Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products[(3)], Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products[(4)], Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products[(5)], and Council Directive 92/74/EEC of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products[(6)] have been frequently and substantially amended; in the interests of clarity and rationality, the said Directives should therefore be codified by assembling them in a single text.

(2) The primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health.

(3) However, this objective must be achieved by means which will not hinder the development of industry and trade in medicinal products within the Community.

(4) In so far as the Member States already have certain provisions laid down by law, regulation or administrative action governing veterinary medicinal products, such provisions differ in essential principles. This results in the hindering of trade in medicinal products within the Community, thereby directly affecting the functioning of the internal market.

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(5) Such hindrances must, accordingly, be removed; whereas this entails approximation of the relevant provisions.

(6) It is necessary from the point of view of public health and the free movement of veterinary medicinal products for the competent authorities to have at their disposal all useful information on authorized veterinary medicinal products in the form of approved summaries of the characteristics of products.

(7) With the exception of those medicinal products which are subject to the centralised Community authorization procedure established by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[7], a marketing authorization in one Member State ought to be recognized by the competent authority of the other Member States unless there are serious grounds for supposing that the authorization of the veterinary medicinal product concerned may present a risk to human or animal health, or to the environment; in the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken at a Community level, lead to a single decision on the area of disagreement, binding on the Member States concerned. This Decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.

(8) For this purpose, a Committee for Veterinary Medicinal Products should be set up in accordance with the European Agency for the Evaluation of Medicinal Products laid down in the aforementioned Regulation (EEC) No 2309/93.

(9) This Directive is only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products. However, for this purpose, new measures will prove necessary, in the light of experience gained — especially within the Committee for Veterinary Medicinal Products — for the removal of the remaining barriers to freedom of movement.

(10) Medicated feedingstuffs do not come within the scope of this Directive. However, it is necessary, for both public health and economic reasons, to prohibit the use of unauthorized medicinal products in the manufacture of medicated feedingstuffs.

(11) The concepts of harmfulness and therapeutic efficacy can be examined only in relation to one another and have only a relative significance, depending on the progress of scientific knowledge and the use for which the medicinal product is intended. The particulars and documents which must accompany an application for marketing authorization must demonstrate that potential hazards are outweighed by the benefits due to efficacy. Failing such demonstration, the application must be rejected.

(12) Marketing authorization should be refused where a medicinal product lacks therapeutic effect or where there is insufficient proof of such effect. The concept of therapeutic effect must be understood as being the effect promised by the manufacturers.

(13) Such marketing authorization should also be refused where the withdrawal period indicated is not long enough to eliminate health hazards arising from residues.

(14) Before an authorization to market an immunological veterinary medicinal product can be granted, the manufacturer must demonstrate his ability to attain batch-to-batch consistency.

(15) The competent authorities should also be empowered to prohibit the use of an immunological veterinary medicinal product when the immunological responses of the treated animal will interfere with a national or Community programme for the diagnosis, eradication or control of animal disease.

(16) It is desirable in the first instance to provide users of homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety.

(17) The rules relating to the manufacture, control and inspection of homeopathic veterinary medicinal products must be harmonised to permit the circulation throughout the Community of medicinal products which are safe and of good quality.

(18) Having regard to the particular characteristics of these homeopathic veterinary medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those traditional homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the animal.

(19) The usual rules governing the authorization to market veterinary medicinal products must be applied to homeopathic veterinary medicinal products marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect. Member States should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products for pet animals and exotic species, provided that they notify them to the Commission.

(20) In order to better protect human and animal health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorization, Member States should systematically prepare assessment reports in respect of each veterinary medicinal product which is authorized by them, and exchange the reports upon request. Furthermore, a Member State should be able to suspend the examination of an application for authorization to place a veterinary medicinal product on the market which is currently under active consideration in another Member State with a view to recognizing the decision reached by the latter Member State.

(21) In order to facilitate the movement of veterinary medicinal products and to prevent the checks carried out in one Member State from being repeated in another, minimum requirements for manufacture and imports from third countries, and the grant of corresponding authorizations, should be applied to veterinary medicinal products.

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(22) The quality of veterinary medicinal products manufactured within the Community should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.

(23) Measures should also be taken to ensure that distributors of veterinary medicinal products are authorized by Member States and maintain adequate records.

(24) Standards and protocols for the performance of tests and trials on veterinary medicinal products are an effective means of control of these products and, hence, of protecting public health and can facilitate the movement of these products by laying down uniform rules applicable to tests and the compilation of dossiers, allowing the competent authorities to arrive at their decisions on the basis of uniform tests and by reference to uniform criteria, and therefore helping to obviate differences in evaluation.

(25) It is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a veterinary medicinal product which is essentially similar to an innovative product, while ensuring that innovative forms are not placed at a disadvantage. However, there are reasons of public policy for not repeating tests carried out on animals without overriding cause.

(26) Following the establishment of the internal market, specific controls to guarantee the quality of veterinary medicinal products imported from third countries can be waived only if appropriate arrangements have been made by the Community to ensure that the necessary controls are carried out in the exporting country.

(27) 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.

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

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

(30) 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.

(31) 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.

(32) 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.

(33) 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.

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

(35) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[8].

(36) In order to improve the protection of public health, it is necessary to specify that foodstuffs for human consumption may not be taken from animals which have been used in clinical trials of veterinary medicinal products unless a maximum residue limit has been laid down for residues of the veterinary medicinal product concerned in accordance with the provisions of Council Regulation (EEC) No 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[9].

(37) The Commission should be empowered to adopt the changes necessary in order to adapt Annex I to scientific and technical progress.

(38) This Directive should be without prejudice to the obligations of the Member States concerning the time-limits for transposition of the Directives set out in Annex II, Part B,

HAVE ADOPTED THIS DIRECTIVE:

TITLE I

DEFINITIONS

Article 1

For the purposes of this Directive, the following terms shall bear the following meanings:

: [F1]

[F2]2.Veterinary medicinal product : (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.]

: [F1]

4. Substance : Any matter irrespective of origin which may be:

— human, e.g.

human blood and human blood products;

— animal, e.g.