Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2014/0165(COD)
Avoiding trade diversion into the EU of certain key medicines. Codification	Procedure completed

Subject
4.20.01 Medicine, diseases
4.20.04 Pharmaceutical products and industry
6.20.02 Export/import control, trade defence, trade barriers
6.30.02 Financial and technical cooperation and assistance
7.30.02 Customs cooperation

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	JURI Legal Affairs		09/10/2014
		EFD FERRARA Laura	
		Shadow rapporteur	
		S&D GERINGER DE OEDENBERG Lidia Joanna	
	Former committee responsible		
	JURI Legal Affairs		
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	3459	11/04/2016
European Commission	Commission DG	Commissioner	
	Legal Service	BARROSO José Manuel	

Key events

28/05/2014	Legislative proposal published	COM(2014)0319	Summary
11/11/2014	Vote in committee, 1st reading		
28/01/2015	Committee referral announced in Parliament, 1st reading		
24/02/2016	Committee report tabled for plenary, 1st reading	A8-0038/2016	Summary
09/03/2016	Decision by Parliament, 1st reading	T8-0076/2016	Summary
11/04/2016	Act adopted by Council after Parliament's 1st reading		

11/05/2016	Final act signed		
11/05/2016	End of procedure in Parliament		
24/05/2016	Final act published in Official Journal		

Technical information

Procedure reference	2014/0165(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Codification
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 207-p2
Other legal basis	Rules of Procedure EP 159
Stage reached in procedure	Procedure completed
Committee dossier	JURI/8/00466

Documentation gateway

Legislative proposal		COM(2014)0319	28/05/2014	EC	Summary
Committee draft report		PE539.695	10/10/2014	EP	
For information		COM(2014)0737	16/12/2014	EC	
Committee report tabled for plenary, 1st reading/single reading		A8-0038/2016	24/02/2016	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0076/2016	09/03/2016	EP	Summary
For information		SWD(2016)0124	07/04/2016	EC	
For information		SWD(2016)0125	07/04/2016	EC	
Draft final act		00005/2016/LEX	11/05/2016	CSL	
Follow-up document		COM(2016)0785	09/12/2016	EC	Summary

Additional information

European Commission	EUR-Lex

Final act

Regulation 2016/793
OJ L 135 24.05.2016, p. 0039 Summary

Final legislative act with provisions for delegated acts

Avoiding trade diversion into the EU of certain key medicines. Codification

PURPOSE: codification of Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.

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

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Council Regulation (EC) No 953/2003 has been substantially amended several times. On 1 April 1987, the Commission decided to instruct its staff that all acts should be codified after no more than ten amendments, stressing that this is a minimum requirement. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this, stressing the importance of codification.

The European Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast-track adoption of codification instruments.

CONTENT: in the interests of clarity and transparency of Union law, the purpose of this proposal is to undertake a codification of Council Regulation (EC) No 953/2003 to avoid trade diversion into the European Union of certain key medicines.

The new Regulation will supersede the various acts incorporated in it; it fully preserves the content of the acts being codified and hence does no more than bring them together with only such formal amendments as are required by the codification exercise itself.

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 heavily reduced prices. Therefore, those heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets.

The proposed codified Regulation serves the purpose of preventing tiered priced products from being imported into the Union. Exemptions are laid down for certain situations under the strict provision that it is ensured that the final destination of the products in question is one of the countries listed in Annex II. More specifically, the proposed Regulation lays down:

- the criteria for establishing what is a tiered priced product;
- the conditions under which the customs authorities shall take action;
- the measures which shall be taken by the competent authorities in the Member States.

Avoiding trade diversion into the EU of certain key medicines. Codification

The Committee on Legal Affairs adopted the report by Laura FERRARA (EFD, IT) on the proposal for a regulation of the European Parliament and of the Council to avoid trade diversion into the European Union of certain key medicines (codified text).

The committee recommended the European Parliament to adopt its position at first reading, taking over the Commission proposal as adapted to the recommendations of the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission.

According to the Consultative Working Party of the legal services of the European Parliament, the Council and the Commission, the proposal in question contains a straightforward codification of the existing texts without any change in their substance.

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 heavily reduced prices. Therefore, those heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets.

The proposed codified Regulation serves the purpose of preventing tiered priced products from being imported into the Union. Exemptions are laid down for certain situations.

Avoiding trade diversion into the EU of certain key medicines. Codification

The European Parliament adopted by 664 votes to 29, with 4 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council to avoid trade diversion into the European Union of certain key medicines (codified text).

Parliament adopted its position at first reading, taking over the Commission proposal. The proposal in question aims to codify Council Regulation (EC) No 953/2003 which has been substantially amended several times. The proposal contains a straightforward codification of the existing texts without any change in their substance.

The proposed codified Regulation serves the purpose of preventing tiered priced products from being imported into the Union. Exemptions are laid down for certain situations on the strict condition that it is ensured that the final destination of the products in question is one of the countries listed in Annex II. More specifically, the proposal lays down:

- the criteria for establishing what is a tiered-priced product;
- the conditions under which the customs authorities shall take action;
- the measures which shall be taken by the competent authorities in the Member States.

The term tiered-priced product shall mean any pharmaceutical product which is used in the prevention, diagnosis or treatment of a disease, referred to in Annex IV, and which is priced in accordance with one of the optional price calculations set out in the Regulation, verified by the Commission or an independent auditor and entered in the list of tiered-priced products set out in Annex I.

Avoiding trade diversion into the EU of certain key medicines. Codification

PURPOSE: the codification of Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines.

LEGISLATIVE ACT: Regulation (EU) 2016/793 of the European Parliament and of the Council of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines (codification).

CONTENT: in the interests of legal clarity and transparency, this Regulation codifies and repeals Council Regulation (EC) No 953/2003 which

had been substantially amended several times.

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 heavily reduced prices. Therefore, those heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets.

This codified Regulation prohibits the importation into the European Union of tiered-priced products.

Derogations are laid down for certain situations under the strict provision that it is ensured that the final destination of the products in question is one of the countries listed in the Regulations Annex II.

Tiered-priced products are any pharmaceutical products used in the prevention, diagnosis or treatment of a disease such as HIV/AIDS, malaria, tuberculosis and related oppotunistic diseases, which are priced in accordance with one of the optional price calculations set out in the Regulation, verified by the Commission or an independent auditor, and and entered in the list of tiered-priced products in Annex I of the Regulation.

More specifically, the Regulation sets:

- the criteria for establishing what is a tiered priced product;
- the conditions under which the customs authorities shall take action;
- the measures which shall be taken by the competent authorities in the Member States.

The Commission shall monitor on an annual basis the volumes of exports of tiered-priced products listed in Annex I and exported to the countries of destination. It shall report biennially to the European Parliament and to the Council on the volumes exported under tiered prices.

The European Parliament may, within one month of submission of the Commission's report, invite the Commission to an ad hoc meeting of its responsible committee to present and explain any issues related to the application of this Regulation. No later than six months from the date of submission of the report to the European Parliament and to the Council, the Commission shall make the report public.

ENTRY INTO FORCE: 13.6.2016.

DELEGATED ACTS: the Commission may adopt delegated acts to add products to the list of tiered-priced products covered by the Regulation. The power to adopt such delegated acts shall be conferred on the Commission for a period of 5 years from 20 February 2014 (a period that can be tacitly extended for periods of an identical duration). The European Parliament or the Council may raise objections to a delegated act within three months of notification (which may be extended by three months.) If Parliament or Council raise objections, the delegated act will not enter into force.

Avoiding trade diversion into the EU of certain key medicines. Codification

The Commission presented a report on the application of Regulation (EU) 2016/793 of the European Parliament and of the Council to avoid trade diversion into the European Union of certain key medicines.

The Regulation puts in place safeguards to prevent diversion of medicines from poor developing countries into the European Union.

Supplying poor and developing countries with medicines at sustainable low prices is one of the objectives in the fight against the major diseases of HIV/AIDS, malaria and tuberculosis. In order to achieve this, the European Commission has consistently advocated a policy of "tiered pricing" for medicines, combined with market segmentation between rich and poor countries.

This report is the ninth Report under Article 12(2) of the Regulation which foresees biennially reports by the Commission to the European Parliament and to the Council on the volumes exported under tiered prices registered under the Regulation. It covers the period from 1 January 2014 to 31 December 2015.

Evaluation: the Regulation was evaluated on four criteria: effectiveness, efficiency, coherence and relevance. It was assessed against the REFIT criteria of being fit for purpose, having delivered on its objectives at minimum cost and whether there is potential for simplification.

The analysis of stakeholders' and experts' input by the external contractor found no evidence that there was scope for improving the effectiveness of the Regulation by modifying the list of countries of destination.

Exported products: one company, GlaxoSmithKline / ViiV Healthcare, has medicines registered under the Regulation. These products were registered in 2004 and all aim at the treatment of HIV/AIDS.

During the reference period, six products were exported under tiered prices to China, Honduras, Indonesia, Kenya, Moldova, Nigeria, South Africa, and Uganda.

The products were sold to the countries listed at the price of production, with no mark-up, and therefore in accordance with the criteria of the Regulation.