UDENRIGSMINISTERIET

Medlemmerne af Folketingets Europaudvalg
og deres stedfortrædere

Asiatisk Plads 2
DK-1448 København K
Tel. +45 33 92 00 00
Fax +45 32 54 05 33
E-mail: um@um.dk
Telex 31292 ETR DK
Telegr. adr. Etrangeres
Girokonto 300-1806

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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

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TRADE F1 41.235

NOTE FOR THE ATTENTION OF THE 133 COMMITTEE

Subject: **Draft Communication from the European Communities and their Member States to the TRIPs Council relating to paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health**

Origin: **DG Trade F1**

Contact: P.Vandoren/J.C. Van Eeckhaute, Directorate-General for Trade
Tel: 02-29 92436/91920 Fax: 02-299 0586

Purpose: For distribution and discussion.

An informal meeting with IPR experts of the Member States will take place on Monday 3 June in Salle S2 of the 'Charlemagne' building, 170 Rue de la Loi, Brussels starting at 1400

133 COMMITTEE
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COMMUNICATION FROM THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES TO THE TRIPS COUNCIL RELATING TO PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

1. Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health recognises that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. Therefore, the Declaration instructs the TRIPs Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002. The view of the EC is that finding 'an expeditious solution' to this problem means, in effect, that one should be found before the end of 2002.

2. The March 2002 TRIPs Council has allowed Members to present their preliminary views on the possible solution to the problem identified under paragraph 6 of the Declaration on the TRIPs Agreement and Public Health. At this meeting, four basic options were put on the table:

i) an authoritative interpretation based on Article 30,

ii) an amendment to Article 31 in order to overcome the restriction, under Article 31(f), to the possibility to export products manufactured and/or sold under a compulsory licence,

iii) a dispute settlement moratorium with regard to the non-respect of the restriction under Article 31(f), or

iv) a waiver with regard to Article 31(f).

The European Communities and their Member States (hereinafter "the EC") thank those Members who presented their views at that occasion and have carefully taken note of all positions and arguments.

3. It appears from the statements made at that meeting, that several Members consider that the perceived problem mainly stems from the restriction contained in Article 31(f) of the TRIPs Agreement. The latter limits the possibility to export products manufactured under a compulsory licence, as it specifies that any use under a compulsory licence shall be authorised predominantly for the supply of the domestic market authorising such use. The rationale behind this provision lies in the territorial nature of patent law and in the need to avoid circumvention of patent rules. As a result, the present situation is that the uses permitted by a compulsory license are limited to 'predominantly supply the domestic market' of the WTO Member granting such a license. This does nevertheless allow a non-predominant part of the products

concerned to be destined to supply foreign markets (except under the circumstances addressed by Article 31(k)).

4. Therefore, the EC, while considering it worthwhile to maintain the basic principle contained in Article 31(f), are of the view that an appropriate solution to the problem identified in paragraph 6 of the Declaration may consist of adding a new paragraph to Article 31 which would carve out a clearly circumscribed exception to the restriction imposed by Article 31(f) with the view to facilitating the use of a patent, under a compulsory licence, on a pharmaceutical product needed to address public health problems in another Member. This option had already been dealt with in the EC Communication to the TRIPs Council of 4 March 2002 (IP/C/W/339).

5 The EC consider that the addition of such a new paragraph to Article 31 of the TRIPs Agreement offers the best guarantees for a sustainable, balanced and workable solution to the problem raised under paragraph 6 of the Doha Declaration. The insertion of a textual provision into the TRIPs Agreement itself has the advantage of providing for a straightforward, clear, legally secure, effective and permanent solution within an existing legal framework, *i.e.* Article 31 of the TRIPs Agreement.

6. The other options that have been referred to at the March 2002 TRIPs Council have their merits too, but do not necessarily combine all of the advantages mentioned above. A waiver or a dispute settlement moratorium could be appropriate and effective mechanisms for a solution, but they may fall short of providing the type of sustainable and legally secure solution that the EC are aiming for. Likewise, an authoritative interpretation on Article 30 of the TRIPs Agreement may fail to offer the same level of legal security for all parties involved as a textual addition to Article 31(f) would do. Moreover, from a legal point of view, doubts have been expressed as to whether the criteria of Article 30 offer sufficient scope for such an exception, thus questioning the legal merits of this solution.

7. The addition of a new paragraph to Article 31 would fall under the procedural rules set out by Article X of the Marrakesh Agreement. As for all amendments of international agreements, it is a procedure that takes time. However, nothing would prevent Members, once an agreement has been reached on the substance of the amendment, to agree on a temporary arrangement pending the entry intro force of the additional paragraph to Article 31, such as for example a dispute settlement moratorium, or possibly a waiver, although the latter may take more time from a procedural point of view.

8. By proposing the addition of a new paragraph to Article 31 of the TRIPs Agreement, the EC aim at striking the right balance between the call for overcoming the restriction imposed by Article 31(f) to exports of pharmaceuticals produced under compulsory licences and the underlying rationale of Article 31(f). As its objective is to ensure speedy and low priced supplies of pharmaceutical products to those in need, while maintaining a proper legal environment to encourage research and development into new products, it fully conforms to the spirit of the Doha Declaration and to the mandate contained in its paragraph 6.

9. The basic principle of such an exception would be that the Members concerned would not be obliged to apply the condition set forth in Article 31(f) in those cases where a compulsory licence is granted for the use of a patent (here : the acts of manufacturing the product and selling it to an entity importing it into another Member) with a view to supplying another Member, specifically designated in the authorisation, with a patented pharmaceutical product or with a pharmaceutical product manufactured through a patented process, when a number of conditions are fulfilled. This would allow Members in need of a given pharmaceutical product to deal with public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and for which they have no or insufficient production capacity, to rely on another WTO Member to ensure supply under a compulsory licence. The new paragraph should further specify under which conditions the exception can be triggered and applied.

10. Whatever mechanism the WTO Membership will ultimately opt for, the modalities under which the mechanism will operate, such as for instance the product scope, will have to be clearly spelled out.

11. In fact, the product scope is already defined by paragraphs 1 and 6 of the Doha Declaration. The first paragraph reads "We recognize the gravity of the public health problems, afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". The sixth paragraph refers to "the pharmaceutical sector". Hence, the product scope is to be defined as pharmaceutical products needed to deal with public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

12. In line with the spirit of the Doha Declaration, Members that would qualify for importing these products would be developing country Members, focussing especially on least developed country Members and low income Members, with no or insufficient domestic manufacturing capacity, or, in case that product is patented in that Member, no or insufficient manufacturing capacity other than that of the patent holder of the product in that Member.

13. It will be in the interest of all, and not at least of the beneficiaries of the products concerned, that these products would not be diverted from their intended destination and that the system would not be abused for purposes other than to provide pharmaceutical products at strongly reduced prices to those in need. Hence, the need to ensure that the necessary measures are taken to avoid abuses and trade diversion. In the EC's view, such measures should be reasonable in view of the complexity of the problems and the situations that may arise from the practical application of the proposed exception. It is also important to keep in mind that the prevention of trade diversion is of major importance to guarantee the legal security of the right holders concerned and to preserve the basic principles of the TRIPs Agreement.

14. Therefore, if one considers an exception to Article 31(f), one would have to specify that:

i) the products manufactured on the basis of the authorisation, given pursuant to the new paragraph to Article 31, should not be put into circulation on the market of the country of production, but should in their entirety be exported to the Member(s) designated by the authorisation (and not to any other country);

ii) the product will be offered for sale, sold or distributed solely in the Member(s) designated by the authorisation and not be re-exported from that Member;

iii) the Member granting the licence for export has taken all necessary regulatory and administrative measures to ensure that condition (i) is effectively respected; and

iv) the importing Member has taken all reasonable and necessary regulatory and/or administrative measures to ensure that condition (ii) (*i.e.* no further re-exportation) is effectively respected. This means that the new provision would not impose rights and obligations on the producing Member only. A legal obligation will also be incumbent on the importing Member : it will be the importing Member's responsibility to promulgate and enforce measures (and in particular, but not exclusively, proper border controls, supervision over the distribution of the pharmaceuticals concerned and the imposition of the necessary constraints on the distributor(s)) necessary to prevent re-exportation of the products concerned. The EU acknowledges concerns that have been expressed as to the additional burden such obligations may impose on the Members concerned. Therefore, it is crucial that the measures to be taken remain reasonable and proportional, both with regard to the risk of trade diversion as with regard to the institutional and administrative capacities of the Member concerned.

Finally, all WTO Members should take their responsibility in preventing the importation of the products concerned into other markets.

15. The application of the proposed exception would lead to the specific situation that a product sold in one country (in certain cases pursuant to a compulsory licence) would have been produced in another country under a compulsory licence. One would indeed have to deal with a special situation where patent protected products would cross the borders while covered by compulsory licences in both the country of production and the country of consumption (except in those cases where the product in question is not patented in the country of consumption). In view of this situation it will be of paramount importance to ensure full transparency of the process and to ensure that the patent holder(s) and other WTO Members remain fully informed of the steps undertaken in view of granting the authorisation. Furthermore, transparency would also contribute to preventing trade diversion : by being informed of the use of the exception, other Members will be able to increase their vigilance with regard to possible (re-)importation of the products concerned.

16. In line with the spirit of the Doha declaration, the ultimate objective of the proposed exception should be to facilitate the delivery of medicines to the populations in need at strongly reduced prices. To provide confidence that such an outcome can be fully met, within the shortest possible time frame and on a sustainable basis, it will be

crucial to enable the patent holder to make a proposal to rapidly solve the issue by making sustainable voluntary licensing and strongly reduced pricing offers, though without unduly delaying the procedure leading to the possible granting of a licence. Therefore,

i) It would be appropriate that both Members involved would, in any event, promptly notify the right holder of their intention to issue a compulsory licence. In case the product in question is not patented in the country without manufacturing capacity, the intention to request another Member to issue a licence in view of its supply should be notified to the WTO. A significant advantage of this procedure would be that Members interested in manufacturing and delivering the goods could make themselves known to the Member without manufacturing capacities.

ii) The right holder should be given the opportunity, within a short timeframe after notification, to make an offer to supply the relevant products at strongly reduced prices;

iii) If such commitment by the original manufacturer of the product meets the needs of the Member without manufacturing capacity, notably in terms of price, safety and sustainability, this should be a sufficient reason not to resort to a compulsory licence under the proposed exception. It would be up to the Member without manufacturing capacity to judge whether the offer by the original manufacturer is sufficient to meet its needs.

What matters most is to ensure adequate, speedy and sustainable supply of reliable pharmaceutical products. In this respect, the EC welcome the fact that a number of pharmaceutical producers, both research-based and generic, have expressed their willingness to deliver pharmaceutical products to developing countries at strongly reduced prices. Therefore, opportunities need to be created and maintained to facilitate such speedy solutions. The objective of achieving sustainable supply of pharmaceutical products at strongly reduced prices is best served if all possible options are explored when resort to a compulsory license is being considered.

17. Finally, in order to allow for a swift procedure in cases of extreme urgency or national emergency in the importing Member, the new paragraph to Article 31 should specify that, if the use of the product is intended to address such a case of a national emergency or other circumstances of extreme urgency in the importing Member, the Member authorising the production will not be obliged to first apply the condition set out in the first sentence of subparagraph (b). This would, in other words, stretch the already existing exception under Article 31(b) to situations where a compulsory license is issued in a Member other than the Member facing a national emergency or other circumstances of extreme urgency, in view of supplying the latter Member. This should not be a reason for both Members involved not to promptly notify the right holder of the intention to grant a licence.

18. All relevant requirements of Article 31, other than Article 31(f), would remain fully applicable to the Member granting the licence under the proposed exception. Also, in case the pharmaceutical product concerned is patented in the country of importation, the latter will have to issue a compulsory licence for its import, thereby

also respecting the relevant requirements of Article 31 of the TRIPs Agreement. If no such patents are in place, importation would not be circumscribed by patent rules.

19. The Doha Declaration on TRIPs and Public Health shows the WTO Membership's willingness to engage in a constructive and fruitful debate and its ability to find a balanced solution that takes into account the interests of all. The EC are convinced that Members will continue their work in the same spirit, and will make all necessary efforts to come to a reasonable and satisfactory solution within the timeframe prescribed by paragraph 6 of the Doha Declaration with a view to improving access to affordable medicines.

20. The EC welcome any comments other Members of the WTO may have and remain open to consider any alternative solution that might solve the problem identified under paragraph 6 of the Doha Declaration in a timely and adequate manner.