Europaudvalget
(Alm. del - bilag 273)
sundhedsministerråd
(Offentligt)

Medlemmerne af Folketingets Europaudvalg

og deres stedfortrædere

Bilag	Journalnummer	Kontor	
1	400.C.2-0	EU-sekr.	25. november 2002

Til underretning for Folketingets Europaudvalg vedlægges Kommissionens forordningsforslag vedrørende hindring af ulovlig parallelimport af medicin.

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, xxx

COM(2002) yyy final

2002/aaaa (ACC)

Proposal for a

COUNCIL REGULATION

to avoid trade diversion into the European Union of certain key medicines

(presented by the Commission)

EXPLANATORY MEMORANDUM

The Commission presented a policy framework on *'Accelerated Action targeted at major communicable diseases within the context of poverty reduction'* in September 2000 on the need for accelerated action targeted at major communicable diseases within the context of poverty reduction. It explains the issue of communicable diseases as a burden on the poorest and an obstacle to development, analyses the major policy issues involved, reports on the rationale for continuous Community involvement and sets out a framework with three broad areas for targeted action; (1) Reaching optimal impact of existing interventions, services and commodities targeted at the major communicable diseases affecting the poorest populations. (2) Increasing affordability of key pharmaceuticals through a comprehensive and synergistic global approach. (3) Increasing investment in research and development of global goods targeted at the three major communicable diseases.

Many of the poorest developing countries face severe health crises and are in urgent need of improved access to affordable essential medicines for treatment of communicable diseases. These countries are, normally, heavily dependant on imports of medicines as local manufacturing is exceptional. The reasons why this is so include, but are not limited to, the effects of international and national pricing policies, tariffs and taxation and implementation of intellectual property rights agreements. Options to improve access and affordability include, *inter alia*, sustainable application of tiered pricing set in a comprehensive global approach.

In February 2001 the Commission adopted a *Programme for Action: Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction* which establishes a broad and coherent Community response over the period 2001-2006, to address the global emergency caused by the three major communicable diseases.

The Programme for Action proposes that manufacturers and exporters offer the lowest possible prices to the poorest developing countries, as defined in the Programme without profits being threatened in developed countries. This should build on a volume/price trade off where the poorest countries benefit from low tiered prices. Price segmentation between developed country markets and the poorest developing country markets is necessary.

Legislative and regulatory instruments are in place in most developed countries to prevent importation, in certain circumstances, of pharmaceutical products, but these instruments risk becoming insufficient as substantial volumes of strongly discounted pharmaceuticals are sold to the poorest developing country markets and the economic interest in trade diversion into high priced markets therefore may increase significantly. Effective measures need to be in place to prevent this trade. Such measures should also encourage the industry to commit itself to offer essential medicines at tiered prices on a sustainable basis. In future, tiered pricing for the poorest developing countries should no longer be the exception, but the rule.

To achieve the objectives set by the Programme for Action the proposed Regulation is prohibiting the entering into the Customs territory of the Community of products that have been approved as tiered priced and subsequently exported to a poor developing country as defined. For a product to qualify as tiered priced in the meaning of the proposed regulation, it must be included in Annex 1 of the present Council Regulation. Applications may be submitted*, on a voluntary basis*, for inclusion in Annex 1 in accordance with the rules and procedures set out in the Regulation. At this stage the proposed Regulation is addressing the three major communicable diseases and the poorest developing countries i.e. it fully adopts the scope set out in the Programme for Action. The proposed Regulation is, however, providing for review in the future, with regard to the scope of diseases and recipient countries in light of existing and future health crises in the developing world as well as of the general criteria for the implementation of Article 3 depending on the experience gained in terms of increased volumes supplied to the poorest countries (contained in Annexes 2 to 4).

2002/aaaa (ACC)

Proposal for a

COUNCIL REGULATION

to avoid trade diversion into the European Union of certain key medicines

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,

Having regard to the opinion of the European Parliament ,

Whereas:

(1) The Commission adopted a Communication to the Council and the Parliament on accelerated action targeted at major communicable diseases within the context of poverty reduction on 21 February 2001, COM (2001) 96 under which the Commission is instructed to *inter alia* establish a global tiered pricing system for key pharmaceuticals for prevention, diagnosis and treatment of HIV/AIDS, TB and malaria and related diseases for the poorest developing countries and to prevent product diversion of these products to other markets by ensuring that effective safeguards are in place.

(2) The Council in a resolution dated 14 May 2001 on accelerated action on HIV, TB and malaria has underlined the need to reinforce safeguards against diversion of low priced pharmaceuticals destined for poor markets and prevent price erosion in developed countries markets.

(3) On 15 March 2001 a European Parliament Resolution on access to drugs for HIV/AIDS victims in developing countries noted the inclusion of a commitment to tiered pricing in the Commission's Programme for Action and called for a system allowing developing countries equitable access to medicines and vaccines at affordable prices.

(4) Many of the poorest developing countries are in urgent need of access to affordable essential medicines for treatment of communicable diseases. These countries are heavily dependant on imports of medicines as local manufacturing is scarce .

(5) Price segmentation between developed country markets and the poorest developing country markets is necessary to ensure that the poorest developing countries are supplied with essential pharmaceutical products at strongly reduced prices.

(6) Legislative and regulatory instruments are in place in most developed countries to prevent importation, in certain circumstances, of pharmaceutical products, but these instruments risk becoming insufficient as substantial volumes of strongly discounted pharmaceuticals are sold to the poorest developing country markets and the economic interest in trade diversion into high priced markets therefore may increase significantly.

(7) There is a need to encourage the pharmaceutical producers to make available pharmaceutical products at strongly reduced prices in significantly increased volumes by ensuring through this Regulation that these products remain on these markets. Donations of pharmaceutical products may qualify under this Regulation on equal conditions, bearing in mind that donations are not contributing to improve access to these products on a sustainable basis.

(8) For the purpose of this Regulation, it is necessary to establish a procedure which identifies the products, countries and diseases covered by this Regulation.

(9) The procedure set out in this Regulation foresees prohibition of tiered priced products sold to countries of destination to be imported in to the Community for purposes of entry, release for free circulation, re-export, placing under suspensive procedures or placing in a free-zone or free warehouse and shall apply as soon as the merchandise is brought under customs supervision as foreseen in Article 38 of Council Regulation (EC) 2913/92 of 12 October 1992 establishing the Community Customs Code.

(10) Manufacturers of tiered priced products shall differentiate the appearance of tiered priced products to facilitate the task of identifying them.

(11) It will be appropriate to consider the possibility of expanding the scope of this Regulation to cover additional diseases and countries in the light, *inter alia*, of the experience gained from the implementation of this Regulation.

(12) In accordance with Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, measures for the implementation of this Regulation should be adopted by use of the advisory procedure provided for in Article 3 of that Decision.

(13) With regard to tiered priced products contained in travellers' personal luggage for personal use, the same rules as set out in Council Regulation 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods, currently being reviewed, shall apply.

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation shall lay down:

(a) the criteria for establishing what a tiered priced product is;

(b) the conditions under which the customs authorities shall take action;

(c) the measures which shall be taken by the competent authorities in the Member States .

2. For the purpose of this Regulation:

(a) 'A tiered priced product' means any pharmaceutical product used in the prevention, diagnosis and treatment of diseases as set out in Annex 4 that is priced in accordance with one of the optional price calculations set out in Article 3 herein, verified by the Commission as described in Article 4 hereof and entered to the list of tiered priced products contained in Annex 1.

(b) 'Countries of destination' referred to in Article 4 are those countries listed in Annex 2.

(c) ' Competent authority' means the authority designated by a Member State to determine whether goods suspended by the customs authorities in the respective Member State are tiered priced products and to give instructions to either destroy or release the goods depending on the outcome of the review.

Article 2

1. It shall be prohibited to import into the Community tiered priced products as listed in Annex 1 and marked with the logo set out in Article 7 of this Regulation for purposes of entry, release for free circulation, re-export, placing under suspensive procedures or placing in a free-zone or free warehouse.

2. Transshipments of tiered priced products for purposes of export to a country defined in Article 1 as duly documented, shall not fall within the prohibition set out in paragraph 1 above.

Article 3

The tiered price referred to in Article 4 (2) (ii) of this Regulation shall, at the option of the applicant manufacturer or exporter, be either

(a) no higher than the percentage set out in Annex 3 of the average ex factory price charged by a manufacturer in OECD markets for the same product at the time of application; or, alternatively,

(b) a manufacturer's direct production costs as verified and certified by an independent auditor appointed in agreement between the manufacturer and the Commission, with the addition of a maximum percentage which is set out in Annex 3.

Option (b) could be considered by a manufacturer in cases where direct production costs for a certain product are high and therefore the price achieved under option (a) would be insufficient to cover production costs. Any information submitted by a manufacturer to the independent auditor shall at any time remain confidential.

Article 4

1. In order for products to benefit from this Regulation, manufacturers or exporters of pharmaceutical products shall submit applications to the Commission.

2. Any application addressed to the Commission shall contain the following information:

(i) the product name and substance and sufficient information to verify which disease it is preventing, diagnosing or treating;

(ii) the price offered in relation to either of the optional price calculations set out in Article 3 in sufficient detail to enable verification. In case the alternative set out under Article 3(b) is chosen by the applicant, only the certificate on cost of production issued by the independent auditor and the additional margin allowed for shall be submitted; and

(iii) country or countries of destination to which the applicant intends to sell the product concerned.

3. In accordance with the procedures laid down in Article 5, the Commission shall determine whether a product fulfils the criteria set out in this Regulation.

4. Where the requirements set out in this Regulation are fulfilled, the product shall be added to Annex 1 at the next following update. The applicant shall be informed of the decision of the Commission within 15 days.

5. In the event an application is not sufficiently detailed for review of substance, the Commission shall in writing ask the applicant to submit such missing information. In case the applicant does not complete the application within the time period set out in that communication, the application shall be null and void.

6. In case the Commission finds that the application does not fulfil the criteria set out in this Regulation, the application shall be rejected and the applicant be informed within 15 days from the date of the decision. Nothing shall prevent a manufacturer or an exporter from re-submitting a modified application for the same product.

7. Donations from manufacturers or exporters may be notified accordingly for approval and insertion in Annex 1.

8. Annex 1 to this Regulation shall be updated every second month by the Commission.

Article 5

1. The Commission shall be assisted by a Committee**,** composed of representatives of the Member States and chaired by the representative of the Commission. The advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply.

2. Where applications are submitted in accordance with Article 4 of this Regulation, the Commission shall consult with the Committee referred to in paragraph 1. When determining whether the product or products covered by the application qualify as tiered priced product(s), the Commission shall take the utmost account of the opinion expressed by the Committee regarding each application.

3. Where adjustments to Annexes 2, 3 and 4 are necessary, the advisory procedure referred to in paragraph 1 shall apply.

Article 6

A product which has been approved as a tiered priced product and entered in Annex 1 shall remain on that list as long as the conditions set out in Article 4 are fulfilled and annual sales reports have been submitted to the Commission in accordance with Article 11 herein. The applicant is obliged to submit information on any change occurred with respect to scope or conditions set out under Article 4 to the Commission to ensure that these requirements are met.

Article 7

1. Once a product has been approved as a tiered priced product under this Regulation and added to Annex 1 the manufacturer and exporter shall affix a logo as set out in Annex 5 on any packaging or product and any document used in connection with the approved product sold at tiered prices to countries defined under Article 1. This obligation shall apply as long as the tiered priced product remains listed in Annex 1.

2. Manufacturers and exporters of tiered priced products sold in the poorest developing countries, may in addition identify these products by affixing the text **"Approved as tiered priced product by EC under Regulation ……."** in any of the official languages of the European Union on any packaging or by differentiating the product in a way as may seem fit.

ot;Approved as tiered priced product by EC ge

3. Any additional information in terms of means of transport, trading routes, batch-numbers etc of tiered priced products exported available to the exporter, should be made available to the customs authorities to assist them in allocating and identifying tiered priced products as set out in Article 8 hereof. Where possible, additional technical information related to the products and their packaging shall also be submitted to customs authorities to allow for their identification.

Article 8

1. Customs authorities shall suspend the release of or detain the tiered priced products listed in Annex 1 and marked with the logo set out in Article 7 of this Regulation, for purposes set out in Article 2 during the time necessary to obtain a final decision of the competent authorities on the character of the merchandise.

2. It shall be sufficient reason for the customs authorities to suspend the release of or detain products if the product is listed in Annex 1 and there is sufficient information available as set out in Article 7.3 to consider that the product in question is tiered priced.

3. The customs authorities shall immediately notify the competent authority in the Member State concerned of the suspended release or detention and forward all information available with respect to the products suspended taking account of national provisions on the protection of personal data, commercial and industrial secrecy and professional and administrative confidentiality. The importer shall be given ample opportunity to supply the competent authority with information which he deems appropriate regarding the products.

Article 9

1. If products which are suspended for release or detained by customs authorities are recognised by the competent authority as tiered priced products defined under this Regulation, the competent authority shall issue a decision instructing the customs authority to destroy these products unless the importer is prepared to make the goods available for humanitarian purposes to the benefit of countries listed in Annex 2. The destruction is carried out normally at the expense of the importer but in any case without cost to the exchequer.

2. Where imported products suspended for release or detained by customs authorities subsequent to further control by the competent authority are found not to qualify as tiered priced products as defined in this Regulation, the competent authority shall issue a decision to that effect enabling the customs authority to release the products to the consignee .

3. The competent authority shall inform the Commission of all decisions adopted under this Regulation.

Article 10

This Regulation shall not apply to goods of a non-commercial nature contained in travellers' personal luggage for personal use within the limits laid down in respect of relief from customs duty.

Article 11

1. The Commission shall monitor on an annual basis the volumes of exports of tiered priced products as listed in Annex 1 and exported to the countries as defined in Article 1 on the basis of information provided to it by pharmaceutical manufacturers and exporters. For this purpose a standard form will be issued by the Commission. Manufacturers and exporters are obliged to submit such sales reports annually for each tiered priced product to the Commission on a confidential basis.

2. The Commission shall periodically report to the Council on the volumes exported under tiered prices. The report shall examine the scope of countries and diseases and general criteria for the implementation of Article 3.

Article 12

1. The application of this Regulation shall in no circumstances interfere with procedures laid down in Directive 2001/83 and Council Regulation 2309/93 concerning the production, use, evaluation and supervision of medicines for human and veterinary use within the European Union.

2. This Regulation shall not interfere with intellectual property rights or rights of intellectual property owners.

Article 13

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

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

Done at Brussels,

For the Council

The President

ANNEX 1

List of Tiered Priced Products

Product Producer/exporter Country of destination Date of approval

ANNEX 2

Countries of Destination

Afghanistan	Madagascar
Angola	Malawi
Armenia	Maldives
Azerbaijan	Mali
Bangladesh	Mauritania
Benin	Moldova

Bhutan

Burkina Faso

Burundi

Cambodia

Cameroon

Cape Verde

Central African Republic

Chad

China

Comoros

Congo, Democratic Republic of

Congo, Republic of

Djibouti

East Timor

Equatorial Guinea

Eritrea

Ethiopia

Gambia

Ghana

Guinea

Guinea Bissau

Haiti

Honduras

India

Indonesia

Ivory Coast

Kenya

Kiribati

Korea, Democratic Republic of

Kyrgyz, Republic of

Lao People's Democratic Republic

Lesotho

Liberia

Mongolia

Mozambique

Myanmar

Nepal

Nicaragua

Niger

Nigeria

Pakistan

Rwanda

Samoa

Sao Tome and Principe

Senegal

Sierra Leone

Solomon Islands

Somalia

Sudan

Tajikistan

Tanzania, United Republic of

Togo

Turkmenistan

Tuvalu

Uganda

Vanuatu

Vietnam

Yemen

Zambia

Zimbabwe

ANNEX 3

Percentages Referred to in Article 3

Percentage referred to in Article 3(a): 20%

Percentage referred to in Article 3(b): 10%

ANNEX4

Scope of Diseases

HIV/AIDS, Malaria, TB and related opportunistic diseases

ANNEX 5

Logo

Yellow stars and a blue "E" on a white background

EUROPEAN COMMISSION

Directorate-General for Trade

Directorate F - Trade questions in the field of agriculture, biotechnology, standards and certification, and new technologies; investment; sustainable development; export credits

New technologies, intellectual property, public procurement

Brussels, 4 November, 2002

TRADE F-1 LS 41.506

NOTE FOR THE ATTENTION OF MEMBERS OF THE 133 COMMITTEE

Subject: Proposal for a Council Regulation to avoid trade diversion into the European Union of certain key medicines

Contact: P.Vandoren/L. Sundstrom, Directorate-General for Trade

Tel: 02-299 2436/53366 Fax: 02-299 0586

Purpose: For discussion

Attached: Proposal for a Council Regulation adopted by the College on 30 October, 2002

133 COMMITTEE
MD : 539/02
SOURCE : Commission
FOR : Information
DATE RECEIVED : 05-11-02