

**Request for a preliminary ruling from the Bundesgerichtshof (Germany) lodged on
14 December 2018 — ratiopharm GmbH v Novartis Consumer Health GmbH**

(Case C-786/18)

Language of the case: German

Referring court

Bundesgerichtshof

Parties to the main proceedings

Appellant on a point of law: ratiopharm GmbH

Respondent in the appeal on a point of law: Novartis Consumer Health GmbH

Questions referred

Is Article 96(1) of Directive 2001/83/EC¹ to be interpreted as meaning that pharmaceutical companies may also distribute free finished medicinal products to pharmacists, if their packaging is labelled ‘for demonstration purposes’, the medicinal products are used by the pharmacist to test the product, there is no risk of further distribution (of the unopened product) to end users and the further conditions for distribution set out in Article 96(1)(a) to (d) and (f) to (g) of that directive are met?

If the answer to Question 1 is in the affirmative: Does Article 96(2) of Directive 2001/83/EC permit a national provision such as Paragraph 47(3) of the Arzneimittelgesetz (Law on medicinal products; ‘the AMG’), if that provision is interpreted as meaning that pharmaceutical companies may not distribute free finished medicinal products to pharmacists, if their packaging is labelled ‘for demonstration purposes’, the medicinal products are used by the pharmacist to test the product, there is no risk of further distribution (of the unopened product) to end users and the further conditions for distribution set out in Article 96(1)(a) to (d) and (f) to (g) of that directive and in Paragraph 47(4) of the AMG are met?

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 (OJ 2001 L 311, p. 67), in the version last amended by Regulation (EU) No 2017/745 (OJ 2017 L 117, p. 1).