

Judgment of the Court (Second Chamber) of 2 March 2023 (request for a preliminary ruling from the Verwaltungsgericht Wien — Austria) — Kwizda Pharma GmbH v Landeshauptmann von Wien

(Case C-760/21, ⁽¹⁾ Kwizda Pharma)

(Reference for a preliminary ruling — Food safety — Food — Regulation (EU) No 609/2013 — Article 2 (2)(g) — Concept of ‘food for special medical purposes’ — Other particular nutritional requirements — Dietary management — Modification of the diet — Nutrients — Use under medical supervision — Ingredients not absorbed or metabolised in the alimentary canal — Distinction in relation to medicinal products — Distinction in relation to food supplements)

(2023/C 155/26)

Language of the case: German

Referring court

Verwaltungsgericht Wien

Parties to the main proceedings

Applicant: Kwizda Pharma GmbH

Defendant: Landeshauptmann von Wien

Operative part of the judgment

1. Article 1(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, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, and Article 2(2)(g) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009,

must be interpreted as meaning that for the purposes of distinguishing between the concepts of ‘medicinal product’ and ‘food for special medical purposes’, which are defined in those provisions respectively, it must be assessed in the light of the nature and characteristics of the product concerned, whether it is food intended to meet particular nutritional requirements or a product intended to prevent or cure human disease, to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis, or where appropriate, presented as such.

2. Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that first, the concept of ‘dietary management’ covers requirements caused by a disease, disorder or health condition, the satisfaction of which is indispensable to the patient from a nutritional point of view, secondly, the classification as a ‘food for special medical purposes’ cannot be made subject to the condition that the satisfaction of ‘nutritional needs’ caused by a disease, disorder or health condition secondly, the qualification of ‘food for special medical purposes’ cannot be made conditional on the satisfaction of ‘dietary management’ needs caused by a disease, disorder or health condition, and therefore the effect of the product, necessarily taking place during or following digestion and, thirdly, the concept of ‘modification of the normal diet alone’ includes both situations in which a modification of the diet is impossible or dangerous for the patient and situations in which the patient can only with great difficulty satisfy his or her nutritional requirements with ordinary food.

3. Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that for the purposes of the application of that regulation, which does not define the concept of 'nutrient', reference must be made to the definition of that concept in Article 2(2)(s) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

4. Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that first, a product must be used under medical supervision if the recommendation and subsequent assessment of a health professional are necessary in the light of the dietary management needs arising from a particular disease, disorder or health condition and the effects of the product on the patient's dietary management and on the patient, and, secondly, that the requirement that a food for special medical purposes is 'to be used under medical supervision' is not a condition for qualification of a product as such.

5. Article 2 of Directive 2002/46 and Article 2(2)(g) of Regulation No 609/2013

must be interpreted as meaning that the concepts of 'food supplement' and 'food for special medical purposes', which are defined in those provisions respectively, are mutually exclusive and that it is necessary to determine on a case-by-case basis and according to the characteristics and conditions of use whether a product falls within one or other of those concepts.

⁽¹⁾ OJ C 138, 28.3.2022.

Judgment of the Court (Third Chamber) of 2 March 2023 (request for a preliminary ruling from the Oberlandesgericht Graz — Austria) — Proceedings relating to the recognition and execution of a European Investigation Order concerning MS

(Case C-16/22, ⁽¹⁾ Staatsanwaltschaft Graz (Düsseldorf Tax Office for Criminal Tax Matters))

(Reference for a preliminary ruling — Area of freedom, security and justice — Judicial cooperation in criminal matters — Directive 2014/41/EU — European Investigation Order — Article 1(1) — Concept of 'judicial authority' — Article 2(c) — Concept of 'issuing authority' — Order issued by a tax authority without being validated by a judge or public prosecutor — Tax authority assuming the rights and the obligations of the public prosecutor's office in the context of a criminal tax investigation)

(2023/C 155/27)

Language of the case: German

Referring court

Oberlandesgericht Graz

Parties to the main proceedings

Applicant: MS

other parties: Staatsanwaltschaft Graz, Finanzamt für Steuerstrafsachen und Steuerfahndung Düsseldorf

Operative part of the judgment

The first subparagraph of Article 1(1) and Article 2(c)(i) of Directive 2014/41/EU of the European Parliament and of the Council of 3 April 2014 regarding the European Investigation Order in criminal matters