



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 24 March 2004 (01.04)  
(OR. fr)**

**7255/04  
ADD 1**

**PV/CONS 14  
COMPET 40  
RECH 55**

**ADDENDUM TO DRAFT MINUTES <sup>1</sup>**

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Subject: **2570th meeting of the Council of the European Union (COMPETITIVENESS)  
(INTERNAL MARKET, INDUSTRY AND RESEARCH), held in Brussels on  
11 March 2004**

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<sup>1</sup> The information from the Council minutes which is contained in this addendum is not confidential and may therefore be released to the public.

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## Agenda items released to the public concerning the final adoption of Council acts

"A" items (list: 7181/04 PTS A 12 + ADD 1)

When finally adopting the "A" items relating to legislative acts, the Council agreed to enter the following in these minutes:

### **Item 6. Review of pharmaceuticals legislation**

- **Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency**  
PE-CONS 3612/1/04 ECO 14 AGRILEG 10 SAN 12 CODEC 109 REV 1  
(Legal basis: Articles 95 and 152(4)(b) of the Treaty establishing the European Community).
- **Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use**  
PE-CONS 3613/1/04 ECO 15 AGRILEG 11 SAN 13 CODEC 110 REV 1  
(Legal basis: Article 95 of the Treaty establishing the European Community).
- **Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products**  
PE-CONS 3614/1/04 AGRILEG 12 ECO 16 SAN 14 CODEC 111 REV 1  
(Legal basis: Articles 95 and 152(4)(b) of the Treaty establishing the European Community).

The Council approved the European Parliament's amendments to the common position; the Belgian delegation voted against; the above Regulation and Directives are therefore deemed to have been adopted in the form of the common positions thus amended.

### GENERAL STATEMENTS

#### **1. Statement by the Council and the Commission on the Acceding States**

"The Council and the Commission will give full and timely consideration to any request for a transitional period presented by the new Member States with respect to the new pharmaceutical acquis."

**2. Statement by the Czech, Estonian, Cyprus, Latvian, Lithuanian, Hungarian, Maltese, Polish, Slovenian and Slovakian delegations**

"Welcoming the joint statement of the Council and the Commission on the review of Community legislation on pharmaceuticals in relation to Acceding States, the new Member States stress that timely consideration of a request for transitional period presented by the new Member States means a timeframe that will allow putting any necessary provisions in place before the deadline for transposition of the new *acquis* expires."

**3. Statement by the Commission**

"The Commission states that it will submit in 2004 a proposal for a specific Regulation to the Council and the European Parliament aiming at providing a genuine legal framework for the development and authorisation of medicinal products for human use in order to meet the specific therapeutic needs of the paediatric population."

**4. Statement by the Luxembourg delegation**

"Luxembourg states that, in implementing the new Community pharmaceuticals legislation under Luxembourg law, it will make allowance for the very small size of Luxembourg's domestic market and for the limited administrative capacity and expertise at present available within the country."

**STATEMENTS CONCERNING THE REGULATION**

**5. Statement by the German, Italian, Portuguese and United Kingdom delegations**

"Germany, Italy, Portugal and the United Kingdom recall the Statement by the United Kingdom, German, Italian, Spanish, Portuguese and Danish delegations to the minutes of the 2512th meeting of the Council of the European Union (Employment, Social Policy, Health and Consumer Affairs), held in Luxembourg on 2 and 3 June 2003, on the legal base for the "amended proposal for a Regulation of the European Parliament and of the Council 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.

Germany, Italy, Portugal and the United Kingdom still believe that Article 308 of the Treaty rather than Article 95 would be the correct legal base. Therefore, these delegations give their agreement to the Regulation under the assumption that its legal base cannot be considered as setting a precedent for future decisions regarding issues of **a similar nature**."

## 6. Statement by the German delegation

"Germany considers it important to make the following point:

The European Medicines Agency must be financed within the applicable financial perspective. The annual funding will be approved by the budgetary authority within the limits of the financial perspective. In view of the tightness of heading 3 of the Community budget, it must be ensured that the applicable financial perspective is adhered to, while allowing for existing and future programmes and for a safety margin below the ceiling of heading 3."

## **STATEMENT CONCERNING THE DIRECTIVE ON VETERINARY MEDICINAL PRODUCTS**

### 7. Statement by the Belgian, German, Greek, Spanish, French, Italian, Austrian and Portuguese delegations

Re: Article 1(21) – Definition of "veterinary prescription"

"The Belgian, German, Greek, Spanish, French, Italian, Austrian and Portuguese delegations assume that, with respect to the definition of "veterinary prescription" in Article 1(21), the veterinarian is the qualified professional person who should prescribe veterinary medicinal products."

### **Item 7. Directive of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use PE-CONS 3630/04 ECO 45 SAN 43 CODEC 285**

The Council approved the European Parliament's amendments to the common position; the above Directive is therefore deemed to have been adopted in the form of the common position thus amended (Legal basis: Article 95 of the Treaty establishing the European Community).

**Item 8. Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 1734/94 on financial and technical cooperation with the West Bank and the Gaza Strip**

PE-CONS 3619/04 MED 5 CODEC 174 + COR 1 (fi)

The Council adopted the above Regulation (Legal basis: Article 179 of the Treaty establishing the European Community).

**Item 11. Regulation of the European Parliament and of the Council on detergents**

PE-CONS 3629/04 ENT 50 ENV 1424 CODEC 284

The Council approved the European Parliament's amendments to the common position; the above Regulation is therefore deemed to have been adopted in the form of the common position thus amended (Legal basis: Article 95 of the Treaty establishing the European Community).

**8. Statement by the Portuguese delegation**

"Portugal considers that the modernisation of the legislation regulating detergent biodegradability, which dates back to the early 1970s and has since been overtaken by technological developments, is to be welcomed.

Portugal has therefore argued for a more stringent set of harmonised principles, making allowance in particular for child protection, which it hopes all Member States can accept.

It is sorry to see that a Regulation designed to harmonise all rules on additional labelling makes no provision to guard against the risk of detergents being swallowed, especially by children, by preventing packaging from showing pictures of fruit or other foodstuffs which might mislead them.

Protection against the risk of swallowing was included in Directive 1999/45/EC, which only covers dangerous substances and preparations, and Portugal sees a need to extend that coverage to all detergents as the only way to guarantee total harmonisation with a high level of health and safety protection.

In addition, Portugal does not consider it right for a Regulation to impose national testing methods without having them published as an integral part of it, for reasons of quality of Community legislation, legal and practical applicability and also competition, although it does welcome the Commission's statement that it will ask the European Committee for Standardisation (CEN) to review those methods and prepare a European standard for inclusion in the Regulation in future.

As it has not been possible for these concerns to be accommodated in the Regulation in the form of an amended common position, Portugal regrets that it has to reject its adoption."

**"B" item (agenda: 7146/04 OJ CONS 14 COMPET 38 RECH 52)**

**Item 6. Council Regulation amending Regulation (EC) No 1177/2002 concerning a temporary defensive mechanism to shipbuilding**  
6532/04 COMPET 27 IND 26 MI 50 RC 7 WTO 20 OC 136

The Council adopted the above Regulation; the Danish, Netherlands, Finnish and Swedish delegations voted against it. (Legal basis: Articles 87(3)(e), 89 and 133 of the Treaty establishing the European Community).

**9. Statement by Italy**

"While voting in favour of the adoption of the proposal extending Regulation (EC) No 1177/2002 until 31 March 2005, Italy regrets that it was not seen fit to take this opportunity to improve the effectiveness of the temporary defensive mechanism to shipbuilding with reference to the industry's actual requirements."

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