ANNEX IV

ANNEX II

ACAF/00/18

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

Fourth ACAF Meeting 4 May 2000 – Agenda Item 5

HERBAL AND HOMOEOPATHIC ADDITIVES

Action required: This paper provides the Committee with information on procedures for authorising herbals and registering homoeopathics as veterinary medicinal products. Ray Anderson of the Veterinary Medicines Directorate will be available at the meeting to address any queries arising.

Secretariat April 2000

HERBAL AND HOMOEOPATHIC ADDITIVES

Purpose

1. The purpose of this paper is to provide the Advisory Committee on Animal Feedingstuffs with information on the procedures for authorising herbals and registering homoeopathics as veterinary medicinal products.

Background

2. At its meeting in March the Committee requested that the Veterinary Medicines Directorate provide a paper on herbal and homoeopathic additives. There are no herbal or homoeopathic feed additives authorised under the terms of Directive 70/524/EC. Herbal and homoeopathic veterinary medicinal products are subject to the same rules that apply to all other veterinary medicinal products, as laid down in Directive 81/851/EC. Before being granted a marketing authorisation, an applicant must satisfy the Licensing Authority as to the product's safety, quality and efficacy.

3. For both herbal and homoeopathic products, the central issue is whether, in the terms of Directive 65/65/EC, "they are presented for treating or preventing disease" (medicinal by presentation). The other test applied by the Directive is whether the product is medicinal by function ("any substance or combination of substances which may be administered .... with a view to making a medicinal diagnosis or to restoring, correcting or modifying a physiological function .... is likewise considered a medicinal product").

Herbal Products

4. Herbal products are considered to be medicinal by presentation if medicinal claims are made or if they contain ingredients derived from plants that have undergone processing such as fractionation, refining or extraction to concentrate particular components. Most herbal products containing dried parts of plants or unrefined vegetable, volatile and fixed oils are not considered to be medicinal products unless medicinal claims are made. However, some herbal products may be considered medicinal by function if they contain certain herbal ingredients, whether unprocessed or processed. For example, a product containing pyrethrum or pyrethrins or alkaloids, such as digoxin from *Digitalis* sp., would be considered medicinal by function. In such cases a marketing authorisation is required.

Homoeopathic Products

5. For homoeopathic products already on the market on 31 March 1997, a marketing authorisation is optional, provided that no medicinal claim is made. For homoeopathic products placed on the market since 31 March 1997, there is a simplified registration scheme, which was established by the Homoeopathic Veterinary Medicinal Products Regulations 1997. It applies only to those homoeopathic products intended for use in non-food producing animals, without therapeutic claims and where there is sufficient dilution to guarantee the safety of the medicinal product. However, no new homoeopathic product has so far been registered under the scheme. All other homoeopathic veterinary products placed on the market after 31 March 1997 must have a marketing authorisation. To date, no homoeopathic veterinary medicinal product has been authorised for use in food producing animals.

Medicated Feedingstuffs

6. The Medicated Feedingstuffs Regulations 1998 implement the controls for the preparation, placing on the market and use of medicated feedingstuffs. Such feedingstuffs contain veterinary medicinal products prepared on the advice of a veterinary surgeon and in accordance with a medicated feedingstuffs prescription (MFS). The veterinary surgeon is required to issue an MFS prescription to a stockfarmer or holder of animals for the supply of a medicinal product for use in an animal feedingstuff. There is an exception to this in that listed anthelmintics (wormers) will continue to be made available without an MFS prescription under a derogation in the Medicated Feedingstuffs Directive (90/167/EEC). All manufacturers and distributors of medicated feedingstuffs must be inspected and approved by the Royal Pharmaceutical Society of Great Britain (RPSGB) or the Department of Agriculture and Rural Development in Northern Ireland (DARD). This requirement includes farmers who, if mixing premixtures into feed for their animals, must also be approved by the RPSGB or DARD. Regular inspections of premises will take place, and samples of the products may be taken for analysis.

Zootechnical Feed Additives

7. The Feedingstuffs (Zootechnical Products) Regulations 1999 implement controls for the preparation, placing on the market and use of zootechnical feed additives, i.e. antibiotics, coccidiostats and growth promoters. Such additives are listed in the Annexes to Council Directive 70/524/EEC as amended, and are permitted to be marketed only in accordance with the requirements of the Directive. All establishments handling zootechnical feed additives, premixtures of feedingstuffs containing zootechnical additives must be approved by the RPSGB or DARD. As far as VMD is aware, no herbal or homoeopathic feed additive has yet been authorised under the terms of the Directive.

Veterinary Medicines Directorate
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