European Ombudsman

Decision of the European Ombudsman on complaint 545/98/(OV)/GG against the European Agency for the Evaluation of Medicinal Products

Decision
Case 545/98/GG - **Opened on** 15/06/1998 - **Decision on** 14/06/1999

Strasbourg, 14 June 1999 Dear Dr S., On 12 May 1998, you submitted a complaint against the European Agency for the Evaluation of Medicinal Products (EMEA) which concerned Opinion No. 347/97 of the CVMG, the EMEA's Committee for Veterinary Medicinal Products. By a letter dated 29 May 1998 you supplemented this complaint. On 15 June 1998, I forwarded the complaint to the Chairman of the Managing Board of the EMEA. The EMEA sent its opinion on 20 July 1998 and I forwarded this opinion to you with an invitation to make observations, if you so wished. I did not receive any observations from you. I am writing now to let you know the results of the inquiries that have been made.

THE COMPLAINT

On 12 August 1994 the complainant submitted, in application of Article 7 of Regulation (EEC) No. 2377/90, an application to the Commission for the establishment of maximum residue limits for a homeopathic product called Aristolochia spp. produced by it. In 1995, the Committee for Veterinary Medicinal Products (CVMG) of the European Agency for the Evaluation of Medicinal Products (EMEA) recommended that it was not necessary for the protection of public health to establish maximum residue limits for a number of substances including Aristolochia spp. provided that the concentration of any such substance in the product did not exceed one part per ten thousand. The Commission followed this recommendation and the product concerned was accordingly included in Annex II of Regulation (EEC) No. 2377/90 (which lists the substances for which no maximum residue limits are required). In 1997, the competent German authorities drew the attention of the CVMG to the need to adopt specific measures with regard to Aristolochia spp. in order to protect public health. The CVMG thereupon adopted, on 15 October 1997, Opinion No. 347/97 in which it came to the conclusion that residues of Aristolochia spp. constituted a hazard for the health of the consumer and recommended that the relevant substance should therefore be included in Annex IV to Regulation (EEC) No. 2377/90 (which lists the substances for which no maximum residue levels can be fixed). The complainant thereupon lodged a complaint with the Ombudsman (Complaint no. 1010/97/OV). In a letter of 18 November 1997 the Ombudsman informed the complainant that his complaint was inadmissible since the complainant had failed to make the appropriate administrative approaches to the body concerned. The complainant subsequently approached the EMEA and asked for the recommendation of the CVMG to be reconsidered. Together with this request it

submitted two toxicological reports prepared by experts. In a letter of 20 February 1998, the EMEA informed the complainant that the CVMG had reviewed the issue but come to the conclusion that the explanations supplied by the complainant did not justify a change to the opinion it had previously adopted. The complainant thereupon sent a new complaint to the Ombudsman. The allegations contained in this complaint may be summarised as follows: First, the complainant expressed the view that the CVMG had not taken into account the arguments which it had submitted to the EMEA. Second, the EMEA had (contrary to its usual practice when examining homeopathic substances) failed to send a questionnaire to the complainant in order to gather further information. Third, the complainant submitted that to the best of its knowledge the CVMP had not associated any expert for homeopathic products when examing the complainant's product.

THE INQUIRY

The EMEA's opinion The comments made by the EMEA in its opinion may be summarised as follows: The CVMP had reached its Opinion No. 347/97 after having re-evaluated the product concerned on the basis of additional, comprehensive toxicological information which had not been available when the recommendation to include this product in Annex II of Regulation (EEC) No. 2377/90 was made in 1995. When the complainant had raised objections against this opinion, the CVMG had carefully considered these objections and the written evidence that had been supplied by the complainant. After having discussed the issue at its meeting on 13 to 15 January 1998, the CVMG had even deferred its final decision to the meeting on 10 to 12 February in order to give the members of the committee additional time to consider the issue. In the end, however, the CVMG had felt obliged to confirm its previous opinion, given that residues of the relevant product in foodstuffs of animal origin constituted a hazard to the health of the consumer. It was therefore not correct to say that the CVMG had taken no account of the complainant's arguments. As to the second allegation of the complainant, the EMEA pointed out that lists of questions were sent out for products that were undergoing their first examination. In the case of Aristolochia spp., the first assessment had already taken place in 1995. Further information and extensive data had been provided together with the request to carry out a further assessment. It had therefore not been necessary to ask further questions. Finally, the composition of the CVMG was fixed in accordance with Council Regulation (EC) No. 2309/93. The CVMG, which was supported by more than 450 experts, covered an extremely wide range of expertise in relation to veterinary medicine, which included veterinary homeopathy. The EMEA further pointed out that these experts had been accepted as being competent when the CVMG had recommended to include homeopathic substances in Annex II of Regulation (EEC) No. 2377/90 in 1995.

THE DECISION

1 Consideration of the complainant's arguments by the CVMG 1.1 The complainant alleges that the Committee for Veterinary Medicinal Products (CVMG) of the European Agency for the Evaluation of Medicinal Products (EMEA) failed to take into account the arguments which the complainant had put forward against Opinion No. 347/97 in which the CVMG had come to the conclusion that residues of Aristolochia spp. constituted a hazard for the health of the consumer and had recommended that the relevant substance should therefore be included in Annex IV to Regulation (EEC) No. 2377/90. The EMEA is of the opinion that the CVMG had carefully

considered all these arguments. 1.2 According to the information provided by the EMEA the CVMG carefully examined the arguments and the supporting evidence submitted by the complainant and even postponed the final decision on the issue in order to give its members more time to consider the matter. The EMEA points out that in the end the CVMG had felt obliged to confirm its original opinion in view of the health risk which in its view were caused by residues of the substance concerned. In these circumstances the Ombudsman considers that the allegation of the complainant relating to the lack of consideration of its arguments by the CVMG cannot be regarded as well-founded. **2 Failure to ask further questions** 2.1 The complainant relies on the fact that the EMEA did not comply with its usual practice (in cases concerning homeopathic products) to send out a questionnaire in order to gather further information relating to the substance concrned. The EMEA replies that such questionnaires are only sent out in the case of products that are undergoing their first examination. In the case of the complainant's product, there was no need to ask for further information since the relevant substance had been examined before and since the EMEA had already received sufficient information. 2.2 There is a general principle that decisions should only be taken after all the relevant data has been collected. However, the explanation provided by the EMEA for the fact that it did not consider it necessary to send out a questionnaire in this case appears to be reasonable. **3 Failure to include expert for homeopathic products** 3.1 The complainant invokes the fact that the CVMG, when examining the complainant's case, did not have recourse to a special expert for homeopathic products. The EMEA replies that the CVMG disposes of a considerable number of experts covering an extremely wide range of expertise, including expert knowledge as to homeopathic products. 3.2 The EMEA is the European Union's agency for the evaluation of medicinal products. The evidence in the possession of the Ombudsman does not allow the conclusion that the EMEA does not itself dispose of the resources and expertise necessary to carry out its mission. According to the EMEA, the EMEA and the CVMG are assisted by a considerable number of experts who cover a wide range of expertise, including matters relating to homeopathic products. The fact that the CVMG did not consult or associate a special expert for homeopathic products when dealing with the complainant's product does therefore not appear to establish an instance of maladministration. **4 Conclusion** On the basis of the European Ombudsman's inquiries into this complaint, there appears to have been no maladministration by the European Agency for the Evaluation of Medicinal Products. The Chairman of the Managing Board of the European Agency for the Evaluation of Medicinal Products will also be informed of this decision. Yours sincerely Jacob SÖDERMAN