WRITTEN QUESTION P-1243/04
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to the Commission

Subject: Regulation (EC) No 1804/1999: homeopathic and phytotherapeutic medicinal products

Regulation (EC) No 1804/1999[1] supplementing Regulation (EEC) No 2092/91[2] on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production states (17) that preference should be given to phytotherapeutic or homeopathic medicinal products with a real therapeutic effect, and limits the use of allopathic medicinal products. Proof of this therapeutic effect must be provided by a marketing authorisation.

Bearing in mind the particularities of homeopathic medicines, Directive 2001/82/EC[3] does not permit obtaining marketing authorisation for such medicinal products destined for animals producing food products. Since homeopathic medicinal products are made up of materials at infinitesimal doses, it is not possible in practice to meet the requirements for allopathic medicinal products in terms of dosage by weight (standards and protocols).

As part of the revision of Directive 2001/82/EC, it is planned that homeopathic medicinal products destined for animals producing food undergo a simplified registration procedure allowing them to exist without, however, being able to claim a therapeutic indication (Article 17) or to prove the effectiveness of the treatment.

This makes it impossible to meet the requirements of Regulation (EC) No 1804/1999. Organic livestock farmers are being deprived of medicinal products preferable for disease prevention and veterinary care.

Homeopathy's principles of infinitesimality and tradition, recognised by Directives 2001/83/EC[4] and 2001/82/EC, apply also to animals producing food.

Why not propose specific rules for pharmacological, toxicological and clinical trials of homeopathic medicinal products intended for these species?

In the same way, phytotherapeutic medicinal products cannot satisfy the standards and protocols for chemical and immunological medicinal products. For example, there is a lack of adequate legal requirements and guidelines on kinetics and metabolism for phytotherapeutic products containing multiple and very varied active ingredients.

In terms of phytotherapeutic medicinal products destined for humans, the specific characteristics of these products have been taken into account in the drawing up of a specific directive.

Why not recognise these specific characteristics in veterinary medicine and create specific rules for the evaluation of phytotherapeutic medicinal products destined for animals producing food?

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1 OJ L 222, 24.8.1999, p. 1.
2 OJ L 198, 22.7.1991, p. 1.
3 OJ L 311, 28.11.2001, p. 1.
4 OJ L 311, 28.11.2001, p. 67.