

Review of the SPC Manufacturing Waiver: a First Industry Report

June 2023

Introduction

The Supplementary Protection Certificate (SPC) is a *sui generis* protection that extends the market protection of patented medicines by up to five and half years (including a paediatric extension) to compensate the time lost in obtaining regulatory approval of medicines. As such, the European Union protection is the longest in the world.

As a policy measure, the SPC proved to produce unintended results: the generic and biosimilar medicines industry was forced to produce medicines outside of Europe, to be able to launch their product in export markets and in the EU immediately at intellectual property (IP) protections expiry. This disadvantaged EU-based manufacturers. To fix this issue, the SPC manufacturing waiver ('SPC Waiver') has been introduced in the EU with Regulation (EU) 2019/933 ('SPC Waiver Regulation').

Due to its transitional provisions, the SPC Waiver Regulation is applicable since 2 July 2022. In February/March 2023, Medicines for Europe conducted a survey with its Member Companies, to gather feedback on the first experiences in the use of the SPC manufacturing waiver. The results of the Medicines for Europe survey described in this Report are a preliminary stock-taking exercise reflecting eight months of practical experience. Already during this period, significant flaws of the SPC Waiver Regulation are manifest. During the further usage of the SPC Waiver Regulation, companies may experience additional flaws and complications.

In a first section ("*Findings*"), we are summarising the main feedback received from the responding Medicines for Europe member companies, leading to clear requests for revision of the SPC Waiver Regulation ("*Policy Recommendations*"). The recommendations remove the obstacles that are today built into the SPC Waiver Regulation, and optimise the practical use of the SPC Waiver, so that it can effectively achieve its stated objectives.

Overall, the SPC Waiver is seen as a step in the right direction, but there is ample consensus that it needs significant improvement in several aspects in order to be able to produce the results it is intended for.

Findings

Findings on the Business Impact of the SPC Manufacturing Waiver

- Usage:

More than half of the 13 responding companies have submitted at least one SPC manufacturing waiver notification in one or more Member States since the regulation was enacted. The use of the SPC Waiver seems to be gradually growing, showing European companies' interest in manufacturing in Europe for **maintaining and re-establishing competitiveness vis-à-vis non-EU industry in European as well as in export markets.**

- Business impact:

The majority of respondents found the SPC Waiver to have a significant impact on their business, with ratings ranging from 6 to 9 on a scale of 1-10. However, almost all respondents are of the opinion **that SPC Waiver in its current version does not achieve the expected results.**

- Reasons for not using the Waiver:

Since the adoption of the SPC Waiver, responding companies reported that they decided to manufacture in Europe 25 products, whereas they have **decided NOT to manufacture in Europe 24 products. The main reason for opting for a non-EU supply were the complexities embedded in the legislation which cause legal uncertainty, unnecessary disclosure of confidential information, unnecessary limitations and the risk of frivolous/abusive litigation** (these obstacles are described in detail in the sections below).

Regarding biosimilars, a respondent reported that **for the production of one biosimilar they opted for a 100% non-EU supply chain due to the too short timelines (6 months) and the storage requirements for production for EU countries, and the disclosure of commercially sensitive information.** In a non-EU country without an SPC, the manufacturing for the EU can start at any time and with no legal uncertainty, or disclosure of commercially sensitive information.

- Effect of not using the Waiver:

The loss of business activity for the EU derived from not using the waiver and investing abroad was estimated by two respondents, with one stating a "low amount of millions" lost, and the other **estimating a transfer of 30% to 80% of production capacities to Europe if certain amendments were made to the current system.**

- Positive effects where the Waiver is used:

Several respondents reported having increased operations (including for small molecule APIs) and investing in new equipment and facilities in Europe. One respondent reported increased business in Europe with higher revenues for one specific product only, and another mentioned the decision to expand or build three EU manufacturing sites, resulting in investments of EUR 600 million, and 300 new manufacturing jobs.

However, some respondents reported they did not increase operations in Europe due to the SPC Waiver, with one stating that the Waiver, in its current form, is not attractive for investments in the EU. These companies expressed dissatisfaction with the legal uncertainties and the unnecessary conditionalities and limitations in the legislation. Some respondents stated they have not elaborated data on the increase of operation in Europe yet. Some preferred not to disclose this information.

Savings for companies triggered by the SPC Waiver have been reported to be up to €10mn. Most companies, however, found it too early to assess the amount of savings, or do not expect savings at all with the current version of the SPC Waiver.

In terms of jobs, 7 companies said the waiver allowed them to create up to 100 new jobs within the EU. One company reported 100-500 new jobs and for the other respondents this information is still unknown.

- **How to increase use and business impact of the Waiver:**

44% of the respondents stated that they would have decided to use the SPC Waiver in the absence of the existing complex conditionalities and limitations for its use. These limitations discouraged them from investing in Europe and led them to choose a non-EU country for manufacturing investments. In detail, uncertainties in the application of the SPC Waiver, the 6 month limitation being too short period for EU Day-one launch, and concerns with disclosing sensitive information were named.

- **How users increase the impact of the Waiver:**

Respondents have made a variety of changes to their manufacturing strategies to improve the impact of the Waiver, such as moving some manufacturing back to the EU (44%), increasing existing manufacturing activity in the EU (44%), starting manufacturing in the EU (33%), moving manufacturing back to countries that frequently have SPCs (11%), setting up a monitoring system for SPCs (33%), and adopting *ad-hoc* business development procedures (11%).

- **Time to fix the issues**

In regard to the 5-year period to revise the regulation and assess if it has achieved its stated objectives, respondents highlighted its huge importance and the need to fix the existing issues already during the first review period (2024). The next possibility (in 2029) would be too late. It was stressed that uncertainties and shortcomings are already evident and should be fixed now to stop further transfer of manufacturing capacities outside of the EU. Some respondents also stressed that the review should be conducted objectively, limiting external influences, which have already affected a regulation that started with the best intentions but ended being almost unusable.

Respondents requested the EU to reduce uncertainties and provide clarifications in the SPC Waiver framework by amending the regulation and in parallel by introducing a broad Bolar exemption, since both measures aim at the same objective: Day-1 competition.

Findings on the Notification System

- **Publication of SPC Waiver notifications:**

Multiple respondents felt very uncomfortable about the national patent office (NPO) publishing the notification that contains commercially confidential information. Some companies stressed that they

prefer not to use the SPC Waiver due to the disclosure of the information. This publication is today contained in recital 14 of the SPC Waiver Regulation.

Particularly commercially sensitive aspects for respondents are: (i) the country of manufacturing, (ii) the third country information, and (iii) the supply chain information (e.g., in relation to country of related acts).

Respondents suggested that **the notification information should only be disclosed to national patent offices (NPOs) and SPC holders, and NPOs should only publish the receipt of a SPC Waiver notification for a given SPC, and not its contents.**

- **SPC holders' responses to SPC Waiver notifications:**

In response to notifications, some respondents were **threatened with legal action to clarify whether the exported goods were considered infringing in the country of destination.**

Some respondents experienced pressure from SPC holders, **despite stipulations not to launch** in the target country before the SPC expiry. Another respondent received a **warning letter and was sued in the country of export named in the notification, but not in the country of manufacturing**, reporting that the notification appeared to be the triggering act for that litigation.

These actions are not conform with the SPC Waiver regulation: information in the notification is allowed to be used exclusively to verify the applicability of the waiver (Art. 5.4), and not to inform a lawsuit in a third country.

Another response from a SPC holder was **threatened judicial action, claiming production under the export waiver was not allowed while IP protection in the export countries is in place.** This interpretation is considered to run against the goal of restoring a global level playing field for makers of generics and biosimilars in and outside the Union.

In some cases, since the costs of a potential lawsuit in the export country were higher than the benefit of producing in Europe, the SPC export waiver was then abandoned, leading to a general disincentive to use the waiver.

In one case related to an API production, **a SPC owner raised unjustified doubts about the effectiveness of a notification submitted by a company, creating uncertainty as to the starting time limits to act under the SPC Waiver.** No further communication confirming/denying that alleged ineffectiveness was received.

- **Terms requiring clarification:**

Half of the responses to the survey expressed concern about the **interpretation of 'maker'**. Two responses highlighted the complexities in determining the "maker" when production is commissioned by one entity but marketed by another. A potential literal interpretation of "on behalf" as meaning "the making must be done purely in the interest of the maker" is seen as insufficient to reflect the complexity of the pharmaceutical manufacturing process.

A respondent highlighted the **difficulties with tracking marketing authorisations** and updating the waiver notification accordingly in different countries for successful products.

The **notification submission process seems to work well for most users, except in cases where full address details of the SPC holder are not available on NPO's registers or in multinational companies' registers.** One company mentioned potential issues with data protection laws in its country. Moreover, it was reported that **foreign SPC holders prefer that generic manufacturers contact their subsidiaries in the EU instead of following the requirement of the waiver to notify the SPC holder, creating legal uncertainty.**

It was suggested that **all national patent offices should provide confirmation of receipt and an indication about the waiver request status, to provide legal certainty** for the user.

The language "**strictly necessary**" ("Making a product or medicinal product containing that product and *any related act strictly necessary...*") in the Art.5.2 (a) (ii) and (iv) has received mixed opinions from respondents. Some believe that it is too restrictive and unclear, while others believe that "necessary" alone would be sufficient. There is **concern that the lack of a clear definition of "strictly necessary" may lead to uncertainty in the supply chain, leading to litigation.**

One reported situation related to API includes the case in which as a result of an analysis made by a customer in a third country, it turned out that the exported API did not meet specification requirements. As it was not certain that this was covered as "related act", the API could not be re-imported to the EU for re-processing by the maker, with a significant loss for the maker.

It is suggested that the design of a supply chain should be dictated primarily by supply chain considerations, and any necessary steps should be considered "related acts", and that "strictly" be deleted from the provisions on related acts.

Findings specifically on EU Day-1 Launch

- **Hurdles to EU Day-1 Launch and the single market:**

Multiple respondents stressed that they **do not find it feasible to launch generic or biosimilar products in the EU on Day-1 after SPC expiry.** This is due to flaws in the SPC waiver (6-months' time limitation, storage requirement, EU countries without SPCs not being addressed), **combined with the lack of a broad Bolar exemption covering also pricing and reimbursement procedures.** This stresses that the revision of the SPC Waiver Regulation and the revision of the general pharma legislation need to be concerted and work synergistically to enable EU day 1 competition.

All respondents agreed that **intra-EU transportation of the products/medicinal products should be allowed under the SPC waiver to make Day-1 market entries possible:** Preparations such as storing the product and transportation take time. **Delaying distribution until Day-1 at the earliest delays market entry in many Member States, which defeats the purpose of the waiver and frustrates the single market.** Some respondents stated that transit of IP protected goods should be allowed anyway, and in case the SPC Waiver did not allow it, the legislation should be amended accordingly.

In response to the argument that the storage limitation was necessary to prevent illicit diversion, some responses argue that not at least, **packaging and labeling (i.e., compliant with the falsified medicines directive rules) would prevent illicit diversion anyway.** Indeed, some **respondents showed surprise about the stated risk of illicit diversion in a highly regulated market like the EU.** According to some respondents, there would be no need for any additional unnecessary internal market restriction: **limiting**

storage to certain countries for not fully justified reasons undermines the EU single market and free movement of goods. It is stressed that pharmaceutical markets are constantly monitored and subject to numerous regulations: **the idea that illicit diversions somehow remain undetected is therefore farfetched and there is no persuasive evidence to the contrary.**

Another respondent underlined that **if the product can be stored anywhere within the Member State of making (as the legislation suggests), there is no reason why the product should not be transported for storage in another Member State, for the sake of the single market.**

Moreover, respondent submitted there could be several interpretations of “Member State of making”, which renders the storage requirement unclear.

Therefore, **the storage limitation of the current SPC Waiver Regulation is unnecessary and should be deleted.**

- **Advantages of non-EU manufacturers:**

Some respondents reported that **manufacturers located in non-EU countries** have an advantage over those in the EU for selling products covered under a SPC, as they do not need to use the Waiver, and don't need to comply with the 6-month time limitation prior to SPC expiry, and can start ramping up production earlier.

It has been stressed that **these limitations have made the SPC Waiver completely unattractive in comparison with using a non-EU manufacturer.** In this context, it was again stressed that production for EU countries without SPC is not addressed under the current SPC waiver scheme. Certain respondents stressed that **for this exact reason they had to outsource production to non-EU third-party manufacturers.** They believe that this goes **blatantly against the purposes of the legislation** and a legislative fix is absolutely necessary to explicitly permit this type of launch. The current SPC Waiver is seen as favoring third-party manufacturers outside the EU for what concerns launch in these EU unprotected Member States, which clearly goes against the original intention of the legislation.

Multiple respondents stressed that the **6-month period for making and storing is insufficient to produce a finished dosage form especially for more complex products.** The length of time required depends on the complexity of the molecule, production process, and manufacturing capacities. For simple molecules or later production steps, 6 months may be enough, but **for complex generics or biosimilars, it is reported not to be sufficient.** It was reported that **if both API and final dosage forms are manufactured under SPC waiver in the EU, the 6-month period is clearly insufficient,** since API manufacture may involve for many molecules up to 10-12 synthetic steps or complex processes and long testing in different sites (for DRX, heavy metals, microbiology, etc.). Therefore, this prevents being on time to produce, test and release the final dosage form. Manufacturing capacity at contract manufacturing organisations (CMOs) for biologics must be booked years in advance, and the mere drug substance manufacture takes alone more than 6 months. This is **particularly detrimental for EU API producers, since, considering the very short timeframe, finished dosage form producers tend to prefer sourcing API from producers in non-EU countries.**

Specifically for biologic products, it was reported that those products are most often sensitive and require sterile manufacture and filling, frozen or cooled transportation, and delicate handling and packaging. Often, they require filling into special vials and assembly into delivery devices. **The pure making of a**

biosimilar molecule from primary structure (most often proteins expressed by genetically engineered cells) **to bulk** (most often the protein in a specific formulation for intravenous or subcutaneous injection) **might require already 9 months**. After that drug substance manufacture, it takes approximately **at least another 3 months to produce the medicinal product** (fill and finish activities, such as sterile filling into vials, labelling and secondary and tertiary packaging, quality testing and assays and release of the batch).

It was **suggested that the 6-months limitation should be deleted, since such limitation is completely unjustified and is contrary to the core purpose of the legislation (i.e. Day-1 launch)**.

- **Problems related to pediatric extensions:**

It is possible that **pediatric extensions (PEs) are granted less than 6 months before SPC expiry**. Some respondents gave specific examples of late-granted pediatric extensions, such as 11 out of 65 PEs in the UK being granted less than 6 months prior to the original SPC expiry date, and two examples in Portugal.

The majority of respondents (83%) believed that if an **SPC pediatric extension** is granted during the 6-month SPC waiver period, generic manufacturers should not be liable for SPC infringement for any acts undertaken under the waiver.

Findings specifically on Export

- **EU countries without SPC not addressed in SPC Waiver regulation:**

Some respondents underlined the fact that **limiting “Export” to third countries** (i.e. non-EU countries), could **exclude from its scope those EU Member States without SPC protection, undermining the purposes of the SPC Waiver when a medicinal product is produced and stored in a Member State with SPC for a EU country without SPC**.

It was reported that an SPC may well be revoked or invalidated in one EU Member State (non-SPC protected EU country) but remains in force in the EU country of making under SPC Waiver. Even in this case, the SPC Waiver arguably does not allow the manufacturer to supply the product to the non-SPC protected EU country.

This puts the EU manufacturer at a competitive disadvantage vis-à-vis non-EU producers (which is the primary issue that the SPC Waiver intends to tackle) and **affects timely access to medicines in the Member State without SPC, undermining at the same time the concept of single market**.

Removing the distinction between “export” and “stockpiling” waiver, and instead providing a single SPC Manufacturing Waiver, would solve the problem.

One situation related to API production was strongly stressed: if an API manufactured under the waiver in an EU SPC protected country needs to be sent to another EU country with no SPC to manufacture the finished dosage form (FDF), innovators have argued that it would not be possible to apply the export waiver because the API will be sent to an EU country (i.e., not exported to a third country as defined in the Regulation). At the same time, it would not be formally possible to request the waiver in that EU country where the FDF is produced, because there is no SPC. **This kafkaesque situation could be solved by including those EU countries with no patent or SPC within the notion of third countries.**

- **Overstepping territoriality of IP rights:**

Some respondents stated that **they were sued and/or threatened to be sued because of the existence in the export country of an SPC-like protection at the moment of start of manufacturing.** In a recent case, litigation was started in Ireland on the basis that the user of the waiver could not actually rely on the waiver because there were patents in force in the US. This has now settled, but it shows that litigation is not just threatened.¹

Respondents stressed that using the SPC manufacturing waiver to prevent production in Europe in light of a protection in a third country is inconsistent with the purposes of the legislation and highlighted that **using the SPC Waiver to enforce in Europe a patent/SPC in place in a non-EU country is abusive/frivolous litigation.** They propose that the wording of Recital 8 be clarified to avoid ambiguity and ensure that the SPC Waiver can be applied fairly without **illegitimately extending in Europe protections that exist in third countries.**

- **Labelling requirements unnecessary:**

While most respondents were able to comply with **labelling requirements for export** to third countries, they stressed the requirement was unnecessary. One respondent mentioned that having a product for Northern Ireland that is compliant with both the SPC Waiver regulation and the Falsified Medicines Directive is impossible (see point on Northern Ireland below). Another respondent mentioned that labeling requirements may contradict national regulatory requirements in some export countries.

Findings on Other Aspects

- **Northern Ireland problem:**

One respondent pointed to conflicting requirements in the SPC Waiver regulation (duty not to apply unique identifiers to product for third countries) and in the Falsified Medicines Directive on the active unique identifier, which requires a unique identifier on product for Northern Ireland. This could be solved by deletion of Art. 5.8.

- **Unnecessary Due Diligence requirements:**

Most companies have not yet faced big obstacles in complying with **due diligence requirements to inform supply chain** actors about potential SPC infringement. However, some companies find the requirement superfluous (since the notification is made public) and impractical, **creating legal uncertainty. The due diligence requirements may be used by SPC holders to force disclosure of commercially confidential information, potentially offering to SPC holders a way to block logistics.** They argue that SPC holders can simply enforce their SPC in case of any infringing act not falling under the SPC Waiver regulation, anyway, without the need for any due diligence. There are also concerns that smaller players such as SMEs in the value chain may be unfamiliar with SPC law and disadvantaged by these measures.

Moreover, there is uncertainty as to the actual “persons in contractual relationship with the maker” that need to be informed in accordance with the due diligence requirement and on how the SPC holder might try to control compliance with the formal requirements set out in the due diligence requirement.

¹ JANSSEN BIOTECH INC -V- AMGEN TECHNOLOGY [IRELAND] UNLIMITED COMPANY 2023/1328 P

Generic/biosimilar companies' confidential or commercially sensitive information on like supply chain or employees needs to be kept confidential at all times.

- **Inflexibility and uncertainty:**

Most respondents have faced or expect to face other issues with the use of the Waiver. These issues include the **lack of flexibility in the use of the Waiver to adapt to companies specificities, , other forms of threat of litigation, especially for smaller companies and SMEs and uncertainty regarding API manufacturing.**

A reported situation is the case in which one small step of production must be carried out in a non-EU CMO due for example to missing technical abilities, which may require some flexibility to export and re-import.

Policy Recommendations

1. Enable effective Day-1 competition in the EU

- The **6-month time limitation** for making products destined for EU Member States (currently in Art. 5.2 (a) (iii)) **must be deleted**. It does not provide any safeguard against phantom illicit diversions and prevents day-1 competition in the EU, especially for complex products, such as biosimilars. It also creates uncertainty in case an SPC paediatric extension is granted while a SPC Waiver is already in use.
- **Allow intra-EU export to EU countries with no SPC in force**. This will help remove a fundamental gap that frustrates the EU single market and the purposes of the SPC Waiver, defeating EU producers' competitiveness vis-à-vis non-EU producers that can actually enter those markets on Day-1. Under the current SPC Waiver legislation, production for those Member States is not addressed.

2. Remove existing discriminations against EU based pharmaceutical manufacturers

- The **aspects of the current SPC Waiver that disadvantage EU based manufactures and distort competition without providing any benefits need to be removed**. These include:
 - The **publication of SPC Waiver notification details** (today Art. 5.5). Non-EU manufacturers are advantaged since their manufacturing and business plans are not published anywhere. Therefore, to tackle anticompetitive disclosure of commercially confidential information, the notification should be sent only to National Patent Offices and SPC holder, and only a receipt of notification should be published.
 - The **unnecessary "Due Diligence requirements"** (today Art. 5.9), to avoid that SPC holders forces disclosure and obtains access to highly commercially sensitive information throughout the whole supply chain and open the doors to potential abuses. Today, this potentially makes the makers and their contractual partners, which are often SMEs, a target for unnecessary litigation.
 - The **notification of marketing authorisation numbers in third countries** (today Art. 5.5(e)), which today is used for unnecessary litigation or threat of litigation.
 - The **unnecessary "labelling requirements"** (today Art. 5.2 (d)).
- Additionally, the **European Commission should clarifying**:
 - That **third country IP right status is of no relevance for the EU SPC Waiver**, since otherwise this would illegitimately extend in Europe protections that exist in third countries and open the doors for abusive litigation or threatened litigation especially against SMEs.
 - Safeguards against **abusive litigation**, with concrete examples of abusive litigation and a **mechanism for competition authorities to monitor litigation or threatened litigation** in relation to the SPC Waiver.
 - Limited exemptions to **re-importing due to technical reasons**.

3. Remove barriers to free movement of goods in the EU single market and ensure equitable access in the EU

- The EU needs a **single SPC manufacturing waiver** without differentiation between “export” and “stockpiling” waiver, and **without any limitations regarding storage and intra-EU transportation, which today prevent Day-1 launch** and timely access in some Member States frustrating the EU single market rule.
- There needs to be **no specific requirements on the unique identifier** (today Art. 5.8), which are redundant (the Falsified Medicines Directive (2011/62/EU) and the Commission Delegated Regulation (EU) 2016/161 apply in any case) and are at odds with the regulatory requirements for Northern Ireland.

How these policies need to be implemented in 2024

- **Fix the SPC Waiver in 2024**: the legislators should seize the earliest opportunity to fix the apparent flaws in the current SPC Manufacturing Waiver legislation, *i.e.* immediately after the first review period, in 2024. Waiting further would mean losing further business investments in Europe.
- **One legislation design instead of a patchwork**: this timing provides the unique opportunity to craft a “one-design”, coherent EU legislation on pharmaceuticals. It coincides with the EU Pharma legislation reform, which contains many other policies with the same objective, *i.e.* Day-1 competition (*e.g.*, the clarification of the EU Bolar exemption in the revised directive on human use medicines). It also coincides with the recasting of the relevant EU SPC law with Proposals for regulations on supplementary protection certificates as part of the IP Action Plan.
- **Regulations: the relevant Articles on the SPC Waiver in the relevant Regulations should be amended in 2024**, to facilitate application of the SPC Waiver in practice, and to reduce the likelihood of unnecessary abusive litigation in the Member States.