

to quality, safety and efficacy, in particular those laid down in Section 4 of Part II of Annex I to Directive 2001/83/EC, as amended by Directive 2003/63/EC.

- (iii) The competent institutions of the Republic of Lithuania have themselves established that the documents relating to the medicinal product 'Grasalva' do not contain any information concerning pre-clinical or clinical trials provided in accordance with Section 4 of Part II of Annex I to Directive 2001/83/EC, as amended by Directive 2003/63/EC, concerning compliance by the medicinal product 'Grasalva' with the safety and efficacy requirements applied to similar biological medicinal products.
- (iv) The national marketing authorisation for the medicinal product 'Grasalva' fails to meet the requirements of Section 4 of Part II of Annex I to Directive 2001/83/EC, as amended by Directive 2003/63/EC, with the result that, as from the date of accession, that medicinal product could be placed on the market only if marketing authorisation for it had been granted centrally pursuant to Article 3(1) of Regulation (EEC) No 2309/93 (applied up to 20 November 2005) or Article 3(1) of Regulation (EC) No 726/2004 (applicable from 21 November 2005).

- (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).
- (²) Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ 2003 L 159, p. 46).
- (³) Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).
- (⁴) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1).

Action brought on 30 July 2008 — Commission of the European Communities v Republic of Austria

(Case C-356/08)

(2008/C 247/17)

Language of the case: German

Parties

Applicant: Commission of the European Communities (represented by: E. Traversa and A. Böhlke, Agents)

Defendant: Republic of Austria

Form of order sought

- declare that, by imposing an obligation on every medical doctor becoming established in Oberösterreich (*Land of Upper Austria*) to open a bank account with the Oberösterreichische Landesbank to which fees for benefits in kind are to be transferred by the health insurance funds, the Republic of Austria has failed to comply with its obligations under Articles 43 EC, 49 EC and 56 EC;
- order the Republic of Austria to pay the costs.

Pleas in law and main arguments

The mandatory opening of an account, to which, moreover, all fees for benefits in kind from health insurance funds must be transferred, is disproportionate to the need to ensure the proper calculation and levying of the contributions payable to the medical councils by medical doctors established in Oberösterreich. The disputed rules for that reason amount to unjustified restrictions of three fundamental freedoms guaranteed by the Treaty, namely the freedom of establishment of medical doctors established in other Member States and that of banks, their freedom to provide services and the free movement of capital.

Action brought on 4 August 2008 — Commission of the European Communities v Hellenic Republic

(Case C-357/08)

(2008/C 247/18)

Language of the case: Greek

Parties

Applicant: Commission of the European Communities (represented by: G. Zavvos)

Defendant: Hellenic Republic

Form of order sought

- declare that, by not adopting the laws, regulations and administrative provisions necessary to comply with Directive 2005/14/EC (¹) of the European Parliament and of the Council of 11 May 2005 amending Council Directives 72/166/EEC, 84/5/EEC, 88/357/EEC and 90/232/EEC and Directive 2000/26/EC of the European Parliament and of the Council relating to insurance against civil liability in respect of the use of motor vehicles, or in any event by not notifying those provisions to the Commission, the Hellenic Republic has failed to fulfil its obligations under that directive;
- order the Hellenic Republic to pay the costs.