Judgment of the Court (First Chamber) of 13 March 2014 (request for a preliminary ruling from the Conseil d'État — France) — Octapharma France SAS v Agence nationale de sécurité du médicament et des produits de santé (ANSM), Ministère des Affaires sociales et de la Santé

(Case C-512/12) ([1])

(Approximation of laws — Directive 2001/83/EC — Directive 2002/98/EC — Scope — Labile blood product — Plasma prepared by means of an industrial process — Simultaneous or exclusive application of the directives — Option for a Member State to provide for a less rigorous regime for plasma than for medicinal products)

(2014/C 135/09)

Language of the case: French

Referring court

Conseil d'État

Parties to the main proceedings

Applicant: Octapharma France SAS

Defendants: Agence nationale de sécurité du médicament et des produits de santé (ANSM), Ministère des Affaires sociales et de la Santé

Re:

Request for a preliminary ruling — Conseil d'État (France) — Interpretation of Article 2(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34) — Interpretation of Article 4(2) of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30) and of Article 168 TFEU — Labile blood products — Plasma prepared by means of an industrial process — Simultaneous application of two directives or application of the provisions of Directive 2001/83/EC alone due to the less strict scheme implemented by Directive 2002/98/EC — Option for a Member State to adopt or maintain national provisions implementing a less strict scheme for plasma prepared by means of an industrial process than for medicinal products — *De facto* non-application of Directive 2001/83/EC regarding the condition of the prior grant of a marketing authorisation.

Operative part of the judgment

1) *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, and Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83 must be interpreted as meaning that plasma from whole blood which is prepared by a method involving an industrial process and which is intended for transfusions comes, in accordance with Article 109 of Directive 2001/83, within the scope of Directive 2002/98 with respect to its collection and testing, and within the scope of Directive 2001/83, as amended by Directive 2004/27, with respect to its processing, storage and distribution, on condition that it satisfies the definition of a medicinal product under Article 1(2) of the latter directive;*

2) *Article 4(2) of Directive 2002/98, read in the light of Article 168 TFEU, must be interpreted as meaning that it allows the maintenance or introduction of national provisions which make plasma which is prepared by a method involving an industrial process subject to a more rigorous regime than that to which medicinal products are subject solely with respect to its collection and testing.*

([1]) OJ C 26, 26.1.2013.