Veterinary medicinal products: Community code

2001/0254(COD) - 29/09/2003 - Council position

The Council common position, adopted by unanimity, introduced a number of changes in the Commission's amended proposal. The Council incorporates, in totality, 14 amendments adopted by the European Parliament and accepts 16 in part or in principle. The common position incorporates a number of technical and editorial changes, which the Commission accepts. In addition, the Council has introduced a number of changes of substance, which depart from the Commission's proposal. Some of the changes have been introduced to align the text of the veterinary directive to that of the political agreement concerning the Regulation and the Directive relating to medicinal products for human use. The common position is consistent with the objectives and main principles contained in the proposal. The common position does not purport to amend the legal basis of Directive 2001/82/EC, since the Council considers that this is neither necessary nor appropriate. To increase the availability of veterinary medicinal products, the Council has widened the scope of the "cascade" procedure for food-producing animals (Article 11, paragraph 1). The scope of the procedure would in fact be the same in principle for all animals, but additional safeguards, particular as regards withdrawal periods, would remain in place for food-producing animals. In Article 67, which specifies those veterinary medicinal products that are to be available only on prescription, point (d) no longer contains a reference to the magistral formula. This was superfluous, since the magistral formula by definition requires a veterinary prescription. To be consistent with the rule for authorised veterinary medicinal products, veterinary prescription would be necessary for veterinary medicinal products prepared in accordance with the officinal formula only when destined for food-producing animals. As regards food from test animals, the common position provides two options for withdrawal periods. In addition to reinstating the existing provision of Article 95, which deals only with cases where maximum residue limits have been established, it provides for the use of the withdrawal periods set out in Article 11, paragraph 2 as an alternative. More specifically, as regards the European Parliament amendments accepted in full, the Council has accepted the amendment concerning allowing manufacturers of generic veterinary medicinal products to submit an application 8 years after the granting of the marketing authorisation for the reference products. It would permit the placing on the market of authorised generics 10 years after the granting of the marketing authorisation for the reference product. The Council has accepted amendments concerning transparency, and included them in its common position with some drafting changes. The common position also incorporates amendments relating to : - the mutual recognition procedure; - prescriptions; - the inspection of premises; - advertising. The common position is consistent with the principle of a number of amendments that have the aim of increasing the availability of veterinary medicinal products, namely those concerning: ??the cascade procedure : since the same cascade procedure wouldapply to all non food-producing animals and would permit the exceptional use of veterinary medicinal products authorised for use with another animal species or for another condition in the same species, including those authorised in another Member State; - providing for additional commercial incentives by widening the circumstances in which extended data-protection periods would be available (Article 13); - establish simplified procedures for the administration of homeopathic veterinary medicinal products provide a derogation from the requirement to establish maximum residue limits for animals of the equidae family that are not intended for slaughter for human consumption. As concerns the renewal of marketing authorisations, the Council has accepted the principle of the amendment on this issue. It agrees that there should be one renewal after a 5-year period and that, after that, the validity of the marketing authorisation ought generally to be unlimited. However, the Council believes that it would be administratively simpler for the 5-year period to start running on the date of the marketing authorisation. In addition, the Directive should, like the Regulation and the human Directive, enable the competent authority to require one extra 5-year renewal to take place on justified pharmacovigilance grounds. The Council believes that this addition would provide the competent authority with an extra tool to ensure the effective surveillance of authorised products. The common position is also consistent with the principle of the amendments concerning: - the definition of a "homeopathic veterinary medicinal product" and the labelling of such products; - clarifying the definitions

of risks and of the risk-benefit balance; - pharmacovigilance information : it would require all applications for marketing authorisations to include information on pharmacovigilance and potential risks to the environment; - the "sunset clauses" for authorised veterinary medicinal products that are never placed on the market or cease to be placed on the market; - withdrawal periods : in that it provides for the modification of the minimum withdrawal periods specified for the cascade procedure if there are valid reasons for such modification. On the other hand, the Council cannot accept three amendments relating to the prescription of veterinary medicinal products: - since it would place undue restrictions on the definition of a "veterinary prescription". Instead, the Council agrees with the Commission that Directive 2001/82/EC should contain a definition of "veterinary prescription" corresponding to the definition of "medical prescription" in Directive 2001/83/EC. To clarify the definition, the common position states explicitly that national law will specify which are the professional persons qualified to issue such prescriptions. While this person will very often be a veterinarian, it would not be appropriate to exclude the possibility of other professional qualified persons delivering prescriptions in certain circumstances. Although the Council agrees that Article 67 ought to establish the general principle that veterinary medicinal products for food-producing animals fall into the category of veterinary medicinal products available only on prescription but provide for exceptions, it cannot accept the amendment. Since there is freemovement of live animals and food within the Community, the Council believes that it is desirable to have harmonised rules for exemptions from the general principle. The common position therefore provides for the adoption of harmonised criteria through comitology by 31 December 2006. While it cannot accept detail of the amendment concerning new active substances, the Council has in fact reduced the period during which all veterinary medicinal products containing new active substances must be available only on prescription from 7 to 5 years. The Council could not accept a number of amendments relating to homeopathic veterinary medicinal products: - it believes that there is no need to reinstate the current requirement for Member States to take due account of products that other Member States register or authorise, since this would not create any legal requirement for Member States to recognise each other's actions. - it considers that "potentisation" is not the correct terminology in this context as potentisation and dilution are different operations.