Case no 15, Advertising statements, misleading claims

Members of the Marketing Board:	Viveka Bonde (chairman), Ulrika Forshell, Ursula Larsson
Decision date:	05 april 2023
Complainant:	Boehringer Ingelheim Animal Health Nordics A/S
Defendant:	Zoetis Animal Health
Subject-matter:	Advertising statements, misleading claims

On 23 February 2023 ViNordic received a complaint regarding certain marketing actions taken by Zoetis Animal Health ("Zoetis") in Sweden.

The marketing actions concerned the claim made on a Zoetis banner (the "Banner") concerning the prescription veterinary product Simparica (the "Drug"): "*Ingen risk för miljön*". The Banner was used on the website VeterinärMagazinet.se and on the printed version of Veterinär Magazinet NR 1/2023.

The position of the parties

The Complainant claimed that Zoetis does not have enough data to justify the statement and that Zoetis's advertisement is unjustified and highly misleading. The Banner contains a link to the European Public Assessment Report (EPAR) issued by the European Medicines Agency's (EMA) committee responsible for veterinary medicines, the Committee for Veterinary Medicinal Products (CVMP). The Complainant is of the opinion that the EPAR says nothing about the environmental impact of 'sarolaner' but only waivers the commitment to do further environmental assessments after Phase I. Further on, the Complainant refers to the decision issued by the Danish Marketing Board in the Danish case nr. 354 which it considers to be relevant to this Case.

In response, Zoetis wrote on the 10 March 2023 that the statement outlined in the Case is taken from the corresponding CVMP Assessment Report for Simparica, which constitutes the scientific evaluation and basis of the given Marketing Authorization for Simparica. Zoetis also stated that it has not interpreted the meaning of the text in the EPAR and that there is a clear reference in the advertisement to the report. Zoetis further mentioned that the statement has not been taken out of any larger context. Zoetis further claimed prior cases determined by the Danish Marketing Board as non-admissible to the decision of this complaint.

The Marketing Board's assessment

The Marketing Board's examination concerns whether the claim made on the Banner, "*ingen risk för miljön*", is misleading and not supported by any documentation. Such information does not appear in the Drug's product summary.

Except for information that appears in the product summary, 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 it must be 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.

It appears from Annex 1 submitted to the case, that the Banner was published in the Veterinär Magazinet, both in print and digitally. In both formats of the magazine, the claim refers to "CVMP Assessment Report for Simparica", which constitutes the scientific evaluation and basis of the given marketing authorization for Simparica issued by the European Medical Agency. The Swedish Marketing Board notes that an environmental risk assessment was carried out by EMA's CVMP and that the conclusion of such assessment was that "*the Drug is not expected to pose a risk for the environment when used according to the Drug's product summary*".

The purpose of a CVMP assessment

It is the Swedish Marketing Board's understanding that the CVMP is responsible for the scientific assessment of veterinary medicinal products in the EU. One of the key functions of the CVMP is to perform risk assessments (EPAR) for veterinary medical products. It follows from the "Guideline on the environmental impact assessment of veterinary medicinal products, in support of the VICH guidelines GL6 and GL38" published by the EMA, that the risk assessments performed by the CVMP aim to identify and evaluate potential risks associated with the use of veterinary medicinal products, and to assess the benefits and risks of these products in order to determine whether they can be authorized for use in the EU.

The CVMP risk assessment process is mandatory in the EU, meaning that all manufacturers that seek marketing authorization for their veterinary medicinal products must undergo such process.

Vet & Etikett

The environmental risk assessment (in ERA) which has been referred to, is based on *how* the medicine will be *used* (individual treatment of companion animals and to a relatively

small numbers of them) and *not on the active substance* in the pharmaceutical, which is a substance with evident insecticidal and acaricidal effect and thus the existence of potential impact on these groups of animals in the environment.

Moreover, the standard evaluation that is included in the Environmental risk assessments (ERA) for all small animal parasiticides, pertains to the assessed minimal risk of administering the product to a small number of individuals (as opposed to parasiticides administered at herd level for food producing animals).

In conclusion, the CVMP evaluation is not applicable to the actual substance's and/or metabolites' effect *per se* on the environment when eliminated.

In the light of this, the Swedish Marketing Board concludes that the marketing of the Drug by solely using a reference to the CVMP evaluation, without additional scientific documentation that may support the claim, is in breach of Article 1, Article 4 and Article 5 Vet & Etikett.

The Banner is not naming the EPAR, but instead only providing a link to the EPAR.

The Swedish Marketing Boards considers that there is a risk of non-familiarity with the VMP-supporting documentation available on the EMA website. Moreover, the fact that some readers may not be able to access information published online should not be ignored.

The Swedish Marketing Board concludes that the full title of the publication and the author(s) shall be provided when referencing scientific evidence in any marketing materials, including online and printed marketing materials.

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.

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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 Banner. 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.