Reports of Cases

Case C-451/24

Kwizda Pharma GmbH

(Request for a preliminary ruling from the Verwaltungsgericht Wien)

Judgment of the Court (Ninth Chamber) of 4 September 2025

(Reference for a preliminary ruling – Medicinal products – Product which may fall within the definition of 'medicinal product' and within the definition of 'product covered by other Community legislation' – Applicable legal framework – Directive 2001/83/EC – Article 2(2) – Rule of precedence – Scope – Effectiveness – Procedural autonomy of the Member States – Article 4(3) TEU – Principle of sincere cooperation)

1. *Approximation of laws – Medicinal products for human use – Directive 2001/83 – Scope – Product covered by other Community legislation – Concept – Other regulated products defined by the acts of EU law governing them*
(European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Art. 2(2))

(see paragraphs 49-52, operative part 1)

2. *Approximation of laws – Medicinal products for human use – Directive 2001/83 – Medicinal products by presentation – Medicinal products by function – Applicability of the rule of precedence – Conditions*
(European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, recital 7 and Arts 1(2)(b) and 2(2))

(see paragraphs 58-68, operative part 2)

3. *Approximation of laws – Medicinal products for human use – Directive 2001/83 – Placing a product on the market as a food for special medical purposes – Prohibition of placing on the market by the national authority competent to enforce the legislation relating to those foods – Different authority from the authority competent to enforce the legislation on medicinal products – Product constituting a medicinal product by presentation – Not permissible – Medicinal products by presentation placed on the market – Obligation to inform the authority competent to enforce the legislation on medicinal products*
(Art. 4(3) TEU; European Parliament and Council Directive 2001/83, as amended by Directive 2004/27, Arts 1(2)(b) and 2(2) and (6))

(see paragraphs 73-77, 83-89, operative part 3)

See the text of the decision.