

SPC Manufacturing Waiver Note

What is an SPC?

In the EU, a Supplementary Protection Certificate (SPC) extends the protection of patented medicines by up to 5 years to compensate the time lost in obtaining regulatory approval of the medicine. During this period European manufacturers of generic and biosimilar medicines cannot produce their medicines in the EU.

Why do we need an SPC Manufacturing Waiver?

Manufacturers based in non-EU countries where SPC protection does not exist (e.g. in Canada, Brazil, Russia, India and China), or where protection is shorter in duration, can enter unprotected markets up to five years earlier than is possible for EU-based manufacturers.

The unintended consequence of the SPC Regulation is that it prevents EU-based generic manufacturers from producing during the period of SPC protection of the reference medicine for export to unprotected markets. In particular, this situation prejudices competitiveness of EU companies in the US market, where patents and patent extensions will, in most cases, expire earlier than in the EU due to the more rapid introduction of new medicines. This is the case with major biological products as well as chemical molecule products, as shown in the tables included in the annex.

In addition, this situation gives an unintended lead time advantage to non-EU based operators as regards entering the EU Member States generic medicines market immediately upon the SPC protection expiry.

This forces European manufacturers of generic and biosimilar medicines to move their production outside the EU - either via delocalisation or long-term outsourcing contracts (often the only option for SMEs) - to overcome these legal hurdles and to stay globally competitive. EU reliance on foreign-manufactured medicines might be increasing, with the loss of high value jobs in the EU.

An SPC Manufacturing Waiver would fix these unintended side effects of the SPC by allowing developers of generic and biosimilar medicines to produce during the SPC period in order to supply unprotected markets as soon as possible. In no way will it undermine or change the existing IPR equilibrium in the EU.

What is the state of play?

On 28 October 2015, the **European Commission** launched its report entitled '*A Single Market Strategy for Europe - Analysis and Evidence*'¹, where it considers a proposal for a manufacturing waiver during the SPC period in Europe. As stated in the strategy and in line with the policy priorities established by the Juncker Commission, the SPC manufacturing waiver would increase manufacturing and R&D in Europe, create new high skill pharmaceutical jobs and stimulate economic growth in the EU.

¹ https://ec.europa.eu/growth/single-market/strategy_it

On 15 February 2017 the European Commission officially published an Inception Impact Assessment based on the Single Market Strategy of October 2015, '*Optimising the Internal Market's industrial property legal framework relating to supplementary protection certificates (SPC) and patent protection research exemptions for sectors whose products are subject to regulated market authorisations*'.² The SPC manufacturing waiver is a key point in the abovementioned Roadmap. A **Public Consultation** was launched on 12 October 2017 and will be open until 4 January 2018.³ With the Public Consultation, **the Commission published a study on the impact of the SPC Manufacturing Waiver, showing that it would create €9.5 billion additional net sales for the EU pharmaceutical industry, 25.000 additional direct jobs and savings to the EU pharmaceutical spending of €3.1 billion.**⁴

The **European Parliament** called several times on the Commission to rapidly introduce the SPC Manufacturing Waiver: *i.e.* Reports on options for improving access to medicines (Cabezón Ruiz - 2 March 2017); on the Single Market Strategy (Comi– 26 May 2016); on the strategy on IPR in third countries (Mosca - 9 June 2015); on re-industrialising Europe to promote competitiveness and sustainability (Butikofer - 15 January 2014).

The **Council** conclusions on the Single Market Strategy also supported the part of the strategy related to Intellectual Property, highlighting the importance of strengthening competitiveness of the European industry.

What is next?

The European Commission should rapidly introduce the SPC Manufacturing Waiver through a targeted amendment to the SPC Regulation.

The urgency for its introduction derives from the expiry of SPCs of blockbuster products in the next few years. A failure to rapidly introduce the SPC manufacturing waiver would promote the outsourcing of our pharmaceutical industrial base.

The SPC Manufacturing Waiver, being an industrial policy proposal, should remain separate from the other current reviews conducted by the Commission (*i.e.* 1) SPC legal review and 2) pharma incentives review), due to the different natures, purposes and timelines.

² http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_grow_051_supplementary_protection_certificates_en.pdf

³ https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en

⁴ <https://publications.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en>

ANNEX

Comparison of expiry dates of protection worldwide

The table below shows that in 80% of the cases (in yellow), molecules' protections expire in Europe later than in other regions of the world, putting EU manufacturers at competitive disadvantage vis-à-vis non-EU developers.

MOLECULES		EXPIRY DATES					
		EU	USA	KOREA	CHINA	INDIA	CANADA
1.	ABATACEPT	23/11/2022	02/07/2021	02/07/2021	02/07/2021	NA	02/07/2021
2.	ABIRATERONE	15/03/2018	13/12/2016	17/06/2013	Expired	Expired	22/09/2014
3.	ADALIMUMAB	16/10/2018	31/07/2017	04/01/2019	10/02/2017	NA	10/02/2017
4.	AFATINIB	12/12/2026	22/01/2022	09/02/2026	12/12/2021	12/12/2021	12/12/2021
5.	AFLIBERCEPT (EYLEA)	23/05/2025	18/11/2023	23/05/2020	23/05/2020	23/05/2020	23/05/2020
6.	AFLIBERCEPT (ZALTRAP)	01/02/2028	02/12/2025	02/12/2025	02/12/2025	02/12/2025	02/12/2025
7.	ALEMTUZUMAB (LEMTRADA)	16/09/2028	24/08/2029	11/09/2027	11/09/2027	11/09/2027	11/09/2027
8.	ALISKIREN	07/04/2020	21/07/2018	17/01/2018	17/04/2015	Expired	13/04/2015
9.	ALISKIREN, AMLODIPINE	07/04/2020	21/07/2018	13/04/2015	17/04/2015	NA	13/04/2015
10.	ALISKIREN, HYDROCHLOROTHIAZIDE	07/04/2020	21/07/2018	17/01/2018	17/04/2015	NA	13/04/2015
11.	ALOGLIPTIN	15/03/2018	13/12/2016	17/06/2013	Rejected	15/12/2014	15/03/2015
12.	ALOGLIPTIN, METFORMIN	23/09/2028	27/06/2028	28/01/2026	15/12/2024	15/12/2024	15/12/2024
13.	AMBRISENTAN	03/10/2020	29/07/2018	07/10/2015	07/10/2015	Expired	07/10/2015
14.	ANIDULAFUNGIN	18/03/2018	17/02/2020	25/01/2014	18/03/2013	NA	15/03/2013
15.	APREPITANT	13/05/2019	17/04/2015	16/12/2016	13/12/2014	NA	13/12/2014
16.	ATAZANAVIR	04/03/2019	20/12/2017	14/04/2017	14/04/2017	NA	14/04/2017
17.	ATOMOXETINE	28/05/2019	26/05/2017	NA	04/01/2016	Expired	04/01/2016
18.	ATORVASTATIN, EZETIMIBE	15/09/2019	25/04/2017	29/04/2016	14/09/2014	Expired	14/09/2014
19.	BAZEDOXIFENE	16/04/2022	04/04/2017	14/12/2018	18/04/2017	NA	Expired
20.	BELATACEPT	23/05/2026	15/06/2025	23/05/2021	23/05/2021	NA	23/05/2021

21.	BELIMUMAB	15/06/2026	17/07/2023	15/06/2021	15/06/2021	NA	15/06/2021
22.	BEVACIZUMAB	16/12/2019	04/07/2019	03/04/2018	03/04/2018	NA	03/04/2018
23.	BILASTINE	03/06/2022	04/06/2017	NA	04/06/2017	04/06/2017	04/06/2017
24.	BORTEZOMIB	26/04/2019	03/11/2017	28/12/2015	27/10/2015	NA	25/10/2015
25.	BRENTUXIMAB VEDOTIN	25/10/2027	18/01/2025	NA	NA	NA	31/07/2023
26.	CANAKINUMAB	26/08/2028	02/11/2027	24/10/2026	24/10/2026	NA	24/10/2026
27.	CASPOFUNGIN	25/10/2016	26/07/2015	10/03/2014	10/03/2014	NA	10/03/2014
28.	CERTULIZUMAB PEGOL	01/10/2024	13/04/2024	05/06/2021	05/06/2021	NA	05/06/2021
29.	CEFTAROLINE FOSAMIL	17/12/2023	11/04/2022	17/12/2018	17/12/2018	NA	17/12/2018
30.	CINACALCET	26/10/2019	08/03/2018	09/05/2017	23/10/2015	Expired	23/10/2015
31.	CLEVIDIPINE	03/11/2019	05/01/2021	03/11/2014	03/11/2014	Expired	03/11/2014
32.	DABIGATRAN	17/02/2023	28/12/2021	17/07/2021	16/02/2018	12/02/2018	16/02/2018
33.	DARIFENACIN	17/03/2015	13/03/2015	01/11/2011	17/03/2010	Expired	15/03/2010
34.	DARUNAVIR	24/02/2019	09/05/2017	24/08/2013	Expired	Expired	24/08/2013
35.	DASATINIB	22/11/2021	28/06/2020	12/04/2020	12/04/2020	12/04/2020	12/04/2020
36.	DEFERASIROX	02/09/2021	05/04/2019	24/06/2017	24/06/2017	NA	24/06/2017
37.	DENOSUMAB	26/05/2025	19/02/2025	17/04/2025	25/06/2022	25/06/2022	25/06/2022
38.	DERQUANTEL	25/06/2021	27/06/2016	27/06/2016	27/06/2016	NA	27/06/2016
39.	DRONEDARONE	06/08/2011	26/07/2016	08/09/2015	Expired	Expired	24/07/2011
40.	DULOXETINE	11/08/2018	18/01/2015	18/12/2018	17/07/2015	Expired	13/07/2015
41.	ECULIZUMAB	01/05/2020	16/03/2021	01/05/2015	NA	NA	01/05/2015
42.	EFAVIRENZ, EMTRICITABINE, TENOFIVIR DISOPROXIL	03/08/2018	21/11/2013	06/08/2013	06/08/2013	Expired	29/07/2013
43.	EMTRICITABINE, TENOFIVIR DISOPROXIL	24/02/2020	25/01/2018	09/11/2017	25/07/2017	Rejected	25/07/2017
44.	ERLOTINIB	21/03/2020	08/05/2019	30/10/2016	28/03/2016	13/03/2016	06/06/2015
45.	ETRAVIRINE	01/09/2023	13/12/2020	01/12/2019	24/09/2019	24/09/2019	24/09/2019
46.	EVEROLIMUS	19/01/2019	09/03/2020	18/12/2014	Expired	Expired	24/09/2013
47.	EZETIMIBE	18/04/2018	25/04/2017	01/07/2014	01/07/2014	NA	14/09/2014
48.	EZETIMIBE, ROSUVASTATIN	15/09/2019	25/04/2017	29/04/2016	14/09/2014	Expired	14/09/2014
49.	EZETIMIBE, SIMVASTATIN	02/04/2019	25/04/2017	29/04/2016	14/09/2014	Expired	14/09/2014
50.	FESOTERODINE	24/04/2022	11/05/2019	22/08/2020	11/05/2019	25/03/2018	11/05/2019
51.	FINGOLIMOD	18/10/2018	18/02/2019	13/02/2018	NA	NA	13/10/2018
52.	FLUTICASONE	16/01/2023	03/08/2021	19/08/2021	03/08/2021	03/08/2021	03/08/2021
53.	FOSAPREPITANT	28/02/2020	04/03/2019	Rejected	28/02/2015	Expired	28/02/2015
54.	GEFITINIB	04/03/2019	05/05/2017	01/12/2016	23/04/2016	19/04/2016	25/04/2016
55.	GLIMEPIRIDE, PIOGLITAZONE	21/06/2021	19/06/2016	20/06/2016	20/06/2016	NA	20/06/2016

56.	IMATINIB	21/12/2016	04/07/2015	03/06/2013	02/04/2013	NA	01/04/2013
57.	GOLIMUMAB	05/04/2025	03/02/2024	07/08/2021	07/08/2021	07/08/2021	07/08/2021
58.	INSULIN DETEMIR	04/12/2019	16/06/2019	27/01/2016	16/09/2014	16/03/2015	16/09/2014
59.	INSULIN GLARGINE	06/05/2015	12/02/2015	06/02/2016	Expired	Expired	01/04/2014
60.	INSULIN GLULISINE	01/05/2020	18/06/2018	19/06/2018	19/06/2018	18/06/2018	18/06/2018
61.	IPIIMUMAB	24/08/2025	25/03/2025	17/11/2020	24/08/2020	NA	24/08/2020
62.	IVABRADINE	25/03/2018	25/09/2012	Expired	Expired	Expired	25/09/2012
63.	LACOSAMIDE	30/08/2023	19/03/2022	19/03/2022	19/03/2022	NA	Expired
64.	LAPATINIB	12/06/2023	29/09/2020	11/06/2019	08/01/2019	08/01/2019	08/01/2019
65.	LASOFOXIFENE	24/04/2020	09/01/2015	08/01/2016	08/01/2016	21/12/2015	24/04/2015
66.	LENALIDOMIDE	23/07/2022	04/10/2019	24/10/2017	Expired	NA	24/07/2017
67.	LINAGLIPTIN	24/04/2022	24/04/2017	24/07/2017	24/07/2017	NA	24/07/2017
68.	LINEZOLID	16/03/2017	18/05/2015	16/08/2014	16/08/2014	Expired	16/08/2014
69.	MARAVIROC	20/09/2022	06/08/2021	09/11/2021	09/05/2021	09/05/2021	09/05/2021
70.	METFORMIN, SITAGLIPTIN	08/04/2023	26/07/2022	05/07/2022	05/07/2022	05/07/2022	05/07/2022
71.	METFORMIN, VILDAGLIPTIN	05/11/2024	09/12/2019	04/03/2022	09/12/2019	09/12/2019	09/12/2019
72.	MICAFUNGIN	29/09/2020	17/03/2019	06/07/2017	29/09/2015	06/10/2015	29/09/2015
73.	MIRABEGRON	01/01/2028	04/11/2023	20/11/2024	04/11/2023	04/11/2023	04/11/2023
74.	NATALIZUMAB	25/01/2020	16/3/2016	25/01/2015	25/01/2015	NA	25/01/2015
75.	OMALIZUMAB	14/08/2017	30/11/2016	NA	NA	NA	14/08/2012
76.	PALIPERIDONE	02/02/2015	27/04/2010	27/11/2016	NA	NA	16/10/2009
77.	PEGFILGRASTIM	25/08/2017	20/10/2015	08/02/2015	08/02/2015	NA	31/07/2024
78.	PERTUZUMAB	23/06/2025	15/07/2025	23/06/2020	23/06/2020	NA	23/06/2020
79.	POSACONAZOLE	20/12/2019	19/07/2019	10/10/2015	20/12/2014	NA	20/12/2014
80.	PRASUGREL	27/02/2019 ⁵	14/10/2017	24/12/2013	09/09/2012	NA	08/09/2012
81.	PRUCALOPRIDE	16/11/2020	16/11/2015	15/03/2018	16/11/2015	20/11/2015	16/11/2015
82.	RALTEGRAVIR	02/01/2023	03/10/2023	21/10/2022	21/10/2022	21/10/2022	21/10/2022
83.	RANIBIZUMAB	23/01/2022	04/07/2019	03/04/2018	03/04/2018	Expired	03/04/2018
84.	RASAGILINE	12/10/2019	07/02/2017	22/05/2016	22/05/2016	Expired	12/10/2014
85.	RIVAROXABAN	02/10/2023	28/08/2024	03/10/2021	11/12/2020	11/12/2020	11/12/2020
86.	ROFLUMILAST	02/07/2019	27/01/2020	02/07/2019	02/07/2014	Expired	02/07/2014
87.	ROMIPLOSTIM	05/02/2024	19/01/2022	22/10/2019	24/01/2020	NA	22/10/2019
88.	SAXAGLIPTIN	04/10/2024	31/07/2023	12/12/2022	05/03/2021	05/03/2021	05/03/2021
89.	SEVELAMER	10/08/2019	16/09/2014	10/08/2014	Expired	Expired	10/08/2014
90.	SILODOSIN	26/11/2018	30/11/2018	20/01/2016	Expired	Expired	01/12/2013
91.	SITAGLIPTIN	05/07/2022	26/07/2022	01/09/2023	05/07/2022	05/07/2022	05/07/2022

⁵ Market Exclusivity expires on 27/02/19. SPC expires on 10/09/2017.

92.	SOLIFENACIN	16/12/2018	19/11/2018	03/07/2017	27/12/2015	NA	27/12/2015
93.	SONIDEGB	18/08/2030	25/07/2029	04/05/2027	04/05/2027	04/05/2027	04/05/2027
94.	SORAFENIB	21/07/2021	12/01/2020	17/09/2020	12/01/2020	12/01/2020	13/01/2020
95.	SUNITINIB	24/07/2021	15/02/2021	15/02/2021	15/02/2021	Revoked	15/02/2021
96.	T AFLUPROST	22/12/2022	18/12/2022	26/12/2017	26/12/2017	NA	23/12/2017
97.	TEDUGLUTIDE	11/04/2022	14/04/2020	NA	11/04/2017	Expired	11/04/2017
98.	TEMSIROLIMUS	14/04/2020	15/08/2019	14/04/2015	14/04/2015	NA	14/04/2015
99.	TIGECYCLINE	21/02/2018	09/04/2016	21/05/2016	03/10/2012	NA	03/10/2012
100.	TOCILIZUMAB	16/01/2024	30/07/2024	14/02/2023	14/02/2023	NA	14/02/2023
101.	TRABECTEDIN	20/09/2022	28/06/2027	NA	15/05/2020	NA	15/05/2020
102.	TRASTUZMAB + HYALURONIDASE	27/08/2028	12/10/2027	05/03/2024	05/03/2024	05/03/2024	05/03/2024
103.	TRASTUZUMAB EMTANSINE	19/11/2028	02/07/2028	12/10/2024	12/10/2024	12/10/2024	12/10/2024
104.	TULATHROMYCIN	13/11/2018	24/05/2019	27/05/2019	29/05/2018	NA	29/05/2018
105.	VARENICLINE	28/09/2021	10/05/2020	08/02/2021	08/02/2021	NA	13/11/2018
106.	VILDAGLIPTIN	27/09/2022	09/12/2019	04/03/2022	09/12/2019	09/12/2019	09/12/2019
107.	VINFLUNINE	19/07/2019	19/07/2014	Expired	Expired	Expired	19/07/2014
108.	VORICONAZOLE	24/07/2016	24/05/2016	26/09/2011	02/02/2011	25/01/2011	30/01/2011
109.	ZOLEDRONIC ACID	16/05/2013	02/03/2013	10/12/2011	Expired	Expired	25/02/2014

NB: Each pharmaceutical product is covered by several patents. The tables only include expiry dates of substance patents. These include SPC paediatric extensions where applicable.

Sources: Medicines for Europe Company Members