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REPORT

on the Commission communication to the Council and the European Parliament on availability of veterinary medicinal products
(COM(2000) 806 – C5-0105/2001 – 2001/2054(COS))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Avril Doyle

CONTENTS

Page

PROCEDURAL PAGE

By letter of 5 December 2000, the Commission forwarded to Parliament a communication to the Council and the European Parliament on availability of veterinary medicinal products (COM(2000) 806 – 2001/2054(COS)).

At the sitting of 15 March 2001 the President of Parliament announced that she had referred the communication to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Agriculture and Rural Development for its opinion (C5-0105/2001).

The Committee on the Environment, Public Health and Consumer Policy had appointed Avril Doyle rapporteur at its meeting of 9 January 2001.

The committee considered the Commission communication and the draft report at its meetings of 21 March and 10 April 2001.

At the last meeting it adopted the motion for a resolution unanimously.

The following were present for the vote: Caroline F. Jackson, chairman; Guido Sacconi, vice-chairman; Avril Doyle, rapporteur; Maria del Pilar Ayuso González, Emmanouil Bakopoulos, Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Martin Callanan, Dorette Corbey, Chris Davies, Jillian Evans, Carlo Fatuzzo, Marialiese Flemming, José Manuel García-Margallo y Marfil, Robert Goodwill, Françoise Grossetête, Christopher Heaton-Harris, Mary Honeyball, Anneli Hulthén, Hedwig Keppelhoff-Wiechert, Christa Klaß, Eija-Riitta Anneli Korhola, Hans Kronberger, Carlos Lage, Peter Liese, Torben Lund, Minerva Melpomeni Malliori, Patricia McKenna, Erik Meijer, Jorge Moreira da Silva, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Neil Parish, Béatrice Patrie, Marit Paulsen, Dagmar Roth-Behrendt, Jacques Santkin, Amalia Sartori, Ursula Schleicher (for Emilia Franziska Müller), María Sornosa Martínez, Bart Staes, Dirk Sterckx, Robert William Sturdy, Roseline Vachetta, Phillip Whitehead.

The Committee on Agriculture and Rural Development decided on 27 February 2001 not to deliver an opinion.

The report was tabled on 11 April 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

MOTION FOR A RESOLUTION

European Parliament resolution on the communication from the Commission to the Council and the European Parliament on availability of veterinary medicinal products (COM(2000) 806 – C5-0105/2001 – 2001/2054(COS))

The European Parliament,

– having regard to the communication from the Commission (COM(2000) 806 – C5-0105/2001),

– having regard to Council Directive 81/ 851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products[1],

– having regard to Council Regulation (EEC) n° 2377/90 of 26 June 1990, laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin[2],

– having regard to Commission Decision 2000/68/EC of 22 December 1999 amending Commission Decision 93/623/EEC and establishing the identification of equidae for breeding and production[3],

– having regard to the Note for Guidance of the Committee for Veterinary Medicinal Products (CVMP) of the European Agency for the evaluation of Medicinal Products on the risk analysis approach for residues of veterinary medicinal products in food of animal origin (EMEA/CVMP/187/00-FINAL),

– ***having regard to the formal noting by the Commission at a meeting of the Council on the 14/12/1999 (Council ref. 14171/99) that Member States need not withdraw certain drugs pending the adoption of legislative proposals,***

– having regard to Rule 47(1) of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0119/2001),

A. Whereas the crisis ***on the availability of veterinary medicines*** has resulted from the withdrawal since 1st January 2000, of marketing authorisations for all existing veterinary products containing substances for which no maximum residue limits (MRLs) have been established;

B. Whereas the lack of medicines in the veterinary sector has serious consequences for animal health and welfare, with unacceptable situations caused especially by unavailability of local anaesthetics;

[1] OJ L 317, 6.11.1981, p.1.
[2] OJ L 224, 18.8.1990, p.1.
[3] OJ L 23, 28.01.2000, p.72.

C. Whereas many products with a well established use have been withdrawn from the market because the data required to renew their marketing authorization were not generated and it included such data for the establishment of MRL's;

D. Whereas ***due to the existing legal provisions and product specific characteristics***, there is a lack of economic interest in carrying out necessary research and development on veterinary medicines for certain species such as sheep and horses, and other minor species, e.g. goats, turkeys, rabbits or bees;

E. Whereas the Commission has announced on several occasions that one of its objectives is to improve the level of animal health, in particular by increasing the number of medicinal products available;

F. Whereas the CVMP concluded that specific MRLs for specific target species may not be necessary to ensure the protection of the health of the consumer against possible harmful effects resulting from the ingestion of residues and that MRLs can be extrapolated between species;

G. Whereas ***analytical methods*** are already available for those substances on which the MRL extrapolation will be based;

H. Whereas specific measures must be implemented for horses, as the general measures contemplated for the other species cannot address the problem of equine medicines;

I. Whereas Commission decision 2000/68/EC recognises that treatment of horses may require the administration of medicinal products containing substances without MRLs and ***the need to provide*** a control mechanism to protect consumers from possible harmful residues;

1. Welcomes the objectives of the Commission to facilitate the veterinary use of medicinal products not available in the Member State concerned but authorized elsewhere in the Community and to enhance pharmaceutical firms' interest in certain market segments;

2. Considers however that the Commission's hopes that applications for the extrapolation of MRLs will be submitted by interested organizations are unlikely to be met;

3. Considers that ***there should be systematic*** extrapolation ***of MRLs*** between species;

4. Therefore urges the Commission to make proposals for its immediate application and in particular for modifying the annexes I, II and III of Council Regulation No 2377/90 in accordance with the CVMP conclusions in its Note for Guidance;

5. Considers that requiring species-specific ***analytical methods*** for the purpose of the MRL extrapolation between species would negate the flexibility offered in the first place and therefore urges the CVMP, the Commission and the Member States only to require ***the provision of*** such additional ***analytical methods*** at the time of granting ***specific*** marketing authorizations;

6. Considers that the extrapolation of MRLs will help to maintain many products intended for minor species without compromising consumer protection; but will not solve the problem of equine medicines as many of the medicinal products used in equine medicine contain substances with no MRL in any species at all;

7. Therefore urges the Commission to submit without delay proposals to amend Directive 81/851/EEC and Council Regulation (EEC) No 2377/90 to allow in horses the veterinary use of medicinal products containing substances without MRLs***, without prejudice to the need to protect human health***;

8. Calls on Member states to cooperate on the establishment of a Pan-european licensing system that will allow, in the near future, on the basis of mutual trust, any national market authorisation to be ***valid throughout the*** European Union;

9. Instructs its President to forward this resolution to the Council and Commission.

EXPLANATORY STATEMENT

Requirements for the placing of veterinary medicinal products on the market have been harmonised since the early 80s when Council Directive 81/851/EEC[1] was adopted. As serious availability problems have arisen compromising animal health and welfare across most species, there is a need for urgent short term solutions as well as for a broad review of all legislation.

No veterinary medicinal product can be used in food-producing animals[2] unless maximum residue limits (MRLs) were set up for its active substances. MRLs correspond to the maximum concentration of residue resulting from the use of a veterinary medicinal product, which may be tolerated in food of animal origin. Substances for which an MRL has been established are included in Annex I, II or III of Council Regulation (EEC) n° 2377/90[3].

A recent evaluation of the EU product licensing procedures[4] observed "significant concern in the veterinary sector about the decreased availability of established medicinal products for food producing animals as a result of the introduction of the MRL requirements".

In its Communication, the Commission announces a number of short- (extrapolation of MRLs) and medium-term actions (incentives for industry, more flexible rules for the use of products and the revision of existing legal instruments) to increase the availability of products. These actions are to be welcomed and in particular the extrapolation of MRL between species, that could help to maintain on the market many products intended for minor species.

The rapporteur would also encourage Member States to develop a Pan-european licensing system, whereby veterinary medicines could move more freely between member states.

Finally, the Commission already proposed in December 1999 to allow the veterinary use of substances without MRLs in horses, provided records of treatments are kept and that horses do not enter into the food-chain before 6 months after such use. The provisions relating to the equine passport were modified through Decision 2000/68[5] to that effect. Passports are now obligatory for all horses and contain a new annex for recording of veterinary treatments. Directive 81/851/EEC and Council Regulation (EEC) No 2377/90 are however still to be amended to allow such use.

The rapporteur recommends that the Commission submit without delay the long overdue proposals to amend Directive 81/851/EEC and Council Regulation (EEC) No 2377/90 to allow in horses the use of veterinary medicines containing substances without MRLs.

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[1] Council Directive 81/ 851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products. OJ L 317, 6.11.1981, p.1.
[2] A food-producing animal is defined as an animal whose flesh or products are intended for human consumption.
[3] Council Regulation (EEC) n° 2377/90, laying down a Community procedure for the establishment of maximum residue limits (MRLs) of veterinary medicinal products in foodstuffs of animal origin. OJ L 224, 18.8.1990, p.1.
[4] Report of Cameron Mc Kenna on the evaluation of Community procedures for the authorisation of medicinal products. This report was commissioned by the European Commission.
[5] Commission decision 2000/68/EC establishing the identification of equidae for breeding and production, OJ L 23, 28.01.2000, p.72.