INFORMATION ON UNPUBLISHED DECISIONS

Reports of Cases

Judgment of the General Court (Fifth Chamber) of 20 October 2016 — August Wolff and Remedia v Commission

(Case T-672/14)

(Medicinal products for human use — Article 31 of Directive 2001/83/EC — Article 116 of Directive 2001/83 — Active substance estradiol — Commission decision ordering the Member States to withdraw or amend national marketing authorisations for medicinal products with 0.01% estradiol by weight for topical use — Burden of proof — Proportionality — Equal treatment)

1. *Actions for annulment — Admissibility criteria — Natural or legal persons — Action brought by several applicants against the same decision — Capacity to act of one of them — Admissibility of the action as a whole (Art. 263, fourth para., TFEU) (see para. 18)*

2. *EU law — Interpretation — Methods — Literal, systematic and teleological interpretation — Recourse to the origin of a provision — Lawfulness (see para. 30)*

3. *EU law — Interpretation — Principles — Independent interpretation — Limits — Reference in certain cases to the law of the Member States (see para. 31)*

4. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Reference to the committee on medicinal products for human use — Purpose (European Parliament and Council Directive 2001/83, Art. 31) (see paras 37, 38, 46)*

5. *Approximation of laws — Medicinal products for human use — Authorisation to market — Commission guide to procedures for marketing authorisation — Binding nature — None — Account taken by the EU judicature — Whether permissible (European Parliament and Council Directive 2001/83, Art. 31) (see para. 45)*

6. *EU law — Principles — Prohibition of abuse of right — Scope (see para. 53)*

7. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Reference to the committee on medicinal products for human use — Conditions — Existence of an EU interest — Scope (European Parliament and Council Directive 2001/83, fifty-seventh recital and Art. 31) (see paras 61, 63, 64)*

8. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Reference to the committee on medicinal products for human use — Nomination of a rapporteur having the nationality of the Member State of the party to the procedure — Not sufficient to establish the existence of a breach of the impartiality requirement (Charter of Fundamental Rights of the European Union, Art. 41; European Parliament and Council Directive 2001/83, Art. 31) (see paras 90, 91, 94)*

9. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Opinion of the committee on medicinal products for human use — Judicial review — Limits (European Parliament and Council Directive 2001/83, Art. 31) (see paras 117-119)*

10. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Conditions — Not cumulative — Recourse by the competent authority to a series of serious and conclusive indicators likely to cast doubt on the harmlessness and therapeutic effect of the medicinal product — Admissibility (European Parliament and Council Directive 2001/83, Art. 116) (see paras 128-130)*

11. *Approximation of laws — Medicinal products for human use — Authorisation to market — Modification of the authorisation — Withdrawal and prohibition on marketing — Conditions — Evidentiary requirements — Allocation between the applicant and the competent authority — Subsistence of scientific uncertainties concerning the harmlessness or effectiveness of a medicinal product — Application of the precautionary principle — Scope — Limits (European Parliament and Council Directive 2001/83, Art. 116) (see paras 135-140, 174-178)*

12. *EU law — Principles — Proportionality — Scope (Art. 5(4) TEU) (see para. 203)*

13. *EU law — Principles — Equal treatment — Concept (see para. 211)*

Re:

APPLICATION based on Article 263 TFEU and seeking the annulment of Commission Decision C(2014) 6030 final of 19 August 2014 concerning, in the context of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for high concentration of estradiol containing human medicinal products for topical use in so far as it requires Member States to comply with the obligations imposed in the implementing decision for the medicinal products listed in Annex I to the implementing decision and those not listed with 0.01% estradiol by weight for topical use, with the exception of the restriction that the medicinal products named in Annex I to the implementing decision with 0.01% estradiol by weight for topical use may be administered only intravaginally.

Operative part

The Court:

1. Dismisses the action;

2. Orders Dr. August Wolff GmbH & Co. KG Arzneimittel and Remedia d.o.o. to pay the costs of the proceedings and of those relating to the application for interim measures.