Country code report: Norway

As early as 1975, the pharmaceutical industry created a self-regulatory body. In 2000, Dnlf (The Norwegian Medical Association) and LMI (The Norwegian Association of Pharmaceutical Manufacturers) were appointed as a joint independent self-regulatory body (the Council) for members of Dnlf and LMI members.

The Committee for Drug Information (The Committee) shall decide for alleged breach of the cooperation agreement between Dnlf and LMI, LMI's Industry Rules (code), and other industry-related rules and guidelines. Anyone can file complaint.

Committee sanctions are fees. The pharmaceutical companies may be imposed fees from NOK 20.000, - up to NOK 300.000,-. The Committee can also comment on basic questions.

The Appeal Board handles Committee decision appeals.

COMMITTEE COMPOSITION, GENERAL TASKS AND FUNCTIONS

The Committee consists of a leader and five Committee members.
The Leader is appointed by Dnlf and LMI combined. One member is appointed by the patient organization FFO. Two members are appointed by the LMI and two members by the Dnlf.

For an updated list of members please view http://reklameregler.lmi.no/radet/

Daily operations of the Committee's activities are handled by the secretariat; a secretary from LMI works with day-to-day operations.

The Committee's working methods are meetings.

According to the statutes, anyone can file a complaint.

The Committee deals with specific matters addressed by the Complainant and may additionally comment on matters of principle.

The Appeal Board consist of a leader and two members. The leader is appointed by LMI and Dnlf combined, one member by LMI and one member by Dnlf.

ENFORCEMENT, CASES HANDLED BY THE SELF-REGULAION BODY IN 2018

The Committee has dealt with nine pre-statements, and made decisions in eight cases, respectively five cases at first instance and three cases in the Appeal Board.

A total of eight cases were filed, four cases by the Committee Secretariat, two cases by the pharmaceutical industry and two cases by hospital doctors. Of the registered complaints, all were sanctioned and charged fees.

The Committee may impose sanctions on pharmaceutical companies in the form of fees; from kr. SEK 20,000 to DKK 300.000, -. In 2018, the fees ranged from NOK 25 000.- to NOK 130 000.-

Committee (primary legal authority):

There were five complaints. The Committee issued preliminary statements in 9 cases.

Appeal board (secondary legal authority):

In 2018, the Appeal Committee handled a total of three cases.

TRAINING

LMI by the secretariat arranges a numerous of courses. Activities in 2018 were as follows:

- Code training, May 28th
- Law and industry courses, April 10th - 12th
- Law and industry courses, October 30th - November 1st
- Specialist code course April 18th – 19th
- In total approximately 300 attended courses and training
- E-learning (approx. 1200 attendees over the last two years)

NEWS/SUMMARY/CODE REVISIONS

In 2018 there was an increase in requests for preliminary statements. Pre-approvals give companies an assurance that the planned activity or planned promotions are compliant with the regulatory framework. The Committee is increasingly addressing such issues.

The Secretariat conducted in 2018 increased and systematic surveillance of advertising. The Secretariat reviewed promotional material to look for violations of paragraph 8.4; balanced advertising and highlighting of precautions in advertising. Some of these cases were raised in the Committee.

A major update and revision of the e-learning course on drug advertising rules was made. The course was updated in relation to the industry rules and national rules and regulations. The course also got a new layout.

Regulatory developments related to LMI's industry rules in 2018 were made in the following areas:

• New rules regarding hospitality. This to improve academic updates.

• Alternative legal basis for disclosure and clarifications of the rules for disclosure in chapter 26.

• Digital participation is now treated equally as regular participation regarding the congress ban. The industry may not pay for health professionals' full participation at a Congress.

• Increased guidance on destinations to clarify which destinations are appropriate.