COMMISSION DIRECTIVE 2000/37/EC

of 5 June 2000

amending Chapter VIa 'Pharmacovigilance' of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 81/851/EEC of 28 September 1981 on the appriximation of the laws of the Member States relating to veterinary medicinal products [1], as last amended by Directive 93/40/EEC [2], and in particular Article 42i thereof;

Whereas:

(1) In order to ensure the continued safety of veterinary medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Community are continually adapted to take account of scientific and technical progress.

(2) For public health protection, relevant data on adverse effects in humans related to the use of veterinary medicines should be collected and evaluated.

(3) The pharmacovigilance systems should consider the available data on lack of efficacy.

(4) In addition, collection of information on adverse reactions due to off-label use, investigations of the validity of the withdrawal period and on potential environmental problems may contribute to improve regular monitoring of good usage of veterinary medicines.

(5) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.

(6) The increasing use of the mutual recognition procedure established by Directive 81/851/EEC requires that current procedures for reporting and dissemination of suspected adverse reactions be amended to ensure better co-ordination between Member States.

(7) The increasing use of electronic means of communication of information on adverse reactions to veterinary medicinal products marketed in the Community is intended to allow a single reporting point for adverse reactions, at the same time ensuring that this information is shared with the competent authorities in all Member States.

(8) It is necessary to further define terms currently used within the veterinary pharmacovigilance systems.

(9) It is the interest of the Community to ensure that the veterinary pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.

(10) Holders of marketing authorisations should additionally be proactively responsible for ongoing pharmacovigilance of the veterinary medicinal products they place on the market.

(11) The measures provided for in this Directive are in conformity with the opinion of the Standing Committee on veterinary medicinal products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Chapter VIa 'Pharmacovigilance' of Directive 81/851/EEC is hereby amended as follows:

1. Article 42a, is hereby replaced by the following text:

'*Article 42a*

In order to ensure the adoption of appropriate regulatory decisions concerning the veterinary medicinal products authorised within the Community, having regard to information obtained about suspected adverse reactions to veterinary medicinal products under normal conditions of use, the Member States shall establish a veterinary pharmacovigilance system. This system shall be used to collect information useful in the surveillance of veterinary medicinal products, with particular reference to a dverse reactions in animals and in human beings related to the use of veterinary medicinal products, and to evaluate such information scientifically.

Such information shall be collated with available data on the sale and prescription of veterinary medicinal products.

This system also takes into account any available information related to the lack of expected efficacy, off-label use, investigations of the validity of the withrawal period and on potential environmental problems, arising from the use of the product, interpreted in accordance with the Commission guidelines referred to in Article 42g, which may have an impact on the evaluation of their benefits and risks.'

[1] OJ L 317, 6.11.1981, p. 1.
[2] OJ L 214, 24.8.1993, p. 31.