Making Medicines Affordable

POSITION PAPER

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON COMPULSORY LICENSING OF PATENTS RELATING TO THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS FOR EXPORT TO COUNTRIES WITH PUBLIC HEALTH PROBLEMS

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EGA POSITION PAPER: FINAL DRAFT

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON COMPULSORY LICENSING OF PATENTS RELATING TO THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS FOR EXPORT TO COUNTRIES WITH PUBLIC HEALTH PROBLEMS (COD/2004/0258 - COM(2004)0737)

The EGA welcomes the European Commission's initiative to propose a Regulation aimed at implementing the Decision of the WTO General Council of 30 August 2003 to allow countries with insufficient or no manufacturing capacities to make effective use of compulsory licensing.

However, it must be stressed that — in both the Decision and the draft Regulation — the procedures are complicated, the terms under which new producers must operate are very restrictive, and the various measures proposed are ambiguous. For these reasons, it is important that adoption of the Regulation does not draw attention away from other initiatives, such as EU and global funding for essential medicines, which are aimed at improving access to medicines in other countries.

Similarly, greater attention should be given to preventing the inclusion of TRIPs PLUS requirements into bilateral trade agreements between members of the WTO that have a negative impact on the supply of generic medicines in countries with health needs.

1. EGA welcomes the following positive aspects of the Regulation:

- Exclusion of a list of restrained products.
- Exclusion of a list of restrained diseases.
- Exclusion of a 'right of first refusal' provision[1] (misleadingly termed "*Equal Opportunity to supply countries in need*")
- Inclusion of a provision[2] allowing derogation of Data Exclusivity: no requirement to provide results of pre clinical and clinical trials. Possibility of obtaining the Marketing Authorisation immediately rather than having to wait 8 years.
- Inclusion of a provision[3] allowing derogation of the Sunset Clause: in case a Marketing Authorisation exists, it will not expire after 3 years without marketing the product.
- Exclusion of a 'Too commercial in nature' clause[4].

[1] *This provision gives the patent holder the right to assume contracts negotiated between generic producers and purchasers in the importing countries. The effect is that it blocks a Compulsory License for a generic.*
[2] *Article 16 of the proposed Regulation*
[3] *Article 16 of the proposed Regulation which derogates Article 14(4) and (5) of Regulation (EC) no. 726/2004*
[4] *The patent owner can challenge in court a generic company contract if the selling price in the contract is higher than 25% of the brand name price -and consequently have CL revoked-.*

Making Medicines Affordable

2. The EGA is concerned about the following aspects of the Regulation

2.1 Healthcare Perspective

2.1.2 All countries in need should be covered by the provision

As the draft EC Regulation is limited to members of the WTO, more than 40 Least-Developed Countries (non-WTO members) are automatically excluded and will not benefit from the compulsory licensing system, as presented in the Commission's proposal. These countries are continuously confronted with public health problems (i.e. HIV, TB and malaria).

Furthermore, Canada and Norway, which were the first countries to implement the WTO General Council Decision, do not restrict the list of countries in need only to WTO members.

2.1.3 The buyer should not be restricted to a foreign government or its agent.

NGOs delivering frontline healthcare services in developing countries with health problems should be have access to the medicines to assure their correct distribution.

2.1.4 There are no incentives or funding mechanisms for cases in which medicines are still too expensive for the poorest countries.

Under the proposed Regulation, European companies will only be able to supply these medicines to Least Developed Countries or countries with non-existent or insufficient manufacturing capacities. These countries often have limited ability to pay for even the lowest cost medicines available. Solvable demand needs to be guaranteed for producers.

Moreover, a new producer must start from zero research, manufacturing and developing for each product provided. These companies cannot finance this development and production by means of sales on European or US markets as is the case for companies selling the patented medicines. In this context it will be important to see what incentives or guaranteed purchase funding can be provided (either through Community funding or national foreign aid policies) to help companies produce and sell these specially required medicines.

Making Medicines Affordable

2.2 Practical use of the system.

The procedure to issue a compulsory license should be quick and easy, rather than discretionary and complex.

2.2.1 Article 5.3(c) Identification of patent(s) and SPC(s) in the application

The patent-holder can patent several molecules (different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance) along with their manufacturing process. The identification of all patents and SPCs by the applicant would be extremely difficult and constraining. Therefore the applicant should only be required to identify the product which, by extension, would cover all patents related to the product. (It should be noted that the identification of patents subject to a compulsory license is not required by the WTO Decision).

2.2.2 Article 5.3(g) Tendering

This article implies that the producer can only respond to a specific request from a WTO member. It seems to exclude the possibility of using a compulsory license in the case of international tendering to purchase medicines. The relationship between the tendering procedure and the procedure for obtaining a compulsory license is extremely unclear and should be clarified, as the tendering procedure will be by far the preferred method of manufacturing and supplying medicines to countries in needs.

2.2.3 Article 5.4. Additional formal and administrative requirements

Supplementary requirements on the applicant could discourage an application for a compulsory licence or result in an increase in the cost of the medicine concerned. This article should be deleted.

2.2.4 Article 6.2. Volume restriction in compulsory license issued in an EU Member State

The requirement in Article 6.2 ensuring that the combined volume of product from each compulsory license issued within the EU must not exceed the total volume requested by the importing country is impractical and unworkable for the following reasons:

- There is no reporting mechanism in EU Member States to track the issuance of compulsory licenses.
- Restricting the volume in each compulsory license before knowing which company will in fact win/respond to an EU global tender would result in restrictions of supply, particularly where one or more of the companies receiving a compulsory license failed to win or respond to tender.
- In any event, the purpose of the article to restrict volume cannot be enforced as it does not take into account the issuance of compulsory licenses in WTO countries outside the EU.

This requirement should therefore be dropped and replaced by a simple statement that 'the CL is issued to meet the requirements of the importing countries until these needs are

met'. Failure to make this change will render it virtually impossible for 'competing' companies to operate in the CL/tender market.

2.2.5 Article 7. Promotion of voluntary agreements. Requirement to obtain authorization from right holder.

Article 7 imposes the obligation on the applicant to provide evidence that efforts have been made to obtain authorisation from the right holder on reasonable terms and conditions, and that such efforts have not been successful within a reasonable period of time.

However, Article 31 (b) of the TRIPS Agreement allows this requirement to be waived in the following situations: national emergency, extreme urgency, public non-commercial use or where the CL is issued to remedy an anticompetitive practice. Article 7 is therefore too restrictive as it merely orders that these situations be taken into account when determining 'a reasonable period of time' for obtaining the voluntary license. It appears that the applicant would have to try to obtain a voluntary license even in cases where the WTO member has declared a situation of national emergency. Such an approach will create uncertainty and delay. In conclusion, the prior negotiation requirement imposed by article 7 should be waived where the importing country indicates one of the circumstances listed in article 31 (b) of TRIPs.

Moreover, Article 7 needs clarification. As currently worded, it creates legal uncertainty in the context of an export procedure that is meant to be as simple and least burdensome as possible. It provides no clear definition of how long a new producer must attempt to negotiate a voluntary license. A fixed period of 30 days must be set for these negotiations, as otherwise they could drag on endlessly, delaying — or even stalling permanently — the delivery of medicines.

2.2.6 Article 8.3 Rights conferred

This article limits the scope of the license "strictly to acts of manufacturing and selling for export". In line with the WTO Decision — which is much broader in this aspect — the importation of APIs (active pharmaceutical ingredients) to produce the pharmaceutical products requested should specifically be permitted.

2.2.7 Article 8.9. Royalties concerning compulsory licensing

Article 8.9 also needs to be clarified as the term "adequate remuneration" is too vague. Certainty must exist on the royalties to be paid when a Compulsory License is granted. Otherwise, the generic producer would be placed in the impossible position of being expected to enter into export agreements before knowing the royalty rate, the duration of the agreement, the quantity permitted by the CL, or even whether the CL was obtainable at all.

A more suitable approach would be to calculate the royalty on the basis of the UN's Human Development Index (HDI) rank. Under this approach, the maximum royalty payable would

be a maximum 4% of the total value of the product exported under the license. This is the formula adopted under Canadian legislation.

2.2.8 Article 10. Evaluation time

A set period for evaluating an application should be established for the entire EU in order to harmonize the maximum time of proceeding with compulsory licensing in all Member States. To make short work of products with no delay, the maximum duration of evaluation should be short and well defined. This would provide an approximation of the first delivery date to the countries in need, taking into account the time for R&D, manufacture, and delivery of products. The CL could be granted within, for example, 30 days from the date of application.

2.2.9 Article 15. Appeal and interlocutory injunctions

This article permits an "appeal against any decision of the competent authority".
Because of Article 15, the patentee could readily obtain a frivolous injunction blocking delivery of the medicines. This type of measure serves to create a high level of uncertainty for new producers. It should be made clear that an appeal by the patentee will not automatically suspend the execution of the compulsory license.

2.2.10 Article 16. Derogation of Data exclusivity.

It is assumed that the provisions in Articles 16.1 and 16.3 derogate the data exclusivity provision (formula 8+2+1) provided for in Article 10(1) of Directive 2001/83/EC. The derogation of data exclusivity should be expressed more clearly.

2.2.11 Article 12. Re-importation issue

Article 12 contains provisions for the "detention and disposal" of a product when a reason exists "to suspect re-importation". Certain safeguard measures should be established to avoid anticompetitive strategies such as false allegations of re-importation designed to block the generic producer. However, EGA recognises the need to set up control mechanisms to avoid re-importation.

2.2.12 Guarantee for new producer to supply product free from competition from the originator

Once a compulsory license has been granted, guarantees should be given that the new producer(s) will be able to supply the product free of competition from the originators. Otherwise, the new producers will be reluctant to undertake the necessary investment if this can subsequently be undermined by a supply of the patented product.