Cooperation agreement on The Ethical Committee for the Pharmaceutical Industry (ENLI)

Preamble

Pharmaceutical companies cooperate regularly with all relevant parties in the health service (healthcare professionals, patient associations, decision makers, etc.). The aim of the collaboration is to disseminate existing and new knowledge as well as information about therapies and thus create the basis for optimizing the patients' access to medical prevention and treatment.

In order to ensure high professionalism and ethics in the pharmaceutical companies' contact to and cooperation with the relevant parties in the health service, the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic and Biosimilars Medicines Industry Association (IGL) and the Association for Parallel Importers of Medicine (the "Contracting Parties") have entered into the present agreement (the "Agreement") on the self-regulatory agency Ethical Committee for the Pharmaceutical Industry (ENLI), which checks the member companies' and affiliated companies' compliance with applicable legislation and ethical rules and agreements in this field.

The agreement replaces, with effect from 7 December 2018, the parties' cooperation agreement of 1 May 2018.

Purpose, jurisdiction etc.

Art. 1 Purpose

ENLI's purpose is:

a) to control and sanction that the Rules, as stipulated in art. 2, are complied with by the affiliated pharmaceutical companies,
b) to ensure that professionalism and ethics are paramount and exclude pressure opportunities and unethical dependencies between pharmaceutical companies on the one hand, and health professionals, hospitals, patient associations or decision makers on the other,
c) to disseminate knowledge about the rules in the field to prevent infringements.

Art. 2 Jurisdiction

ENLI's jurisdiction is to:

a) Check that affiliated pharmaceutical companies comply with the following set of rules (Rules):

- The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals" (Promotion Code). This code incorporates the following rules:
  - *The International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) Code of Pharmaceutical Marketing Practices*
  - *The European Federation of Pharmaceutical Companies and Associations (EFPIA) Code on the Promotion of Prescription-only Medicines to, and interactions with Healthcare Professionals (EFPIA HCP Code)*
  - *The European Federation of Pharmaceutical Companies and Associations (EFPIA) Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations (EFPIA Disclosure Code)*
  - *Medicines for Europe's Code of Conduct on Interactions with the Healthcare Community*
  - *Relevant parts of Directive 2001/83/EC establishing a Community Code Relating to Medicinal Products for Human Use, as amended*
  - *Relevant parts of the current Act on Medicines, Executive Order on Advertising, etc. for medicines with related guidance on advertising etc. for medicines*
  - *The World Health Organisations' Ethical criteria for medicinal drug promotion*

  At the implementation, the rules that are most restrictive to the pharmaceutical companies, are chosen.

- Ethical Rules for Collaboration between Patient Organisations, etc., and the Pharmaceutical Industry (Patient Organisations Code). This code incorporates the *EFPIA Code of Practice on relationships between the Pharmaceutical Industry and Patient Organisations, and Medicines for Europe's Code of Conduct on Interactions with the Healthcare Community.*

- Ethical rules for dialogue and negotiations with decisionmakers (Lobbying Code)

- Ethical rules for pharmaceutical companies' relations with the Danish hospital sector

- Ethical rules for the pharmaceutical industry's donations and grants (Donation Code)

- Joint Declaration on clinical drug trials and non-intervention trials

- Applicable cooperation agreements with the regions on cooperation between the individual regions' healthcare professionals and the pharmaceutical companies on knowledge sharing, professional advice and financing of continuing education for healthcare professionals

b) Sanctioning the violation of the Rules by affiliated companies in accordance with the Penalties and Fees Regulations.
c) Prepare guides and educate on the content and interpretation of the Rules in order to prevent potential violations thereof.
d) Publish the Rules, the Agreement and the Penalties and Fees Regulations on its website.
e) Publish ENLI's decisions on its website.
f) Prepare an annual report that reproduces the work and achievements of ENLI in the past year and which will be published on the ENLI website. ENLI must also ensure that an English version of the report is submitted to the EFPIA Code Committee.

Art. 3 Affiliated Pharmaceutical Companies

The following companies are affiliated with ENLI's jurisdiction:

- Lif's members
- IGL's members
- The Association for Parallel Importers of Medicine's Members
- Other pharmaceutical companies or associations that have opted to join ENLI, even if they are not members of the aforementioned associations.

The above companies are fully obliged to act in accordance with the overall set of rules, unless specifically stated that a specific provision applies only to selected companies.

Art. 4 Independence

ENLI carries out its control and decision-making activities pursuant to Art. 2, sec. 1 (a) and (b), in relation to specific cases, independently of the affiliated companies and their organizations. Neither the companies nor the organizations can give instructions to ENLI about the decision or processing in specific cases, just as ENLI cannot receive instructions on this.

Organisation

Art. 5 Overall framework

Lif has the financial ownership and responsibility of ENLI. ENLI is run in an independent limited liability company with Lif as sole proprietor. Lif must ensure that the operation of ENLI takes place in accordance with the Agreement.

ENLI consists of two instances:
- an Investigators Panel, and
- an Appeals Board.

A Steering Committee with representatives of the Contracting Parties shall, within the framework of the Agreement, make decisions on the overall principles of ENLI's business.

Art. 6 Steering Committee

Sec. 1.
The Steering Committee consists of five members, of whom:

- three members are appointed by Lif,
- one member is appointed by IGL,
- one member is appointed by The Association for Parallel Importers of Medicine.

Lif acts as secretariat for the Steering Committee.

Lif appoints a chairman of the Steering Committee for 2 years at a time.

Sec. 2.
Within the framework of the Agreement and ENLI's budget, the Steering Committee has the authority to make decisions on the following matters:

- appointment of investigators, including the head of secretariat, and members of the Appeals Board,
- changes to the rules,
- changes to the case handling rules of ENLI,
- changes to ENLI's Penalties and Fees Regulation.

In addition, the Steering Committee may discuss and coordinate any joint political or communicative initiatives in relation to ENLI.

Sec. 3.
Decisions are made by simple majority unless otherwise stated in the Agreement. Each member of the Steering Committee has one vote. In the event of a tie, the Chairman has the casting vote. The Steering Committee is quorum when four members are present.

Sec. 4.
For the adoption of amendments to the Rules, Code of Procedure for ENLI or ENLI's Penalties and Fees Regulations, which impose significant new restrictions, duties or expenses on affiliated organizations or companies, or which discriminate against companies, subject to ENLI's jurisdiction, all five members of the Steering Committee shall be required to agree.

Lif's members of the Steering Committee, regardless of the above, may at any time decide to change the Rules with effect for Lif's members, without this requiring the consent of the other members of the Steering Committee. Such changes apply only to IGL's and the Association of Parallel Importers of Medicine's Members if the respective members of the Steering Committee for IGL and the Association of Parallel Importers of Medicine respectively agree.

Sec. 5.
The Steering Committee may ask ENLI's case handling bodies to explain issues of a principled nature such as new interpretations of rules, ENLI's practice, etc. The Steering Committee may request ENLI's case processing bodies to get any doubt on interpretation clarified by the Danish Medicines Agency if the agency is the right authority. Or by EFPIA, Medicines for Europe or IFPMA in the case of EFPIA, Medicines for Europe or IFPMA rules.

The Steering Committee may request ENLI's case handling bodies to elaborate or specify guidance to the Rules where this is deemed to be lacking.

Sec. 6.
ENLI is obliged externally by signature of the chairman in conjunction with another member of the Steering Committee or in the chairman's absence by the secretariat manager's signing in association with a member of the Steering Committee.

Art. 7 Investigator Panel

Sec. 1.
The Investigator Panel is made up of the investigators appointed by the Steering Committee, all of whom are independent of the pharmaceutical industry. The investigators decide at first instance and sign all decisions. Those concerned are appointed by the Steering Committee and are composed of:

- a number of investigators with legal expertise, as well as
- a number of investigators who are doctors with clinical pharmacological knowledge.

One of the legal investigators is given the responsibility of the secretariat manager. A secretariat can be affiliated with assistant employees who can prepare cases for the investigators and otherwise act as secretary(s) for the Investigation Panel.

Sec. 2.
The tasks of the Investigators Panel are:

a) To exercise control on compliance with the Rules, including:
    - to carry out random checks in the companies' reports of cases according to the pharmaceutical industry's code on promotion etc. for medicinal products aimed at healthcare professionals,
    - to deal with complaints from eligible companies and others,
    - to raise cases ex officio, where there are grounds for doing so, e.g. cases that have been dealt with in the press or that others have drawn attention to

b) To make a decision in the sec. 2 (a) mentioned the cases and sanction any violations of the Rules in accordance with the Penalties and Fees Regulation.

c) To make decisions in companies' request for pre-approval.

d) To provide information and guidance on the rules and legislation in the pharmaceutical field with a view to preventing infringements, including:
    - provide advice,
    - prepare and update guides on the respective topics,
    - prevent violations of the Rules and the relevant legislation by contacting companies, congress organizers, etc. before violations take place,
    - communicate decisions, practices and news via ENLI's website, at information meetings, etc.
    - teach at Atrium on the respective topics.

Sec. 3.
Cases pursuant to art. 7, sec. 2 (b) and (c) shall be decided by one investigator. Cases where the investigating officer believes that the specific offense may result in a fine of DKK 75,000 and above must, however, be dealt with by three investigators. The decision is made by simple majority.

Guidelines as mentioned in art. 7, sec. 2, (d), is prepared and amended by at least two investigators in association, at least one of which must have legal expertise.

The Head of Secretariat is responsible for managing and allocating the work of the Secretariat as well as for the Investigation Panel.

Sec. 4.
The Investigators Panel's case processing must be in accordance with the Code of Procedure for ENLI set by the Steering Committee at any time.

Art. 8 The Appeals Board

Sec. 1.
The Appeals Board processes and makes decisions in all appeals that are appealed after a decision in the Investigation Panel.

Practice decided by the Appeals Board cannot be changed by the Investigator Panel.

Sec. 2.
The Appeals Board consists of three people:

- a lawyer as chairman,
- a doctor with clinical pharmacological knowledge,
- a member who has previously worked in the pharmaceutical industry.

None of the above members of the Appeals Board must be affiliated with the pharmaceutical industry.

Sec. 3.
The Appeals Board meets approx. three-four times a year. The chairman prepares and plans meetings of the Appeals Board and writes down and disseminates decisions made by the Appeals Board to the companies concerned.

The Investigators Panel's secretariat or investigators generally do not participate in the meetings, unless otherwise provided by the Code of Procedure for ENLI.

Sec. 4.
The Appeals Board may make decisions in urgent cases without holding physical meetings, but on the basis of electronic communication (e.g. web meetings, e-mail correspondence or the like) or telephone meeting, and on the basis of the written case presentation.

Sec. 5.
The aim is for the Appeals Board to reach a decision in agreement. In case of disagreement between the board members, the chairman's vote is decisive.

Sec. 6.
The chairman and members of the Appeals Board are appointed by the Steering Committee for up to two years at a time.

Sec. 7.
The Appeals Board's case processing must be in accordance with the Code of Procedure for ENLI laid down by the Steering Committee at any time.

Financial framework

Art. 9 Ownership and economy

Sec. 1.
Lif has the financial ownership of and responsibility for ENLI, cf. art. 5. None of the affiliated organizations and companies are directly liable for ENLI's obligations.

Sec. 2.
ENLI's operations are financed through fees and fines. It is an objective to strive for financial balance in ENLI's business, so that the economy rests in itself for a number of years. Lif can, if necessary, subsidize the operation of ENLI.

Sec. 3.
The affiliate association's member companies do not pay affiliation fees.

Sec. 4.
The financial year is the calendar year.

Lif is responsible for and prepares a budget for the coming financial year and an annual report for the last financial year.

The annual report and budget are presented to the Steering Committee for information.

Changing the Agreement, etc.

Art. 10 Change or withdrawal of the Agreement and Resolution

Sec. 1.
For the adoption of amendments to the Agreement, agreement is required between the parties to the agreement. However, if a contracting party has resigned, cf. sec. 2, agreement is only required between the remaining Contracting Parties.

Sec. 2.
An affiliated company or organization, including a Contracting Party, may withdraw from the Agreement with six months' notice to the end of a month, after which the entity or its affiliates will no longer be subject to ENLI's jurisdiction. Companies, including member companies, which at the time of withdrawal have pending cases for ENLI, are however, in the specific case, subject to ENLI's jurisdiction until a final decision has been made and any fine paid.

Companies that are subject to ENLI's jurisdiction as a result of membership of an affiliated organization cannot resign from this agreement.

Sec. 3.
Lif can, regardless of sec. 1 terminate the Agreement with six months' notice to the end of a calendar year and is then entitled to continue ENLI on its own or in cooperation with others.

Sec. 4.
No financial settlement is made in connection with the termination of the Agreement or the withdrawal of an organization or company. Any fees and fines due must be paid. Already paid affiliation fees are not fully or partially refunded in connection with the withdrawal.

This Cooperation Agreement has been signed by Lif, IGL and the Association for Parallel Importers of Medicine.

Copenhagen, 7 December 2018

Lif: Christoffer Dahl, Julie Enevold Brooker and Ida Sofie Jensen
IGL: Peter Jørgensen
The Association for Parallel Importers of Medicine: Helle Sandager