Reports of Cases

Joined Cases C-627/13 and C-2/14
Miguel M. and Others

(Request for a preliminary ruling from the Bundesgerichtshof)

(Request for a preliminary ruling — Drug precursors — Monitoring of trade between the Member States — Regulation (EC) No 273/2004 — Monitoring of trade between the European Union and third countries — Regulation (EC) No 111/2005 — Trade in medicinal products containing ephedrine or pseudoephedrine — Definition of 'scheduled substance' — Composition — Exclusion of all medicinal products or only those containing scheduled substances and the composition of which does allow those substances to be readily extracted — Directive 2001/83/EC — Definition of 'medicinal product')

Summary — Judgment of the Court (Fifth Chamber), 5 February 2015

1. *EU law — Interpretation — Texts in several languages — Uniform interpretation — Differences between the various language versions — Taking into account of the general scheme and purpose of the legislation*

2. *Approximation of laws — Monitoring of trade in drug precursors — Regulations No 273/2004 and No 111/2005 — Scope — Scheduled substances — Definition — Medicinal products within the meaning of Directive 2001/83 — Not included*

   (European Parliament and Council Regulations Nos 273/2004, Art. 2(a), and Annex I, and No 1259/2013; Council Regulation No 111/2005, Art. 2(a) and Annex; European Parliament and Council Directive 2001/83, as amended by Regulation No 1901/2006, Art. 1, para. 2)

1. See the text of the decision.

(see paras 48, 49)

2. Articles 2(a) of Regulation No 273/2004 on drug precursors and of Regulation No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors respectively must be interpreted as meaning that a medicinal product as defined in Article 1(2) of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Regulation No 1901/2006, cannot be categorised as a 'scheduled substance' as such, even if it contains a substance referred to in Annex I to Regulation No 273/2004 and in the annex to Regulation No 111/2005 and can easily be used or extracted by readily applicable or economically viable means.

It is not apparent from any part of Regulation No 273/2004 that it seeks to make medicinal products containing a substance referred to in Annex I thereto and able easily to be used or extracted by readily applicable or economically viable means subject to an additional authorisation and control system other than that applicable to medicinal products under Directive 2001/83. With regard to Regulation No 111/2005, although it does indeed provide a set of precise rules which do not correspond to any in Directive 2001/83 on medicinal products, it cannot be deduced from that fact alone that the EU legislature intended to make medicinal products containing a substance referred to

in Annex I thereto and able easily to be used or extracted by readily applicable or economically viable means subject not only to Directive 2001/83 but also to this regulation. It is also for that reason that the EU legislature decided, in the context of Regulation No 1259/2013, amending Regulation No 111/2005, to make only medicinal products containing two scheduled substances subject to the control system for trade in drug precursors between the EU and third countries.

(see paras 59, 61, 62, 65, 67, operative part)