

# Brussels Brief

A weekly overview of the regulatory, legal and political developments of the institutions and the issues facing the European Union



30 June 2006

## Key Developments

### Biotechnology: EU Supports Orphan Drug Development

Andrea Hamilton

The European Commission has issued a report announcing that its programme to incentivise the development of orphan drugs has facilitated the approval of 22 such drugs in five years. Orphan drugs treat rare and life-threatening conditions, and would not be developed under normal market conditions. Five years ago, Regulation (EC) No. 141/2000 encouraged pharmaceutical and biotech companies to develop orphan drugs by, *inter alia*, creating a single EU-wide marketing authorisation, providing ten-year market exclusivity for orphan drugs, reducing fees due to the European Medicines Agency, and supporting research and development. Since 2000, more than 450 applications for orphan drug designations have been filed, 260 have received such designation, and 22 have been introduced on the market. Given these and other incentives from EU Member States, the number of orphan drugs is expected to increase in coming years.

### Agriculture: Reform of EU Common Market Organisation for Wine

Elena Kostadinova

The European Commission has published a Communication on reform of the EU common market organisation for wine. The Commission plans to submit a legislative proposal by January 2007. The reform measures would include: (i) aid of EUR 2.4 billion for uncompetitive producers who decide to leave the market; (ii) expiry of the system of planting rights by 2013; (iii) abolition of market management tools such as support for by-product distillation; and (iv) a ban on the use of sugar for enriching the alcohol content of wine. The aid will be administered by the rural development funds. The Commission is in favour of a simpler and more transparent quality policy, establishing two classes of wine, with and without geographical indication. New labelling rules should allow the indication of grape variety and vintage on wines without geographical indication. The Commission proposes three backup options if profound reform is not received positively by Member States and stakeholders.

### Environment: EU Prohibition of Hazardous Substances Effective on 1 July

Philip Torbøl and Susan Cooke

On 1 July 2006, the Restriction of Hazardous Substances (RoHS) Directive (Directive 2002/95/EC) takes effect throughout the European Union. This Directive prohibits electrical and electronic equipment from containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). As supplemented by four Commission Decisions, the RoHS Directive provides, however, for certain exemptions. These include a *de minimis* concentration exemption for each of the prohibited substances. There are also total exemptions for certain types of lead solder and lamps containing mercury. All 25 EU Member States have incorporated the Directive's prohibition into their national legislation.

### Internal Market: Commission Challenges Minimum Retail Prices for Cigarettes

Michal Cieplinski

The European Commission has sent a reasoned opinion to France and Belgium within the framework of an Article 226 infringement procedure. The Commission took the view that, based on well-established case law of the European Court of Justice (ECJ), minimum retail prices for cigarettes infringe Community law, distort competition and only benefit manufacturers by safeguarding their profit margins. The Commission suggested that to achieve the objective of reducing tobacco consumption, the EU institutions should instead advocate increasing excise duty on cheap cigarettes. Unless the legislation in the Member States concerned is brought into compliance within two months of receipt of the opinion, the Commission may decide to refer the case to the ECJ. See Brussels Brief of 14 April 2006.

### Intellectual Property: Storck Trademark Appeal Rejected

James Fox

The European Court of Justice (ECJ) has rejected an appeal made by Storck against the Court of First Instance's refusal to annul the decision made by the Office for Harmonisation in the Internal Market. This decision did not recognise two marks

relating to Werther's Original sweets as Community trademarks. The three-dimensional shape and image of a sweet wrapper were deemed too indistinguishable from other basic shapes used by confectionary makers. The ECJ ruled that the mark does not depart significantly from the norm of the confectionary sector, and as such the public cannot immediately recognise it as a trademark.

### **Internal Market: Italy Referred to ECJ over Special Powers in Privatised Companies**

Maria Scimemi

The European Commission has referred Italy to the European Court of Justice (ECJ) because it considers that certain provisions of Italian Privatisation Law constitute unjustified restrictions to EU rules on free movement of capital and right of establishment. This law introduced special powers of opposition by the Minister of Economy in cases where the vital interests of the State are threatened, and applies with respect to privatised companies such as Telecom Italia, ENEL and ENI. The criteria for exercising these powers are identified in a Prime Ministerial Decree of 2004. According to the Commission, these criteria are vague and indeterminate in scope, giving the authorities wide discretionary powers in judging risks to the interests of the State. Moreover, the Commission considered that public interest concerns (i.e. ensuring the supply of certain services of general interest) could have been pursued by less restrictive arrangements.

### **Competition: Commission Revises Guidelines on Method of Setting Fines**

Yannis Virvilis

The European Commission has revised its method for calculating fines in competition cases. The Commission intends to increase the deterrence function of fines, especially in the case of repeat offenders, as well as to clarify the methodology used for setting such fines. Within the limit of ten per cent of the total annual turnover of an offender, the fines can be as much as 30 per cent of the company's annual sales to which the infringement relates, multiplied by the number of years of participation in the infringement. In case of repeat offences, the Commission can now take into account not only its past decisions but also those of National Competition Authorities. The increase in fines can in these cases amount to 100 per cent instead of the current 50 per cent.

## Next Week's Events

**Monday 3 July – Friday 7 July 2006**

### **COUNCIL MEETINGS**

- No meetings scheduled for next week

### **COURT OF JUSTICE**

#### **Judgments**

Freedom of establishment

- C-346/04 Conijn

Intellectual property

- C-53/05 Commission v Portugal

Social policy

- C-212/04 Adeneler and Others
- C-154/05 Kersbergen-Lap and Dams-Schipper

Taxation

- C-251/05 Talacre Beach Caravan Sales
- Joined Cases C-439/04, C-440/04 Kittel

#### **Opinions**

Company law

- C-239/05 BVBA Management, Training en Consultancy

Free movement of goods

- C-281/05 Montex Holdings

### **COURT OF FIRST INSTANCE**

#### **Judgments**

Competition

- T-177/04 easyJet v Commission
- T-304/02 Hoek Loos v Commission

Law governing the institutions

- Joined Cases T-391/03, T-70/04 Franchet and Byk v Commission

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