Intellectual Property Office

Draft legislation:

supplementary protection certificate manufacturing waiver in a 'no deal' outcome.

Contents

Introduction

1. In April, the UK and the European Union agreed an extension to the Article 50 period until 31 October 2019 at the latest, with the option to leave earlier as soon as a deal has been ratified. Until that time, the UK remains a Member State of the European Union and EU law continues to apply.

2. Until a deal is approved by Parliament, the Government remains committed to preparing for all scenarios, including leaving with no deal on 31 October 2019 ("exit day"). Although Parliament has rejected leaving without a deal multiple times, this remains the legal default at the end of the extension period and preparing for a no-deal outcome therefore remains a priority for the Government.

3. The EU has recently introduced new legislation relating to supplementary protection certificates (SPCs), establishing a new "manufacturing waiver". Like all EU law in force in the UK, this will be retained as UK law on exit day. The basis of this call for views is a proposed statutory instrument which seeks to fix various provisions relating to this manufacturing waiver which will no longer function correctly after the UK leaves the EU.

4. We are seeking views on the drafting of the proposed statutory instrument, and particularly on whether the proposed drafting achieves the aims discussed in the sections below. We are keen to ensure that the amendments will work in practice for users of the system and to avoid any unintended consequences.

5. This document is directed primarily at those most likely to use or be affected by the manufacturing waiver; namely individuals, businesses, and organisations who are generally familiar with the patents system and supplementary protection certificates.

Note to respondents

6. When responding, please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

7. It is not necessary to respond to all the questions; you are welcome to provide answers only to those issues of most interest or relevance to you. The Government will note all responses and publish a response document in due course but will not respond to comments on an individual basis.

8. This call for views will run for five weeks; the closing date for responses is 11:45pm on 9 August 2019. Responses can be submitted by email or post to the details below:

SPC Waiver Legislation Consultation
Patents Legal Section, Intellectual Property Office
Concept House
Cardiff Road
Newport
NP10 8QQ

Email: SPCconsultation@ipo.gov.uk

Confidentiality and data protection

9. This call for views and the processing of personal data that it entails is necessary for the exercise of our functions as an executive agency of Government. If your answers contain any information that allows you to be identified, IPO will, under data protection law, be the controller for this information. You do not have to give us this personal information. If you do provide it, we will use it only for the purpose of this call for views. Your information will be kept securely within the IPO internal systems and destroyed within 12 months after this call for views has closed. IPO's privacy pages have more information about your rights in relation to your personal data, how to complain and how to contact the Data Protection Officer.

10. Information provided in response to this call for views, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes - these are primarily the Freedom of Information Act 2000 ("FoIA"), the Data Protection Act 2018 ("DPA"), and the Environmental Information Regulations 2004.

11. If you want other information that you provide to be treated as confidential, please be aware that, under the FoIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, if you consider information you have provided to be confidential, it would be helpful if you could explain to us why this is the case. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Intellectual Property Office ("IPO").

Background

The supplementary protection certificate system

12. Supplementary protection certificates (SPCs) provide for an additional period of protection for patented medicines, to compensate for delays caused by the need to get regulatory approval before these products can be sold.

13. Currently, this protection is provided through EU law - Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products ("the SPC Regulation") - although the SPCs themselves are national rights.

The manufacturing waiver

14. Normally, an SPC gives its holder the same rights as the patent on which it is based. This means that the SPC holder can take steps to prevent a third party from making or storing the medicine in the country where it is protected, amongst other things.

15. The new "manufacturing waiver", which came into effect on 1 July 2019, introduces an exception to this general principle. The waiver allows third parties to make the medicine without needing the permission of the SPC holder, but only for specific purposes.

16. This can only be done if the medicine is being made for export to a country outside the EU, or, in the final six months of the SPC, for storing to sell on the EU market once the SPC has expired ("stockpiling").

17. This new waiver was implemented by Regulation (EU) 2019/933 ("the waiver Regulation"), which amended the SPC Regulation to insert the relevant exceptions.

The Withdrawal Act

18. The European Union (Withdrawal) Act 2018 ("the Withdrawal Act") is designed to ensure that, as far as possible, the same rules and laws will apply on the day after exit as on the day before. The Withdrawal Act automatically preserves EU law as it stands on exit day as part of UK domestic law, and this is known as "retained EU law".

19. Under the Withdrawal Act, the version of the SPC Regulation that exists on exit day will be retained automatically as UK domestic law. This will include the amendments that are made by the waiver Regulation. As Regulations, these will be treated as equivalent to UK primary legislation in future. This means that only an Act of Parliament, or a power provided in an Act, can make amendments to them in future.

20. Section 8 of the Withdrawal Act gives Ministers specific powers to make changes to the retained EU law to fix the parts that do not work, so that the retained law functions effectively as UK law following exit from the EU.

21. However, the Withdrawal Act powers only permit changes to be made where there is an issue that needs to be addressed to make the legislation work correctly after exit. This means that anything more extensive can only be introduced by primary legislation.

22. There will be parts of the SPC Regulation which are introduced by the waiver Regulation, and kept by the Withdrawal Act, that will not work correctly. As the purpose of the Withdrawal Act and its powers is to ensure a functioning statute book, we need to make sure that appropriate fixes are made. This is what the draft instrument is designed to achieve.

How this instrument relates to the previous "no deal" patents SI

23. In early 2019, Parliament approved the Patents (Amendment) (EU Exit) Regulations 2019 ("the 2019 Regulations"). These regulations used the power provided by the Withdrawal Act to make changes to a number of areas of patent law which would be affected when the UK leaves the EU. This included the SPC Regulation.

24. The 2019 Regulations will come into force on exit day, and the changes included within them will take effect at that point.

25. As the waiver Regulation had not been completed at the time the 2019 Regulations were made, the 2019 Regulations do not include any provisions to deal with the changes the waiver Regulation introduces. This is why this new instrument is needed.

26. The new instrument only relates to the changes introduced in the waiver Regulation; as the 2019 Regulations are already approved and their changes made, they cannot be revisited under the power in the Withdrawal Act.

Proposed changes

27. This section sets out where issues arise in the waiver Regulation, and the changes we are proposing to resolve them.

28. References to Articles are to the Articles of the SPC Regulation which were amended by the waiver Regulation, rather than to those of the waiver Regulation itself. References to Schedules and paragraphs are to provisions in the draft instrument.

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

29. The manufacturing waiver is designed to function within the context of the European Union; the manufacture of the medicine must take place "in the Union", export is to a "third country", while stockpiling is for sale in the "market of Member States".

30. After the UK leaves the EU, it will no longer fall within any of these concepts, and so the current wording would seem to prevent the waiver from working effectively in the UK post-exit. The instrument therefore needs to clearly set out the scope of the waiver in the UK, so that all parties know what is and is not permitted.

31. The waiver is designed so that the territory to which export is permitted and the territory for which stockpiling for sale is permitted do not overlap. This ensures a clear distinction between the two activities - export is external to the 'home' market where SPC protection arises, while stockpiling is internal to that market. We believe that this should continue to be the case.

32. We propose that, after a no-deal exit, the legislation would allow UK-based manufacturers to make SPC-protected medicines for export outside of the UK, or, in the last six months of the SPC, for storage in the UK ready for sale on the UK market after the SPC expires. So, the UK will become the 'home' market (although, see below in connection with the Isle of Man).

The rest of this document refers to this approach as the "UK waiver".

33. We will make changes consistent with this throughout the rest of the waiver provisions - so, the definition of a "maker" in Article 1 will be limited to someone operating in the UK (Schedule, paragraph 2), reimportation into the UK or importation merely for repackaging would be prohibited (Schedule, paragraph 3(f)), and so on. The question of "related acts" is dealt with in the next section.

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?

Are there any issues you might foresee with the drafting?

34. Because “third country” is an EU-specific concept referring to countries outside the Union, it does not have a general definition in UK law. Rather than create a new definition for “third countries”, we propose to replace the reference with “outside the United Kingdom” (Schedule, paragraph 3(a)(i)).

Are there any issues with replacing the references to “third countries” in this way?

Related acts

35. The waiver also covers “related acts” which take place in the EU. These are actions connected with the manufacture, export or stockpiling - for example, temporary storage of the product in an export port, or importing ingredients for the manufacturing process. These actions can take place in different Member States, and so the waiver exempts them from the scope of protection of SPCs in those Member States as well. This ensures that supply chains can function correctly.

36. As an example, if a product were legally manufactured in the UK under the waiver pre-EU exit, but transported to Rotterdam for export, the UK manufacturing would not infringe the UK SPC, and the act of bringing the product into the Netherlands would not infringe any Dutch SPC on the product.

37. In terms of how “related acts” would operate under the UK waiver, it is important to note that any related acts carried out in other countries would not infringe a UK SPC, and so would not need to be exempted under a waiver. In addition, UK law cannot make acts carried out in other countries lawful in those countries; it cannot operate on an extra-territorial basis.

38. Any issues of infringement would be dealt with in those countries according to their national law; whether UK law permitted it would not be a relevant factor. So, using the example above, even though the product would not infringe the UK SPC under the UK waiver operating after Exit day, the act of bringing the product into the Netherlands may still infringe a Dutch SPC granted for that product.

39. As a result, we propose that only related acts taking place within the UK would fall within the scope of the UK waiver. These acts must still be strictly necessary for the making of, export, or stockpiling of the product.

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

Isle of Man

40. The Isle of Man is treated as if it was part of the United Kingdom under the Patents Act 1977 and the Patents Rules 2007. In areas of intellectual property law where the UK law does not extend directly to the Isle of Man, the Isle of Man Government maintains its legislation in line with that of the UK by means of Manx law.

41. SPCs granted in the UK also have effect in the Isle of Man. We are working with the Isle of Man Government to make sure that products manufactured, or intended for sale, in the Crown Dependency are treated appropriately under the UK waiver.

42. We propose that the 'home' market, for which medicines can be stockpiled for sale in after SPC expiry, covers both the United Kingdom and the Isle of Man. For this draft instrument, this means that, in the UK, the Isle of Man will not be a permitted market for export, but it will be permitted to stockpile in the UK for sale in the UK or the Isle of Man after SPC expiry. The effects of the waiver in the Isle of Man will be dealt with by Manx law.

43. This will ensure that UK-based manufacturers will be able to manufacture and store the product in the UK for subsequent sale in the Isle of Man without it being an infringement to do so in the UK. Again, infringement in the Isle of Man will be dealt with by Manx law.

Article 5(2)(b) - notification requirements

44. Under the current waiver, the maker of the product is required to inform both the SPC holder and the national IP authority in the country where they are making the product of their intention to rely on the waiver. They must do the same in the country where the first of any related acts is to take place (if this is before the making of the product).

45. Since the UK waiver will only apply to UK SPCs and only to acts or related acts taking place in the UK, we propose that the maker only needs to notify in advance of making or related acts taking place in the UK (Schedule, paragraph 3(b)).

Article 5(2)(d) - the logo

46. Under the current waiver, the manufacturer of the 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 logo is set out in Annex -I of the SPC Regulation.

47. Clearly, if a product is made in the UK after EU exit then it would be misleading to affix a logo with the words and symbol indicating an EU-made product. It would also create confusion as to which waiver was being relied upon. A different logo is therefore required to ensure clarity and avoid misidentification.

48. Rather than producing a new graphical design for a logo, the proposed changes set out in descriptive terms the wording (and its legibility requirements) to be affixed to the packaging of the medicine to meet the requirements of the Article (Schedule, paragraphs 3(d)(ii), 6). This wording will still need to be provided on the outer packaging of the product and, where possible, on the immediate packaging.

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

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

Article 5(5) - information requirements

49. Article 5(5) sets out what information needs to be provided by the maker of the product to the SPC holder and the national authority.

50. As the UK waiver will only deal with activities taking place in the UK, there will be no distinction between the locations where the manufacturing and the related acts take place. Also, because the UK waiver only applies to UK SPCs, there is no need to provide information on SPCs in other countries.

51. The proposed changes will therefore remove Article 5(5)(c) entirely and take out the requirement in Article 5(5)(d) to state the number of an SPC in a Member State where related acts would be taking place.

Article 5(6) - the form

52. Article 5(6) requires a specific form to be filed with the relevant national authority, containing the information required by Article 5(5). The form is provided in an annex to the SPC Regulation.

53. UK patent law has its own mechanism for setting out what forms are required for patent and SPC actions - section 123 of the Patents Act allows the Comptroller to state this in rules, and to set out what the forms themselves look like in non-legislative directions. Existing SPC forms are already provided through that mechanism.

54. If this form remains part of the SPC Regulation, we will only be able to modify or update it using primary legislation. We therefore propose removing the form from the SPC Regulation and replacing it with a reference to a “prescribed” form. (Schedule, paragraphs 3(h)(ii), 6) We also propose to add a new rule to the Patents Rules which identifies that form as Patents Form SP5 (Paragraph 4). As with all other Patents

Forms, the form SP5 itself will then be set out in directions which will come into force on the same day as this instrument.

55. Although this new form will likely be formatted to look like other IPO forms, we do not intend to change the information required from the existing EU form, other than the changes discussed above in relation to notification requirements - so the form will not ask for information on acts or SPCs in EU Member States.

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

Would you prefer a single form covering both initial notification and renotification, or separate forms for each action?

Other changes

56. In the 2019 Regulations, we made several changes to the SPC Regulation which replace references to a generic national IP authority with a specific reference to the comptroller. As the waiver Regulation introduces new references to the generic authority, we want to ensure consistency by replacing those as well (Schedule, paragraphs 3(b)(i), 3(c), 3(h)(i), 4).

57. Recent changes elsewhere in EU law mean that medicines for sale in the EU must feature a unique identifier which can be used to verify the authenticity of the product as it moves through the supply chain[1]. The waiver Regulation states that any products which are made under the waiver for export must not carry an active identifier.

58. When the UK leaves the EU, the EU law which implements this identifier will no longer apply, and so the requirement will be redundant. The instrument therefore removes it (Schedule, paragraph 3(j)).

59. The waiver Regulation also introduces a provision which requires the European Commission to conduct an evaluation of the new waiver, and report to the other substantive bodies of the EU on its effectiveness. Retaining this provision would impose an obligation on a body outside the UK upon which we have no power, and it would therefore have no legal effect. We therefore propose to remove the provision. (Schedule, paragraph 5)

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

1 Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

Fees

60. The waiver Regulation allows Member States to charge a fee for the processing of waiver notifications if they wish to. It does so by updating Article 12 of the SPC Regulation.

61. The 2019 Regulations will remove that Article from the SPC Regulation. This is because the Comptroller already has the power to charge fees in relation to any service which is carried out by the IPO in relation to patents, including SPCs[2]. A separate ability to set fees for SPCs is therefore unnecessary.

62. Because the 2019 Regulations will amend the SPC Regulation as it stands on exit day, they will remove Article 12 altogether, including the additional provision inserted by the waiver Regulation. This makes it unnecessary for us to cover the Article again in this instrument.

Transitional provisions

63. We have not included transitional provisions in the review draft. However, we are conscious that the SI may need to deal with cases which fall across particular transition points.

64. Under the terms of the waiver Regulation, the manufacturing waiver applies to applications for SPCs filed after 1 July 2019. It will also apply to applications filed before 1 July 2019 which come into effect after that date, but only from 2 July 2022. If no transitional provisions are included, all of these will move across to the new waiver scope on the day the SI enters into force.

65. When considering what transitional provisions, if any, to apply, it is important to bear in mind that the ability to manufacture which the waiver provides does not take effect until the SPC itself does, and then only after notification has been made in advance. In the case of applications filed after 1 July, we expect that most, if not all, of these would come into effect as SPCs after the SI enters into force.

66. Even so, there remains the possibility that a small number of SPCs may have been applied for after 1 July 2019 and have taken effect before the SI enters into force.

67. We therefore propose that only this group of SPCs be subject to transitional arrangements. In these cases, we propose that any actions which have been taken before the SI comes into force which rely on the waiver as it was will continue to be exempt from infringement. The new waiver scope will otherwise apply to those SPCs going forward.

2 Section 123(2)(c) of the Patents Act 1977, which applies to SPCs by way of Schedule 4A.

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

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

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?

Other issues

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

Next steps

68. Once the call for views has ended, the IPO will consider the comments that have been provided as part of the final drafting process. A response document will be issued in due course.

69. The instrument will then be laid before Parliament for approval at an appropriate time, taking into account when the changes need to be brought into effect and the demands of Parliamentary business.

Annex A: Draft Instrument

Draft Regulations laid before Parliament under paragraph 1(3) of Schedule 7 to the European Union (Withdrawal) Act 2018 for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2019 No. XXXX

EXITING THE EUROPEAN UNION

PATENTS

The Patents (Amendment) (No.2) (EU Exit) Regulations 2019

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act([3]).

A draft of these Regulations has been approved by resolutions of both Houses of Parliament pursuant to paragraph 1(3) of Schedule 7 to that Act.

Citation and commencement

1. These Regulations may be cited as the Patents (Amendment) (No.2) (EU Exit) Regulations 2019 and come into force on **** 2019.

Amendments to Regulation (EC) No 469/2009

2. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products is amended as set out in the Schedule.

Amendment to Regulation (EU) No 2019/933

3.— (1)Regulation (EU) 2019/933 of the European Parliament and of the Council of 20th May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products is amended as follows.

(2) After Article 2 (entry into force), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.".

(3) 2018 c.16. See section 20(1) of that Act for a definition of "Minister of the Crown".

Amendment to the Patents Rules 2007

4. In the Patents Rules 2007([4]), after rule 116, insert—

"Notifications relating to supplementary protection certificates

116A. Notifications under Articles 5(2)(b) and (c) of the Medicinal Products Regulation must be made on Patents Form SP5.".

Name

Title

Date

Department for Business, Energy and Industrial Strategy

SCHEDULE

Regulation 2

Amendments to Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products

Interpretation of Schedule

1. In this Schedule, a reference to an Article, paragraph, point or Annex is to that of the Regulation mentioned in regulation 2.

Article 1: interpretation

2. In Article 1, in relation to the definition of "maker"—

(a) for "Union", substitute "United Kingdom";

(b) for "to third countries", substitute "outside the United Kingdom and the Isle of Man";

(c) renumber that definition as paragraph (k) and insert after the definition of "UK authorisation([5])".

Article 5: effects of the certificate

3. In Article 5—

(a) in paragraph 2(a)—

(i) in point (i), for "to third countries", substitute "outside the United Kingdom and the Isle of Man";

(ii) in point (ii), for "Union", substitute "United Kingdom";

(iii) in point (iii)—

(aa) for "Member State of making", substitute "United Kingdom";

(bb) for "Member States", substitute "the United Kingdom and the Isle of Man";

(cc) omit "corresponding";

(iv) in point (iv), for "Union", substitute "United Kingdom";

(b) in paragraph 2(b)—

(i) for "authority" to "take place", substitute "comptroller";

(ii) for "that Member State", substitute "the United Kingdom";

(iii) for "a", where it appears before the last occurrence of "certificate", substitute "that";

(4) S.I. 2007/3291, as amended by S.I. 2009/546, 2010/33, 2011/2052, 2014/2401, 2016/517 and 2016/892.

(5) The definition of "UK authorisation" is inserted by The Patents (Amendment) (EU Exit) Regulations 2019, SI 2019/801.

(c) in paragraph 2(c), for "authority referred to in Article 9(1)", substitute "comptroller";
(d) in paragraph 2(d)—
  (i) for "to third countries", substitute "outside the United Kingdom and the Isle of Man";
  (ii) for "a logo, in the form set out in Annex -I, is affixed", substitute "the words 'UK export' are affixed so as to be sufficiently visible to the naked eye";
(e) in paragraph 2(e), omit from "and" to the end of the sentence;
(f) in paragraph 3, for "Union", substitute "United Kingdom";
(g) in paragraph 5—
  (i) omit point (c);
  (ii) in point (d), omit from "granted" the first time it appears to "making" the second time it appears;
  (iii) in point (e)—
    (aa) omit "third", both times it appears;
    (bb) after "countries", insert "outside the United Kingdom and the Isle of Man";
(h) in paragraph 6—
  (i) for "authority", substitute "comptroller";
  (ii) for "contained in Annex -la", substitute "prescribed by rules made under section 123 of the Patents Act 1977([6])";
(i) in paragraph 7—
  (i) omit "third";
  (ii) after "country", the first time it appears, insert "outside the United Kingdom and the Isle of Man";
(j) omit paragraph 8, including its footnote.

Article 11: publication

4. In Article 11(4)—
(a) for "authority referred to in Article 9(1)", substitute "comptroller";
(b) for "It", substitute "The comptroller".

Article 21a: evaluation

5. Omit Article 21a.

Annex -I and Annex -I: logo and standard form

6. Omit Annex -I and Annex –Ia.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU legislation to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union. These Regulations relate to supplementary protection certificates for medicinal products.

(6) 1977 c.37.

Annex B: Mark-up of waiver provisions

Deletions are marked in strikethrough italic; additions in underlined bold. Provisions which are removed entirely are not included.

In Article 1:

~~*(f)*~~ **(k)** "maker" means the person, established in the ~~*Union*~~ **United Kingdom**, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export ~~*to third countries*~~ **outside the United Kingdom and the Isle of Man** or for the purpose of storing, is carried out;

In Article 5:

Article 5

Effects of the certificate

1. Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate ("the certificate holder"), if the following conditions are met:

(a) the acts comprise:

(i) the making of a product, or a medicinal product containing that product, for the purpose of export **to third countries outside the United Kingdom and the Isle of Man;** or

(ii) any related act that is strictly necessary for the making, in the ~~*Union*~~ **United Kingdom,** referred to in point (i), or for the actual export; or

(iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the ~~*Member State of making*~~ **United Kingdom**, in order to place that product, or a medicinal product containing that product, on the market of ~~*Member States*~~ **the United Kingdom and the Isle of Man** after the expiry of the ~~*corresponding*~~ certificate; or

(iv) any related act that is strictly necessary for the making, in the ~~*Union*~~ **United Kingdom**, 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.

(b) the maker, through appropriate and documented means, notifies the ~~*authority referred to in Article 9(1) in the Member State in which that making is to take place*~~ **comptroller**, and informs the certificate holder, of the information listed in paragraph 5 of this Article no later than three months before the start date of the making in that ~~*Member State*~~ **the United Kingdom**, or no later than three months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by ~~*a*~~ **that** certificate, whichever is the earlier;

(c) if the information listed in paragraph 5 of this Article changes, the maker notifies the ~~*authority referred to in Article 9(1)*~~ **comptroller** and informs the certificate holder, before those changes take effect;

(d) in the case of products, or medicinal products containing those products, made for the purpose of export ~~*to third countries*~~ **outside the United Kingdom and the Isle of Man**, the maker ensures that ~~*a logo, in the form set out in Annex -I, is affixed*~~ **the words 'UK Export' are affixed so as to be sufficiently visible to the naked eye** to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

(e) the maker complies with paragraph 9 of this Article ~~*and, if applicable, with Article 12(2*~~).

3. The exception referred to in paragraph 2 shall not apply to any act or activity carried out for the import of products, or medicinal products containing those products, into the ~~*Union*~~ **United Kingdom** merely for the purpose of repackaging, re-exporting or storing.

4. The information provided to the certificate holder for the purposes of points (b) and (c) of paragraph 2 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.

5. The information to be provided by the maker for the purposes of point (b) of paragraph 2 shall be as follows:

(a) the name and address of the maker;

(b) 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;

~~*(c) 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;*~~

(d) the number of the certificate ~~*granted in the 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

(e) for medicinal products to be exported to ~~*third*~~ countries **outside the United Kingdom and the Isle of Man**, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each ~~*third*~~ country of export, as soon as it is publicly available.

6. For the purposes of notification to the ~~*authority*~~ **comptroller** under points (b) and (c) of paragraph 2, the maker shall use the standard form for notification ~~*contained in Annex -Ia*~~ **prescribed by rules made under section 123 of the Patents Act 1977.**

7. Failure to comply with the requirements of point (e) of paragraph 5 with regard to a ~~*third*~~ country **outside the United Kingdom and the Isle of Man** shall only affect exports to that country, and those exports shall, therefore, not benefit from the exception.

~~*8. The maker shall ensure that medicinal products made pursuant to point (a)(i) of paragraph 2 do not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161 (*1).*~~

9. The maker shall ensure, through appropriate and documented means, that any person in a contractual relationship with the maker who performs acts falling under point (a) of paragraph 2 is fully informed and aware of the following:

(a) that those acts are subject to paragraph 2;

(b) that the placing on the market, import or re-import of the product, or the medicinal product containing that product, referred to in point (a)(i) of paragraph 2 or the placing on the market of the product, or the medicinal product containing that product, referred to in point (a)(iii) of paragraph 2 could infringe the certificate referred to in paragraph 2 where, and for as long as, that certificate applies.

10. Paragraph 2 shall also apply to certificates that have been applied for before 1 July 2019 and that take effect on or after that date. Paragraph 2 shall only apply to such certificates from 2 July 2022.

Paragraph 2 shall not apply to certificates that take effect before 1 July 2019.

~~*(*1) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).';"*~~

In Article 11:

4. The ~~*authority referred to in Article 9(1)*~~ **comptroller** shall publish, as soon as possible, the information listed in Article 5(5), together with the date of notification of that information. ~~*It*~~ **The comptroller** shall also publish, as soon as possible, any changes to the information notified in accordance with point (c) of Article 5(2).;

Annex C: Summary of consultation questions

Scope of the waiver

1. 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?
2. Are there any issues you might foresee with the drafting?
3. Are there any issues with replacing the references to “third countries” in this way?
4. Is it sufficiently clear that only related acts within the UK fall within the scope of the UK waiver?

The logo

5. Does the proposed drafting do enough to avoid confusion with the EU approach?
6. Do you have any suggestions as to alternative definitions or features that you may wish to see included/not included?

The form

7. Do you foresee any issues with removing the form from the SPC Regulation and making it a prescribed form?
8. Would you prefer a single form covering both initial notification and renotification, or separate forms for each action?

Other changes

9. Are there any issues with the changes suggested in this section?

Transitional provisions

10. Can you foresee any issues with all relevant SPCs becoming subject to the new waiver scope?
11. Are there any further transitional provisions you think may be needed?
12. 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?

Other issues

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

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Published: July 2019
DPS-009156