



Law Society
of Scotland



Consultation Response

Draft legislation: supplementary protection certificate
manufacturing waiver in a 'no deal' outcome

August 2019



Introduction

The Law Society of Scotland is the professional body for over 12,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's solicitor profession.

We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

Our Intellectual Property Law Sub-Committee welcomes the opportunity to consider and respond to the Intellectual Property Office's Inquiry on *Draft Legislation: Supplementary Protection Certificate Manufacturing Waiver in a 'No Deal' Outcome*.¹ We have the following comments to put forward for consideration.

Response to questions

Q1: Do the proposed changes correctly establish that the UK waiver permits export to countries outside the UK and stockpiling for sale on the UK market post-SPC expiry?

Yes, but see further our response to Q3 regarding retaining the phrasing of "Third Country" in the drafting.

Q2: Are there any issues you might foresee with the drafting?

We do not consider that the drafting adequately addresses the distinction between countries other than the UK that are within the EU and countries outwith both the UK and the EU. This will be important when dealing with any further transitional provisions that may be required.

Q3: Are there any issues with replacing references to "third countries" in this way?

¹ <https://www.gov.uk/government/consultations/supplementary-protection-certificate-waiver-no-deal-legislation>

"Third Country" in the sense it appears in the original EU legislation is an EU-specific concept: it might be more appropriate to refer to export as simply "*to countries outside the United Kingdom and the Isle of Man*", to avoid any confusion with the drafting.

Q4: Is it sufficiently clear that only related acts within the UK fall within the scope of the UK waiver?

Yes.

Q5: Does the proposed drafting do enough to avoid confusion with the EU approach?

Currently, the manufacturer of a waiver-protected product must ensure that a specific logo, bearing the words "EU export" and the EU emblem is placed on the packaging of any product destined for export. The proposed approach of changing the wording from "EU export" to "UK export" is clear.

However, the logo provided at Annex I of Regulation (EU) 2019/933 is an image of the EU flag. As it would be misleading to indicate that the product was EU-made and it could create confusion as to which waiver is being relied on, we consider that a new logo is required in order to avoid confusion.

Q6: Do you have any suggestions as to alternative definitions or features that you may wish to see included/not included?

As noted above, we consider that a new logo should be created to avoid confusion.

Q7: Do you foresee any issues with removing the form from the SPC Regulation and making it a prescribed form?

We do not foresee any issues.

Q8: Would you prefer a single form covering both initial notification and re-notification, or separate forms for each action?

We are content that notifications and updates for existing notifications continue to be done via a single form.

Q9: Are there any issues with the changes suggested in this section?

The changes suggested in this section are as follows:

1. Replacing references to the generic authority with a specific reference to the "Comptroller" as per the changes made by Regulation (EU) 2019/933.
2. Removal of the requirement for medicines for sale in the EU to feature a unique identifier, as the EU law implementing this will no longer apply when the UK leaves the EU.
3. Removal of obligation on the EC to conduct an evaluation of the new waiver, as retaining this would impose an obligation on a body outwith the UK.

We do not consider that these changes would be problematic. However, we note that where a medicine is being exported to the EU, then EU law will continue to apply to that product.

Q10: Can you foresee any issues with all relevant SPCs becoming subject to the new waiver scope after the SI comes into force?

We do not foresee any issues.

Q11: Are there any further transitional provisions you think may be needed?

We have no comment on this question.

Q12: If you do not agree with the approach we have set out:

- a) What types of situations should be accounted for?
- b) Should there be a distinction between how we treat applications for SPCs filed (i) between 1 July and exit day; (ii) between exit day and when this SI comes in?
- c) Should the date of grant of the SPC be considered in any transitional provisions?

We agree that SPCs applied for after 1 July 2019 that take effect prior to the SI comes into force should be subject to transitional provisions.

Q13: Please raise any other issues or concerns you feel are appropriate.

We have no further comments.

For further information, please contact:

Carolyn Thurston Smith
Policy Team
Law Society of Scotland
DD: 0131 476 8205

carolynthurstonsmith@lawscot.org.uk