

Case no 16, Advertising statements, misleading claims

Members of the Marketing Board: Viveka Bonde (chairman), Thomas Manske, Ursula Larsson

Decision date: 03 May 2023

Complainant: Elanco Denmark ApS
Defendant: Zoetis Animal Health

Subject-matter: Advertising statements, misleading claims

On 2 March 2023 ViNordic received a complaint regarding certain marketing actions taken by Zoetis Animal Health ("Zoetis") in Sweden.

The marketing actions concerned two statements about the veterinary product Librela published in the Swedish magazine Svensk Veterinärtidning published in July, October, November and December 2022:

- "Ger hundar fler dagar med lek", ("the first claim") and
- "Back in stock - Back in play" ("the second claim").

The position of the parties

The Complaint states that these statements are not in line with the summary of product characteristics (SPC) for Librela. The Complaint also mentions that these statements are irrelevant and not based on professional and relevant information about the medicine. Elanco also submitted a decision issued by the Danish Marketing Board (case 392) in which similar statements have been appealed and the board's conclusion was that the advertisement did not meet the requirements for factuality in Article 119, paragraph 1 of the Veterinary Medicinal Products Regulation. The Complaint does not indicate which articles of Vet&Etiket were allegedly breached.

Zoetis answered the Complaint on the 27 March 2023 and requested a rejection of the Complaint.

In its answer, Zoetis wrote, that while it does not agree with the points outlined by Elanco, it has decided to discontinue marketing of the mentioned materials throughout the Nordics as a result of the submitted decision from the Danish Marketing Board. In addition, the legislation referred to as substantiation for the Danish decision is based on the Danish official guidance (nr 9401, dated 20/04/2022), which finds no legal basis in Sweden. Despite the reasoning in the Danish decision, that the requirement for factualness is "absolute" and the fact that the marketing materials were only directed to veterinarians, the advertisements in question did not relay any of the imagined properties as portrayed by Elanco to neither professional nor to

layman, as the actual properties of the product were clearly and factually outlined when considering the format and type of advertisement.

The Swedish Marketing Board's assessment

The Swedish Marketing Board's overall's examination concerns whether the claims are misleading and/or not supported by relevant documentation.

The Swedish Marketing Board notes that the indication for Librela described in the product summary (SPC) is: *For the alleviation of pain associated with osteoarthritis in dogs.*

Article 1 Vet & Etikett states that the SPC should be the basis for pharmaceutical products. Except for information that appears in the SPC, any oral or written information about a veterinary medicinal product must be, as per Article 4 in Vet & Etikett, valid, balanced, fair and objective, and based on an up-to-date evaluation of scientific evidence, clearly reflecting such evidence. Further, Article 5 of Vet & Etikett states that all information contained in any drug information must be capable of substantiation by means of documentation. Documentation is to be understood to mean representation in writing or pictorial form containing the presentation of scientific facts and findings.

Assessment of the first claim

The Board notes, that there is no information in the SPC stating that Librela makes treated dogs neither more active nor playful. Although a more active and playful dog may be a result of analgesic treatment, the SPC mentions neither a change in the ability nor desire to play in treated animals. The wording "*more days of play*" might even suggest that the use of the Drug may prolong the life expectancy of treated dogs. These claims violate the demand, that marketing activities or drug information should be based in the relevant summary of product characteristics. The Marketing Board therefore finds that the information in the first statement is not to be regarded as valid, balanced, fair and objective according to Article 4 of Vet & Etiquette.

It can also be noted, that there are no studies mentioned in the product summary which refer to such effects. According to Article 5 in Vet & Etikett, all information about a product must be able to be substantiated with documentation. According to the same provision, the documentation must maintain a good scientific standard. Because there are no clinical studies to support the first claim, Zoetis has violated Article 5 in Vet & Etikett.

Assessment of the second claim

The Board notes, that there is no information in the summary characteristics stating that the Drug makes treated dogs more active or playful. The SPC mentions neither a change in the ability nor desire to play in treated animals. The Marketing Board therefore does not find the information in the second statement valid, balanced, fair and objective

according to Article 4 of Vet & Etikette. For the same reasons stated above, the Swedish Marketing Board assesses that also this second claim is in breach of Article 5 in Vet & Etikett.

In the light of this, the Swedish Marketing Board concludes that the marketing of the Drug is misleading and in breach of Article 4 and Article 5 Vet & Etikett.

Relevance of the praxis of the Danish Marketing Board

Although cases decided by the Danish Marketing Board can be of relevance and applied analogously, it must be noted that each complaint requires a case-by-case assessment, in the light of the relevant national system of rules applicable to the respective ViNordic board. As such, the referred Danish decision has not been applied by the Swedish Marketing Board in the assessment of this Case.

The Swedish Marketing Board's decision

The overall assessment of the Swedish Marketing Board is that Zoetis has breached Articles 1, 4 and 5 of Vet & Etikett when performing marketing actions regarding the claims.

While the Swedish Marketing Board notes Zoetis' response, stating that the company decided to discontinue marketing activities containing the abovementioned claims, it cannot assess whether this has been done.

Thus, Zoetis is ordered to pay a fine of SEK 10,000 in accordance with § 4 par. 3. p. B in the Swedish statutes, as well as a fee for the complaint to the Marketing Board of SEK 5,000 according to § 5 in the Swedish statutes. The payment must reach the Marketing Board within 30 days from the day of the decision. At the same time, the Marketing Board obliges the company to immediately cease using the material to which the complaint relates.