Position Paper
An assessment of the SPC manufacturing waiver proposal

The European Commission on 28 May 2018 launched the legislative proposal for the introduction of the Supplementary Protection Certificate (SPC) manufacturing waiver in the SPC Regulation. The SPC protection extends the market exclusivity of innovative medicines by up to 5 years in order to compensate for the time needed for the approval of the product by medicines agencies. The stated objective of the SPC manufacturing waiver, without touching the market exclusivity granted by the SPC, is to remove the unintended effect of the SPC protection in Europe, which forces the EU pharmaceutical manufacturing industry to invest in the R&D and production of generic and biosimilar medicines out of the EU in order to be able to compete with non-EU producers in non-EU export markets and in the EU market as soon as intellectual property (IP) protections expire.

However, the current text of the proposal does not reflect the positive findings of all the studies published by the European Commission. The current proposal covers production during the SPC period for the purpose of export to non-EU countries only. It does not cover production for EU day-1 launch (*i.e.* launch of generics and biosimilars in EU markets immediately after SPC expiry). The proposal includes anti-competitive, unnecessary and unjustified anti-diversion measures (*i.e.* notification, labelling, due diligence). The manufacturing waiver does not apply to existing SPCs.

As a result, the current text does NOT serve the purpose for which the SPC manufacturing waiver has been conceived for, with negative or no impact on patients, Member States' healthcare budgets and the EU business developments of the generic and biosimilar medicines industry.

Therefore, Medicines for Europe strongly encourages the European Parliament and the Council to work with the European Commission to improve the SPC manufacturing waiver amendment and actually stimulate investments with the three following elements:

- Introduce the "EU day-1 launch"
- Remove anti-competitive, unjustified and unnecessary anti-diversion measures
- Allow an immediate applicability of the SPC manufacturing waiver

Without these three key elements, the SPC manufacturing waiver would be practically impossible to use and would produce no benefits for patients, Member States' healthcare budgets and the generic and biosimilar medicines industry.

Abbreviations:

Impact Assessment	(IA)
Explanatory Memorandum	(EM)
Max Planck Institute Study	(MPI)

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

"EU day-1 launch"

The current text of the EC proposal allows production only for export out of the EU and does NOT cover the production for EU day-1 launch. There is no reason or justification for not allowing a EU day-1 launch together with the possibility to export outside the EU. On the contrary, the EU day-1 launch:

- **Solves one of the two recognised problems for which the SPC manufacturing waiver is proposed:**
  The SPC manufacturing waiver is meant to solve the anti-competitive disadvantage that EU companies face 1) in export markets; and 2) in the EU market on day-1 after SPC expiries, with all the related negative effects on patient access, Member States' healthcare budgets, business investments and jobs.
- **Reduces unjustified delays to access to life-saving medicines for EU patients:**
  All companies producing in the EU would be able to enter the EU market immediately, not weeks or months after the SPC expiry.
- **Doubles the savings foreseen by the Commission in the next years:**
  The Commission's studies and analyses show that by introducing both the export and the EU day-1 launch waiver, the savings for the EU Member States' healthcare budgets would be cumulative: 4% plus 4% respectively: why not aiming at saving 8% annually rather than limiting it to 4%?
- **Increases European investments in R&D and manufacturing sites in Europe:**
  Only with a comprehensive SPC manufacturing waiver would EU companies increase investments in Europe: why should a European company produce in EU for a non-EU market and in a non-EU territory for the EU?
- **Is in line with the *ratio* of the Bolar exemption:**
  The purpose of the Bolar exemption is to allow generic medicines to be approved during the exclusivity period of the innovative medicines in order to be ready to be on the market as soon as protections expire. The public health objective of the Bolar cannot be achieved without the EU day-1 launch.
- **Stimulates originator companies producing biosimilars out of Europe to re-invest in Europe:**
  Several originator companies have invested in R&D and manufacturing of biosimilar medicines out of the EU due to the need to enter the EU market on day-1. The EU day-1 launch would stimulate them to re-invest in R&D and manufacturing in Europe.
- **Removes the unintended anti-competitive delays faced by European manufacturers on the EU market:**
  The fact that EU companies need to produce generic and biosimilar medicines out of the EU in order to be competitive vis-à-vis non-EU producers has a strong anti-competitive effect on SMEs that have no resources to outsource production out of the EU. Being immediately on the market with a generic or biosimilar medicine is fundamental in a very competitive sector.
- **Addresses the unintended effects of the longest protection worldwide:**
  In 80% of the cases, SPCs expire in Europe later than US, CHINA, JAPAN, CANADA, KOREA etc. As a result, EU generic developers are forced to produce abroad. Europe is losing year after year R&D and manufacturing sites to third countries.
- **Is compatible with the CETA, TRIPs and other FTAs:**
  The EU-Canada CETA allowed Canada to introduce an SPC export waiver. Differently from Europe, Canadian generic companies can also produce for day-1 launch in Canada under their broader Bolar. Nothing in the CETA prevents Europe from introducing "EU day-1 launch". EU FTA provisions contain an obligation for the EU and its partners to enact SPC protection while leaving a certain degree of freedom on how to implement it in practical terms. EU trading parties cannot legitimately claim that the

introduction of a comprehensive SPC manufacturing waiver in EU legislation would contravene FTA provisions because of the *sui generis* nature of the SPC protection.

<u>The studies published by the European Commission include NO argument or figure against the EU day-1 launch. On the contrary, **the EC provided data, figures and arguments only in support of the EU day-1 launch**</u>:

- The EC clearly recognises in the Impact Assessment (IA) "*two specific problems, (a) the **loss of export markets due to delayed entry** and (b) delayed entry onto EU markets, that **decrease the competitiveness of EU-based manufacturers of generics and biosimilars***." And that "***[a]n SPC manufacturing waiver for both export and stockpiling purposes would address both identified problems***". (IA, p. 42)
- The IA clearly states that being immediately on the market is fundamental in such a competitive sector: "***the market for generics and biosimilars is highly competitive with a strong 'first mover' effect (i.e. a clear advantage for the first mover) both in the export and EU markets***". (IA, p. 17) Also: "***For biosimilars, studies show that in 2016, the first biosimilars to reach the market captured over 70% market share***". (IA, p.18) The EC also states that "***only the first few generics/biosimilars to enter the market capture a significant market share and are financially viable***". (EM, p. 3)
- The IA shows that "***originators tend to increasingly manufacture biosimilars and generics outside the Union, and notably in Canada, the USA and Asia***." (IA, p.12) Therefore, these originators will be able to enter the EU market on day-1, but from out of Europe. Without a manufacturing waiver for EU day-1 launch, EU generic and biosimilar companies would be incentivised to do exactly the same. With a manufacturing waiver for EU day-1 launch "***[o]riginators will also create jobs for their biosimilars activities in the EU and can benefit from this option***." (IA, p. 46)
- The EC states that allowing EU day-1 launch is in line with "***the Bolar exemption [that…] was intended to ensure that a generic could enter the market as soon as possible after the expiry of patents/SPC protection***." It continues: "***The absence of an SPC manufacturing waiver, in practical terms, results in unduly extending SPC protection beyond its legal term. This is detrimental to the day-1 entry of generics/biosimilars onto the EU market***". (IA, p.15)
- In terms of *ACCESS*, the IA maintains that "***[p]atients in a certain Member States were not able to access to certain treatments until a biosimilar is available. Therefore, limiting the day-1 entry capacity for EU biosimilars in those Member States could make a difference for some EU patients***" (IA, p. 23), also because "***[p]atients […] would enjoy additional sources of supply of medicines with this stockpiling waiver***". (IA, p. 41) Indeed, "***[p]atients and doctors favoured an SPC manufacturing waiver on the ground that it would promote early competition in the market, and thus more affordable medicines***". (IA, p. 37)
- In terms of *SAVINGS*, in the comparison of the impacts of policy options the EC states:
    - With an SPC manufacturing waiver for EXPORT only, patients "***would enjoy some improvement in better timely access to generics/biosimilars of high EU-made quality, and therefore a more diversified source of supply***". (IA, p. 46) "***Additional savings to public spending […] of the order of upwards of 4%***". (EM, p. 12)
    - An SPC manufacturing waiver for STOCKPILING, "***would result in savings on pharmaceutical expenditure from this earlier competition and therefore lead to a speedier reduction of prices in Member States upon expiry of the SPC***" (IA, p. 41) and "***savings on pharmaceutical expenditure would amount to EUR 1.1bn over a three-year period for the sample examined, due to the faster decline in prices, corresponding to a 4% saving***". (IA, p. 41)

- With an SPC manufacturing waiver for EXPORT & STOCKPILING, the impacts of previous options "***would be cumulative***". "***Estimated savings on public health budgets expenditure on pharmaceuticals of up to 8%***". (IA, p. 47)

- In terms of *JOBS*, the IA states that only a manufacturing waiver for both EXPORT & EU DAY-1 LAUNCH would produce "***an increase of 20 000 – 25 000 direct jobs***" (IA, p. 47) and that the impacts of export and EU day-1 launch "***would be cumulative***" (IA, p. 47), *i.e.* would double up.
- In the IA, the EC explained that it considered also the option of "***cutting down the duration of the SPC***" (IA, p. 28), but the EC excluded this option because: *1.* this would "***affect the current period of exclusivity***" (IA, p. 28); *2.* this "***would not solve the issue of timely* day-1 *entry onto the EU market***" (IA, p. 28). After excluding this option, not introducing the EU day-1 launch would be contradictory.
- According to the EC, "***[t]his stockpiling waiver would also support EU generics/biosimilars manufacturers that are only interested in selling within the EU. In this regard, 3,372 pharmaceutical SMEs manufacture in the EU, 1,765 of those SMEs export, and 1,362 of them export outside the EU***." (IA, p. 41). However, the EC decided to propose an export waiver only, justifying it by saying that exporting SMEs "***might be able, after SPC expiry, to use the same manufacturing capacity (or scale it up) with a view to swiftly supplying the EU market***", and recalls "***that 1 362 EU-based pharmaceutical SMEs already export outside the Union***" (IA, p. 48)
- "***would be especially beneficial for EU SMEs manufacturing generics or developing biosimilars, because they do not necessarily have access to the necessary funding or skills to outsource or delocalise production outside the EU***" (IA, p. 42)
- From a purely *LEGAL* perspective, the MPI study confirms that "***neither the production for export, nor the production for stockpiling purposes run counter to the legal objectives of the SPC system***", and "***arguably the only effect of prohibiting stockpiling would be to boost the business opportunities of non-EU companies to the disadvantage of generic manufacturers established here.***" (MPI, part 3, section 15.3.7.3)
- With regard to the objectives of the SPC regulation, the MPI also states "***that the expectation expressed by the historical lawmakers about the impact on (re)location of research centres was somewhat unrealistic from the beginning***". (MPI, part 1, section 2.1.5) It follows that there cannot be any impact of a manufacturing waiver for EU day-1 launch on the originators decision of whether to invest in R&D or not. On the contrary, the only impact on R&D would be to incentivise investments in the EU.

Medicines for Europe strongly believes the European Parliament, the Council of the EU and the European Commission should introduce a comprehensive SPC manufacturing waiver including not only export to non-EU countries, but also the EU day-1 launch, in order to achieve the stated objectives of the SPC manufacturing waiver.

Removal of anti-competitive, unjustified and unnecessary anti-diversion measures

The current text of the legislative proposal includes several anti-diversion limitations accompanying the introduction of the SPC manufacturing waiver. There is no justification for the introduction of unnecessary, unjustified and anti-competitive measures in the SPC manufacturing waiver:

- **There is NO evidence of any risk of diversion within the EU:**
  On average, SPCs are not registered in 8 out of 28 EU MS. Therefore, today, on a daily basis, generics are on EU SPC-free markets while at the same time they cannot enter EU SPC-protected markets. No evidence of any diversion has been provided. Why should this change with a waiver?
- **With a comprehensive SPC manufacturing waiver there is no need to include a special labelling for export:**
  With a legislative proposal covering both export to non-EU markets and EU day day-1 launch there is no need for any special labelling for export. This measure would have a negative impact especially on EU SMEs that would face a huge increase of costs in the manufacturing process.
- **The measures proposed represent a serious risk for the maintenance of fair competition within the sector:**
  The text requires the disclosure of very sensitive and confidential information, *i.e.* date of commencing making the product, names of manufacturers of API and excipients, list of export countries, etc. The disclosure of this sort of information, considered by EU legislation commercial confidential information, would have an extremely anti-competitive effect vis-à-vis any competitor.[1]
- **The introduction of the Falsified Medicines Directive (FMD) traceability system removes any possible alleged risks of diversion:**
  In February 2019 the FMD directive will be in force with the introduction of a system to track and trace all medicines. Therefore, it will remove any possibility to introduce illicit medicines on the market. What justifies the need for any extra measures?
- **The Bolar exemption has shown that no risk of illicit diversion exists within the EU:**
  The use for several years of the Bolar exemption in the EU, which is a form of manufacturing waiver, even during both patents and SPCs, has shown not risk of diversion in the EU.
- **Anti-diversion measures have a strong dissuasive effect on SMEs:**
  SMEs would need to bear the costs of all the administrative requirements, including impactful costs for attorney and additional manufacturing costs.
- **Similar models introduced in the French system or in the EU compulsory license legislation have almost never been used and clearly failed their objectives:**
  The licensing system introduced in France and the EU compulsory licensing systems include a notification system that is very similar to the one proposed in the SPC manufacturing waiver. Due to the burdensome requirements and the complexity of the systems, they have been used extremely rarely and are not considered by the industry a viable mechanism. If the EU needs more investments in medicines production, why then introduce an unworkable system that, if ever used, would have huge anti-competitive effects?

[1] For instance, Directive 2016/943, "Blokestein Directive", EMA guidelines, etc.

In the studies conducted or commissioned by the European Commission there is NO explanation why or evidence justifying the introduction of any anti-diversion or limitative measure. On the contrary, the studies published by the EC show:

- The EC stresses that the originators' "***concerns may […] be overstated, as the economic impact on originators of the introduction of a manufacturing waiver would be minimal (SPC holders maintain full SPC-related market exclusivity in the Union)***" and that "***[d]espite the waiver, the global IPR protection and enforcement framework in the EU would remain the strongest worldwide.***" (IA, p. 35)
- The EC replies to the originators' concerns about a risk of illicit diversion of generics/biosimilars stressing that a "***risk of foreign products being illicitly placed on the EU market is already present today. It is kept at bay by the EU's pharmaceutical legislation and its legislation regarding the enforcement of intellectual property rights***". (IA, p.35)
- The EC notes that "***there is no evidence of illicit diversion resulting from the existence of the 'Bolar exemption' in the EU, which itself if a form of manufacturing waiver for clinical trials purposes (and is available during the term of both patents and SPCs)***". (IA, p. 35)
- The EC recalls that respondents to the public consultation stressed that any risk of diversion is very low, since "***The supply of medicines is highly regulated by the EU acquis on falsified medicines (Directive 2011/62/EU), which includes: - Obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of medicines; - A common, EU-wide logo to identify legal online pharmacies; - Tough rules on the import of active pharmaceutical ingredients; - Strong record-keeping requirements for wholesale distributors***". (IA, p. 37)
- The EC concedes that the Falsified Medicines Directive would not only make a special labelling for export unnecessary, but also remove the alleged risks of diversion. The EC openly admits that "***[t]he labelling measures proposed for option 2-bis above (waiver for export-only purposes with anti-diversion measures) might be unnecessary for this option 3-bis (stockpiling for entry in the EU market) in view of the strict traceability requirements imposed by Directive 2011/62/EU on falsified medicines.***" (IA, p. 41)
- The EC recognises the significant side effects of its anti-diversion measures: "***The design of specific anti-diversion measures would need both to take into consideration the level of additional burden for SMEs […] and to address confidentiality concerns***.". (IA, p. 31) Indeed, it states that the notification requirement "***would create a slight additional administrative burden for generics/biosimilars manufacturers, and might create confidentiality issues if overly detailed information was required from such manufacturers***". (IA, p. 39) It goes further in saying that "***[a]nti-diversion measures in options 2-bis, 3-bis and 4-bis should take account of potentially dissuasive costs for SMEs (additional operational costs (e.g. labelling), the need to contract specialised attorneys (e.g. for potentially complex notification procedures, and court proceedings)***." (IA, p. 42)
- The EC even recognises that such measures "***could potentially have a dissuasive effect regarding the actual use of the waiver***". (IA, p. 39)

Medicines for Europe urges the European Parliament and the Council to work with the European Commission to remove these unjustified, unnecessary, anti-competitive and disproportionate anti-diversion measures from the text that would make the proposal unusable.

Immediate applicability of the SPC manufacturing waiver

The European Commission proposed to apply the SPC manufacturing waiver only to the SPCs granted *after* the entry into force of the amending regulation. This would make the proposal produce its effect not before the next 10-15 years. However:

- **The SPC manufacturing waiver does NOT touch the SPC protection:**
  With the introduction of the SPC manufacturing waiver, the protection granted by the SPC remains fully intact. This would have NO impact on the SPC protection and the SPC holder.
- **Urgency: in 2020 there is a huge 'Patent Cliff' that represents a concrete opportunity for the whole EU:**
  The Commission justifies the introduction of the SPC manufacturing waiver by calculating the benefits on the existing SPCs expiring in the next few years: 25.000 additional direct jobs, €9.5 billion net sales for EU pharma industry, €3.1 billion savings to EU pharma spending and over €90 billion of business opportunities for biosimilars. By applying it to SPCs in 15 years, all these benefits would be lost.
- **Exceptions to IP protections have been already introduced in Europe:**
  Art. 27 of the UPC Agreement introduces exceptions to unitary patent protection with an immediate application on existing patents. The immediate applicability of exceptions is not a new concept.
- **Bolar exemptions applied to existing patents:**
  When the Bolar exemptions was introduced it had an effect also during patents already granted. Why should the EU approach be different in the case of the SPC manufacturing waiver?
- **The SPC protection introduced in 1992 was applied to existing patents, with massive effects on patient access and Member States' healthcare budgets:**
  The introduction of the SPC protection in the EU system on the existing patents had a dramatic effect on patient access (*i.e.* delay of access to generics by up to 5 years) and on healthcare budgets (*i.e.* delay by up to 5 years of price competition).
- **The Charter of Fundamental Rights of the EU is a balance of the rights it protects:**
  The Commission explains that the SPC manufacturing waiver would NOT be applicable to existing SPCs otherwise it would be contrary to Art. 17 of the European Chart of Fundamental Rights (right to property – acquired rights). However, the EC also confirms that the SPC waiver leaves the SPC fully intact. Therefore, art. 17 of the Charter should not be applicable at all. On the contrary, art. 35 of the Charter (right to health care) should guarantee faster and increased access to treatments for European patients, which is what the SPC manufacturing waiver would produce.
- **The evaluation of the effects of the Regulation in 5 years would be a useless exercise:**
  The proposal foresees an evaluation of the effect of the SPC manufacturing waiverin 5 years. However, if the waiver is applicable only to newly granted SPCs, with concrete effects on SPCs starting in 10-15 years, it will be hard to see any effect in 5 years.

The current text excludes the applicability of the regulation also to SPCs already granted and it moves away completely from what stated in the official studies commissioned by the European Commission:

- In the Explanatory Memorandum (EM), the EC justifies the proposal estimating that, with IP expiries, "***over EUR 90 billion of the first generation of* blockbuster *biologics will become open to biosimilar competition by 2020. This will create huge additional opportunities for growth and jobs***" (EM, p.3).

- The EM also states that the proposal "***is projected to generate, over the next 10 years, additional net annual export sales of well in excess of EUR 1 billion, which could translate into 20 000 to 25 000 new jobs over that period***". (EM, p.4)
- The EM even states that "***with the patents or the SPC coming to the end of their term – in the coming years***" this would "***generate significant new market opportunities for generics and biosimilars in particular***". Therefore, "***[u]nless action is taken now, Europe risks missing the opportunities offered by this upcoming 'patent cliff'***". (EM, p.4)
- The EC also states that there is an "***[u]rgent need to tackle the specific problems faced by EU-based generics and bioismilars manufacturers***", and that "***[t]his has been understood by EU's trade partners that recently have been investing in pharmaceutical manufacturing and biosimilars development***". Therefore, the EC concludes that "***[d]oing nothing, or postponing an initiative would, firstly, further weaken the EU pharmaceutical industry (by not allowing it to seize the new emerging opportunities), and secondly, unravel the EU's pioneering-effect competitive advantage in the biosimilar sector in particular***". (IA, pp. 16-17)
- The EC justifies the postponed applicability of the waiver by mentioning the "***legitimate expectations of holders of SPCs***". (EM, p.8) However, in the same EM, the EC stresses very strongly that "***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***". It goes even further by saying that "***it takes account of the interests of SMEs active in R&D for 'original' products, as it leaves the core rights of SPC protection unaffected***". (EM, p.12)

Medicines for Europe believes that the European Parliament, the Council and the European Commission should allow an immediate applicability of the SPC manufacturing waiver to all SPCs, in order to produce the expected economic and healthcare benefits calculated for the next decade.