Review of the SPC Manufacturing Waiver: a 2026 Industry Report

Updated in June 2026

Executive Summary

The Supplementary Protection Certificate (SPC) Manufacturing Waiver Regulation is applicable since 2 July 2022. The SPC Waiver has been introduced with the objective to remove the competitive disadvantage that European manufacturers of generic and biosimilar medicines are facing vis-à-vis third countries' manufacturers, which can start manufacturing generics and biosimilars earlier due to shorter IP protection periods.

This Report, based on the feedback of EU generic and biosimilar companies that have had experience in the use of the SPC Waiver, offers an updated, industry- perspective of the practical implications of the main requirements of the SPC Waiver. It shows, in particular, that while the use of SPC Waiver has increased since 2023 and certain companies have been able to launch products successfully or shift production to Europe, the overall uptake remains limited. Many manufacturers continue to avoid using the SPC Waiver due to legal uncertainty, operational constraints, and risks of abusive litigation. The SPC Waiver, in its current form, is not considered to be completely suitable for removing the obstacles it was meant to remove and it also failed to generate all the both tangible manufacturing and export opportunities it could potentially have generated.

The 2026 Medicines for Europe Survey confirms and deepens the concerns already expressed in 2023, 2024 and 2025. Many generic and biosimilar companies reported being directly threatened with legal action or faced actual lawsuits after submitting waiver notifications. Ambiguities and complexities in the interpretation of the Regulation's language have created opportunities for SPC holders to misuse safeguards to deter waiver use. Moreover, concerns over disclosure of confidential information, unnecessary and unreasonable short timelines for EU Day 1 launch, especially for biosimilars' manufacturing, and the treatment of EU Member States without SPC protection remain unresolved.

At the same time, despite all these challenges, the SPC Waiver has allowed some companies to make investments to start or expand manufacturing in Europe, create jobs, and invest in production sites. Some companies also decided to relocate some of their manufacturing activities back to EU. However, a number of companies reported cancelling or diverting manufacturing plans to non-EU countries due to the waiver's design flaws. Key examples cited include inability to complete biosimilar production in six months, exposure

to litigation simply for naming a Marketing Authorisation (MA), or being discouraged by unclear storage and labelling requirements.

Other companies, instead, made no adjustments to the existing manufacturing or investment strategies because the SPC Waiver Regulation was not considered sufficiently impactful due to the obligations and requirements laid down.

As a consequence, the **following recommendations** are put forward in order to improve the SPC Manufacturing Waiver. Due to the urgency expressed by generic and biosimilar medicines investors, **the European Union should correct immediately the evident SPC Manufacturing Waiver issues in currently negotiated legislative acts, such as the Biotech Act**. These recommendations should also be implemented **in the Regulation** as a result of the **5-year review required by the Regulation and that, while originally foreseen for 2024, has not yet taken place. There is now a clear expectation that it will be carried out in 2026, offering a critical opportunity to address the well-documented flaws that are undermining the effectiveness of this policy tool**. In addition, the Report stresses the need to rapidly issue a Guideline/Notice to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders:

1. **<u>Enable effective Day 1 competition in the EU & Remove barriers to free movement of goods in the EU single market, ensuring equitable access in the EU</u>**

- 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, for which it appears to be simply unrealistic. As shown in the table at page 8, this has a direct impact on imports of biosimilars into Europe. It also creates uncertainty in case an SPC paediatric extension is granted while a SPC Waiver is already in use. A differentiation between the export waiver and the EU storing waiver has resulted to be artificial and inconsistent with the way the EU manufacturing industry works. As stressed also by EFPIA in the European Parliament (SANT) Hearing on "*Overreliance on imports of Active Pharmaceutical Ingredients (APIs)*" of 29 February 2025, **API manufacturing alone takes at least 12 months**.
- The EU needs **a single SPC manufacturing waiver** without artificial differentiation between "export" and "stockpiling" waiver, and **without any limitations regarding storage (as currently included in the "stockpiling" waiver) and intra-EU transportation**, **which today prevent Day-1 launch** and timely access in some Member States frustrating the EU single market rule.
- **Explicitly 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. <u>Remove existing discriminations against EU based pharmaceutical manufacturers</u>

- **The aspects of the current SPC Waiver that disadvantage EU based manufacturers and distort competition without providing any benefits <u>need to be removed</u>**. These include:
  - The **notification** (Art. 5.2.(b)(c)). Today this is used as a trigger for unnecessary litigation or threat of litigation, raising questions about what should be considered 'abusive litigation'. Non-EU manufacturers are advantaged since they do not need to notify the SPC holder and there is no disclosure of their manufacturing and business plans.
  - The **unnecessary "Due Diligence requirements"** (Art. 5.9), to avoid that SPC holders force disclosure and obtain 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. In addition, this unnecessary safeguard discourages manufacturers intending to produce in the EU, due to the risks of unnecessary litigation that outside of Europe would not exist.
  - The **unnecessary "labelling requirements"** (Art. 5.2 (d)).
  - The **misleading reference to the IP status in third countries** (Rec. 42 & 44), which is an extraterritoriality matter. In order to avoid further unnecessary and frivolous litigation on this issue it is necessary to remove the misleading references in the legislation to "countries in which protection does not exist or has expired"', which have been relied on by SPC holders to create confusion. Such a reference was introduced to highlight that while in Europe there would be a longer protection due to the SPC, in other regions there may be shorter protection that cause a competitive disadvantage.
- Additionally, **due to the legal uncertainty as to the interpretation, application of and obligations under the SPC Manufacturing Waiver, which has been compounded by conflicting national decisions in Janssen v Formycon ("Formycon"), Janssen v Samsung Bioepis ("Samsung Bioepis"), Amgen v. Samsung Bioepis Regeneron v. Sandoz ("Sandoz") and Regeneron v. Alvotech ("Alvotech"),** the **European Commission should <u>clarify</u>**:
  - That **third country IP right status is of no relevance for the EU SPC Waiver**. Otherwise, this would break the territoriality doctrine of IP rights and extend to the EU the effects of foreign IP rights, opening the doors for abusive litigation in the EU based on those foreign rights, which is especially deterrent for SMEs.
  - The safeguards against **abusive litigation**, with **concrete examples of abusive litigation**, a **mechanism for competition authorities to monitor litigation or threatened litigation** in relation to the SPC Waiver.
  - The possibility to **re-import due to technical reasons** (i.e. certain related act being possible in third countries for example when certain steps in the manufacturing including packaging must be carried out in a third country and the product must then be re-imported into the EU for final

manufacturing and release). This may also add value to the EU manufacturing without disregarding basic principles of global trade.

- That there should be **no unnecessary restrictions on storage** in the use of the export waiver.
- That, **day 1 launch is an explicit objective of the SPC Waiver both for launch in EU countries as well as for export** and launch in third countries, since the objective of the waiver is to create a level playing field between EU and non-EU manufacturers.

No More Delay - Corrections to the SPC Manufacturing Waiver are Urgently Needed

- **Correct immediately the evident SPC Waiver issues in currently negotiated legislative acts, such as the Biotech Act**: waiting for additional years for introducing the urgent correction would be too late. The EU should take advantage of the currently negotiated legislative acts that aim at stimulating manufacturing and development of (biotech) products in the EU, in order to stop any further transfer of manufacturing capacities outside of the EU.
- **Conduct the overdue legislative review without further delay**: the review of the SPC Waiver Regulation, originally foreseen for 2024, has not yet been conducted. There is now a clear expectation that this essential review will take place in 2026. The European Commission and co-legislators should seize this critical opportunity to fix the widely acknowledged shortcomings of the current SPC Manufacturing Waiver legislation and ensure that it delivers on its intended purpose. Delaying the review any further would mean prolonging the regulatory uncertainty, weakening the attractiveness of Europe as a manufacturing hub, and continuing to push business investments and operations outside the EU — contrary to the EU's stated goal of achieving strategic autonomy in pharmaceuticals and of strengthening the competitiveness of its industry.
- **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 as well as with the currently discussed Biotech Act.
- **Regulations**: **the relevant Articles on the SPC Waiver in the relevant Regulations should be amended** as soon as possible to facilitate application of the SPC Waiver in practice, and to reduce the likelihood of unnecessary abusive litigation in the Member States.
- **Guideline/Notice: as an additional and rapid short-term measure**, the European Commission should issue guidelines or a Notice to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders.

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 early 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 were described in the First Report published in June 2023 as a preliminary stock-taking exercise reflecting eight months of practical experience. Already during that period, significant flaws of the SPC Waiver Regulation were manifest. A subsequent survey conducted in April 2024 has gathered additional feedback on the use of the SPC Waiver. This 2024 Updated Report confirms the issues described in the 2023 First Report and describes additional issues that emerged over the past year, including in the first case law. Despite early recognition of these issues, the formal review of the SPC Waiver Regulation — mandated for 2024 — has not yet taken place.

In this context, a third industry Survey was conducted in early 2025 and confirmed that these issues persisted, and captured further experiences with the waiver's application, then embedded in the 2025 Updated Industry Report. This 2026 Updated Report reflects the consolidated insights of generic and biosimilar manufacturers across Europe, further confirming the issues and the flaws already identified in the 2023, 2024 and 2025 Reports. The 2026 Report also identifies where the SPC Waiver enables investment — and where it still fails to deliver the expected positive externalities.

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 in a second section ("*Policy Recommendations*"). The recommendations aim to remove the unnecessary and unreasonable 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 still viewed as a positive step in principle, but its practical limitations, legal ambiguity, and misuses by SPC holders have significantly constrained its impact. The findings presented here should serve as a clear mandate for reform — both in the upcoming legislative review and through interim clarifications by the European Commission.

Findings

Findings on the Business Impact of the SPC Manufacturing Waiver

- **Usage**:

  In the first 8 months since the Regulation was enacted, more than half of the 13 responding companies had submitted at least one SPC manufacturing waiver notification in one or more Member States. In the following 12 months, replying companies have reported to have filed SPC Waiver notifications for over 36 additional products. The 2025 survey confirmed continued use, with 21 more product reported as manufactured in the EU under the SPC Waiver.

  According to the results of the 2026 survey, about 141 products were manufactured in the EU since 2022 in light of the implementation of the SPC Manufacturing Waiver Regulation. One respondent reported that they have notified relevant authorities of their intent to use the SPC Waiver for 11 products.

  The use of the SPC Waiver continues, 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 4 to 9 in 2024 on a scale of 1-10.

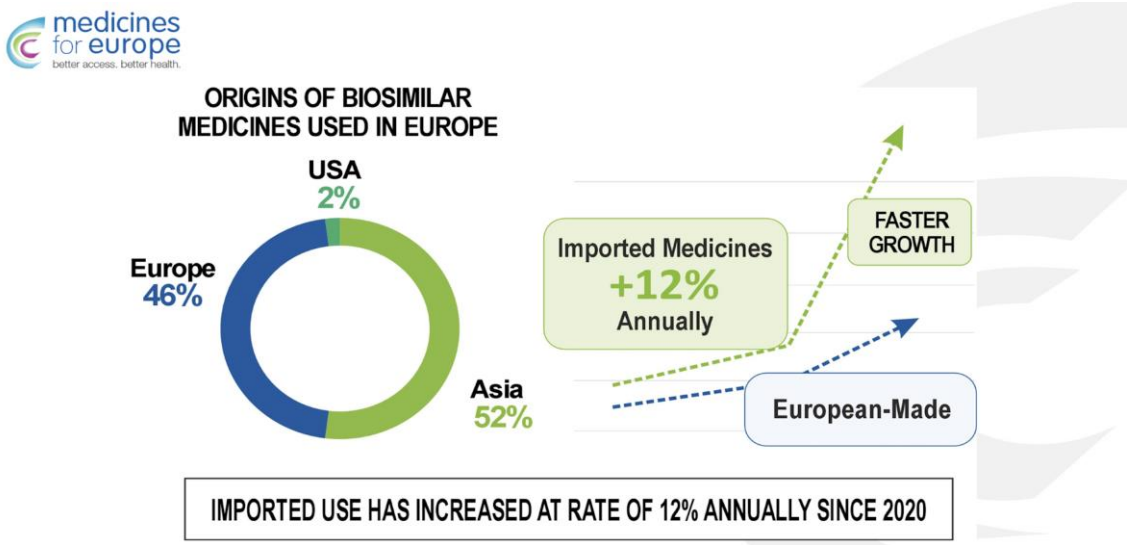
  The 2025 survey showed again a variety of opinions. However, almost all respondents are of the opinion **that SPC Waiver in its current version does not achieve the expected results**.

  The 2026 survey showed once again a wide range of ratings from 2 to 10 on a scale of 1-10. The downward shift in industry perception over 2024-2026 timeframe suggests that the SPC Waiver is progressively losing strategic relevance for generics and biosimilar manufacturers, reflecting a growing dissatisfaction with its current design. These data show, indeed, how the SPC Waiver may potentially have a significant impact on business, but still fails to pursue its expected goals due to more or less severe limitations perceived by companies. While some respondents stated that activating the SPC Waiver allowed them to successfully launch biosimilars in non-EU markets, the majority still shows a low level of satisfaction with the SPC Waiver and states that the current formulation of the Regulation with the operational complexities, stemming from the burdensome obligations and uncertain interpretation, limits the positive impacts the SPC Waiver may have for EU-based manufacturers.

  Moreover, it is to be stressed that, due to the abovementioned issues, SPC Manufacturing Waiver Regulation failed to provide a positive business impact for the biosimilar sector. Data (see table 1 below) have shown that, although Europe has historically been the main global hub for biosimilar production, the use of imported biosimilars in Europe has increased at a rate of 12% annually since 2020 (1 year after

the entry into force of the SPC Waiver), demonstrating that the waiver has not worked for biosimilars as expected and how such criticalities need to be addressed **urgently.**

Table 1: Origins of Biosimilar Medicines Used in Europe



- **Reasons for not using the Waiver:**

  Despite the SPC Manufacturing Waiver's stated goal of levelling the playing field for EU-based producers, a number of companies continue to avoid using it altogether or limit their use significantly. Since the adoption of the SPC Waiver, responding companies reported that they decided to manufacture in Europe over 141 products (25 according to the 2023 Survey, 36 additional products according to the 2024 Survey, 21 more products according to the 2025 Survey and 59 additional products according to the 2026 Survey), whereas they have **decided NOT to manufacture in Europe 52 products** (24 according to the 2023 Survey, 10 additional products according to 2024 Survey, 6 according to 2025 Survey and 12 more according to the 2026 Survey). The 2026 Survey reaffirms once again that **legal uncertainty**, **regulatory burdens**, and **fear of litigation** remain the primary deterrents.
  Key reasons cited by respondents include:

  - **Risk of litigation due to legal ambiguity**: Several companies reported either receiving warnings or being sued after sending waiver notifications. In one case, the SPC holder demanded that the manufacturer delay production until three months after disclosing an MA number — a condition not required under the Regulation. Another case involved **frivolous litigation** initiated in the country of manufacturing after an update on MA status was provided.
  - **Short timeline for day 1 readiness**: Companies reiterated that the **6-month limitation** for manufacturing prior to SPC expiry is **unrealistic**, especially for biologics and biosimilars. The majority of the respondents called for removing the time limitation altogether to align with real-world production needs, especially for biosimilars, since there is no real justification or rationale for it. One of the respondents highlighted that, by the time products are ready for manufacturing under the

Waiver, the remaining period of SPC protection is often too limited to justify operational and regulatory efforts required. As stressed also by EFPIA in the European Parliament (SANT) Hearing on "*Overreliance on imports of Active Pharmaceutical Ingredients (APIs)*" of 29 February 2025, **API manufacturing alone takes at least 12 months**.

- **Ambiguity around "related acts"**: Respondents expressed confusion over whether critical preparatory activities such as labelling, artwork creation, packaging, test and release, fall under the waiver. This lack of clarity has already caused at least one company to cancel plans for EU-based packaging and labelling.
- **Unclear scope of the export provision**: Some respondents were warned by SPC holders that even **manufacturing for export** to non-EU countries could be considered infringing if the product remained protected in the destination market — an unfounded misinterpretation that deters use of the waiver.
- **Overly burdensome notification requirements**: Companies highlighted that some of the notification requirements are not aligned with the practical realities of export scenarios, requiring to manage multiple notifications to different stakeholders (such as APIs suppliers, National Patent Offices and SPC Holders), as well as that tracking and updating marketing authorisation numbers in export countries is **resource-intensive** and offers little benefit, while also raising concerns about disclosing commercially sensitive information that may be misused by originators.

In some cases, companies have opted to manufacture entirely outside the EU despite having EU facilities, citing the **greater predictability, reduced legal exposure and lesser regulatory burdens** in third countries. As a result, the waiver is not fulfilling its role in retaining or attracting industrial activity to the EU and strengthening the competitiveness of the industry.

- **<u>Effect of not using the SPC Waiver</u>:**

The loss of business activity for the EU derived from not using the waiver and investing abroad was estimated by two respondents in 2024 and confirmed in 2025, 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**. In the 2026 survey, several respondents stated that the SPC Waiver did not mitigate or ameliorate the business challenges they have to face in relation to the manufacture of products for which an SPC is in force, the SPC Waiver not being sufficiently impactful to justify any modification to the already existing manufacturing or investment strategies.

- **<u>Positive effects when the SPC Waiver is used</u>:**

Several respondents reported having increased operations (including for small molecule APIs) and investing in new equipment and facilities in Europe. One respondent to the 2023 survey had 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. Additionally, in the 2024 survey, one respondent stated that they were able to successfully launch 2 products from the EU on day 1 thanks to the SPC waiver provision; otherwise, the launch would not have been as successful, or the volumes would have been much lower. One respondent also reported to have manufactured 6 APIs and 5 finished dosage forms in Europe thanks to

the SPC Waiver. Furthermore, the SPC Waiver provision was reported to be a stimulating factor for establishing partnerships using EU-based manufacturing site as the main supply chain. It also stimulated the establishment of a new manufacturing site in the EU for highly potent products. Additional new manufacturing activities were reported in Germany, Austria, the Netherlands and Ireland. In the 2025 survey, some companies confirmed continued or expanded investment in EU manufacturing, with one reporting sustained expansion of a production site in Slovenia, and another stating that the waiver contributed to their decision to relocate some activities back to the EU. The waiver has also encouraged several respondents to implement internal SPC monitoring systems in preparation for potential future use. In the 2026 survey, one respondent stated that they were able to successfully launch a biosimilar medicine in non-EU market thanks to the use of the SPC Waiver, while another one affirmed that they made investments to increase manufacturing capabilities considering to leverage the SPC Waiver for future products. Another respondent also stated that the SPC Waiver allowed them to launch products immediately upon patent expiry within the EU, while also enabling them to accelerate product launches outside the EU by several years.

However, some respondents confirmed 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 in 2023 were reported to be up to €10mn. In 2025, companies again reported the same level of savings. In 2026 survey, companies' savings on manufacturing costs and related operations from the entry into force of SPC Waiver Manufacturing Regulation were reported to be on average around €10 mln.
In terms of **jobs**, one company reported the creation of 100-500 new jobs in the EU. Seven companies reported the SPC Waiver allowed them to create up to 100 new jobs within the EU according to the 2023 Survey, and two additional companies reported the same numbers in the 2024 Survey. In the 2025 Survey, no new job creation data was reported, and, for other respondents, this information remains unknown. In the 2026 survey, it emerged that, since the introduction of the SPC Manufacturing Waiver Regulation in 2022, nine companies estimated that the number of jobs created in the EU amount to 0-100, while one respondent estimated 100-500.

How companies increased and improved the business impact of the SPC Waiver since the application of the SPC Manufacturing Waiver Regulation in 2022:

Respondents have made a variety of changes to increase and improve the business impact of the SPC Waiver since the application of the SPC Waiver Regulation in 2022.

21% of the respondents affirmed that they have made **investments to increase existing manufacturing capacity in the EU**.

- **24%** affirmed that they have set a **monitoring system** for SPCs.

- **15%** of the respondents stated that they have **relocated some of their manufacturing activities back to the EU**.**9%** of the respondents stated that the SPC waiver **has not been as helpful as they would have expected for their companies.**
- **6% of the respondents** reported **no change in their business strategies** in light of the SPC Manufacturing Waiver Regulation due to the limited incentives deriving from the Regulation.
- **3% of the respondents** reported that they have moved manufacturing back to countries that frequently have SPCs.

Data show that the generics and biosimilars producers still show interest in the implementation of the SPC Waiver Regulation provisions. Yet, despite the relocation of some of the activities in the EU and the investments made to increase the existing manufacturing capacity, several criticalities remain, with the overall level of satisfaction low among the companies. The rationale behind the SPC Manufacturing Waiver is considered positive in principle, but the current design and implementation limit its usability and effectiveness in the real-world scenarios.

Limitations and burdensome obligations made, according to some of the respondents, the SPC Manufacturing Waiver Regulation not as useful as expected, with one respondent affirming that they use the SPC Waiver only when other options are not feasible.

- **<u>Time to fix the issues</u>**

Respondents highlighted the urgent need to carry out the **overdue review and revision of the Regulation** to assess if it has achieved its purpose as a policy measure (originally foreseen for 2024 according to the Regulation). Waiting for additional years would be too late. It was confirmed that **uncertainties and shortcomings are already evident and should be fixed immediately, even potentially in the context of other legislative acts (*eg*. the Biotech Act), to stop further transfer of manufacturing capacities outside of the EU**. The 2026 survey confirms that the **uncertainties, unnecessary burdens, and shortcomings** of the current SPC Waiver framework continue to place EU-based manufacturers at a competitive disadvantage, making it more difficult to retain and attract manufacturing activity within the EU.

Several respondents noted that while the Regulation began with strong intentions, its final form introduced **so many limitations and ambiguities** that it has become **difficult to use effectively**, particularly for Day-1 launches and complex manufacturing chains.

Respondents repeated their call for the EU to reduce uncertainties and provide necessary clarifications by:

- **Amending the Regulation** to simplify conditions, expand the scope, and remove legal ambiguities;
- **Introducing a broad Bolar exemption** in parallel, as both instruments pursue the same goal: ensuring timely day 1 competition;
- **Issuing an EU Commission Guideline or Notice** as a short-term and more rapid measure to remove existing uncertainties and curb the misuse of safeguards by SPC holders, including **abusive litigation** and **overreaching disclosure demands**.

Without immediate action, the intended industrial and access-to-medicines benefits of the SPC Waiver risk being permanently undermined.

Findings on the Notification System

- **SPC holders' responses to SPC Waiver notifications - (1) Lawsuits & conflicting case law:**

  Since the publication of the 2023 First Report, **several national Court decisions concerning the SPC Waiver have been published**, showing not only a **conflicting understanding of the language of the SPC Waiver Regulation**, but also the **attempt of a SPC holders to create artificial obstacles to the use of the waiver via frivolous litigation**, raising questions about **what could be considered 'abusive litigation'**.

  Respondents show a strong concern **about conflicting decisions by national Courts around Europe on the SPC Waiver Regulation interpretation.**

  The first decision on this matter was issued by the Munich District Court, Germany in October 2023, in the case *Janssen v Formycon*[1] ("*Formycon*").[2] In this judgement, the Munich District Court adopted an inordinately restrictive interpretation of the SPC manufacturing waiver, which cannot be derived from the letter of the law, and which contradicts the purpose and spirit behind the amendments that were introduced during its inception until its final approval. This utterly frustrates the aims of the Regulation.

  The Munich Court judgement purports that SPC Waivers for export would require notification of a marketing authorisation (MA) number – even if no MA number is publicly available yet – or the disclosure of confidential information about future countries of submission, deducing those requirements from an alleged need to ensure that no conflicting IP rights should exist in the foreign country of export. Respondents stressed that both purported requirements are not supported by the letter of the law and are in conflict with the objectives of the SPC manufacturing waiver, as evidenced by the legislative history and its explanatory memorandum.

  The judgment further suggests that for manufacturing in the EU and export to a third country to be permissible, a granted MA in such third country is required, a position which is fundamentally wrong and is a complete misunderstanding of which activities require a marketing authorisation under pharmaceutical regulatory laws. Whilst this is a matter of the national law of each country, generally only placing a medicinal product on the market requires a MA, not the manufacture, making or import.

  Moreover, **despite there being no limitation on the duration of storage for export in the Regulation**, the Court even suggested that long-term storage would not be permissible.

  Although it is a first-instance judgment in an expedited procedure, issued in a single – but, for the pharmaceutical industry, significant – EU country, **it is already being used by SPC holders to further threaten existing and future users of the SPC Manufacturing Waiver with lawsuits, or to sue them, a practice that distorts the use of the waiver, frustrating its goals.** The judgement even maintains that

[1] Janssen Biotech, Inc v Formycon, Regional Court of Munich, October 2023

[2] https://www.medicinesforeurope.com/wp-content/uploads/2024/01/Press-release-SPC-waiver-18-Jan-2024.pdf

"*the Regulation is not intended to put manufacturers within the Union on a completely equal footing with manufacturers in third countries*"[3] , which clearly reflects a **fundamental misunderstanding by the Court of the aims of the regulation**.

This judgement shows that the **current SPC Waiver legislation is drafted in a way that allows SPC holders to misinterpret the language before Courts to the detriment of EU-based manufacturers**, and to the benefit of producers established out of Europe. Respondents to this survey report that this threatens planned and committed investments in manufacturing in Europe to the detriment of the fundamental goals of the legislation.

Following the Munich District Court decision, **several lawsuits have already been reported with the same unfounded argument that at least one MA in export markets should be included in any initial notification for the SPC Waiver to be valid**. For instance, in the previous surveys, a respondent has reported having received even **4 lawsuits for 1 product in 1 Member State.** Another respondent reported having been sued even without any warning letter. Another one reported being sued for an allegedly ineffective notice as the country of export was not named.

In the 2024 survey, a respondent stressed that if, in an absurd hypothesis, a final MA in a non-EU country were required for validly using the SPC Waiver in the EU, the SPC Waiver would be unusable for biosimilars, for which **approval timelines are about 12 months in major third countries**, and waiting until a MA publication for starting manufacturing in Europe would be such a disadvantage that no company would ever use the waiver.

In the second case, ***Janssen v Samsung Bioepis***[4] ("*Samsung Bioepis*"), in direct contrast to the Munich District Court in *Formycon*, the **District Court of the Hague held that it is clear from the wording of Article 5(5)(e) of the Regulation that the maker is required to provide the MA for each exporting third country *"only as soon as it is available to the public*."** Moreover, it stated that **there is no requirement under the Regulation for intended export countries to be free of patent rights nor that the manufacturer must demonstrate this in advance**, citing that it would **otherwise be contrary to the objective of the Regulation** to ensure a level playing field with global competition.

The Dutch Court considered the opposing ruling in *Formycon* but disagreed with the Munich Court's reasoning, noting that **the requirement to name the exporting countries in the notification had been removed during the legislative procedure due to concerns about the disclosure of trade secret information by manufacturers**.

As to limitations to storage in case of export, whilst the Munich Court suggested that "long-term storage" was not allowed, the **Dutch Court was of the view that there is no requirement in the Regulation that products manufactured for export must be exported "almost immediately" nor is there a requirement in terms of the maximum duration of the storage**.

[3] Unofficial translation

[4] Janssen Biotech, Inc., v Samsung Bioepis NL B.V, District Court of the Hague, 23 January 2024

Janssen lodged an appeal on multiple grounds against that decision, including an alleged misinterpretation by the Court of the Marketing Authorization requisite. However, the Jannsen's appeal was rejected with the Dutch Court of Appeal stating that, as for the MA, Janssen's arguments found **no support** in the wording of Article 5 of the SPC Waiver Regulation which, on the contrary, did not preclude the reliance on the waiver if the Marketing Authorization reference number was not yet publicly available because no Marketing Authorization had yet been obtained.

The Court of Appeal further noted that Janssen's arguments in this regard also found no support in the recitals or drafting history of the SPC Waiver Regulation.

Following this rejection, Janssen filed an appeal for the cassation of the decision, repeating multiple arguments and insisting on their interpretation of a final MA being mandatory to rely on the export waiver granted by the Regulation. In his opinion for this case, the Dutch Supreme Court Advocate General rejected all the Janssen's arguments for cassation, including the argument that a manufacturer can rely on the SPC Manufacturing Waiver only if a definitive MA is already available at the time of notification. The core of his considered reasoning is supported by **textual, systematic and purposive interpretations of the Regulation**.

The Advocate general also emphasized that the wording of Article 5 does not impose a condition requiring the existence of a granted MA before triggering the waiver because, otherwise, the text would be contradicted. Moreover, imposing a requirement of a final MA would **delay or even neutralise the practical utility of the Waiver, reintroducing the very competitive disadvantage the Regulation was designed to remove.** Finally, requiring a granted MA at the notification stage would force premature disclosure of strategic regulatory information, contrary to the Regulation purpose[5].

It is worth noting that both the Dutch court of first instance and Court of Appeal also rejected Janssen's arguments that: (i) at the time of making a notification, the intended third country of export must be free of patent rights/market protection; and (ii) the export exemption does not permit storage within the EU of products intended for export. As above, **these arguments were rejected on the basis that there was no support for them in the Regulation**; a view also endorsed by the Dutch Advocate General.

The excessively strict and ***contra-legem*** **interpretation of the Regulation in *Formycon*** and the uncertainty due to the **conflicting interpretation in *Samsung Bioepis*** will likely lead to further unwillingness by generic and biosimilar manufacturers to utilise the SPC Waiver, potentially resulting in more divestment outside of the EU and/or delays to access of affordable medicines in the EU, frustrating the primary goals of the Regulation.

Moreover, in a decision by the Brussels Enterprises Court, ***Amgen v. Samsung Bioepis***, of December 2024, the Court clarified that the notification **must not** contain a marketing authorisation number and name the exporting countries for Waiver to be used. It also confirmed that exporting countries must not be patent-free in order for the manufacturer to rely on the Waiver, and that there is no limit to stockpiling under the Waiver for export.

[5] Advocate General Conclusions in Jannsen v. Samsung BioEpis, Appeal for Cassation, 2026.

In the 2025 survey, one respondent reported being asked by the SPC holder not to begin manufacturing until **three months after providing a marketing authorisation (MA) number** — a condition that is **not required under the SPC Waiver Regulation**. When the respondent subsequently provided the MA for an ex-EU country, **litigation was initiated in the country of manufacturing**, despite full compliance with the Regulation's formal requirements. This case reinforces concerns that SPC holders are using **unsupported legal interpretations** to deter use of the waiver through litigation threats, distorting its intended function and undermining legal certainty for EU-based manufacturers.

Furthermore, in November 2025, the French-speaking Brussels Enterprise Court ruled in a case involving **Sandoz v. Regeneron** about, **once again**, the correct interpretation of the notification system's requirements laid down in the SPC Waiver Regulation. At the beginning of 2024, Sandoz notified the Belgian Intellectual Property Office and Regeneron in compliance with the SPC Waiver Regulation's provisions that they intended to manufacture a biosimilar medicine both for export and for stockpiling for day-1 launch in the EU. No Marketing Authorization had been granted in the third country of export yet and, consequently, no Marketing Authorization number was available at that moment to be included in the notification.

In its findings the Brussels Enterprise Court found that there was **no requirement to provide the Marketing Authorization number at the time of the notification**, noting that Article 5(5) of the Regulation permits the Marketing Authorization number to be provided as soon as it is publicly available. In this regard, the Brussels Enterprise Court also noted that it was not convinced by the ruling of, and underlying reasoning previously applied by, the Munich court.

Moreover,in Regeneron v. Alvotech, in 2025, a UK Court was asked to judge on a case concerning, once again, the waiver requirements laid down in Article 5 of the SPC Waiver Regulation. More in details, the Court had to rule about the alleged invalidity of a notification made pursuant to Article 5 that did not include the reference number for the intended country of export because it was not publicly available yet. The Court, following the same line of thought of decisions from the Dutch and the Belgian Courts, stated that the correct interpretation of the SPC Waiver Regulation, along with its rationale and its recitals, did not require the mention of the reference number in the waiver notification if it had not been made publicly available yet or if it was confidential.

Finally, it was stressed that the **costs associated with attempting to avoid litigation** — both financially and in terms of time — are exorbitant, often involving exhaustive interactions with the SPC holder over notification details that should not be contentious.

Despite being a significant step in the right direction, rulings from such Courts – though favourable and aimed at a correct interpretation of the SPC Waiver Regulation – cannot be fully relied on to avoid frivolous litigation and a correct use of the SPC Waiver in the future. **Litigation means burdensome costs and uncertainties on generic and biosimilar companies that discourages them to manufacture in Europe and launch their products on the market, thus betraying the rationale of the SPC Waiver Regulation**

and making its positive externalities substantially ineffective for enhancing competition and European competitiveness.

- **SPC holders' responses to SPC Waiver notifications - (2) Threats of litigation**

  The 2024 and 2025 surveys showed that, in response to notifications, almost all respondents were **threatened with legal action**, *e.g*. to clarify whether the exported goods were considered infringing in the country of destination or requesting to disclose confidential information not foreseen in the notification requirements. One respondent reported being **threatened to be sued in all the Member States of manufacturing as well as in all the export markets**. Several 2026 respondents confirmed again that SPC holders continued to issue legal threats or warnings. One company reported that after submitting a valid waiver notification, they were asked by the SPC holder to confirm they would not manufacture until **three months after providing a marketing authorisation number** — a condition not required under the SPC Waiver Regulation.

  In some cases, since the expected costs of an expected lawsuit in the export country were higher than the benefit of producing in Europe under the SPC Waiver, the SPC export waiver was then abandoned, leading to a general disincentive to use the waiver (as a consequence, also for the day 1 launch in Europe). In general, from the 2024 and 2025 survey, several abusive/frivolous behaviours emerged, like the threat of judicial action on the ground that production under the export waiver was not (allegedly) allowed while IP protections in the export countries were in place, which is an odd interpretation of the Regulation considering its goal of restoring a global level playing field for makers of generics and biosimilars in and outside the Union. Moreover, some respondents also reported receiving a request of disclosing commercially sensitive information about their manufacturing processes.

  This, in addition to the case-law described above, confirms a **regular attempt by SPC holders to use Recitals 8 and 18 (reference to third-country markets where "the protection does not exist or has expired") to achieve extra-territorial protection of patents by limiting manufacturing in EU Member States based on non-EU patents or other non-EU IP rights**.

  The 2026 survey confirmed the concerns raised in the previous years. More in detail, respondents to the survey stated that the notification requirements, in the current wording, are *de facto* a trigger for unnecessary judicial litigation or threat of litigation because of the potential unduly strict interpretation of the necessary formalities. This, in the context of litigations and/or preliminary injunctions, represents a significant business risk that may discourage manufacturer to trigger the waiver. Respondents confirmed receiving litigation threats with requests for confidential information about their manufacturing processes, including planned activities, production timelines, involved parties, jurisdictions, and planned export markets when no foreign marketing authorisation is public. One respondent also stated that **the risk of misuse of the notification requirements does not allow proper implementation of the SPC Waiver Regulation**. Another respondent also reported that they continue to rely on the SPC Manufacturing Waiver for their industrial strategy but with severe limitations stemming from the awareness of the potential risks of abusive/frivolous litigation.

Safeguards against 'abusive litigation' (art. 5.4 & recital 20):

The **arguments used by SPC holders in the case law described above triggered questions for respondents around what should be considered 'abusive litigation'**, as referred to in Recital 20.

The safeguard provided for in **Art. 5(4) is considered ineffective or even detrimental** for the generic industry, since **its presence suggests there is some form of anti-abuse provision, some sort of fair or level playing field, but in reality it has no effect**. The 2026 survey reaffirmed that **SPC holders continue to rely on speculative legal challenges**, effectively bypassing the intended safeguard and **discouraging reliance on the Waiver even when conditions are met**.

Respondents emphasized the **need for stronger safeguards against abusive litigation**, including a possible clear **definition of what would actually constitute abusive litigation** within the Regulation and also proposing, in the previous surveys, possible solutions, such as **the creation of a bond deposit or a higher court fee required for SPC holders** when filing claims under the SPC Waiver regulation, as well as including **provisions regarding cost liability for the damages** suffered by the users of the Waiver.

This illustrates how the current framework enables a **climate of legal intimidation**, particularly where SPC holders may use vague or overlapping IP claims to discourage legitimate use of the waiver. Respondents stressed that this chilling effect — even without formal lawsuits — should be recognised as part of what may constitute **abusive litigation tactics**.

Additional safeguards could be provided in guidelines, which could clarify, at least in the short term while providing a structural reform of the SPC Waiver, certain meanings of the terms of the SPC Waiver, to avoid that every single word's interpretation need to be clarified in courts in frivolous litigation, potentially even in several EU Member States and judicial instances.

- **<u>Publication of SPC Waiver notifications</u>:**

  The majority of respondents felt **very uncomfortable about sharing confidential information with competitors (incl. the SPC holder) and 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 in the notification**. This publication is today foreseen by 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).

  A respondent also suggested that in cases there are third party SPCs on the same product, the notification should only need to be addressed to the originator's SPC, in order to avoid uncertainty, which could still be a valid and reasonable solution.

  Case law and past experiences from generic and biosimilar manufacturers show that **the notification should be removed altogether since the evidence is overwhelming that the notification system is being misused to block the use of the waiver and create obstacles to generic and biosimilar medicines developers, which is contrary to the stated purpose of the legislation**.

- **Terms triggering uncertainty:**

  Many interpretative issues on the terms used by the SPC Waiver Regulation emerged in the previous years still remain unaddressed and demand for clarification in order to avoid legal uncertainties and promote a correct and effective use of the waivers.

  The **notification submission process seems to work 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.** 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**.

  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 this 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. Since innovators may consider this 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 was also reported that the **requirement to update waiver notifications with reference numbers for marketing authorisations as soon as they become publicly available** has proven to be unnecessarily **administratively burdensome**, particularly for companies with multiple products and operating on multiple markets.

Findings specifically on EU day-1 Launch

- **Hurdles to EU day 1 Launch due to 6-month time limitation and restriction of the single market:**

  Multiple respondents confirmed 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 on storage ahead of EU Day 1 Launch, 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.

  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 labelling (i.e., compliant with the falsified medicines directive rules) would prevent illicit diversion anyway, along with the EU Pharmaceutical Legislation and the IP enforcement system already in force**. **As for the stated risk of illicit diversion in a highly regulated market like the EU**, 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**.

Furthermore, the **assumption that enabling generic and biosimilar manufacturers to start production for day 1 EU entry (or for export) would increase the risks** of generic or biosimilar products being placed on the EU market prior to SPC expiry has **never been supported by any evidence**.

Whether the manufacture of a generic or biosimilar product takes place within or outside of the EU bears no relevance to the level of risk of an illicit diversion onto the EU market during the term of the SPC. Since **the Bolar exemption was introduced in EU law, without any of the safeguards implemented for the SPC Manufacturing Waiver, there has not been any evidence that the exemption has led to an increased risk of illicit diversion**.

It emerges that the legislator's reasoning is premised on the **two further mistaken assumptions** that: **(i)** the first time an SPC holder will become aware of a generic or biosimilar launch is after the generic or biosimilar product is placed on the EU market; and **(ii)** if that were the case, it would be too late for the SPC holder to effectively enforce its rights.

From both a regulatory and practical perspective, this is not the case. Medicinal products are heavily regulated. In all Member States the grant of a marketing authorisation, the grant of price and reimbursement status, and the placing on the market of generic or biosimilar products are already subject to **official publications allowing SPC holders to monitor these activities and enforce their rights** if they believe they are infringed by an illegitimate launch, including by seeking a preliminary injunction, in accordance with Directive 2004/48/EC on the enforcement of IP rights. Clinical trials (for hybrid and biosimilar products) are also already subject to official publications.

The alternative scenario, where an SPC holder failed to monitor generic and biosimilar activities and does not have sufficient advance notice of a generic or biosimilar launch, is highly unlikely but even in such circumstances, **SPC holders are entitled to enforce their rights and can (and have been able to) obtain urgent interim relief to protect their monopoly**.

It was strongly stressed by all the respondents that **the 6-month limitation does not provide any protection against phantom illicit diversion**. The European Commission itself, in its impact assessment, recognized this risk being sufficiently dealt with through the pharmaceutical legislation and IP protection already in force: ***"[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." (EC Impact Assessment)

In view of the above, **the majority of the safeguards under the Regulation are unnecessary and detrimental to generic and biosimilar manufacturers, undermining the Legislator's fundamental objective** of putting generic and biosimilar manufacturers in the EU on a level playing field with manufacturers based in third countries.

A respondent in the 2026 survey underlined that **the current limitation on where and how the products can be stored or moved within the EU from one production site to another before the SPC expiration creates logistical barriers and prevents generic and biosimilar manufacturers to prepare for a synchronized EU-wide launch**.

Moreover, there could also be several interpretations of "Member State of making", which renders the storage requirement furtherly unclear.

Therefore, **the 6-months storage limitation for Day-1 Launch under the current "stockpiling" waiver 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 do notneed 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,** including, for instance, biosimilars. 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 may take 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. **In a conservative estimate, 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 also stressed that the 6-month limitation, on top of being a too short timeframe, would also put limits to the quantities potentially produced, since **6 months would be a too short timeframe for producing bigger quantities of products**, creating another unnecessary obstacle to the competitiveness of EU producers.

It was **suggested that the 6-months limitation should be deleted, since such limitation is completely unjustified, unnecessary to avoid phantom illicit diversion, as stressed by the European Commission in its impact assessment, and is contrary to the core purpose of the legislation (i.e. day 1 launch)**.

- **Problems related to paediatric extensions:**

  It is possible that **paediatric extensions (PEs) are granted less than 6 months before SPC expiry**. Some respondents gave specific examples of late-granted paediatric 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 generic and biosimilar manufacturers believes that if an **SPC paediatric 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 was intended 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 has been strongly stressed also in the 2026 survey: 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**.

- **Storage limitation**

  As highlighted above, the existing case law shows that an **SPC holder has argued in multiple EU litigations that the export waiver implicitly includes a limited storage time period** following production. They contend that products manufactured under the SPC Waiver for export should not be stored within the EU at all. **This interpretation, followed by the Munich Court but dismissed by both the Belgian Commercial Court, the Dutch Court of first instance and appeal and the Dutch Advocate General, complicates the use of the export waiver and makes it less attractive**. This stance undermines the practicality and intent of the waiver, which is designed to facilitate competitive manufacturing and export activities within the EU.

- **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 2023 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 case was then settled, but it already immediately showed that litigation is not just threatened and for frivolous reasons.[6] In 2025, one respondent reported receiving a warning from an SPC holder discouraging the use of the waiver based on the alleged existence of IP protection in certain export countries.

  It was noted that, as shown also in the *Formycon* and *Samsung Bioepis* case law described above, SPC holders assert the necessity of knowing the export country to verify if they hold relevant protections, such as patents, in those countries. This is because, if such protections exist, they argue that the notification would be invalid. They base this argument on the last sentence of Recital 18. The presence of any protection — whether a patent, SPC, or Patent Term Extension (PTE) — in a third country should not affect the applicability of the waiver in the EU. If a relevant patent, SPC, or PTE exists in a third country,

[6] Janssen Biotech Inc -V- Amgen Technology [Ireland] Unlimited Company 2023/1328 P

then the rights holder is entitled to enforce it within that country as it sees fit if attempts are made to import into that country.

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 force in a non-EU country is abusive/frivolous litigation**. The 2025 example confirms that such arguments continue to be used in practice, creating legal uncertainty for EU-based producers and undermining the waiver's purpose. No EU Court should assess the validity of IP rights in third countries. The *travaux préparatoires* show that the legislator considered whether foreign IP rights should be taken into account and decided against it. It is not for EU courts to consider the existence and validity/infringement of foreign IP rights.

This view is supported in case law discussed above with the Dutch Advocate General in *Samsung Bioepis* stating that it is explicitly the responsibility of the manufacturer, not the SPC holder, to verify whether IP rights are in force and are being respected in third countries.

Respondents propose that the wording of Recital 18 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**.

One 2025 respondent highlighted a concrete case where legal uncertainty surrounding Recital 8 — specifically the vague reference to "protection" instead of "SPC protection" — prevented the use of the SPC Waiver. In their case, a product partially manufactured in the EU (e.g. combination with a device) was exported for further processing (e.g. packaging) outside the EU. It was unclear whether this product could then be **re-imported for sale in the EU** without infringing the SPC, due to ambiguity about how Recital 8 interacts with such supply chains. This lack of legal clarity was cited as a **decisive factor preventing the use of the waiver**, despite the company's interest in relying on EU-based production.

- **Labelling requirements unnecessary:**

  While most respondents were able to comply with **labelling requirements for export** to third countries, they stressed the requirement was unnecessary and burdensome. Respondents mentioned again that labelling requirements may conflict with export markets' national regulatory requirements, *eg*. Brazil, Switzerland, etc., stressing that this unnecessary requirement and related uncertainty discourages respondents from performing these steps in the EU.

  One respondent emphasized that the regulation **lacks clarity regarding the labelling of intermediate products**. It specifies labelling requirements for the active ingredient (no labelling is required) and the final medicinal product. However, it fails to address cases where an intermediate product, whether in bulk or not fully packaged, is exported. This ambiguity creates a significant compliance gap for products in stages between these two extremes.

  A further submission in 2025 already provided a detailed account of the **legal uncertainty and practical difficulty** caused by the export labelling rules. The Regulation requires the export logo to be affixed to

the **outer packaging** and, "where feasible", to the **immediate packaging** — but fails to clearly define what "outer packaging" means. One company reported having to spend significant time and money to determine whether this refers to the individual product box, grouped cartons, or external transport packaging, including seeking external legal advice to assess the risk of non-compliance.

The same respondent also questioned the meaning of "where feasible" for immediate packaging, asking who decides whether feasibility is met and what criteria apply. They reported that in some cases, affixing a label to the immediate packaging (such as blister packs or glass vials) risks damaging the product, compromising seals, or causing ink lift-off. In addition, removing stickers may require labour-intensive manual work and lead to unnecessary cost and wastage.

The issue is compounded by the fact that many EU production sites rely on **automated packaging lines**. One manufacturer explained that interrupting automated runs to insert stickers would require manual override of highly efficient processes. This could lead to cascading production delays and significantly **reduce site-wide manufacturing capacity**.

The **immediate packaging of biologics** presents another challenge due to its very limited space, making it impossible to add export labels.

Additionally, the need to **remove labels after the expiry of the SPC can cause confusion and inconvenience for customs officials, pharmacists, and patients**. This process incurs substantial costs and demands significant resources, both internally and from regulatory authorities in third countries.

Respondents strongly recommend that the labelling requirement be either **removed** or **substantially revised**, especially for **intermediate packaging stages and highly automated manufacturing**.

Findings on Other Aspects

- **Re-packaging and initial packaging**

  The current language in the SPC Manufacturing Waiver (SPC MW) concerning packaging operations is ambiguous, particularly when distinguishing between re-packaging and initial packaging. It is crucial to explicitly clarify that all packaging operations are considered steps of "making," and thus are integral parts of the manufacturing operations covered under the waiver. This clarification is essential to ensure that these activities are not categorized under the exclusions typically associated with re-packaging, as outlined in the recitals. Emphasizing that packaging is a core manufacturing operation highlights its importance and supports the rationale for onshoring such activities within the EU.

- **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. Even if theoretically it does not appear particularly difficult to comply with this requisite, it does not add any particular value and the main issue remains: generic and biosimilar manufacturers remain concerned**

that the due diligence requirements may be misused 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. Generic/biosimilar companies' confidential or commercially sensitive information on 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, for example due to missing technical abilities, which may require some flexibility to export and re-import.

Policy Recommendations

Considering the continued legal uncertainty, limited uptake, and significant industrial and access challenges documented across three years of data collection, Medicines for Europe recommends the following urgent measures to ensure the SPC Manufacturing Waiver achieves its intended policy objectives:

1. Enable effective Day-1 competition in the EU & Remove barriers to free movement of goods in the EU single market, ensuring equitable access in the EU

- **Delete the 6-month time limitation** for making products destined for EU Member States (Art. 5.2 (a) (iii)). 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, for which it appears to be simply unrealistic. It also creates uncertainty in case an SPC paediatric extension is granted while a SPC Waiver is already in use. A differentiation between the export waiver and the EU storing waiver has resulted to be artificial and inconsistent with the way the EU manufacturing industry works. As stressed also by EFPIA in the European Parliament (SANT) Hearing on "*Overreliance on imports of Active Pharmaceutical Ingredients (APIs)*" of 29 February 2025, **API manufacturing alone takes at least 12 months**.

- The EU needs **a single SPC manufacturing waiver** without artificial differentiation between "export" and "stockpiling" waiver, and **without any limitations regarding storage (as currently included in the "stockpiling" waiver) and intra-EU transportation**, **which today prevent Day-1 launch** and timely access in some Member States frustrating the EU single market rule.
- **Explicitly 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 **notification** (Art. 5.2.(b)(c)). Today this is used as a trigger for unnecessary litigation or threat of litigation, raising questions about what should be considered 'abusive litigation'. Non-EU manufacturers are advantaged since they do not need to notify the SPC holder and there is no disclosure of their manufacturing and business plans.
  - The **unnecessary "Due Diligence requirements"** (Art. 5.9), to avoid that SPC holders force disclosure and obtain 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. In addition, this unnecessary safeguard discourages manufacturers intending to produce in the EU, due to the risks of unnecessary litigation that outside of Europe would not exist.

- The **unnecessary "labelling requirements"** (Art. 5.2 (d)).
- The **misleading reference to the IP status in third countries** (Rec. 42 & 44), which is an extraterritoriality matter. In order to avoid further unnecessary and frivolous litigation on this issue it is necessary to remove the misleading references in the legislation to "countries in which protection does not exist or has expired"', which have been relied on by SPC holders to create confusion. Such a reference was introduced to highlight that while in Europe there would be a longer protection due to the SPC, in other regions there may be shorter protection that cause a competitive disadvantage.

- Additionally, **due to the legal uncertainty as to the interpretation, application of and obligations under the SPC Manufacturing Waiver, which has been compounded by conflicting national decisions in Janssen v Formycon ("Formycon"), Janssen v Samsung Bioepis ("Samsung Bioepis"), Amgen v. Samsung Bioepis, Regeneron v. Sandoz ("Sandoz") and Regeneron v. Alvotech ("Alvotech"),** the **European Commission should <u>clarify</u>**:
  - **Irrelevance of third-country IP rights under the EU SPC Waiver:** otherwise, this would break the territoriality doctrine of IP rights and extend to the EU the effects of foreign IP rights (thereby preventing day-1 launch in export countries), opening the doors for abusive litigation in the EU based on those foreign rights, which is especially deterrent for SMEs.
  - **Concrete safeguards against abusive litigation**: the Regulation must be accompanied by **practical guidance** including clear examples of what constitutes **abusive litigation under Recital 20**, a **mechanism for competition authorities to monitor litigation or threatened litigation** in relation to the SPC Waiver.
  - The possibility to **re-import due to technical reasons** (i.e. certain related act being possible in third countries for example when certain steps in the manufacturing including packaging must be carried out in a third country and the product must then be re-imported into the EU for final manufacturing and release)**.** This may also add value to the EU manufacturing without disregarding basic principles of global trade.
  - That there should be **no unnecessary restrictions on storage** in the use of the export waiver.
  - That, **day 1 launch is an explicit objective of the SPC Waiver both for launch in EU countries as well as for export** and launch in third countries, since the objective of the waiver is to create a level playing field between EU and non-EU manufacturers.

3. <u>No More Delay - Corrections to the SPC Manufacturing Waiver are Urgently Needed</u>

- **<u>Correct immediately the evident SPC Waiver issues in currently negotiated legislative acts, such as the Biotech Act</u>**: waiting for additional years for introducing the urgent correction would be too late. The EU should take advantage of the currently negotiated legislative acts that aim at stimulating manufacturing and development of (biotech) products in the EU, in order to stop any further transfer of manufacturing capacities outside of the EU.
- **<u>Conduct the overdue legislative review without further delay:</u>** the review of the SPC Waiver Regulation, originally foreseen for 2024, has not yet been conducted. There is now a clear expectation

that this essential review will take place in 2026. The European Commission and co-legislators should seize this critical opportunity to fix the widely acknowledged shortcomings of the current SPC Manufacturing Waiver legislation and ensure that it delivers on its intended purpose. Delaying the review any further would mean prolonging the regulatory uncertainty, weakening the attractiveness of Europe as a manufacturing hub, and continuing to push business investments and operations outside the EU — contrary to the EU's stated goal of achieving strategic autonomy in pharmaceuticals and of strengthening the competitiveness of its industry.

- **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 as well as with the currently discussed Biotech Act.
- **Regulations**: **the relevant Articles on the SPC Waiver in the relevant Regulations should be amended** as soon as possible to facilitate application of the SPC Waiver in practice, and to reduce the likelihood of unnecessary abusive litigation in the Member States.
- **Guideline/Notice: as an additional and rapid short-term measure**, the European Commission should issue guidelines or a Notice to remove the existing uncertainties and limit the misuses of the – unnecessary – safeguards by SPC holders.