COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 24.10.2006
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2006/0204 (ACC)

Proposal for a

COUNCIL REGULATION

providing for duty-free treatment for specified pharmaceutical active ingredients bearing an "international non-proprietary name" (INN) from the World Health Organisation and specified products used for the manufacture of finished pharmaceuticals and amending Annex I to Regulation (EEC) No 2658/87

(presented by the Commission)

EXPLANATORY MEMORANDUM

The Council is hereby invited to authorise the addition of 1290 pharmaceutical and chemical products to the already-existing list of 7329 products benefiting from bound duty-free treatment upon importation into the EU.

The EC grants duty-free treatment to imports of 7329 products, as provided for under the 1994 Record of Discussions on trade in pharmaceutical products agreed upon within the World Trade Organisation.

A third review of the products covered by the Record was launched in 2000, in accordance with Article 3 of the Record, which requires Participants to review at least once every three years the product coverage with a view to including additional pharmaceutical products for tariff elimination. The EC participated in these technical discussions. In the course of these discussions, Participants concluded that additional INNs and intermediates used for production and manufacture of finished pharmaceuticals should be granted duty-free treatment and that the list of specified prefixes and suffixes for salts, esters or hydrates of INNs should be expanded, thereby adding 1290 new substances to the list of products eligible for duty-free treatment.

The Member States have been consulted during the technical discussions.

The Council is invited to adopt the attached proposal for a Council Decision amending Annex I to Council Regulation (EEC) No 2658/87 in order to extend duty-free treatment in the Community to the above-mentioned 1290 pharmaceutical and chemical products.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the proposal from the Commission[1],

Whereas:

(1) In the course of the Uruguay Round negotiations the Community and a number of countries agreed that duty-free treatment should be granted to pharmaceutical products falling within the Harmonised System (HS) Chapter 30 and HS headings 2936, 2937, 2939 and 2941 as well as to designated pharmaceutical active ingredients bearing an “international non-proprietary name” (INN) from the World Health Organisation, specified salts, esters and hydrates of such INNs, and designated intermediates used for the production and manufacture of finished products;

(2) The results of the discussions, as set out in the record of discussions, were incorporated into the tariff schedules of the participants annexed to the Marrakesh Protocol to GATT 1994;

(3) Participants concluded that representatives of the WTO members party to the record of discussions would meet under the auspices of the Council for Trade in Goods of the WTO, normally at least once every three years to review the product coverage with a view to including, by consensus, additional pharmaceutical products for tariff elimination;

(4) Two such reviews have taken place with the conclusion that a certain number of additional INNs and intermediates used for production and manufacture of finished pharmaceuticals should be granted duty-free treatment and that the list of specified prefixes and suffixes for salts, esters or hydrates of INNs should be expanded;

(5) A third review was deemed appropriate and was launched in 2000; it concluded that a certain number of additional INNs and intermediates used for production and

[1] OJ C […] […], p. […]

manufacture of finished pharmaceuticals should be granted duty-free treatment, that certain of these intermediates should be transferred to the list of INNs, and that the list of specified prefixes and suffixes for salts, esters or hydrates of INNs should be expanded;

(6) Regulation (EEC) No 2658/87[2] established a goods nomenclature, hereinafter referred to as the 'Combined Nomenclature', and set out the conventional duty rates of the Common Customs Tariff;

(7) Regulation (EEC) No 2658/87 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

As of 1 January 2007 the Community shall extend duty-free treatment to the INNs listed in Annex I.

Article 2

As of 1 January 2007 the list of prefixes and suffixes which, in combination with the INNs, describe the salts, esters or hydrates of INNs which are also eligible for duty-free treatment, on condition that they are classifiable in the same 6-digit HS-subheading as the corresponding INN, is replaced by the one in Annex II.

Article 3

As of 1 January 2007 the Community shall extend duty-free treatment to the intermediates used in the production and manufacture of pharmaceutical products listed in Annex III.

Article 4

As of 1 January 2007 the intermediates listed in Annex IV shall no longer benefit from duty-free treatment.

Article 5

Annexes 3, 4 and 6 of Section II of Part three of Annex I to Regulation (EEC) No 2658/87, (Lists of pharmaceutical substances which qualify for duty-free treatment), shall be amended accordingly.

[2] OJ L 256, 7.9.1987, p. 1. Regulation as last amended by Regulation (EC) No 486/2006 (OJ L 88, 25.3.2006, p. 1).

Article 6

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the Council
The President
[…]

ANNEX

Please see attached documents.

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS HAVING A BUDGETARY IMPACT EXCLUSIVELY LIMITED TO THE REVENUE SIDE

1. NAME OF THE PROPOSAL:

Proposal for a Council Regulation providing for duty-free treatment for specified pharmaceutical active ingredients bearing an "international non-proprietary name" (INN) from the World Health Organisation and specified products used for the manufacture of finished pharmaceuticals and amending Annex I of Regulation (EEC) No 2658/87

2. BUDGET LINES:

Chapter and Article: Chap. 12 art. 120

Amount budgeted for the year 2007: 172.5 millions euro

3. FINANCIAL IMPACT

☐ Proposal has no financial implications

x Proposal has no financial impact on expenditure but has a financial impact on revenue – the effect is as follows:

(€ million to one decimal place)

Budget line	Revenue[3]	12 month period, starting dd/mm/yyyy	[Year 2007]
Article 120	*Impact on own resources*	01/01/2007	- 172.5

4. ANTI-FRAUD MEASURES

Special provision C. Pharmaceutical products of Section II of Part one Preliminary provisions of Annex I Combined Nomenclature to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256 of 7.9.1987, as last amended by Regulation (EC) No 1719/2005, OJ L 286 of 28.10.2005).

[3] Regarding traditional own resources (agricultural duties, sugar levies, customs duties) the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % of collection costs

5. OTHER REMARKS

The estimated cost of this operation has been calculated by the European Chemical Industry Council – CEFIC.

With regard to the 2nd update, the tariff savings generated had been estimated at around 100 million euro for European companies engaged in pharmaceutical business. Based on this figure, the following approach has been made for the 3rd update:

- In the update of 1999, 272 new INNs and 365 new intermediates or a total of 637 new products were included in the pharmaceutical agreement.

- In the 3rd revision, 820 new INNs and 470 new intermediates or a total of 1290 new products will be added.

Dividing the amount of 100 million euro by 637 and then multiplying the result by 1290 gives roughly 200 million euro as a first estimate. Taking into account an inflation figure of 15 %, we estimate that the value for 2007 is about 230 million euro.

The impact on the loss of revenue resulting from this Regulation may therefore be estimated at 230 million euro (gross amount, expenses incurred in collection included) x 0.75 = **172.5 million euro for the year 2007.**

The shortfall in traditional own resources will have to be made up by the Member States by topping up the GNP component.