# BIA comments on the no-deal SI for the SPC manufacturing waiver

## August 2019

UK BioIndustry Association

The BIA is grateful for the opportunity to comment on the proposed secondary legislation amending the retained EU law for the SPC manufacturing waiver. It is critical that retained EU law functions from a legal perspective and that the changes made do not have unintended and/or adverse impacts on UK businesses at a time when they are already under significant stress as a result of the uncertainty of Brexit.

## Overarching position of the BIA

The BIA has received a strong response from its members on this consultation, especially from the larger multi-national companies. The approach proposed by the Government in the consultation and the one taken in the Patents (Amendment) (EU Exit) Regulations 2019 appear to potentially reduce innovators' intellectual property rights (IPRs) and have not been well received by the global life sciences industry as a result. This is an unhelpful message to be emanating from the UK at a time when the BIA and other industry players are working hard to maintain global confidence in the UK life sciences environment.

If in force in a no-deal Brexit scenario, the Patents (Amendment) (EU Exit) Regulations 2019 will result in reduced SPC terms for medicines in the UK if they do not receive market authorisation (MA) at the same time as it is granted in a European Economic Area Member State[1].

The approach proposed in the current consultation would permit export of UK SPC-protected medicines to EU Member States where an SPC is not in place. This would not be permitted if the UK continued to operate under the EU manufacturing waiver and thus is perceived by our members as a further erosion of existing IPRs by the global industry.

The negative impression created by these potential impacts is exacerbated by the appearance that the two approaches are contradictory: The Patents (Amendment) (EU Exit) Regulations 2019 continue to treat the EU as a home market for calculating SPC terms, but the Government is treating it as an export market in the current consultation. There has been a change in political leadership and the Government's new approach to planning to leave the EU could be resulting in incoherence between past and current approaches, which should be carefully examined and revisited if necessary.

Furthermore, the BIA is concerned that the proposed changes impacting the scope of the waiver could be perceived by Parliament and the courts to be beyond that required to "fix" the retained EU law and that

[1] Also, it is not just the SPC term which is reduced in this way if there is an earlier EEA/EU MA. There is also a similar impact for regulatory data protection (RDP) and orphan market exclusivity (OME) under articles 56 and 64 respectively of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, under which the RDP and OME terms are calculated based on the date the first UK or EU/EEA MA takes effect. The additional 1-year periods of RDP available for new indications that bring a significant clinical benefit and for new indications for well-established substances are also reduced or even eliminated by having an earlier EU MA under article 56.

There is also an additional limitation on UK paediatric extensions of SPCs under article 64 of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 referred to above – Art 64(4) prevents UK MA holders getting an SPC extension if they are entitled to a one year extension of the ten year RDP period for the new paediatric indication even if the extra one year UK RDP was reduced or even eliminated altogether by an MA being granted earlier in the EU/EEA.

Ministers are thus exceeding their powers under the Withdrawal Act. We are keen to work with the IPO to ensure that this is not the case.

In his first speech as Prime Minister, Boris Johnson highlighted the life sciences sector as an "enormous strength" of the UK economy. The Government's approach shown in the consultation risks undermining that positive message. The BIA therefore urges the Government to use the time before 31 October to send out a positive message to the global life sciences industry that the UK intends to remain a world-leading location for the discovery, development and launch of innovative medicines.

## Action proposed by the BIA

In February, the Rt Hon Lord Henley, then Parliamentary Under-Secretary of State at the Department for Business, Energy and Industrial Strategy, committed the Government to "immediately" start to explore the future SPC landscape in the event of a no-deal Brexit. With the Government now stepping up its preparations for a no-deal Brexit and "seizing the opportunities" of being outside the EU, we believe that the Government should act now to send a positive message to the global life sciences industry that the UK is committed to protecting their IPRs and increasing incentives for innovation. This would be in line with the Government's ambitions to establish a trade deal with the United States.

The UK should amend its approach to continue to protect innovators' rights to prevent manufacture for export to EU Member States; this would preserve the status quo and maintain innovators' legitimate rights currently in place under the existing EU Regulation. The Government should also reverse the approach taken in the Patents (Amendment) (EU Exit) Regulations 2019 and The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 to use EU MAs when calculating UK SPC, RDP and OME terms. This is an opportunity to create a good news story for the UK that will be well-received in global Board rooms.

A wider review should then be undertaken as a priority if the UK leaves the EU without a deal, to look at the UK's IP incentives for innovation, including whether the manufacturing waiver is in the best interests of the UK's life sciences sector.

## Detailed comments on proposals

**Article 5(2)(a) + 5(3) – scope of the waiver**

As described in the consultation document, Section 8 of the Withdrawal Act gives Ministers specific powers to make changes to retained EU law to fix parts that do not work. The consultation sets out a premise for a reinterpretation of the waiver Regulation in the event of the UK being outside of the EU, but it does not explain why wording that would maintain the EU as a "home market" would not work. It is therefore possible that Parliament and the courts could take the view that the Government is making a policy change beyond that permitted by the Withdrawal Act.

We appreciate that the IPO has sought to provide some balance in its approach. However, our members are of the view that permitting manufacturing for export to the EU is an erosion of their IPRs protecting their position in the second largest medicines market globally. This is because UK export in the following scenarios may be permitted under the Government's proposed retained law but not the current EU Regulation:

1. A class of older products going to countries which didn't have SPC legislation (potentially as they were not part of the EU) at the time the SPCs in EU Member States were applied for.

2. Products for which the SPC owner did not apply for SPCs at the time in certain Member States for commercial reasons (cost of SPC and market size) being exported to those Member States
3. Export to a country or countries where SPCs are not granted (variations in granting practice exist) or where they are revoked. Revocation of an SPC in, for example, Germany, would allow UK-manufactured generics companies to sell into Germany which would not be the case under the existing EU Regulation. This may be relatively rare but the market sizes could be fairly significant. This could also increase the likelihood of tactical litigation in EU Member States by UK generics seeking to gain earlier entry in some countries than their European competition.

On a point of clarity for the proposed amendment in Art 5(2)(a)(i): it refers to "third countries" but it is our understanding that the Government does not wish to continue to use this concept, which refers to countries outside the EU. The current amendment is therefore confusing.

**Related Acts**

As the wording shown in the mark-up in Annex B of the consultation document currently stands, it could be read to mean that it is just the "making" that takes place in the UK and not the "related acts". To make it abundantly clear, the provisions under Art 5(2)(a)(ii) and (iv) could be re-worded as follows (proposed changes shown in red):

> 2(a)(ii) any related act (carried out in the UK) that is strictly necessary for the making, ~~in the UK,~~ referred to in point (i), or for the actual export; or
>
> …..
>
> 2(a)(iv) any related act (carried out in the UK) that is strictly necessary for the making, ~~in the UK,~~ referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate.

**Isle of Man**

The proposed amendments to Art 1(k) are potentially confusing: the reference to the maker being "established in the UK" and export to "outside the UK and the Isle of Man" could be interpreted in such a way that the "maker" cannot be established in the Isle of Man.

The same is true in respect of stockpiling. The Art 5(2)(a)(iii) provision may be interpreted such that a manufacturer could not stockpile in the Isle of Man.

**Article 5(2)(d) – the logo**

The logo is an important safeguard to prevent diversions back to the home market. We agree that the words "EU export" would be misleading. Removing the EU flag and amending the text to read "UK export only" (or "UK and EU Export") as the minimal change required to achieve proper functioning. A flag or other non-text signifier would be welcome to increase the visibility of the logo and would be analogous to the status quo.

We also believe that "visible to the naked eye" needs further explanation.

**Other changes**

We agree with the necessary changes to refer to UK institutions.

We also agree that in the absence of a functioning unique identifier system in the UK post-no-deal Brexit, it is not necessary to include this specification in the retained law. However, there is much benefit from such a system and we believe the UK Government should explore developing its own system or gaining access to

the EU one. If this is successful, then the Government should reinstate this safeguard in the SPC manufacturing waiver legislation.

We do not agree with the removal of a review provision from the retained law. The UK cannot put this obligation on a body outside the UK, but it can commit the IPO to conducting its own review, which we believe it should do.

**Further comments**

If the UK opts to take the approach proposed by the BIA to restrict exports to EU Member States, the UK should seek to secure a similar restriction of the EU's export market definition under goodwill. It should also include requirements to notify for related acts in each other's jurisdictions to help protect UK and EU innovators' rights.

## About the BIA

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 consultants, IR agencies

We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

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