Basic information

2004/0258(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems Amended by 2023/0129(COD) **Subject** 3.50.16 Industrial property, European patent, Community patent, design and pattern 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
INTA International Trade	VAN HECKE Johan (ALDE)	15/11/2004

Committee for opinion	Rapporteur for opinion	Appointed
DEVE Development	KINNOCK Glenys (PSE)	19/01/2005
ENVI Environment, Public Health and Food Safety	WEISGERBER Anja (PPE-DE)	23/11/2004
JURI Legal Affairs	GARGANI Giuseppe (PPE-DE)	20/01/2005

Council of the European Union

Council configuration	Meetings	Date
Justice and Home Affairs (JHA)	2725	2006-04-27

European Commission

Commission DG	Commissioner
Financial Stability, Financial Services and Capital Markets Union	

Key events

Date	Event	Reference	Summary

29/10/2004	Legislative proposal published	COM(2004)0737	Summary
14/12/2004	Committee referral announced in Parliament, 1st reading		
12/07/2005	Vote in committee, 1st reading		Summary
19/07/2005	Committee report tabled for plenary, 1st reading	A6-0242/2005	
30/11/2005	Debate in Parliament		
01/12/2005	Decision by Parliament, 1st reading	T6-0454/2005	Summary
01/12/2005	Results of vote in Parliament		
27/04/2006	Act adopted by Council after Parliament's 1st reading		
17/05/2006	Final act signed		
17/05/2006	End of procedure in Parliament		
09/06/2006	Final act published in Official Journal		

Technical information

Procedure reference	2004/0258(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amended by 2023/0129(COD)
Legal basis	EC Treaty (after Amsterdam) EC 133 EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	INTA/6/24795

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	ENVI	PE353.621	26/05/2005	
Committee opinion	JURI	PE357.740	07/06/2005	
Committee opinion	DEVE	PE355.333	13/06/2005	
Amendments tabled in committee		PE360.027	01/07/2005	
Committee report tabled for plenary, 1st reading/single reading		A6-0242/2005	19/07/2005	
Text adopted by Parliament, 1st reading/single reading		T6-0454/2005	01/12/2005	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03674/3/2005	17/05/2006	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2004)0737	29/10/2004	Summary
Document attached to the procedure	SEC(2004)1348	29/10/2004	Summary
Commission response to text adopted in plenary	SP(2005)5015	15/12/2005	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0689/2005 OJ C 286 17.11.2005, p. 0004-0007	08/06/2005	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2006/0816
OJ L 157 09.06.2006, p. 0001-0007 Summary

Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

2004/0258(COD) - 01/12/2005 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Johan VAN HECKE (ALDE, BE) by 543 votes in favour, 21 against and 35 abstentions, making several amendments to the Commission's proposal. These compromise amendments were agreed in informal negotiations with the Council.

It is made clear that requests for licensing can come from Non-Governmental Organisations authorised by importing countries or from UN bodies or other international health organisations. In addition:

-Parliament stated in the recitals that the compulsory licensing system should not be used by countries to pursue industrial or commercial policy objectives. This Regulation is designed to create a secure legal framework and to discourage litigation.

-Where pharmaceutical products produced under a compulsory licence have been seized under this Regulation, the competent authority may, in accordance with national legislation and with a view to ensuring that the intended use is made of the seized pharmaceutical products, decide to send these products to the relevant importing country according to the granted compulsory licence.

-In order to ensure the efficient processing of applications for compulsory licences under this Regulation, Member States should have the ability to prescribe purely formal or administrative requirements, such as, rules on the language of the application, the form to be used, the identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought, and rules on applications made in electronic format.

-The simple formula for setting remuneration is intended to accelerate the process of granting a compulsory licence in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement. The figure of 4% could be used as a reference point for deliberations on adequate remuneration in circumstances other than those listed above.

-the scope of the Regulation should not be limited to WTO members but should also include developing countries and least-developed countries. This includes any country that is not a member of WTO, but is listed in the OECD Development Assistance Committee's list of low-income countries with a GNP per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way. In consequence, a new Article is inserted making provision for notification to the Commission, and for the competent authority to terminate a license if the importing country has failed to honour its obligations with regard to public health only criteria.

-Parliament made some amendments to the clauses dealing with the procedure for application of compulsory licences. It inserted separate headings for “Verification” and “Prior negotiation”, and “Compulsory licence conditions”, and made some changes to the provisions on these matters.

-A new clause states that the duration of the licence shall be indicated.

- The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority shall give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

-A further new clause states that the procedure of suspension or detention or seizure of the goods is carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

-When the importing country notifies that the amount of pharmaceutical product has become insufficient for meeting its needs, the competent authority may, following an application by the licensee, modify the conditions of the licence permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned. In such cases the licensee's application shall be processed in accordance with a simplified and accelerated procedure. In situations where Article 7(1) applies but the derogation set out in Article 7(2) does not apply, no further evidence of negotiation with the rights-holder will be required, provided that the additional amount requested does not exceed 25% of the amount granted in the original licence.

-Parliament called for the Commission to report to Parliament and the Council every three years on the application of the Regulation, presenting proposals for amendments where necessary.

Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

2004/0258(COD) - 29/10/2004 - Legislative proposal

PURPOSE : to allow manufacturers of generic pharmaceuticals to produce patented medicines for export to "countries in need" without sufficient capacity to produce them.

PROPOSED ACT : Regulation of the European Parliament and of the Council.

CONTENT : this proposal aims to implement, at Community level, the WTO General Council Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health. The WTO Decision allows WTO Members to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

The proposed Regulation would set up a system for companies who wish to manufacture medicines for export to apply to national authorities for the grant of a "compulsory licence" from a patent holder who has exclusive rights over the manufacture and sale of the products concerned. Most national laws at present do not allow compulsory licences for export because until recently the WTO TRIPS Agreement provided for compulsory licences only "predominantly for the supply of the domestic market". The Doha declaration on trade and health adopted in November 2001 agreed to address the difficulties raised by this restriction for developing countries with no manufacturing capacity. After long negotiations, on 30 August 2003 WTO members agreed on a waiver giving these countries access to much needed generics. Provided countries in need notify to the WTO the medicines they need, it would be up to generic companies to decide to apply for licences to manufacture them. Once export takes place, all parties have an interest in seeing that medicines are not diverted from those who need them. The Commission's proposal would prohibit re-importation into the EU and provide for customs authorities to take action against goods being re-imported. The patent holder could use existing national procedures to enforce its rights against re-imported goods if they do enter the EU, and the licence could be terminated.

While the EU does not require a medicinal marketing authorisation for exported products, importing countries may want to ensure that medicines are safe and effective. In the proposal provision is made for use of the EU's scientific opinion procedure for evaluating medicines under Regulation 726 /2004/EC.

The rules also ensure that marketing authorisations do not lapse for reason of non-use in the EU, and set out exemptions from data protection rules which usually require manufacturers of generic medicines to wait for eight years before they can obtain authorisations using data from previous clinical trials conducted by others.

FINANCIAL IMPLICATIONS : the proposed mechanism is a voluntary one both for the countries in need who seek to obtain affordable medicines and the companies who intend to supply them. Once the legislation comes into force, compulsory licences will be granted by national authorities on the basis of applications from companies and notifications by developing countries that they require particular pharmaceutical products. No financial assistance is involved. Human and administrative resource requirements will be covered from within the budget at EUR 108.000 per year. The duration of the action shall be from 2005-2010 with a total cost of action set at EUR 648.000.

Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

2004/0258(COD) - 17/05/2006 - Final act

PURPOSE: to allow companies to manufacture patented medicines under license for export to those countries with insufficient capacity to manufacture them.

LEGISLATIVE ACT: Regulation 816/2006/EC 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.

CONTENT: the Council adopted this Regulation (with the German delegation abstaining), following intensive cooperation between the Council and the European Parliament. The two co-legislators agreed to modify the Commission's proposal in order to widen the list of countries eligible to import products licensed under this Regulation.

“Compulsory licensing”, which is written into the TRIPS Agreement, allows governments to issue licenses to companies who wish to manufacture patented products - without the permission of the patent holder. In other words, compulsory licensing permits the manufacture and use of generic drugs without the agreement of the patent holder. In order to protect the rights of the patent holder, certain rights are attached to the granting of compulsory licenses. One such right being that holders of compulsory licenses may only produce for the national or domestic market. This “national” requirement, however, leaves countries without a manufacturing base, (typically developing countries with public health problems), vulnerable and unable to import patented drugs made under compulsory licensing.

Without a manufacturing base, access to many medicines is out of the reach of the world’s poorest populations. In order to remedy this situation, the WTO in 2003, agreed to a “Decision” which would waive the “national” provision relating to the manufacture of pharmaceutical products produced under compulsory licensing. In doing so developing countries are able to source cheap medicines manufactured outside of their territories.

In adopting this Regulation the Community is implementing the 2003 WTO Decision or “waiver” into the legal order of the EU. (As a reminder, the EU in a related move, is close to approving a WTO Protocol which implements, on a permanent basis, the waiver. Please refer to 2006/0060/AVC).

The issuing of compulsory licences under this Regulation imposes clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which the products will be exported. The Regulation has been designed to create a secure legal framework in a bid to discourage litigation and to avoid abuse of the provisions.

In adopting this Act the EU establishes a procedure for the granting of compulsory licenses in relation to patented products *intended for export to eligible importing countries who require them for public health purposes*. Those countries eligible are

a) any least developed country appearing on the United Nations list;

b) any WTO member, which has notified the TRIPS Council that it wishes to use the system as an importer; and

c) any country that is not a member of the WTO but is listed in the OECD Development Assistance Committee’s list of low income countries.

Under the terms of this Regulation, any company in the EU can apply for a license to manufacture pharmaceutical products – without the authorisation of the patent holder. Upon being granted a license the licensee will be allowed to export those products to countries classified as “importing countries”. The amount of products manufactured under license may not exceed what is necessary to meet the needs of the importing countries. Further the products made under license must be clearly identified, through specific labelling or marking requirements.

As far as remuneration is concerned the licensee is responsible for paying the patent holder. Remuneration may be 4% of the total price in cases of national emergency or other circumstances of extreme urgency. In all other cases, the remuneration will be determined by taking account of the economic value of the product and according to its use.

Upon granting a compulsory licence the Member States must notify the TRIPS Council of the arrangements. The text of the Regulation makes clear that the compulsory licensing system set up by this Regulation is intended to address public health problems only and should therefore not be used by countries to pursue industrial or commercial policy objectives. Moreover it specifies that products manufactured pursuant to this Regulation reach only those who need them and are not diverted from those for whom they were intended.

Lastly, the European Commission will prepare a report on the application of this Regulation three years after its entry into force.

ENTRY INTO FORCE: 29/06/2006.

Pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

2004/0258(COD) - 29/10/2004 - Document attached to the procedure

COMMISSION'S IMPACT ASSESSMENT

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 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;

For more information concerning the context of this paper, please refer to the previous summary of COM(2004)0737.

2. OBJECTIVE :

The proposed Regulation would provide for a legal basis for competent authorities within the Member 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 European Union of pharmaceutical products manufactured under compulsory licences.

In view of the 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 : 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, as well as companies, individuals, academic institutions and research organisations holding patents concerning such products. However, ancillary suppliers (e.g. packaging, bulk and fine chemicals), distributors and export companies should also be affected. 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 Member States. 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 manufacturers represent additional production within the EU, with a proportionate increase in investment and employment.

CONCLUSION: following discussions with interested parties, 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. FOLLOW-UP : A review shall be provided 3 years after the coming into force of the Regulation, 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.