Basic information

2018/0161(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Supplementary protection certificate for medicinal products Amending Regulation (EC) No 469/2009 2008/0126(COD) **Subject** 3.50.01.05 Research specific areas 3.50.16 Industrial property, European patent, Community patent, design and pattern 4.20.04 Pharmaceutical products and industry 6.20.05 Multilateral and plurilateral economic and trade agreements and relations	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs	DE GRANDES PASCUAL Luis (PPE)	24/09/2018
	Shadow rapporteur WÖLKEN Tiemo (S&D) ZŁOTOWSKI Kosma (ECR) CAVADA Jean-Marie (ALDE) CHRYSOGONOS Kostas (GUE/NGL) REDA Felix (Verts/ALE) BOUTONNET Marie-Christine (ENF)	

Committee for opinion	Rapporteur for opinion	Appointed
INTA International Trade	SÁNCHEZ CALDENTEY Lola (GUE/NGL)	20/06/2018
ENVI Environment, Public Health and Food Safety	WÖLKEN Tiemo (S&D)	26/06/2018
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	

Council of the European Union	**Council configuration**	**Meetings**	**Date**
	Agriculture and Fisheries	3689	2019-05-14

European Commission	**Commission DG**	**Commissioner**
	Internal Market, Industry, Entrepreneurship and SMEs	BIEŃKOWSKA Elżbieta

European Economic and Social Committee

Key events

Date	Event	Reference	Summary
28/05/2018	Legislative proposal published	COM(2018)0317	Summary
02/07/2018	Committee referral announced in Parliament, 1st reading		
23/01/2019	Vote in committee, 1st reading		
23/01/2019	Committee decision to open interinstitutional negotiations with report adopted in committee		
29/01/2019	Committee report tabled for plenary, 1st reading	A8-0039/2019	Summary
30/01/2019	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 72)		
11/02/2019	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 72)		
26/02/2019	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	GEDA/A/(2019)002691 PE637.374	
16/04/2019	Debate in Parliament		
17/04/2019	Decision by Parliament, 1st reading	T8-0401/2019	Summary
17/04/2019	Results of vote in Parliament		
14/05/2019	Act adopted by Council after Parliament's 1st reading		
20/05/2019	Final act signed		
20/05/2019	End of procedure in Parliament		
11/06/2019	Final act published in Official Journal		

Technical information

Procedure reference	2018/0161(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation (EC) No 469/2009 2008/0126(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 114

Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	JURI/8/13264

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE629.542	30/10/2018	
Committee opinion	ENVI	PE627.040	27/11/2018	
Amendments tabled in committee		PE630.706	28/11/2018	
Committee opinion	INTA	PE628.707	05/12/2018	
Committee report tabled for plenary, 1st reading/single reading		A8-0039/2019	29/01/2019	Summary
Text agreed during interinstitutional negotiations		PE637.374	20/02/2019	
Text adopted by Parliament, 1st reading/single reading		T8-0401/2019	17/04/2019	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2019)002691	20/02/2019	
Draft final act	00052/2019/LEX	20/05/2019	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2018)0317	28/05/2018	Summary
Document attached to the procedure	SWD(2018)0240	28/05/2018	
Document attached to the procedure	SWD(2018)0241	28/05/2018	
Document attached to the procedure	SWD(2018)0242	28/05/2018	
Commission response to text adopted in plenary	SP(2019)440	08/08/2019	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_CHAMBER	COM(2018)0317	11/09/2018	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES3800/2018	19/09/2018	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Regulation 2019/0933
OJ L 153 11.06.2019, p. 0001 Summary

Supplementary protection certificate for medicinal products

2018/0161(COD) - 28/05/2018 - Legislative proposal

PURPOSE: to amend Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

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: a **supplementary protection certificate** (SPC) is an intellectual property right available in EU Member States that extends by up to five years the legal effects of a reference patent on a medicinal product that has been authorised by national or European regulatory authorities. A harmonised SPC system is sought to compensate for the loss of effective patent protection due to the time required in order to obtain marketing authorisation (including research and clinical trials). The EU legislation applicable to SPCs on medicinal products is Regulation (EC) No 469/2009.

Reliance on SPC protection is significant and increasing. At the same time however, EU and global pharmaceutical markets are undergoing profound changes. Global demand for medicines has increased massively.

Alongside this, there is a shift towards an ever-greater market share for generics and biosimilars.

Although the EU has been a hub for pharmaceutical research and development (R&D) and production, its competitive position is under threat today. While Europe's trading partners are increasingly involved in the manufacturing of generics and biosimilars, EU-based manufacturers of generics and/or biosimilars face a significant problem: during the SPC period of protection of the product in the EU, they cannot manufacture for any purpose, including export outside the EU to countries where SPC protection has expired or does not exist, while manufacturers based in those non-EU countries can do so.

This competitive disadvantage entails a risk of delocalisation of manufacturing outside of Europe, loss of investment opportunities, and a brake on further innovation and job creation in Europe. The certificate also makes it more difficult for EU manufacturers to enter the EU market immediately after its expiry, given that they are not in a position to build up production capacity until the protection provided by the certificate has lapsed.

The Commission proposed to amend the Union's legislation on Supplementary Protection Certificates for medicinal products by introducing a so-called **manufacturing exemption for export purposes** (manufacturing waiver).

In its resolution of 26 May 2016 on the single market strategy, the European Parliament endorsed the need to take action on the EU SPC regime and urged the Commission to introduce and implement by 2019 **an SPC manufacturing waiver** to boost the competitiveness of the generics and biosimilars sector, but without undermining the market exclusivity granted under the SPC regime in protected markets.

IMPACT ASSESSMENT: the preferred option is the introduction of a targeted and narrow exception to Regulation (EC) No 469/2009. This option is expected to enhance the competitiveness of EU-based generic and biosimilars manufacturers in terms of exports during the SPC term, resulting in

additional net sales of EU pharmaceuticals of up to EUR 1 billion per year. EU patients and health authorities would benefit from a strengthened and more timely supply of medicines (e.g. in terms of diversification of the supply). Additional savings to public spending in Member States on pharmaceuticals, potentially of the order of upwards of 4%, could materialise from increased competition between generics and biosimilars manufacturers in EU markets following SPC expiry in the Union.

CONTENT: the Commission proposes a targeted amendment to Regulation (EC) No 469/2009 on the supplementary protection certificate for medicinal products.

Concretely, the proposal:

- **it introduces an exception**, to enable manufacturers of generics and biosimilars to manufacture such medicines for the purpose of exporting them outside the EU during the SPC protection term. This waiver will remove the competitive disadvantages EU-based manufacturers of generics and biosimilars are currently facing. This proposal leaves SPC protection fully intact as regards placing products on the EU market. SPC holders will keep their market exclusivity in Member States during the full SPC protection term;
- **provides for 'anti-diversion' safeguards**, notably a requirement to notify, *ex ante*, such manufacturing to independent national public bodies (which will hold the relevant information in a publicly accessible register) along with labelling requirements for products that are exported and due diligence requirements on the manufacturer vis-à-vis persons in its supply chain;
- **makes the exception subject to the following conditions**: the exception will apply only to SPCs that have not yet been granted, and only after a transitional period to accommodate pending applications. This transition will allow market players to take account of the new situation when making investment decisions. It will also give national authorities enough time to set up their arrangements for receiving notifications of the intention to make use of the manufacturing waiver.

Supplementary protection certificate for medicinal products

2018/0161(COD) - 29/01/2019 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Legal Affairs adopted the report by Luis de GRANDES PASCUAL (EPP, ES) on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

As a reminder, the Commission proposal aims to amend Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate (SPC) for medicinal products, with the aim of introducing the so-called 'export manufacturing waiver to SPC', thanks to which, in the future, EU-based companies will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the certificate, if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows.

Objective

The amendments introduced clarify that only exports to third countries outside the Union would be covered by the exception and define more precisely the objectives that this proposal should achieve, namely to promote the competitiveness of generics and biosimilars producers in the Union, to enhance growth and job creation in the internal market and to contribute to a wider supply of products under uniform conditions.

This should enable producers to compete effectively on third country markets where complementary protection does not exist or has expired and to ensure EU-Day1 Entry of generic and biosimilar medicines into the Union market after expiry of the relevant supplementary protection certificate.

The amending Regulation would aim to eliminate the unintentional effects of a supplementary protection certificate, but not to the detriment of any other patent or intellectual property right existing in a Member State, so as to allow making of generic products, biosimilars and active ingredients for the purpose of export to third countries and of entry into the Union market immediately after expiry of the relevant supplementary protection certificate.

Information to authorities and SCP holders

Manufacturers would be required to provide certain information to the authority that issued the SPC in the Member State where manufacture is to take place. The manufacturer established in the Union should check that there is no protection or that it has expired in the exporting country, or that it is subject to limitations or exemptions in that country. To this end, Members have inserted a new standard form for notification to the authority in Annex I of the proposal.

In order to ensure a more robust and transparent implementation of the safeguards provided for in the Commission's proposal, Members introduced an additional requirement to inform directly the SPC holders of the intention to manufacture a product under the exception.

This obligation is without prejudice to the protection of confidential or commercially sensitive information and aims at ensuring that the SPC holders have access to the necessary information in order to assess whether the conditions to benefit from the exception are respected and there are no infringements of their intellectual property rights.

Manufacturing acts would only fall within the scope of the exception if the manufacturer (i) has sent a notification to the competent industrial property authority of the Member State of manufacture and (ii) has informed the holder of the issued supplementary protection certificate of the name and address of the manufacturer and the number of the certificate in the Member State at the latest three months before the date of commencement of manufacturing in the Member State concerned.

Combating diversion

Members specified that the Regulation should not affect the rules on the unique identifier provided for in Commission Delegated Regulation (EU) 2016 /161.

In the case of products manufactured for export to third countries, the manufacturer should ensure that a logo, in accordance with the model set out in Annex - I bis, is affixed to the outer packaging of the product or medicinal product.

Application

The exception provided for in the Regulation should only apply to certificates for which the basic patent expired on or after 1 January 2021. The date in question takes into account the need to provide for a sufficiently long transitional period to ensure that holders of supplementary protection certificates are not deprived of their acquired rights. The Regulation should not have any retroactive effect.

Supplementary protection certificate for medicinal products

2018/0161(COD) - 17/04/2019 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 572 votes to 63, with 22 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Derogation for the supplementary protection certificate for medicinal products (SPC)

The amendments to Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the Supplementary Protection Certificate (SPC) for medicinal products shall aim to boost the competitiveness of European producers of generic medicinal products and biosilimar products by introducing an exception for manufacturing for export purposes (manufacturing waiver) to the protection granted to an original medicine by a supplementary protection certificate (SPC).

Thanks to the waiver, EU-based makers of generics and biosimilars will be entitled to manufacture a generic or biosimilar version of an SPC-protected medicine during the term of the SPC if done exclusively for the purpose of exporting to a non-EU market where protection has expired or never existed.

This Regulation shall also allow such makers to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired ('EU day-one entry').

Information to authorities and SPC holders

The exception shall apply if:

- generics or biosimilars are produced exclusively for export to third countries where protection of the original medicine does not exist or has expired or for storage purposes during the last six months before the expiry of the certificate;

- the maker has provided the information required by the regulation to both the authorities of the member state of production and to the holder of the SPC at least three months in advance;

- the maker has duly informed all those involved in the commercialisation of the product covered by the exception that the product can be put on the market only outside the EU;

- the maker has affixed to the packaging of the product the specific logo provided for by the regulation indicating clearly that it is only for export.

The information to be provided by the maker shall be as follows:

- the name and address of the maker;

- an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

- the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

- the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making;

- for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

The information provided to the certificate holder shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

Application

Until 1 July, 2022, the amending regulation will affect only SPCs that are applied for on or after the date of entry into force of the regulation. From then on, the regulation will also affect SPCs applied for before the entry into force of the regulation, but which have become effective after the entry into force of the regulation.

Supplementary protection certificate for medicinal products

2018/0161(COD) - 11/06/2019 - Final act

PURPOSE: to stimulate the competitiveness of European producers of generic medicines and biosilimentaires products.

LEGISLATIVE ACT: Regulation (EU) 2019/933 of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

CONTENT: this Regulation amends Regulation (EC) No 469/2009 in order to remove the competitive disadvantages faced by generic and biosimilar manufacturers established in the EU compared to manufacturers established outside the EU on world markets.

Supplementary Protection Certificates (SPCs) are intellectual property rights that extend (by a maximum of five years) the patent protection of medicines that require extensive testing and clinical trials before they are allowed to be placed on the EU market. SPCs may put producers of generic and biosimilars medicines established in Europe at a disadvantage compared to companies established in third countries, which undermines innovation and job creation in Europe.

Indeed, during the SPC period of protection of the product in the EU, EU-based manufacturers of generic and/or biosimilar-related products cannot currently manufacture for any purpose, including export outside the EUto countries where SPC protection has expired or does not exist, while manufacturers based in those non-EU countries can do so.

Derogation for the supplementary protection certificate for medicinal products (SPC)

The Regulation introduces an exception to the protection granted to an original medicinal product by a protection certificate for export and/or storage purposes.

The aim of this Regulation is to promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of generics and biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets.

This Regulation shall also allow such makers to make and store products, or medicinal products containing those products, in a Member State for a defined period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired (‘EU day-one entry’).

Effects of the certificate

Waivers shall only apply if:

- generics or biosimilars are produced exclusively for export to third countries where the protection of the original medicinal product does not exist or has expired or for storage purposes during the last six months of the CCP's validity;

- the maker, through appropriate and documented means, notifies the authority in the Member State in which that making is to take place, and informs the certificate holder, of the required information no later than three months before the start date of the making in that Member State,

- the maker has duly informed all parties involved in the marketing of the product;

- the maker has affixed to the packaging of the product the specific logo provided for in the Regulation, which clearly indicates that the product is intended solely for export to third countries

Information to be provided

The information to be provided by the maker shall be as follows:

- the name and address of the maker;

- an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

- the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

- the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; and

- for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

The information provided to the certificate holder shall be used exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance.

Member States may require that the certificate be subject to the payment of annual fees.

Application

Until 1 July, 2022, the amending regulation will affect only SPCs that are applied for on or after the date of entry into force of the regulation. From then on, the regulation will also affect SPCs applied for before the entry into force of the regulation, but which have become effective after the entry into force of the regulation.

ENTRY INTO FORCE: 31.6.2019.