



COMMISSION PROPOSAL TO PROHIBIT THE USE OF OESTRADIOL FOR THERAPEUTIC AND ZOOTECHNIC PURPOSES

BACKGROUND INFORMATION

The Commission made a proposal for a European Parliament and Council Directive amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (COM(2000) 320).

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State Officers
Industry and Research
Hygienists

The main element of that proposal is that the Commission would like to definitively ban the use of oestradiol 17 β and its ester-like derivatives in farm animals and to only allow its administration to non-farm animals for therapeutic purposes only.

The European Parliament rapporteur, Erik Olsson, takes the view that, in order to prevent all conceivable risks to consumers, the Commission's efforts to amend the Directive should be supported.

In his report, the rapporteur stresses that *differing interpretations of the available scientific data are probably due to diverging views of the concept of risk and of how risks should be assessed. Those who argue that the dangers of administering these hormones are being exaggerated stress in particular that they are used in small quantities and most often not specifically for growth promotion purposes, and also that their use in the Member States, for clinical, therapeutic and zootechnical purposes - is strictly regulated and regularly subject to veterinary supervision. In response to these views, one could just as well argue, on the basis of the precautionary principle, that there is no actual need to use the hormones for such purposes, especially as a number of alternative medicinal products are available in the Community that produce the same effects.*

The rapporteur also notes that *given that this area of science is as new as it is and the effects of its use are far from being clarified, it must be stressed that the European Union should, through its own research programme and by funding various research projects, help to supplement, consolidate and broaden knowledge of the use of natural and synthetic hormones. This is particularly true in the case of the five substances in respect of the use of which in stockfarming the Commission is proposing to continue the provisional prohibition, with the exception of therapeutic and zootechnical uses. Even before the Directive enters into force, the Commission must put into practice its plans for joining with the competent authorities to develop and provide information on suitable alternatives to the use of oestradiol 17 β for the treatment of individual animals.*

The conclusions of a survey conducted by the French Agency for Veterinary Medicinal Products on the request of the European Commission and of the French Presidency are however the following:

Oestradiols are important veterinary medicinal products used for therapeutic and zootechnical purposes, at least for cattle.

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Member States indicated that in principle alternative active substances to the use of oestradiols exist for all indications, with the exception of the preparation of donors and recipients of embryos in the technique of embryo transfer.

Replacement products are prostaglandins for the lysis of the corpus luteum, gonadotropin releasing hormones (GnRH and analogues), gonadotropins (FSH, LH, PMSG), progestagens and progesterone in support of the ovulation, the implantation and development of the embryo and in preparation of the next cycle.

However, the efficiency in the therapeutic treatment of fertility disorders and in the induction and synchronization of oestrus of prostaglandins are regarded to be inferior when compared to the one of oestradiols. Therefore the success of artificial insemination and in consequence the overall efficiency of dairy and beef cattle herd management programmes are expected to decrease in case of a ban of oestradiols from veterinary medicinal products.

Eight Member States will have to grant additional marketing authorizations for indications in a number of animal species, as today alternative veterinary medicinal products are not authorized in these countries.

These Member States will encounter some difficulties in this undertaking for the following reasons:

?? A pharmaceutical company must be available to:

- Request a marketing authorization, most likely by the mutual recognition procedure*
- Pay the fee for the registration*
- Update the dossier in order to suffice to the requirements of the mutual recognition procedure*
- The time for the updating of the dossier may be difficult to foresee*

?? Difficulties that may be encountered in the mutual recognition procedure

Therefore, they may face difficulties to find a sponsor who will be willing to invest time and money for indications and animal species representing only small economic markets and therefore providing an insufficient return of investment for the company.

Similar difficulties have already been encountered in the European procedures for the establishment of maximum residue limits where a number of products have disappeared from the market leading to a lack of availability of veterinary medicinal products.

The immediate removal of oestradiols from the market will create a number of difficulties, the magnitude and the management of which will have to be assessed and to be assumed by Member States and the EU.

FVE therefore approached MEP Avril Doyle to propose an amendment so that a derogation is introduced to the effect that the use of oestradiol 17 β would be allowed until suitable alternatives would have been developed and marketed.

AMENDMENTS

Report by Karl Erik Olsson

On the Proposal for a European Parliament and Council directive amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (COM(2000) 320 – C5-0357/2000 – 2000/0132(COD))

Text proposed by the Commission ¹

Amendment

(Amendment 1)

ARTICLE 1 (1)
Article 2 (Directive 96/22/EC)

“Article 14a

The provisions laid down in this Directive with regard to oestradiol 17 β shall not apply to farm animals for which it can be certified that, where oestradiol 17 β has been administered to them for therapeutical purposes or zootechnical treatment, this administration has taken place before 1 July 2001.

“Article 14a

The provisions laid down in this Directive with regard to oestradiol 17 β shall not apply to farm animals for which it can be certified that, where oestradiol 17 β has been administered to them for therapeutical purposes or zootechnical treatment, this administration has taken place before 1 July 2001 **or before a suitable alternative was available.**

Justification:

The immediate removal of oestradiol 17 β would create a number of difficulties in the treatment of fertility disorders, in the induction and synchronisation of oestrus, in embryo transfer and in artificial insemination in both cattle and horses. A transition period must therefore be allowed for the development and marketing of suitable alternatives.

¹ OJ C 337, 28.11.2000, p.163.