

**Reference for a preliminary ruling by the Østre Landsret, by decision of that court of 23 May 2001 in the case of AstraZeneca A/S v Lægemedelstyrelsen, interveners: Generics (UK) Ltd, and in the case of A/S GEA Farmaceutisk Fabrik v Lægemedelstyrelsen, joined party: Sundhedsministeriet, interveners: Generics (UK) Ltd and AstraZeneca A/S**

**(Case C-223/01)**

(2001/C 227/19)

Reference has been made to the Court of Justice of the European Communities by decision of the Østre Landsret of 23 June 2001, received at the Court Registry on 5 June 2001, for a preliminary ruling in the cases of AstraZeneca A/S and A/S GEA Farmaceutisk Fabrik v Lægemedelstyrelsen, joined party: Sundhedsministeriet, interveners: Generics (UK) Ltd, on the following questions:

*Question 1*

In a case where an undertaking applies for marketing authorisation on the basis of an abridged application (simplified procedure) under Article 4, third paragraph, point 8(a)(iii) of the first medicinal products directive (Council Directive 65/65/EEC<sup>(1)</sup> as subsequently amended) and states that the product for which marketing authorisation is sought is essentially similar to a reference product which has been approved in the Community for the necessary period of time pursuant to the directive, is it necessary and sufficient that the reference product:

- (a) at the time of the application has been marketed in the Member State for which the application is made, or
- (b) at the time of the application is still being marketed in the Member State for which the application is made, or
- (c) is still being marketed at the time of the application and at the time of notification of marketing authorisation in the Member State for which the application is made?

*Question 2*

Does the term 'marketed' in Article 4, third paragraph, point 8(a)(iii) mean that it is sufficient and necessary that there be approval in the form of marketing authorisation for the reference product in the Member State for which the application is made?

*Question 3*

If Questions 1(b) or 1(c) are answered in the affirmative, does the first medicinal products directive contain a legal basis for enabling the national authorities to dispense with the requirements in question so that an abridged application can nevertheless be examined as to its substance?

<sup>(1)</sup> of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (O), English Special Edition, 1965/1966, p. 20.

**Reference for a preliminary ruling by the First Civil Chamber of the Tribunale Civile di Genova by order of that court of 24 May 2001 in the joined cases of Off-road Action Sas and Model Toys di Luca Luperini against Prefetto di Genova**

**(Case C-225/01)**

(2001/C 227/20)

Reference has been made to the Court of Justice of the European Communities by order of the First Civil Chamber of the Tribunale Civile, (Civil District Court), Genoa, of 24 May 2001, received at the Court Registry on 6 June 2001, for a preliminary ruling in the joined cases of Off-road Action Sas and Model Toys di Luca Luperini against the Prefetto di Genova on the following questions:

- In the light of the principles of the free movement of goods and of proportionality, does Community law preclude in all cases the application of national legislation under which the confiscation of goods is applied by way of secondary penalty for any infringement of administrative regulations governing the importation of such goods into Italian territory, for trade, use or exploitation; or is that penalty compatible with Community law in certain circumstances, because of the seriousness of the offence or the importance of the legal good which the rule infringed seeks to protect?
- In the light of the principle of proportionality, does Community law preclude the application of national legislation which does not confer on the administrative authorities or the courts any discretion — having regard to the seriousness of the offence or the importance of the legal good which the rule infringed seeks to protect — in deciding whether or not to order the confiscation of goods, that being the secondary penalty prescribed for any infringement of the administrative regulations governing the manufacture, use, carriage, holding or alienation of such goods within Italian territory?