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from:	Secretary-General of the European Commission, signed by Ms Patricia BUGNOT, Director
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to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	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 - Preliminary impact assessment

Delegations will find attached Commission document SEC(2004) 1348.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.10.2004
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COMMISSION STAFF WORKING DOCUMENT

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

Preliminary impact assessment

{COM(2004)737 final}

PRELIMINARY ASSESSMENT STATEMENT

1. PROBLEM IDENTIFICATION

Developing country members of the WTO fear that the implementation of the TRIPs Agreement as regards patent protection within their territories might have an impact on prices, which could hamper access to medicines for their poorest populations. In their view, the grant of compulsory licences, to allow manufacture of patented products without authorisation of the patent right holder, would induce competition between patent holders and generic manufacturers and lead to price reductions for the products concerned.

However, although the Doha Declaration on the TRIPs Agreement and Public Health (WT/MIN (01)/DEC/2 of 20 November 2001) clarified the compulsory licensing provisions of the TRIPs Agreement, it was recognised that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making use of these provisions. Paragraph 6 of the Declaration therefore instructs the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002. On the basis of this mandate the WTO General Council adopted, on 30 August 2003, the Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health (WT/L/540 of 2 September 2003).

2. OBJECTIVE OF THE PROPOSAL

The proposed Regulation would provide for a legal basis for competent authorities within the Members States to grant compulsory licences on patents and supplementary protection certificates concerning the manufacture of pharmaceutical products for export to eligible WTO Member States affected by public health problems and disposing of no or insufficient manufacturing capacity for the products concerned.

3. POLICY OPTIONS

Within the Community, patent rights are only granted in or with effect for individual Member States of the European Union, and enforced by right holders before the national courts. Systems for the compulsory licensing of patents are organised at national level. However uniform implementation of the Decision is necessary in order to ensure that the conditions for the granting of compulsory licences for export be the same in all EU Member States, to avoid distortion of competition for operators in the EU single market and in view of the need to apply uniform rules to prevent re-importation into the territory of the European Union of pharmaceutical products manufactured under compulsory licences.

In view of this need for uniform implementation, the very specific nature of the provisions set out under the Decision, the fact that administrative arrangements for compulsory licensing already exist at national level, and the need for urgent implementation of provisions to allow for the export of medicines to countries with public health crises, the Commission proposes that implementation be by way of a Regulation.

4. IMPACTS – POSITIVE AND NEGATIVE

The proposal concerns the manufacture and export of products of the pharmaceutical sector.

The primary sector affected within the Community will therefore be businesses producing active ingredients, pharmaceutical preparations, diagnostic kits, vaccines and the like, as well as companies, individuals, academic institutions and research organisations holding patents concerning such products. However ancillary suppliers (eg packaging, bulk and fine chemicals), distributors and export companies should also be involved.

It will be optional for the primary (manufacturing) businesses to apply for compulsory licences under the proposal. These are likely to be generic pharmaceutical companies, which have an important presence in the new MS as well as in some others. In theory there is nothing to prevent research-based industry also applying for compulsory licences of competitors' patents, though it is not clear what the commercial advantages might be.

Moreover it will be optional for third countries to seek to obtain products through the system by notifying their requirements to the WTO; in the absence of such notifications there will be no basis for the issue of compulsory licences for export.

The extent to which use will be made of the compulsory licence application procedure will depend among other factors on the market demand in the eligible importing countries, and its value to the manufacturer/exporter. To the extent that pharmaceutical products are made and exported under the system set up by this instrument, it can be expected that these manufactures represent additional production within the EU, with a proportionate increase in investment and employment.

Informal discussions have taken place with the European Generics Association, Médecins sans Frontières and EFPIA. In general, interested parties made their positions clear during the negotiations at WTO leading to the August 2003 Decision. The main points of concern are that the mechanism should prove workable in practice so as to make medicines accessible to countries in need without delivering commercial advantage to generics companies over research-based industry.

5. FURTHER ANALYSIS

The proposed Regulation provides for review three years after coming into force, at which time it will be possible to assess to what extent the compulsory licensing provisions have been used. In fact having such provisions in law can act as a stimulus to price reduction, without any licences actually being granted. However the issues surrounding affordability and access to medicines are complex and the contribution made by this initiative must be seen against that background.