advice on measures that have not yet been implemented. Such advice does not constitute a binding advance statement.

§ 4.7 LIF's Compliance Officer decides, on his own initiative or upon notification or enquiry, if a location of a 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

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- § 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).

Organisation

IGN

- § 8.1 The IGN comprises a chairman and at least two and at most four members.
- § 8.2 The chairman of IGN shall be LIFs Compliance Officer.
- § 8.3 At least one member shall represent medical expertise; he or she must be a qualified physician, have a clinical speciality or corresponding expertise and have clinical experience.
- § 8.4 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 for 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 of these members should possess knowledge of market law.
- § 11.4. Two members must represent medical expertise; they must be qualified physicians, have a clinical speciality 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.

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- § 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.
- § 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 placed 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, IML, 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

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- 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).

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

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/have 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 is in conflict 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.
- § 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.

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- § 31.2. If a complaint to the IGN or the NBL or an appeal against a decision issued 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

- § 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 to 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.

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 of 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.
- § 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.

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- § 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 is not in accordance with good industry practice, the pharmaceutical company concerned must pay a fee determined by the NBL.
- § 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 places 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 dependant 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 Läke-medelsindustriföreningens Service AB.

§ 50. Remuneration is payable to the members of the IGN, with an exception to the chairman. 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 will be valid as of 12 February 2018. 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.

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 primarily be focused on the accuracy and reliability of the informational measures. Special attention shall 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

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 compability 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 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 from the date on which the company received the decision.

Reported cases

- p. 19 A report to the IGN with a request to consider and take action against a measure is to be made in writing. The report shall 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 the 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 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, IML, 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 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 the receiving of such contest as mentioned in § 21 in the Statutes for IGN and NBL.

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 the 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.

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 and p. 22 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 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.

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.

These rules of procedure shall take effect as from 12 February 2018.