OPINION OF ADVOCATE GENERAL RUIZ-JARABO COLOMER

delivered on 4 October 2001 [1]

1. The Commission of the European Communities is seeking to have set aside in part a judgment of the Court of First Instance [2] annulling Regulation (EC) No 1312/96 [3] ('Regulation No 1312/96') in so far as, by fixing the maximum limits of clenbuterol residue in foodstuffs of animal origin, it further specifies the therapeutic indications for which Member States may authorise the administration of veterinary medicinal products containing that substance. The Court of First Instance held that by acting in that way the Commission had exceeded its powers under Regulation (EEC) No 2377/90 [4] ('Regulation No 2377/90').

I. Facts

2. Council Regulation (EEC) No 2309/93 [5] ('Regulation No 2309/93') establishes a centralised procedure for the grant of marketing authorisations for veterinary medicinal products; under Article 31(3)(b) of that regulation, such medicinal products intended for administration to food-producing animals require a statement of the maximum residue limit which may be accepted by the Community in accordance with Regulation No 2377/90. Article 34(2) of that regulation provides that the refusal of marketing authorisation is to constitute a prohibition on the placing on the market of the veterinary medicinal product concerned throughout the Community.

3. Pursuant to Article 1(1)(b) of Regulation No 2377/90, 'maximum residue limit' means the maximum concentration of residue resulting from the use of a veterinary medicinal product which may be accepted by the Community to be legally permitted or recognised as acceptable in or on a food. It is based on the type and amount of

1 — Original language: Spanish.

2 — Joined Cases T-125/96 and T-152/96 *Boehringer* v *Council and Commission* [1999] ECR II-3427. An appeal against the same judgment has been lodged by the Council, although on different grounds: see my Opinion in Case C-23/00, delivered on the same date as the present Opinion, [2002] ECR I-1917, I-1919.

3 — Commission Regulation of 8 July 1996 amending Annex III of Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1996 L 170, p. 8).

4 — Council Regulation laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1).

5 — Council Regulation of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).

residue not representing any toxicological hazard for human health as expressed by the acceptable daily intake.

Annex I sets out the pharmacologically active substances for which maximum residue levels have been fixed; Annex II those not subject to maximum residue levels; Annex III those used in veterinary medicinal products for which provisional maximum residue levels have been fixed; and Annex IV those for which no maximum levels can be fixed.

4. In accordance with Article 7 of Regulation No 2377/90, Boehringer Ingelheim Vetmedica GmbH ('BI Vetmedica') applied to the Commission on 20 July 1994 for the establishment of maximum residue limits, as regards bovines and *equidae*, of clenbuterol hydrochloride, a chemical compound in the category of beta-agonist substances. In an opinion of 3 January 1996, the Committee for Veterinary Medicinal Products recommended, for reasons of scientific methodology, the adoption of provisional limits, expiring on 1 July 2000.

5. In April 1996, the Council adopted Directive 96/22/EC, [6] Article 2(b) of which provides that Member States are to ensure that the placing on the market of beta-agonists for administering to animals intended for human consumption is prohibited. Under Article 4(2) Member States may authorise the administering for therapeutic purposes of veterinary medicinal products containing allyl trenbolone or beta-agonists to *equidae*, bovines and pets.

6. BI Vetmedica is practically the only pharmaceutical company within the European Union to produce and market veterinary medicinal products containing a beta-agonist, namely clenbuterol, for the treatment of respiratory disorders in animals intended for human consumption. It accounts for about 97% of sales of the veterinary medicinal products affected by the prohibition on the marketing and administering of beta-agonists laid down in Directive 96/22.

7. The adoption of that directive meant that, with effect from 1 July 1997 (the date on which Member States were to have adapted their domestic laws), BI Vetmedica would be unable to market in those States its veterinary medicines containing clenbuterol for animals intended for human consumption, except for the therapeutic purposes listed in Article 4(2) in the States which authorised such use.

6 — Directive of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ 1996 L 125, p. 3).

8. On 8 July 1996, the Commission adopted Regulation (EC) No 1312/96, which brought clenbuterol hydrochloride within the scope of Annex III to Regulation No 2377/90. It established provisional maximum residue limits ('MRLs') and the therapeutic indications for which, pursuant to Directive 96/22/EC, Member States could authorise the administering of veterinary medicinal products containing that substance, which are, in the case of bovines, solely the induction of tocolysis in cows when calving and, in the case of equines, the induction of tocolysis and the treatment of respiratory ailments.

9. BI Vetmedica and C.H. Boehringer Sohn Ltd ('Boehringer') (the latter being the sole owner of the former and one of the leading 20 pharmaceutical companies in the world) lodged an application with the Court of First Instance on 27 September 1996 in which they raised an objection of illegality against Directive 96/22, claiming that it could not serve as justification for the restrictions in Regulation No 1312/96, which they requested the Court of First Instance to annul. [7]

II. The judgment of the Court of First Instance

10. In paragraph 173 of the judgment under appeal, the Court of First Instance declared the application admissible. In paragraphs 180 and 181 it dismissed the allegation of illegality, and also the two pleas on which the applicants based their action, as unfounded.

11. The Court of First Instance went on to examine whether the Commission had exceeded the power conferred upon it by Regulation No 2377/90 by specifying the permissible therapeutic indications, in addition to fixing the maximum limits for clenbuterol residues in bovines and *equidae*. That argument had been put forward by the Fédération de la santé animale (Fedesa) in its statement in intervention and by the applicants in their replies to the written questions put to them during the procedure.

12. The Court of First Instance held, in paragraph 196 of the judgment, that there was no provision in Regulation No 2377/90 authorising the Commission to limit the MRLs of a veterinary medicinal product permissible in foodstuffs of animal origin to certain therapeutic indications. Nor could such a limitation be justified by the requirements inherent in safeguarding public health on which Regulation No 2377/90 is based. Those requirements were limited to determining the maximum permissible threshold for the concentration of residues of a substance in food intended for human consumption, whatever the therapeutic indication in respect of which that substance was prescribed. It was self-evident that residues of a pharmacologically active substance which were present in food of animal origin were neither more nor less dangerous for health, at a certain

7 — This application gave rise to Case T-152/96 *Boehringer* v *Commission*.

level of concentration, according to whether that substance had been administered in respect of a particular therapeutic indication. It followed that the MRLs for a given pharmacologically active substance could not be determined by reference to the therapeutic properties or indications of that substance, which might be numerous.

13. The Court of First Instance decided that Regulation No 1312/96 must be annulled because it restricted the validity of the MRLs for clenbuterol to certain specified therapeutic indications for bovines and *equidae*, since the Commission had exceeded the powers exercised by it under Regulation No 2377/90.

III. The appeal

14. In its application, which was lodged at the Court of Justice on 7 February 2000, the Commission put forward two grounds of appeal. First, it alleged that the Court of First Instance had erred in law in finding that the Commission had exceeded its powers; and, second, it claimed that the reasoning used to support that conclusion was contradictory, incomplete and wrong. The Stichting Kwaliteitsgarantie Vleeskalverensector (SKV), which had been granted leave at first instance to intervene in support of the forms of order sought by the Commission, submitted a response on 18 April 2000 in which it fully supports the grounds of appeal put forward by the Commission.

In addition to claiming that the judgment of the Court of First Instance should be set aside in part, the Commission and SKV request the Court of Justice to declare the action for annulment of Regulation No 1312/96, submitted at first instance by BI Vetmedica and Boehringer in Case T-152/96, unfounded and to order the latter undertakings to pay the costs of both sets of proceedings.

15. The responses of BI Vetmedica and Boehringer and of the Fédération de la santé animale (Fedesa), which had been granted leave at first instance to intervene in support of the forms of order sought by those undertakings, were lodged on 18 April 2000.

They request the Court of Justice to dismiss the appeal as unfounded and to order the Commission to bear both the costs of these proceedings and the costs which they incurred at first instance.

16. Since none of those concerned submitted an application setting out its reasons for wishing to be heard, the Court of Justice decided, in accordance with Article 120 of the Rules of Procedure, to dispense with the hearing.

A. *The Commission's lack of interest in the appeal*

17. In October 2000 the Commission adopted Regulation (EC) No 2391/00 [8] ('Regulation No 2391/00'), in which it altered the maximum residue limits for clenbuterol without specifying the therapeutic indications for which Member States may authorise the administering of medicinal veterinary products containing that substance.

Immediately after the publication of that regulation, the respondent undertakings filed a document with the Court of Justice, pursuant to Article 42(2) of the Rules of Procedure. They claimed that a new fact had come to light in the case, which cast doubt on the Commission's interest in pursuing its action. The respondents maintained that by adopting that measure the Commission had complied with the judgment at first instance, even though it was not obliged to do so owing to the suspensory effect of the appeal, as provided for in Article 53 of the Statute.

18. The Commission was granted time to respond. In its response, it contends that the adoption of Regulation No 2391/00 is of no relevance to these proceedings, which are not rendered otiose, since in its appeal it is requesting the Court of Justice to rule on the powers which the Commission exercises under Regulation No 2377/90, which is an issue of principle. Furthermore, the appeal does not have suspensory effect, unless suspension is applied for. As the Commission did not apply to have the effects of the judgment at first instance suspended, it was obliged to comply with it, as provided for in Article 233 EC.

19. In view of the Commission's observations, the Court of Justice invited it to explain them in the light of the second paragraph of Article 53 of the Statute, which provides that, by way of derogation from Article 244 EC, decisions of the Court of First Instance declaring a regulation to be void are to take effect only from the date of expiry of the period within which an appeal may be brought or, if an appeal shall have been brought within that period, as from the date of dismissal of the appeal.

20. The Commission replied that Article 230 EC does not permit the Court of First Instance to annul a regulation, since its jurisdiction is limited to reviewing the legality of a decision properly so-called and a decision which, although in the form of a regulation or a decision addressed to another person, is of direct and individual concern to the party seeking its annulment. For that reason, if the Court of First Instance finds in the course of the proceedings that the contested act is of general application, the action must be declared inadmissible. In the judgment under appeal, the Court of First Instance held that BI Vetmedica was in a particular position which distinguished it, as regards the contested measure, from all other traders in such a way that it was individually con-

8 — Regulation of 27 October 2000 amending Annexes I, II and III to Council Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 2000 L 276, p. 5).

cerned. Furthermore, owing to the fact that it does not require any measure to adapt it to national law, the regulation imposes a direct obligation on the traders concerned. That finding places BI Vetmedica in the same position as the person to whom a decision is addressed.

The Commission submits that a literal interpretation of the second paragraph of Article 53 of the Statute would lead to the incongruous situation in which the suspensory effects of an appeal would be treated differently depending on whether the annulled act was a decision addressed to the person concerned or a regulation regarded as a decision of direct and individual concern to that person. In the former case the appeal would not have suspensory effect, whereas in the latter case it would. That difference in treatment is inconsistent with the finding of the Court of First Instance that both appellants are in the same situation; and in the Commission's view that inconsistency may be avoided if the provision is interpreted as not applying when the contested act has been reclassified by the Court of First Instance as a decision of direct and individual concern to the applicant. In order to circumvent the difficulty posed by the interpretation of that provision, the Commission treated the undertaking as though it had been the addressee of a decision which had been annulled, and complied with the judgment.

The Commission goes on to state that the maximum residue limits fixed in Regulation No 1312/96 were provisional, since they were set to expire on 1 July 2000. If new parameters for clenbuterol had not been set, BI Vetmedica would have been in a worse position than if the therapeutic indications had been maintained, since the use of the substance would have been completely prohibited, for all purposes.

21. I recognise that the interpretation of the second paragraph of Article 53 of the Statute proposed by the Commission is lacking in neither ingenuity nor originality. However, I consider that it is illogical and that it is not supported by either the wording of the provision or its purpose; furthermore, it deprives the provision of all practical use, as the respondent undertakings and Fedesa pointed out in the written observations which they submitted when the Court of Justice communicated the Commission's answer to them.

22. First, pursuant to Article 230 EC, an individual can only seek annulment of a regulation before the Court of First Instance when the measure is of direct and individual concern to him. In order to pursue the same action, the Member Sates and the institutions must have recourse to the Court of Justice. It would therefore make no sense to have provided that an appeal against a judgment annulling a regulation should have suspensory effect only when the measure in question is not of direct and individual concern to the person seeking its annulment, since such a situation is impossible.

Second, the fact that the Court of First Instance declares an action by an individual against a regulation admissible and then annuls it does not necessarily mean that the act was deemed to be an individual decision. In paragraph 162 of the judgment under appeal the Court of First Instance states that the provisions of Regulation No 1312/96 apply to objectively determined situations and produce legal effects with respect to categories of persons envisaged in general and abstract terms, namely the pharmaceutical undertakings which produce clenbuterol and those who prescribe and use that substance. By its nature and scope, therefore, Regulation No 1312/96 is legislative in character and does not constitute a decision within the meaning of Article 249 EC.

Nor, third, can it be maintained, and the Commission cannot be thought to have seriously intended it, that it is only necessary to have recourse to the second paragraph of Article 53 of the Statute when the Court of First Instance has declared that a regulation is inapplicable to a specific dispute, in accordance with Article 241 EC. The two provisions differ considerably in scope, since the Statute envisages the annulment of a regulation, which takes effect *erga omnes*, whereas Article 241 EC on the objection of illegality refers to its inapplicability *inter partes*.

23. Therefore, it cannot be claimed that, by the application of Article 53 of the Statute, the Commission was obliged to comply with the judgment under appeal before the Court of Justice gave judgment.

24. I do consider, however, that the Commission was obliged to act when the period for which it had fixed the provisional maximum residue limit for clenbuterol in bovines and *equidae* expired, that is, on 1 July 2000. Had it not done so, Article 13 of Regulation No 2377/90, on an *a contrario* interpretation, would have allowed the Member States to prohibit or impede the movement on their territory of foodstuffs of animal origin with residues of clenbuterol, since neither Annex I nor Annex III had made provision for any maximum residue limit for that substance, nor did it appear in Annex II.

25. For the reasons stated, I consider that the fact that the Commission adopted Regulation No 2391/00 does not mean that it no longer has an interest in pursuing its appeal.

B. *First ground of appeal: error of law*

26. The Commission alleges that the Court of First Instance made an error of law in paragraphs 188 to 190 of the judgment

under appeal.[9] It pointed out that the procedure for the establishment of an MRL under Regulation No 2377/90 was independent of, and distinct from, the procedures for the issue of authorisations for the marketing of veterinary medicinal products laid down in Directive 81/851/EEC[10] ('Directive 81/851') and by Regulation No 2309/93, which expressly provide that marketing authorisation for a product is to be refused where its use is prohibited under other provisions of Community law. However, Regulation No 2377/90 contains no provision authorising the Commission to take account of a ban on marketing in refusing to establish an MRL.

The Commission states that the Court of First Instance made the same error in another judgment delivered some months previously,[11] against which France lodged an appeal; the case is now pending.[12]

The Commission maintains that such a strict distinction cannot be drawn between the obligation to include a substance in Annex III to Regulation No 2377/90 and its right to refuse marketing authorisation, in accordance with Regulation No 2309/93, or the same right which Directive 81/851 confers on Member States. It argues that the measures in question must be interpreted and applied in conjunction with one another, at the same time taking into account Directive 96/22, since otherwise it would be possible to arrive at different and contradictory results, with the consequent risk that the protection of human health, one of the principal tasks of the Community, would be jeopardised. SKV supports the Commission's submissions.

27. BI Vetmedica and Boehringer argue that, as stated in the third recital of the preamble to Regulation No 2377/90, the maximum residue limits are intended to protect public health. For that reason the Court of First Instance was correct to state, in paragraph 186 of the judgment under appeal, that the procedure for fixing MRLs, which may be provisional, for a pharmacologically active substance depends solely on the question whether residues of the substance in question, at the proposed level, constitute a risk to the health of consumers.

They contend that in order to protect public health the maximum residue limit for a pharmacologically active substance must be fixed even if its use is restricted, since foodstuffs may be imported from non-member countries in which animals have been treated with that substance. If no limit has been established or if the validity of the limit is restricted to the uses auth-

9 — Here the Court of First Instance referred to paragraphs 88 to 90 of the judgment in Case T-120/96 *Lilly Industries* v *Commission* [1998] ECR II-2571.

10 — Council Directive of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1).

11 — On 22 April 1999, in Case T-112/97 *Monsanto* v *Commission* [1999] ECR II-1277 paragraphs 89 and 90.

12 — Case C-248/99 P *France* v *Monsanto*, in which the Commission has intervened. Advocate General Alber delivered his Opinion in that case on 29 May 2001.

orised within the Union, there will be a serious lacuna in the protection of public health, which shows that the fixing of a maximum residue limit in Regulation No 2377/90 must not depend on the possibility to use or market a substance in the European Union. Fedesa agrees with the opinion of the respondent undertakings.

28. I am able to accept that the procedure for the establishment of maximum residue limits for veterinary products in foodstuffs of animal origin laid down in Regulation No 2377/90 is autonomous and distinct from the procedures for the grant of authorisation to market veterinary medicinal products regulated by Directive 81/851 and by Regulation No 2309/93. It is sufficient to establish that they are governed by completely different rules. However, that evidence does not lead me to argue that the Commission can fix those limits, in application of Regulation No 2377/90, in a manner divorced from reality, without taking into account the legal and scientific background of each specific case.

29. First, Article 6(1) of Regulation No 2377/90 lays down two conditions for the inclusion in Annex I, II or III of a pharmacologically active substance, namely that it is used in veterinary medicinal products for animals intended for the production of food and that it is marketed in one or more Member States which have not previously authorised the administration of the substance. I agree with the Commission that that provision prevents an undertaking from seeking to have a maximum residue limit fixed for a product the use of which has been prohibited or the marketing of which is forbidden.

30. Second, Article 14 of Regulation No 2377/90 prohibits the administration to food-producing animals in the Community of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III, except in the case of authorised clinical trials which do not cause foodstuffs obtained from livestock participating in such trials to contain residues which constitute a hazard to human health.

If in Regulation No 1312/96 the Commission had fixed the maximum residue limit for clenbuterol without specifying the therapeutic indications in which that substance could be administered to animals, in accordance with Directive 96/22, the rule would have been incomplete, since, in the absence of that information, those to whom it was addressed would have been lawfully entitled to believe that, in application of Article 14, the administration of clenbuterol for indiscriminate purposes, provided that the residues did not exceed the maximum level fixed, was not precluded, since it appeared in Annex III until 1 July 2000.

31. It is common ground that Directive 96/22 prevents the administration in the Community of clenbuterol to bovines and *equidae* while allowing the Member States to authorise the administration of medicinal products containing that substance, subject to certain conditions, for certain very restricted therapeutic purposes. Article 11 supplements the protection of Community consumers by prohibiting the importation from non-member countries of animals or their meat to which any of the prohibited substances have been administered, unless they were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7; and it is Article 4 that establishes the indications for which administration to bovines and *equidae* of medicinal products based on clenbuterol may be authorised by Member States.

It cannot be maintained, therefore, as the respondents claim, that if the maximum residue limits are confined to the uses authorised within the Union there will be a lacuna in health protection, but that the fixing of those limits, specifying at the same time the therapeutic indications for which the medical products may be administered to animals, guarantees coherent and comprehensive consumer protection, since it ensures that the maximum residue limits do not vary, irrespective of whether the meat was produced in the Community or comes from a non-member country.

32. When the Commission adopted Regulation No 1312/96, which established the maximum limits of clenbuterol in foodstuffs of animal origin and at the same time specified the therapeutic indications for which Member States could authorise the administration of medicinal products containing the substance, in accordance with Directive 96/22, not only did it not exceed the powers which it exercised under Regulation No 2377/90, but it ensured the coherence of that measure, which was intended to protect public health.

33. I consider, therefore, that the Court of First Instance erred in law in finding, in paragraph 192 of the judgment under appeal, that, under the procedure for establishing an MRL for clenbuterol pursuant to Regulation No 2377/90, the Commission was not legally entitled to base the limitation on the validity of that MRL on the provisions of Directive 96/22, and that the first ground of appeal is well founded.

C. *Second ground of appeal: the errors in the reasoning*

34. The Commission claims that the line of argument followed by the Court of First Instance is contradictory, because it recognises the position of the Council, defined in Directive 96/22, which completely prohibits some therapeutic indications of clenbuterol and not others, and at the same time states, in paragraph 196 of the judgment, that the requirements inherent in

safeguarding public health on which Regulation No 2377/90 is based are limited to determining the maximum permissible threshold for the concentration of residues of a substance in food intended for human consumption, whatever the therapeutic indication in respect of which that substance was prescribed.

35. I do not believe that the reasoning followed by the Court of First Instance is contradictory, as the Commission maintains. I agree with the respondents and Fedesa that the alleged contradictions are not in fact contradictions and that the Court of First Instance merely distinguished the therapeutic uses of clenbuterol from the illegal use of massive doses used as a growth agent.

36. The Commission goes on to argue that the reasoning is incomplete, because it does not examine any of the consequences harmful to human health which might arise, if the therapeutic indications for which the administering of products based on clenbuterol can be authorised could not be included in Regulation No 1312/96. It gives the example of Member State A, which does not apply the partial prohibition on the use of the compound and which allows it to be administered to calves for the treatment of the bronchial tubes. Article 13 of Regulation No 2377/90 prevents Member State B from prohibiting beef whose content of that substance is within the maximum limits of residues fixed in Regulation No 1312/96 imported from Member State A from entering the food chain.

37. The respondents disagree with the Commission's view, and I agree with them.

With that example, the Commission proceeds from the idea of the non-complying Member State, namely the State which has ignored the provisions of Directive 96/22. However, Community law has provided a specific mechanism to deal with a situation of that nature, namely an action for failure to act under Articles 226 EC and 227 EC, without the Commission being empowered to adopt preventive legislation.

38. Finally, the Commission claims that the reasoning in the judgment is wrong where, in paragraph 192, the Court of First Instance stated that the Commission was not legally entitled to base the limitation on the validity of the maximum residue limit on the provisions of Directive 96/22, when it is a well-known fact that it based it on Regulation No 2377/90.

39. The respondents again disagree and contend that if the Commission had not based itself on Directive 96/22 it would not have referred to that directive.

40. I agree with the Commission that the reasoning preceding the resolution of the

dispute, which consists of paragraphs 182 to 197, contains a number of gross errors capable of rendering it invalid.

41. First, it does not follow from Regulation No 1312/96 that the Commission relied on Directive 96/22 when adopting it. There is a reference to that directive in the seventh recital of the preamble to Regulation No 1312/96, but that does not mean that it forms the legal basis of the regulation. On the contrary, it is clear from the statement of reasons that the purpose of the regulation is to contribute to the gradual introduction of maximum residue limits for all the active pharmacological substances used in the Community in veterinary medicinal products for animals intended for the production of food, in accordance with Regulation No 2377/90, and that the operative part amends Annex III to that regulation.

42. Second, it is incorrect to state, in paragraphs 182 and 192, that by Regulation No 1312/96 the Commission limited the validity of the MRLs to certain specified therapeutic indications.

The only limitation in that provision is temporal in nature, since the limits were fixed provisionally and expired on 1 July 2000. It does not make sense to state that the validity of those limits was restricted to certain therapeutic indications, since, first, from the aspect of public health, if residues are found in the target tissues, the reason why the substance was administered to the animal is irrelevant and, second, it is impossible to ascertain the purpose for which it was used.

The presence of the therapeutic indication in the paragraph headed 'Other provisions' in Annex III to Regulation No 2377/90 is justified, as I pointed out when examining the first ground of appeal, by Article 14 of that provision, which prohibits within the Community the administration to food-producing animals of veterinary medicinal products containing pharmacologically active substances which are not mentioned in Annexes I, II or III, except in the cases provided for, authorised in due form. If the Commission had not taken into account that Directive 96/22 had prohibited the use of clenbuterol and that Member States could only authorise its use in very specific circumstances, the information in respect of that substance which would have appeared in Annex III would have been incomplete and capable of giving rise to uncertainty in those to whom the regulation was addressed.

43. Third, it is also incorrect to state, in paragraph 187 of the judgment, that Article 6(1) of Regulation No 2377/90 does not make the inclusion of a substance in one of the Annexes (I to III) thereto subject to the condition that the product containing that substance must be capable of being directly used and marketed: the

word 'directly' is not to be found in that provision, and two conditions must both be satisfied if a pharmacologically active substance is to be included in one of those annexes, namely it must be for use in veterinary medicinal products applied to animals intended for the production of food and it must be placed on the market in one or more Member States which have not previously authorised the use of the substance in those animals.

44. Finally, it is also incorrect to state, in paragraph 197 of the judgment, that Regulation No 1312/96 prejudges the measures to be taken by Member States to prevent unauthorised use of veterinary medicinal products, in breach of Article 15(2) of Regulation No 2377/90, since the limits to the validity of the MRLs for clenbuterol which it imposes would continue to exist even in the event of annulment, withdrawal or amendment of the relevant provisions of Directive 96/22.

45. The Member States adopt different types of measures to prevent the unauthorised use of veterinary medicinal products. For example, they may require that those medicinal products be sold in specialist centres, that they be sold only in single-application doses, that they be administered only by professional persons, or that a register be kept for each animal, each farm or each medicinal product. I am unable to see in what way Regulation No 1312/96, in specifying the therapeutical indications for which Member States may authorise the use of medicinal products containing that substance, at the time when the maximum residue limits for clenbuterol were fixed, prejudged the measures to be taken by Member States to prevent unauthorised use of veterinary medicinal products.

Nor do I agree that Regulation No 1312/96 is exempt from any of the vicissitudes to which Directive 96/22 is exposed, whether amendment, annulment or derogation. I consider, on the contrary, that, with the purpose of ensuring coherence in such an important area as the protection of public health, when the Community legislature amends the therapeutic indications for which Member States may authorise the use of medicinal products containing clenbuterol provided for in Directive 96/22, the Commission will likewise have to change the therapeutic indications in the corresponding part of 'Other indications' of the Annex in which the substance is classified.

46. For the reasons stated, the Commission's second ground of appeal is also well founded.

The judgment of the Court of First Instance must therefore be set aside in so far as it annuls Regulation No 1312/96 on the ground that, by limiting the validity of the

MRLs established for clenbuterol to certain specified therapeutic indications for bovines and *equidae*, the Commission had exceeded its powers under Regulation No 2377/90.

IV. The action for annulment

47. Under the second sentence of the first paragraph of Article 54 of the Statute, if the Court of Justice sets aside the decision under appeal, it may itself give final judgment in the matter, where the state of the proceedings so permits. That provision should be applied in the present case.

48. The two pleas on which the applicants at first instance based their action for annulment were already dismissed as unfounded in paragraph 181 of the judgment under appeal.

In accordance with the foregoing reasoning, the argument put forward by Fedesa in its statement in intervention that in adopting Regulation No 1312/96 the Commission had exceeded its powers under Regulation No 2377/90, which was upheld by the Court of First Instance as a ground for annulling Regulation No 1312/96, is unfounded and must therefore be dismissed.

V. Costs

49. Article 122 of the Rules of Procedure provides that where the appeal is well founded and the Court of Justice itself gives final judgment in the case, it is to make a decision as to costs.

50. Under Article 69(2) of the Rules of Procedure, which, pursuant to Article 118, applies to the procedure on appeal, the unsuccessful party is to be ordered to pay the costs, which include those of both sets of proceedings, if they have been applied for in the successful party's pleadings.

Since the grounds put forward by the appellant and by SKV, which had requested that the respondents be ordered to pay the costs, have been upheld, the respondents must be ordered to pay the costs incurred by the Commission and by SKV in both sets of proceedings and Fedesa must be ordered to bear its own costs.

VI. Conclusion

51. In the light of the foregoing considerations, I propose that the Court should:

(1) set aside the judgment of the Court of First Instance of 1 December 1999 in so far as it annuls Regulation No 1312/96 on the ground that, by limiting the validity of the MRLs established for clenbuterol to certain specified therapeutic indications for bovines and *equidae*, the Commission exceeded its powers under Regulation No 2377/90.

(2) dismiss the application of BI Vetmedica and Boehringer for annulment of Regulation No 1312/96.

(3) order BI Vetmedica and Boehringer to pay the costs incurred by the Commission and SKV in both sets of proceedings.

(4) order Fedesa to bear its own costs in both sets of proceedings.