Code of Procedure for ENLI

General rules

Art. 1 Impartiality

The Danish Administrative Law's rules concerning impartiality applies in the cases dealt with in both the Investigator's Panel as in the Appeals Board.

Art. 2 Definition

By "Rules" in these rules shall mean the industry regulations covered by ENLI's competence, cf. Cooperation agreement on the Ethical Committee for the Pharmaceutical Industry, Art. 2, paragraph 1, point (a).

Art. 3 Confidentiality

All cases are handled confidentially by ENLI. However, cases where a decision is taken, that there has been a breach of the rules, will be published on ENLI's website, see. Art. 5.

Art. 4 Reasoning of decisions

Sec. 1. The Investigator's Panel and the Appeals Board's decisions must be reasoned and comprehensible.

Sec. 2. Decisions by the Investigator's Panel must at least include the following specified information on:

a) The parties of the case.
b) Background/facts of the case.
c) Information on, how the case is raised.

d) Precise indication of the alleged breach of rule (i.e. stating article, section, paragraph, sentence, and so on).
e) Summary of the parties' submissions.
f) Conclusion/decision including a precise indication of the elements in the case, which has been crucial to the outcome, as well as information about any sanction.
g) Standard appeal instructions if necessary.

Sec. 3. Decisions taken by the Appeals Board must contain the same specified information as decisions taken by the Investigator's Panel (with the exception of information about standard appeal instructions), see. Sec. 2, as well as the Appeals Board assessment of both the decision of the Investigator Panel and the appeals content and justification.

Art. 5 Publication of decisions

Sec. 1. All decisions of the Investigator Panel or Appeals Board, where a company is imposed with a sanction, are published on ENLI's website

Sec. 2. Decisions are published including the company's name and in its full form, regardless of the sanction, however see subsection 3. Names of persons is not subject for publishing, cf. the rules on personal data protection. However, decisions or company names are not published if it would be in conflict with the rules on data protection or other laws. It is the Secretariat of ENLI's responsibility to ensure that publishing is done in accordance with the law, including in an anonymous form, if this is required by law.

Sec. 3. Decisions that exclusively concern breach of the notification requirement as well as breach of Art. 21, sec 8, in the Pharmaceutical Industry's Code on Promotion, etc. for Medicinal Products aimed at Healthcare Professionals, and which only imposed a reprimand shall be published without the company's name.

Sec. 4. Decisions of the Investigator panel shall be published no earlier than after the deadline for appeals expire, see. Art 11, sec 3. If the case is appealed, the decision of the Appeals Board shall be made public when this is taken. The publication must meet the requirements set out in sec. 2. Publication of the Appeal Board's decisions is made no earlier than two days after the decision was forwarded to the company, unless it must be assumed that the company has not received the decision.

Sec. 5. Decisions must be available on ENLI's website for at least two years after they are published.

The Investigator Panels case management

Art. 6 Pre-Approval

Sec. 1. A company that is subject to ENLI's control can against payment of a fee, cf. the Penalties and Fee Regulations for ENLI, request the Investigator Panel on a pre-approval of an arrangement, sponsorship, exhibition, printed advertising material or for other activity, which is subject to the rules. The fee is payable, whether the pre-approval is granted or not. If the amounted proceedings extent is estimated to result in work for the Investigator Panel in addition to 2 hours, e.g. due to extensive materials in the case, the company may, before the proceedings begin, be asked to accept to pay a fee that exceeds the basic fee, cf. the Penalties and Fees regulations for ENLI Art. 7, sec. 3.

Sec. 2. The company is responsible for providing the necessary and accurate information on the activity in connection with the request, so that the Investigator Panel easily can decide on the pre-approval on an informed basis. If the Investigator Panel does not grant a pre-approval, this must be composed as specific as possible, so the company is informed about the specific reason for the refusal, as well as how the rule(s) must be interpreted.

Sec. 3. A granted pre-approval is only valid if the company subsequently does not change the format, content, etc. of the pre-approved activity. If subsequent changes occurs, the pre-approval is no longer valid. In such cases, the company must not provide misleading information to healthcare professionals that the specific activity is pre-approved. In the case of minor amendments, the Investigator Panel, for a fee fixed in the Penalties and Fees Regulations, can conduct an additional assessment of the activity. In the case of major changes the company will have to apply for a new pre-approval. The Investigator Panel determine whether the pre-approved activity is subject for major or minor changes.

Sec. 4. If the Investigator Panel subsequently becomes aware of information, which was not known, when the activity was pre-approved, and which indicates a violation of the rules, the pre-approval is no longer valid, and the Investigator Panel may initiate a case on the present basis.

Sec. 5. The Investigator Panel is responsible to ensure that any decision on pre-approval is taken on the basis of the total content of the rules. A request for pre-approval must be dealt with and decided on by the Investigator Panel within ten working days of receipt of ENLI, or from the receipt of the company's acceptance on payment of the fee in addition to the basic fee, cf. sec. 1.

Art. 7 Control with reported cases

The Investigator Panel shall carry out checks on pharmaceutical companies' compliance with the rules, among other things through the cases notified. The control is carried out, including through random checks on the basis of the declared conditions, including supporting documentation. It is the responsibility of the Secretariat to organize the control.

Art. 8 Complaints

Sec. 1. Entitled to complain are:

a) Companies subject to ENLI's control
b) Authorities
c) Healthcare Professionals
d) Others with a significant and commendable interest in the case

Pharmaceutical companies, which are not subject to ENLI's control is not entitled to complain.

Sec. 2. A complaint from a complaint-entitled, cf. sec. 1 over an affiliated pharmaceutical company for alleged breach of the rules, must be made in writing to the Investigator Panel. Complaints can be filed on affiliated pharmaceutical companies' violation of all the rules governed by ENLI's control.

Sec. 3. A fee is to be paid for filing a complaint, cf. the Penalties and Fees Regulations. The Investigator Panel may, cf. art. 9, in special cases choose to raise a case of its own initiative (ex officio), and thus without payment of fee, on the basis of a complaint from a healthcare professional or an authority, if there is a justified reason to do so, see Penalties and Fees Regulations Art. 7, sec. 7. The complaint must be in writing and reasoned, cf. Art. § 9, sec. 1 and 2. It is the complainant's responsibility to ensure that the complaint contains all information relevant to the Investigator Panel's assessment of the complaint. A complaint may be rejected if it is not sufficiently justified.

Sec. 4. The Investigator Panel will assess on the basis of the complaint, whether there are grounds to initiate a case against the respondent. If there are grounds for initiating a case, the respondent company will receive the proceedings for consultation referred to in article 9. The parties to the proceedings – both complainant and the respondent company – must as a starting point in the entire proceedings receive a copy of the other party's input – this means both complaint and/or consultation responses, after it is received in the Investigator Panel, cf. however Art. 9, sec 6. Complaints musts be dealt with and decided on within the deadlines set out in sec. 5, and Art. 9.

Sec. 5. A complaint can for a fee, cf. the Penalties and Fees Regulations, be processed as a matter of urgency. An urgent matter must be resolved within eight working days from

the receipt of the Investigator Panel. The Investigator Panel must in urgent cases immediately launch a consultation of interested parties by the respondent pharmaceutical company, which will then have four working days to come forward with consultation responses. On the basis of this the Investigator Panel shall make its decision immediately. If consultation responses are not received by the deadline, the Investigator Panel will take a decision on the present basis, if it is considered that the complaint is otherwise sufficiently justified.

Art. 9 Consultation and case management

Sec. 1. If a case is raised ex-officio by the Investigator Panel or on the basis of a random control, the Investigator Panel must prepare a consultation letter which, as a minimum, must include:

a) Information about the parties of the case (The Investigator Panel is regarded as complainants in these cases).
b) Background and facts.
c) An indication of which offenses may be involved with reference to the relevant provisions of the rules.
d) An explanation of why this behavior may constitute a violation of the rules.
e) Conclusion
f) Possible sanction.

Sec. 2. Is a case raised on a basis of a complaint, cf. Art. 8, the complainant is a party to the proceedings, and the complaint must as a minimum contain the same content as sec. 1 (except litra f) and form the basis for the consultation letter.

Sec. 3. When starting a case against a company – either on the basis of a complaint, cf. Art. 8 or ex officio by the Investigator Panel – a consultation letter must be sent, cf. sec. 1 to the respondent company, before the Investigator Panel may decide the case, however see sec. 9. The consultation letter shall indicate the deadline for the respondent company's comments.

Sec. 4. If a case is started against a company, the Investigator Panel has a maximum of ten working days from it has received the notification or complaint to the respondent company receives a consultation letter. In urgent cases the consultation letter shall be sent immediately (max. two working days).

Sec. 5. It is the respondent company's responsibility to ensure that the consultation letter contains the information that the respondent company finds relevant for the sufficient enlightening of the case. The respondent company must submit its consultation letter within the prescribed period, which will normally be 10 working days after receipt of the consultation letter. In urgent cases, see. Art. 8, sec. 5, the deadline is four

working days. If the company does not respond before the deadline, the case will be settled on the present basis.

Sec. 6. The Investigator Panel has the right to seek the matter is sufficient enlightened before it takes a decision, for example by requesting party/parties to provide additional information in the case. The Investigator Panel can in particularly difficult cases and matters of principle request external experts/experts for advice, before making a decision. If new information appears during the proceedings, that the Investigator Panel estimates that the other party may have comments or additional information to, an additional consultation will be made, however, striving for a maximum of three per party. The Investigator Panel will decide when the matter is sufficiently disclosed, and will then complete the consultation.

Sec. 7. Once the consultation has been completed, the Investigators Panel will take its decision within 10 working days after receiving the last submission. In the event of an urgent matter it is made immediately (max two working days).

Sec. 8. The Investigator Panel may grant a postponement of the above mentioned deadlines upon written and reasoned request of the companies involved.

Sec. 9. If a case arises on the basis of a random control, and the Investigator Panel determines that the case is of such a nature that a consultation will be without influence on the outcome of the decision (for example, when the notification has not been made in a timely manner) and the infringement alone will result in a reprimand, the Investigator Panel may make an immediate decision, in which the consultation phase is omitted.

Art. 10 Resumption of proceedings

The Investigator Panel may in special cases resume a case within a reasonable time after the decision if the Investigator Panel finds that new information may lead to an amendment of the decision referred to, see however, Art. 6, sec. 2, Art. 7 and Art. 8, sec. 3. An amendment of the decision can not lead to additional or more onerous penalties.

Procedure of the Appeals Board

Art. 11 Appeal

Sec. 1. Companies, who have received a decision from the Investigator Panel that rules against them, may appeal this decision to the Appeals Board. If a complaint against a company is dismissed as unfounded by the Investigator Panel, or if a complainant are not successful in his complaint, the complainant may appeal the decision to the Appeals Board. Refusal of a pre-approval or a rejection can be appealed to the Appeals Board.

Sec. 2. Referral of a case to the Appeals Board has no suspensive effect. The Appeals Board may decide to grant an appeal suspensory effect, if the complaint purpose would otherwise be wasted.

Sec. 3. Appeals deadline is 21 working days after the company's receipt of the Investigator Panel's decision. The appeal must be in writing and contain a statement of the views and information, on which the appeal is based. The appeal must be submitted via the electronic notification system on ENLI's website.

Sec. 4. The Appeals Board receives the appeal along with the correspondence in the case from ENLI's secretariat. At the same time, the Secretary of the Appeals Board sends a copy of the appeal to the concerned companies or others, who also was involved in the proceedings within 10 working days receiving it. The Appeals Board shall make a decision at the next meeting of the Appeals Board. If the appeal is received later than 10 working days before the next meeting of the Appeals Board, the Appeals Board may postpone examination of the appeal to the next meeting.

Sec. 5. The Appeals Board may request the parties and relevant third parties for further information, just as parties may be given the opportunity to comment in writing. The Appeals Board may, however, exceptionally decide on verbal discussion with a party or any relevant third party, if the Appeals Board considers this appropriate with regard to the elaboration or clarification of the documents, events or else. If new relevant information comes forward, the Appeals Board must submit these to the other parties, who are given the opportunity to comment. Parties may not ask for a meeting with the Appeals Board and does not have the right to elaborate on the matter further in writing.

Sec. 6. The Appeals Board may in particularly difficult cases and matters of principle request external experts/experts for advice before making a decision.

Sec. 7. If the Appeals Board assess, on the basis of a company's appeal of the Investigator Panel's decision that a case is not addressed adequately by the Investigator Panel, or if new relevant facts for the substantive assessment of the specific case is submitted, the Appeals Board may refer the case back for reconsideration.

Sec. 8. The Appeals Board can in special cases resume a definitive appeal within a reasonable time after the decision, if the Appeals Board believes that new information may lead to an amendment of the decision referred to, see however, Art. 6, sec. 2, Art. 7 and Art. 8, sec. 3. An amendment of the decision cannot lead to additional or more onerous penalties.

Guidance

Art. 12 Secretariat of ENLI

Sec. 1. The Secretariat of ENLI supervise on the general understanding of the rules based on the Investigator Panel and Appeal Board's practice. By questions related to specific activities, the companies, who have joined the ENLI's control, are referred to request a pre-approval.

Sec. 2. Since the rules only oblige the companies that have joined ENLI's control, the Secretariat's resources will be prioritized according to their needs. All who contact the Secretariat must therefore initially and unsolicited identify with name and exact indication of who they represent.

Entry into force

Art. 13 Entry into force

This Code of Procedure shall enter into force on 19 February 2015 and replaces the recently published code of 28 January 2013.