Basic information

2014/0165(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Avoiding trade diversion into the EU of certain key medicines. Codification **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		
	Shadow rapporteur GERINGER DE OEDENBERG Lidia Joanna (S&D)	

Former committee responsible	Former rapporteur	Appointed
JURI Legal Affairs		

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	3459	2016-04-11

European Commission

Commission DG	Commissioner
Legal Service	BARROSO José Manuel

Key events

Date	Event	Reference	Summary
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
09/03/2016	Results of vote in Parliament		
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 European Union TFEU 207-p2
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	JURI/8/00466

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE539.695	10/10/2014	
Committee report tabled for plenary, 1st reading/single reading		A8-0038/2016	24/02/2016	Summary
Text adopted by Parliament, 1st reading/single reading		T8-0076/2016	09/03/2016	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00005/2016/LEX	11/05/2016	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2014)0319 	28/05/2014	Summary
	COM(2014)0737		

Commission document (COM)		16/12/2014	
For information	SWD(2016)0124	07/04/2016	
For information	SWD(2016)0125	07/04/2016	
Follow-up document	COM(2016)0785	09/12/2016	Summary

Additional information		
Source	**Document**	**Date**
European Commission	EUR-Lex	

Final act	
Regulation 2016/0793 OJ L 135 24.05.2016, p. 0039	Summary

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

2014/0165(COD) - 24/02/2016 - Committee report tabled for plenary, 1st reading/single reading

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

2014/0165(COD) - 28/05/2014 - Legislative proposal

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

2014/0165(COD) - 09/03/2016 - Text adopted by Parliament, 1st reading/single reading

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

2014/0165(COD) - 11/05/2016 - Final act

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 Regulation’s 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

2014/0165(COD) - 09/12/2016 - Follow-up document

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.