In addition, the applicant pleads a failure to provide a statement of reasons and infringement of the rights of defence, as well as non-compliance with the principles of sound administration and with the duty to have regard for the welfare and interests of officials. Lastly, according to the applicant, there has been an infringement of the Charter of Fundamental Rights, inasmuch as the Commission did not adopt a decision within a reasonable time.

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**Action brought on 25 January 2002 by Albert Albrecht GmbH + Co. KG and 17 others against the Commission of the European Communities and the European Agency for the Evaluation of Medicinal Products**

**(Case T-19/02)**

(2002/C 109/99)

*(Language of the case: English)*

An action against the Commission of the European Communities and the European Agency for the Evaluation of Medicinal Products was brought before the Court of First Instance of the European Communities on 25 January 2002 by Albert Albrecht GmbH + Co. KG and 17 others, represented by Mr Dirk Brinckman and Mr Denis Waelbroeck of Liedekerke Siméon Wessing Houthoff, Brussels (Belgium).

The applicant claims that the Court should:

— annul the contested Decisions requesting the applicants to submit data under the referral procedure of Article 20 of Directive 81/851 and requesting them each to pay the sum of 10 000 Euro;

— alternatively, declare the contested Decisions null and void;

— declare the Notice to Applicants illegal in so far as any of its provisions could be read as implying that the referral procedure under Article 20 is applicable to marketing authorisations issued under national law;

— order the defendants to bear the costs.

*Pleas in law and main arguments*

The applicants in the present case are all companies holding a national marketing authorisation issued by national competent authorities for a veterinary medicinal product containing the pharmacologically active substance benzathine penicillin. That substance is a general antibiotic used in veterinary injectable medicinal products for food producing animals.

The application is lodged against the decisions of the European Agency for the Evaluation of Medicinal Products (EMEA) of 15 November 2001, requesting the applicants, on the basis of Article 20 of the Directive 81/851 [1], to reply to questions put by the Committee for Veterinary Medicinal Products (CVMP) regarding medicinal products containing benzathine penicillin by 25 March 2002 in the framework of a referral procedure initiated by the Irish authorities and each to pay a fee of 10 000 Euro to the EMEA.

In support of their conclusions, the applicants submit that:

— The contested decision infringes Article 20 of Directive 81/851, which is only applicable in the framework of the mutual recognition procedure and not to strictly national marketing authorisations.

— As the Directives are addressed only to Member States and are therefore not able to impose obligations directly on individuals, the Decision in question should be annulled, as Article 20 of the Directive 81/851 cannot constitute a legal basis upon which to oblige the Applicants to comply. The EMEA cannot therefore oblige the applicants to pay an arbitration fee of 10 000 Euro.

— Even if were to be accepted that the arbitration procedure under Article 20 could be applied to veterinary medicinal products authorised under purely national authorisation procedures, which is not the case, the procedure can in any event only affect on the marketing authorisation that is directly affected by the referral. Moreover, it should follow from the very wording of Article 20 that it is only the person responsible for placing the veterinary medicinal product concerned on the market who is bound to forward to the CVMP all available information relating to the matter in question. The procedure under Article 20 should not permit holders of national authorisations of different medicinal products to be compelled to submit data.

— The arbitration procedure could apply in the absence of a mutual recognition procedure, which is not the case: at most it allows information to be requested from the holder of the national marketing authorisation whose product is directly concerned by the referral procedure.

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[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 (OJ L 317, 6.11.1981, p. 1).