BIA guide to the SPC manufacturing waiver

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This guide is not comprehensive and is not intended to constitute legal advice or opinion.

Introduction

Supplementary protection certificates (SPCs) were introduced in Europe in the 1990s to provide supplementary patent-based protection for medicines that took a significant time to obtain regulatory approval and enter the European market. In this way, an SPC provides a scope of protection based on an underlying patent and marketing approval that comes into effect following patent expiry for up to a maximum period of five years (plus six months if the medicine is accompanied by a paediatric investigation plan).

In 2015, the European Commission's Single Market Strategy raised the issue of introducing a waiver to permit the European manufacture of medicines that were otherwise protected by SPCs for the purposes of export. This was particularly described to be on the premise that SPCs put European manufacturers at a competitive disadvantage compared to those outside the EU, especially in relation to the manufacture of generic and biosimilar products.

As a result, there was considerable activity, consultation, and debate as to the legal and economic implications of implementing such a waiver, which culminated in a proposal for new legislation in May 2018 (on which the BIA previously set out its position[1]). That proposal concluded with a new European Regulation which amended the existing SPC Regulation (taking effect on 1 July 2019) to introduce waivers relating to 'making' for the purpose of exporting and also for stockpiling. The BIA's IP Advisory Committee (IPAC) provided a guide for members concerning these changes at the time, dated September 2019[2].

The European Regulations governing SPC law have since been incorporated into UK law as part of the 'retained' EU law, subject to fine-tuning amendments made via UK Statutory Instruments[3]. IPAC participated in the UK Government's consultations leading up to Brexit, which in certain respects led to material changes to the way these provisions work under UK law compared to the original proposals[4].

This new guide updates and supersedes the previous guidance and takes into account how the original European legislation has been preserved and/or changed upon transformation into UK law. First, the relevant legislation is introduced and the SPCs affected by the waivers are considered. This is followed by commentary on two main substantive issues: (1) the acts falling within the waivers; and (2) the compliance requirements to benefit from them. We have included further information in the Annexes, including some key issues to consider from the perspectives of both SPC holders and 'makers'. This guide focuses on the UK perspective, albeit it is appreciated that many BIA members will also need to approach these issues from a dual UK and European perspective depending on supply chains, so we have incorporated both (and some issues are different, some are not).

In any event, as described below, these provisions will impact a significant proportion of SPCs, including rights already granted as well as existing and all future SPC applications. The BIA and IPAC encourage members to consider the new regulations in detail to help assess the impact on the sector and their own businesses, as well as to feed in to any future evaluation.

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[1] https://www.bioindustry.org/resource-listing/bia-comments-on-the-spc-manufacturing-waiver-pdf.html
[2] https://www.bioindustry.org/resource-listing/bia-guide-to-the-spc-manufacturing-waiver-pdf.html
[3] Please note, we focus only on SPC waivers for these purposes and not any of the other aspects of the SPC system which have been incorporated/amended to fit into the UK's Retained EU law.
[4] https://www.bioindustry.org/news-listing/government-changes-uk-spc-waiver-following-bia-intervention.html

The legislation

First, the European legislation implementing SPC waivers:

- Originally came into effect as of **1 July 2019**;
- Was set out in European Regulation (EU) 2019/933 (the "**SPC Amending Regulation**"), which should be interpreted in its own right but operated by amending Regulation (EU) 469/2009 (the "**SPC Regulation**"); and
- Was directly applicable and so automatically formed part of the laws of all Member States (including the UK until January 2021), without the need for any further implementation;

Considering the UK legislative position regarding SPC waivers now:

- Both the SPC Amending Regulation and SPC Regulation were incorporated into UK law as Retained EU law via the by European Union (Withdrawal) Act 2018; and
- Amendments to the SPC Regulation (taking the SPC Amending Regulation into account)were made in The Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1050) – in particular the Schedule therein (the "**UK SI**").

We have included in **Annex 1** a table summarising the provisions and definitions and how they correspond to the headings discussed in the main body of this note and other Annexes. These are still by reference to the SPC Regulation (taking into account the SPC Amending Regulation) and we have included a further column in the table in **Annex 1** commenting on the impact of the UK SI in the UK.

What SPCs are affected?

Only SPCs for medicinal products (human and veterinary) will be affected[5]. SPCs have always been, and remain, national rights. The UK SI accordingly does not impact which UK SPCs are affected by the waivers.

Two dates are critical to determining whether an SPC is affected: (i) application date of the SPC; and (ii) the date the SPC comes into effect[6]. These two dates are largely consistent across Europe because there tend to be parallel patents and marketing authorisation(s) on which SPC applications are filed in parallel across Member States.

These two dates form the basis for three categories of SPC; two that are affected and one that is not:

1. all SPCs *applied for* on or after 1 July 2019 will be affected immediately upon grant;
2. all SPCs *applied for* before 1 July 2019 (whether granted or pending at that date but not yet in effect) will be affected, but only from 2 July 2022;
3. all SPCs already *in effect* before 1 July 2019 will <u>not</u> be affected.

Because SPCs tend to be applied for long before they come into force, most of the effects of the legislation will not been seen until 2 July 2022, thereby providing a three-year transition period from the original legislation. However, each category covers multiple scenarios; one example from each is set out in the diagram contained in **Annex 2**. These are for illustration purposes only but show that an SPC could be partially affected during its term (i.e. from category (2)), and that it is technically possible to see the effects

[5] The new legislation does not change the law governing SPCs for plant protection products under Regulation (EU) 1610/96), which like the SPC Regulation is also (subject to some changes) now incorporated into UK law.

[6] Due to the risk of disparities, earlier proposals based on SPC grant date were replaced.

sooner than 2 July 2022 (i.e. from category (1)). Given the various possibilities, the dates and duration of any particular SPC must be carefully examined[7].

Whenever the first instances occur, in many cases it will already be possible to identify SPCs that will be affected, and so companies will already be considering tangible scenarios of its potential impact. Accordingly, both SPC holders and makers will (and should) be preparing.

Early cases are likely to be heavily scrutinised, potentially before national courts in the UK or EU Member States, to test the scope of the requirements under this legislation and so will be avidly watched through the industry. IPAC is not aware of any notifications made yet to the UK Intellectual Property Office.

The early examples will also form the basis of the evaluation of the waiver, which the legislation expressly obliges the European Commission to carry out no later than July 2024 (i.e. after five years) and every five years thereafter to assess whether the objectives have been achieved (reporting its findings to Parliament, the Council and the European Economic and Social Committee). In particular, the provisions highlight the making for storing waiver and the need to evaluate whether the six-month period is sufficient. However, in the UK, the UK SI deletes this provision, and so an evaluation (or its timing) of the UK system is not mandated.

In any event, the BIA encourages members – both SPC holders and makers – to keep records of examples and any issues arising from this legislation and consider raising them with the BIA/IPAC in order to shape the UK's approach to this system and/or feed into to any Commission evaluation in the EU.

What acts fall within the waivers?

The legislation concerns two waivers, which are based on "*acts*", particularly "*making*":

- **making for export** to countries outside the EU; and
- **making for storing** for sale in the EU at 'Day 1' following SPC expiry.

The UK SI had a considerable impact on the scope of the waivers in the UK, in particular following the responses (including by the BIA) to the UK Government's consultation, which resulted in material changes to the position originally proposed.

Both waivers relate to a "*product*" or the "*medicinal product*" containing that product e.g. including the active ingredient (or combination) and marketed drug, respectively - both defined in the SPC Regulation.

"*Strictly necessary*" related acts are also permitted – the scope of which is subject to considerable discussion in the recitals to the legislation, which include:

- a non-exhaustive list of what could be included, such as: "possessing; offering to supply; supplying; importing; using or synthesising an active ingredient for the purpose of making a medicinal product; or temporary storing or advertising for the exclusive purpose of export to third-country destinations"; and
- acts that should not be included in any event, such as: "placing …on the market of a Member State where a certificate is in force", "re-importation … into the market of a Member State in which a certificate is in force" or "any act or activity carried out for the purpose of import … into the Union merely for the purposes of repackaging and re-exporting."

Note, the wording of the recitals are unchanged by the UK SI, but will remain relevant to its interpretation.

[7] Including any impact of paediatric extensions to SPC duration obtained under Regulation (EU) 1901/2006 (again, as now incorporated into UK law).

The **making for export** waiver:

- Applies to the whole of a qualifying SPC's term (or relevant part thereof).
- Under UK law, 'exporting' must necessarily take place directly from the UK (where the 'making' also takes place). However, in European Member States, 'exporting' is not expressly limited, for example, as to whether export occurs directly from the Member State of making or whether further supply chain steps may be included such that export occurs from another Member State.
- The destination of export remains ex-EU and the UK SI requires export "*outside the United Kingdom, the Isle of Man and the Member States of the European Union*". The prevention of export from the UK to the EU is in line with the firm views of BIA members as to the need to prevent what would have been an erosion of their IP rights protecting their position in the second largest medicines market globally. However, the UK remains a "third country" for the purposes of the waiver in EU Member States – and so should the term of protection in the UK be shorter (or revoked), this waiver *could* be used for making in Europe for export to the UK.
- The destination countries are described as markets in which "*protection does not exist or has expired*". However, this position is only in the recitals of the EU legislation and is not further defined or described in the legislation itself (and the same applies to the UK SI). Accordingly, it is not clear as to what extent "*protection*" must not exist vis-à-vis any intellectual property or other rights that the SPC holder (or any other party) might hold with respect to the relevant product/medicinal product. Elsewhere, the legislation contains a broad statement that it is "*without prejudice to other intellectual property rights that could protect other aspects of a product, or a medicinal product containing that product*". This provision is likely to be heavily scrutinised and is also relevant to the secondary due diligence obligations imposed on the "maker" (discussed below).
- The UK SI had a considerable impact on the scope of the waivers in the UK, in particular following the responses (including by the BIA) to the UK Government's consultation, which resulted in material changes to the position originally proposed.

The **making for storing** waiver:

- Applies only during the final six months of a qualifying SPC's term.
- Even though this is commonly discussed under the ambit of 'stockpiling', it is nonetheless a 'making' waiver (in addition of course to permitted related acts).
- 'Storing' is expressly described in the EU legislation as "*storing in the Member State of making*" – which in the UK is automatically preserved in the UK SI as both storing and making must take place in the UK. This creates a possible contrast to the making for export waiver in the EU.
- The UK SI establishes that the scope of this waiver permits making for storing/stockpiling in the UK ready for 'Day 1' post SPC expiry sales in the UK or EU post SPC expiry. Accordingly, this UK waiver may be utilized for storing/stockpiling for sales to the EU post-SPC expiry (as is the case in a EU Member States – however, again there is disparity in that making and storing in EU Member States would not be permitted for subsequent sales to the UK under this waiver; accordingly such activities would need to be considered only in relation to the making for export waiver (above)).

In summary, the waivers apply an exemption to the "*effects*" of an SPC preventing enforcement by SPC holders under the SPC Regulation. Ordinarily, an SPC provides the "*same rights as conferred by the basic patent*", which are based on the largely harmonised acts of patent infringement across Europe. While in the context of patent infringement "*manufacturing*" is the subject of well-established case law, "*making*" is not

defined in the new legislation. The scope of "*related acts*" is novel and defined across several recitals making its precise scope difficult to predict.

All of the relevant acts and locations in a supply chain network will need to be carefully analysed to determine whether and how the waivers might apply. In particular, as noted in the bullets above, the UK SI can only account for the acts of exporting, storing and all related acts necessarily taking place in same place as the making: i.e. automatically the UK. This is in contrast to the position in EU Member States where only making and storing appear to be tied to the same Member State, whereas making, exporting and all related acts are apparently not.

What do 'makers' need to do to benefit from a waiver?

Assuming the acts fall within the waivers (discussed above), there are a further set of provisions, each of which imposes obligations on the "*maker*".

The critical aspect of these obligations of course is to identify the relevant "*maker*", which is a term defined in the legislation. The UK SI has some impact here as the 'maker' in the UK must be a person established in the UK on whose behalf the making is carried out, whereas in the EU establishment is necessary in any Member State. While the "*maker*" will therefore be established in the UK or EU for the waivers to apply, they do not seem to need to perform the making according to this definition.

In straightforward examples, the maker will be the manufacturer of the product (e.g. active ingredient). However, given the lack of definition of "making" and the apparent separation between "making" and "related acts", it may be complex to identify who the maker(s) is (or are). At least in the UK, the maker must be established here, whereas in Europe, they could be established in any EU Member State. This is a significant compliance issue because it is at least arguable that if a person who is not the maker makes the notification, that all those involved in the supply chain (i.e. performers of 'making' and 'related acts') may lose the benefit of the waiver.

Once identified, the maker is obliged to:

- issue notifications, and, if necessary, update the information therein;
- comply with labelling requirements (only for making for export);
- comply with due diligence requirements in relation to contracting parties; and
- pay fees for notifications (and updates).

We set out further details concerning the notification, labelling and due diligence requirements in **Annex 3**. Furthermore, some key issues from the perspectives of SPC holders and makers are included in **Annex 4**.

The fees are left to the discretion of the authorities of each Member State (but should not exceed administrative costs of processing them) and apply to an original notification, as well as any further update(s). The recitals to the legislation acknowledge that a notification could be provided before the SPC in question is affected (i.e. any time from 1 July 2019). The UK SI requires that form SP5 should be used for notifications and confirms there is no fee[8].

Compliance with these requirements requires careful attention as failure with any may disqualify the maker and those who commit related acts from protection under the waiver(s). This is not expressly stated as such, but compliance appears to be obligatory. The only provision which deals with non-compliance

[8] https://www.gov.uk/government/publications/notification-for-spc-manufacturing-waiver

(concerning notification of marketing authority number when making for export; paragraph 7 of the amended Article 5) limits the effect of non-compliance to only the third country in question. Other non-compliance may disqualify the maker and those who commit related acts from the waiver entirely. For example, it is at least arguable that if a person who is not the maker makes a notification – a potentially complicated issue for the reasons discussed above – that all those involved in the supply chain will lose the benefit of the waiver.

Depending on the requirement in question, it is possible that infringing acts may have already occurred by the time non-compliance is identified (e.g. regarding labelling), whereas in other cases, the requirement may be heavily scrutinised upfront (e.g. regarding notification). Compliance is naturally going to be critical, and no doubt heavily scrutinised between makers and SPC holders.

About the BIA and IPAC

The BIA is the trade association for innovative life sciences in the UK. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

Our members include:

- Start-ups, biotechnology and innovative life science companies
- Pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors; lawyers; IP advisors; and investor relations agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably. The Intellectual Property Advisory Committee (IPAC) helps the BIA shape the environment for IP ownership and protection. The committee includes technical experts and IP professionals from a range of member companies and experienced lawyers from the top private practice IP member firms.

For more information on the content of this guide, please contact Dr Martin Turner, Head of Policy and Public Affairs, BIA, on 0207 630 2192 or mturner@bioindustry.org.

Annex 1 – Overview of provisions of the new legislation

The following table picks out some of the main provisions relating to the headings discussed in the main body and annexes of this note.

Issue	SPC Reg	SPC Amendment Reg		Comment	Material impact/change in UK SI?
		Art (Para)	Recital / Annex		
What SPCs are affected?	Art 5(10)	Art 1(2)	(26), (27)	Based on application date and date of effect, including 3-year transition.	None (same SPCs affected)
Looking ahead	Art 21(a)	Art 1(5)	(28)	Evaluation every 5 years.	Deleted – i.e. no mandatory evaluation.
What acts fall within the waivers?	Art 5(2)(a) (i)-(iv)	Art 1(2)	(8)-(12), (22)	Making for export, making for storing and in each case related acts.	Confirms export must still be outside EU.
	Art 5(3)			And exceptions re import for re-packaging, re-export or storing.	None
Who is/are the maker(s)?	Art 1(f)	Art 1(1)	(4)-(6)	"*Maker*" means the person on whose behalf the making of a product for export / storing was carried out.	Maker must be established in the UK.
Notification requirements	Art 5(2)(b)	Art 1(2)	(14) – (19), Annex 1a	Maker must notify authority and certificate holder no less that 3 months before "making" (or if earlier, related act) begins.	None
	Art 5(2)(c)			Updating obligations.	None
	Art 5(4)			Restrictions on use of information.	None
	Art 5(5)(a)-(e)			Contents of notification.	There are some amendments here – mainly re UK but also to remove from aspects (as all acts will take place in UK)
	Art 5(6)			Standard form (Annex 1a).	Now form SP5 (and no fee)

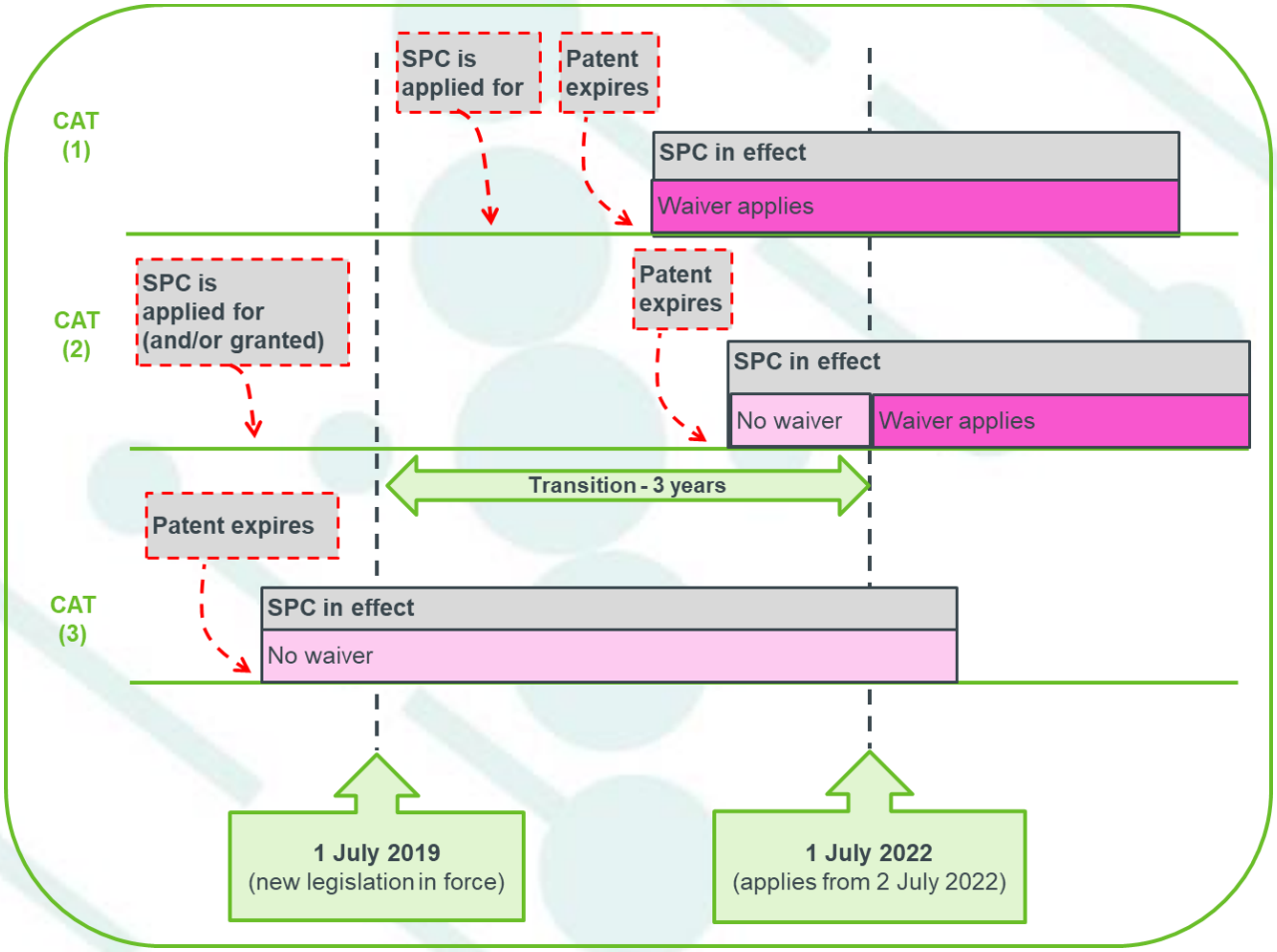
Issue	SPC Reg	SPC Amendment Reg		Comment	Material impact/change in UK SI?
		Art (Para)	Recital / Annex		
	Art 5(7)			Fail to comply with Art 5(e).	None
	Art 11(4)	Art 1(3)		Publication requirements.	None
Labelling requirements	Art 5(2)(d)	Art 1(2)	(21), Annex 1	EU export logo requirements.	Change to "UK Export".
	Art 5(8)		(24)	Active unique identifier restrictions.	Deleted in UK SI
Due Diligence requirements	Art 5(2)(e), 5(9)(a)-(b)	Art 1(2)	(20)	Obligations re supply chain.	
Fees	Art 5(2)(e), 12(2)	Art 1(2), Art 1(4)	(14)	Notification (and update) fees.	None (but UK will not charge a fee)

Annex 2 – SPCs affected by the new legislation

Three categories of SPC will be affected by the new legislation; two that are affected and one that is not:

1. all SPCs *applied for* on or after 1 July 2019 will be affected immediately upon grant;
2. all SPCs *applied for* before 1 July 2019 (whether granted or pending at that date but not yet in effect) will be affected, but only from 2 July 2022;
3. all SPCs already *in effect* before 1 July 2019 will <u>not</u> be affected.

One example scenario (of many) from each of these 3 categories is illustrated below:



Annex 3 – requirements (notification/labelling/due diligence)

Notification

The maker needs to make two notifications:

- to the SPC granting authority in the UK or EU Member State in which the making is taking place; and
- to the SPC holder.

The notification must be:

- no later than **three months** before the start date of making (or the first related act prior to making if it is in an otherwise infringing act, if earlier);
- in certain circumstances, updated;
- subject to a fee (including for updates).

The notification will be published by authorities "as soon as possible", including as to any updates.

The table below sets out more details concerning the content of the notification.

<table>
<tr><td>What form must the notification take?</td><td colspan="2">The new legislation requires that the standard form (in Annex 1a) "shall be used".
There is also reference to "appropriate and documented means", which will be determined by the routes available for the relevant authority and SPC holder. For example, some authorities may make electronic forms available, whereas an SPC holder may only provide a postal address on the register. The content and transparency of SPC registers across Europe should be taken into account.
NOTE: the UK SI contained a transitional arrangement such that if any notification was already made, it is to be treated as having been made in the form required by the new SI and without changing its date.</td></tr>
<tr><td rowspan="6">What information is needed?</td><td colspan="2">This is set out expressly (as well as being determined by the headings in the standard form):</td></tr>
<tr><td rowspan="2">(a)</td><td>the name and address of the maker;</td></tr>
<tr><td>Note: previous proposals requiring the name and address of the premises where making is taking place were removed.</td></tr>
<tr><td rowspan="2">(b)</td><td>an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;</td></tr>
<tr><td>Note: previous proposals requiring the intended start date of making were removed, as was a requirement to provide an indicative list of destination third country(ies) re export.</td></tr>
<tr><td rowspan="2">(c)</td><td>the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;</td></tr>
<tr><td>Note: the intention here seems to be to identify the Member State of making and the first step in the relevant supply chain re any prior related act. There is no reference to related acts after making.
Note also: In the UK SI, this is deleted as all acts will take place in the UK.</td></tr>
</table>

	(d)	the number of the certificate granted in the UK (or Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making); and
		Note: previous proposals requiring details of authorisations in relation to manufacturing or good manufacturing practice were removed.
	(e)	for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each country of export, as soon as it is publicly available.
		Note: the recitals to the legislation describe that if information in this respect is pending publication, the maker should promptly be required to provide it as soon as it is publicly available.
Can any information be left out?	The recitals acknowledge that notices should not include "*confidential or commercially sensitive information*" but there is no further guidance on how this will work versus the headings of information required above.	
Does a notification need to be updated?	If the information listed above changes, the maker is obliged to notify the authority and the SPC holder before those changes take effect.	
Is there a fee?	The legislation permits authorities to charge a fee for both the original notification and updates. *(Note: UK has no fee)*	
Will the information be published?	The authority is required to publish, as soon as possible, the information listed in the notification. *Note: Previous proposals which expressly divided notified information between that provided to the authority and that provided to SPC holders were removed. As noted above, there is also no express guidance on whether this has any relation to the statement concerning the omission of "confidential or commercially sensitive information".*	
Are there any restrictions on using the information?	The legislation states that the information provided to the SPC holder in the notification shall be used "*exclusively for the purposes of verifying whether the requirements of this Regulation have been met and, where applicable, initiating legal proceedings for non-compliance*".	

Labelling

The labelling requirements are different in the UK SI and EU legislation.

There are two labelling requirements, both of which apply only to the making for export waiver and which are again cast as obligations on the "maker".

In the EU legislation:

- The first requirement concerns an 'EU export logo' (set out in Annex 1 to the EU legislation), which must be applied to products (or medicinal products containing those products) *"to the outer packaging"* and *"where feasible, to its immediate packaging"*. Given the diversity of products and medicinal products, this

requirement will depend on the particular circumstances, especially as to the feasibility of applying it to immediate packaging.

- The second requirement concerns prevention of re-importation and obliges the maker (in respect of making, but not expressly in respect of related acts) to ensure that medicinal products intended for export do not contain an 'active unique identifier' within the meaning of Regulation (EU) 2016/161 (regarding falsified medicines). Compared to the EU export logo above, this applies only to medicinal products and so may not be a relevant safeguard where only active ingredients are exported.

In the UK SI:

- The first requirement instead requires "UK export" (along with a minor change that the labelling must be "clear and visible to the naked eye"). There is also a transitional provision meaning that if anyone had already applied the "EU Export" logo that the "UK export" does not need to be affixed as well. More significantly, the new SI gives the Government the power to set out further conditions on how the "UK Export" words should be presented, if needed. This will be an important area for BIA members to monitor given the importance of the logo to safeguard and prevent diversions back to the home market.
- The second requirement re 'active unique identifier' is not included in the UK SI.

Due diligence

The primary due diligence obligation on a maker (applicable to both making for export and making for storing) concern its engagement with contracting parties that perform acts (including related acts) seeking to benefit from a waiver.

These obligations only go so far as ensuring such contracting parties are *"fully informed and aware"* in two respects: (a) an assertion that the acts in question are subject to the waiver; and (b) a warning that straying into certain acts could infringe the SPC, specifying acts in respect of each waiver:

- For making for export, the acts specified are: placing on the market; import or re-import of the product or the medicinal product containing that product – emphasizing again that re-importation of any exported product (or medicinal product made using an exported product) is not permitted.
- For making for storing, the act specified is: placing on the market the product, or the medicinal product containing that product – emphasizing simply that launch is not permitted during SPC term.

The recitals to the EU legislation refer to makers informing *"persons within its supply chain"*, which is different to the language of the provision of *"any person in a contractual relationship"*. Like the main notification requirements, the recitals also refer to this notification being via *"appropriate and documented means"*. However, there is no standard form. The recitals go on to state "*in particular contractual means*", which might suggest that a statement should be made in the relevant contract. The recitals also refer to the cumulative nature of these requirements and state that non-compliance should prevent the maker (and any third party carrying out a related act) from benefiting from the waiver.

There is a secondary due diligence requirement set out in the recitals to the legislation which states that it is the responsibility of a maker seeking to rely on the making for export waiver *"to verify that protection does not exist or has expired in a country of export, or whether that protection is subject to any limitations or exemptions in that country"*. This refers to the need for a maker to have performed due diligence to ascertain that *"protection does not exist"*, which will need to be carefully considered (as discussed above).

Annex 4 – some key issues to consider

Note: these are set at a general, reasonably high level but will need to take into account how they apply either in the UK or in one or more EU Member States.

For SPC holders

- *Calculating the impact* – the applicability of the new legislation will already be calculable in relation to a number of SPCs (granted and/or pending) such that SPC holders can begin to consider and prepare for cases already.
- *Gearing up for administrative formalities* – preparing to receive notifications (and updates) is a key issue, including checking register details in all Member States and what routes of communications will be available to makers. SPC holders may also want to monitor the means by which authorities propose to publish notifications.
- *What to expect from a notification (and updates)* – the lack of clarity of some of the obligations and information means that it may not provide a complete picture of a contemplated supply chain (e.g. where the acts are actually taking place, who all of the other parties in a supply chain are, etc). SPC holders should prepare for what to expect so as to scrutinise non-compliance, potentially with the assistance of commercial intelligence.
- *What to do with a notification* – processing the information contained in the notifications within the business may be an important issue, in particular given the express restrictions on its use. Information channels should be carefully considered, particularly by SPC holders contemplating the enforcement other intellectual property rights aside from the SPC in question.

For makers

- *Identifying SPCs that will be affected* – SPCs affected by the new legislation will have already been applied for and/or granted so opportunities to use a waiver will already be apparent.
- *Gearing up for administrative formalities* – makers will want to monitor the details for relevant SPCs and their holders and understand the means by which notifications may be made to authorities, as well as the relevant fees and how publication will be implemented.
- *Consider your supply chain carefully* – not all of the provisions are clear and will require examination so as to answer a number of questions, including:
  - Determining for all of the acts in a given supply chain, what are the "acts" (i.e. what "making" means) and/or the "related acts", which has associated issues including:
    - are you or another party the "maker" (that needs to comply with notification, labelling and due diligence requirements)?
    - in how many countries do notifications need to be made?
  - For making for export, what is the destination country and is there any *"protection"* there (and what does this mean)?
  - For making for storing, are there any territorial restrictions as between making and storing?
- *What to include in a notification (and updates)* – the lack of clarity of some of the obligations and information means this will require careful consideration, including:
  - Consider the standard form of the notification, including what is and what is not included;

  - Plan for what may be needed initially and what may be updated subsequently (and according to what timing requirements);
  - Consider carefully the acknowledgment that "*confidential or commercially sensitive information*" should not be included and how this works;
- *How may the notification be used/misused by the SPC holder* – noting the restrictions on its use.
- *Comply with labelling requirements* – in particular considering whether it is 'feasible' to apply the logo to immediate packaging and considering the process management as to the inclusion or omission of unique identifiers depending on which waiver is being used.
- *Comply with due diligence requirements* – in particular considering the extent of notifications in your supply chain and what may be needed to be included in any contract(s) (both in respect of notification requirements, but also from the perspective of protection and considering liability as to compliance with the new legislation).