EXPLANATORY MEMORANDUM TO

THE SUPPLEMENTARY PROTECTION CERTIFICATES (AMENDMENTS RELATING TO THE WINDSOR FRAMEWORK) REGULATIONS 2024

2024 No. 1075

1. Introduction

1.1 This explanatory memorandum has been prepared by the Intellectual Property Office, an Executive Agency of the Department of Science, Innovation and Technology, and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Peter Kyle MP, Secretary of State at the Department for Science, Innovation and Technology confirms that this Explanatory Memorandum meets the required standard.

2.2 Chris Mills, Director of Rights Policy and Enforcement at the Intellectual Property Office, confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Max Emery at the Intellectual Property Office, Telephone: 01633 814948 or email: patentspolicy@ipo.gov.uk, can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument makes changes to assimilated supplementary protection certificate (SPC) legislation – specifically, Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products ("the SPC Regulation") – which are consequential to the UK's implementation of the arrangements for novel human medicines under the Windsor Framework.

4.2 The Windsor Framework does not include provisions on SPCs. However, as a result of changes to the Windsor Framework agreed by the UK-EU in February 2023, new arrangements to enable UK-wide authorisation of human medicines are due to take effect from 1 January 2025. The SPC Regulation must be amended to account for these new arrangements.

4.3 The amendments will ensure that innovators are able to continue to obtain SPC protection for eligible human medicines based on the new UK-wide authorisations that will apply on and after 1 January 2025. Transitional provisions will ensure that SPC applications and rights based on existing Great Britain (GB) and/or Northern Ireland (NI) authorisations, either separately or combined, are not adversely affected.

4.4 The instrument also makes technical amendments to update references to legislation regarding the authorisation of veterinary medicines.

Where does the legislation extend to, and apply?

4.5 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is all of the United Kingdom.

4.6 The territorial application of this instrument (that is, where the instrument produces a practical effect) is all of the United Kingdom.

5. Policy Context

What is being done and why?

5.1 A patent protects an invention and lets the owner of that patent take legal action against anyone who makes, uses, sells or imports that invention without the owner's permission – this is known as infringement of the patent. A patent can provide such protection for up to twenty years from the date of filing.

5.2 SPCs are valuable intellectual property rights which take effect when a patent expires. They provide up to five years of additional protection for patented human and veterinary medicines and agrochemicals (collectively referred to below as "products"), to reflect the fact that such products must undergo lengthy regulatory approval procedures during the patent lifetime before marketing authorisations to place the products on the market are granted by the regulatory authorities, limiting the time in which research investment can be recouped effectively. SPCs are therefore tied to the market authorisation(s) for the product as well as the patent. A 6-month extension may be available for SPCs if appropriate studies have been completed on the product's use as a paediatric medicine.

Human medicines

5.3 Under the original arrangements agreed as part of the Withdrawal Agreement, EU medicines legislation applied in NI. The authorisation of novel medicinal products for NI was the responsibility of either the European Medicines Agency (EMA) or the UK's Medicines and Healthcare products Regulatory Agency (MHRA). Such authorisations were granted in accordance with EU law. In GB, these products were licensed by MHRA under domestic law.

5.4 The Supplementary Protection Certificates (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1471) amended the SPC Regulation to account for these arrangements, permitting SPCs to be granted based on GB and/or NI authorisations, where the territory in which the SPC provided protection depended on which authorisations had been approved by the time the SPC came into force. Most SPCs since then have been based on a combination of both types of authorisations, effectively providing UK-wide protection.

5.5 The changes to the Windsor Framework agreed by the EU and UK provide for a UK-wide licensing regime for novel medicines. The same medicinal products, in the same packs with the same labels, will be available across the whole of the UK, without the need for separate marketing authorisations and packaging requirements. Any medicinal products that would previously have fallen within the scope of what is known as the 'centralised procedure' – products that are required or capable of being authorised under EU law across the EU and NI on a centralised basis by the European Commission (on the recommendation of the EMA) – will now be authorised by the MHRA in accordance with UK domestic law. This means that MHRA can authorise all medicines across the UK, including novel medicines such as cancer medicines (the MHRA has existing powers to authorise products falling outside the scope of the

centralised procedure across the UK, where EU law will continue to apply alongside domestic provision).

5.6 It is necessary to amend the SPC Regulation to allow SPCs to be granted based on the new arrangements for authorising human medicines on a UK wide basis from 1 January 2025. This instrument makes changes to that effect. Transitional provisions are also provided to preserve SPCs that have already been applied for, granted or have entered into force before 1 January 2025. These transitional provisions will ensure these SPCs are not adversely affected when the authorisation system changes on 1 January 2025. The transitional provisions also ensure that the territory of in-force SPCs does not change, preserving the existing balance between SPC holders and relevant third parties (i.e. innovative and generic pharmaceutical companies, respectively).

Veterinary medicines

5.7 EU legislation on the authorisation of veterinary medicines applies in NI by virtue of the Windsor Framework. Since 28 January 2022, authorisations for veterinary medicines which apply in NI have been granted under Regulation (EU) 2019/6 ("the EU Veterinary Medicine Regulation"), which repealed and replaced the former legislation, Directive 2001/82/EC. Given this is the first amendment to the SPC Regulation since 2020, we have now reflected the most up-to-date regulation to ensure that new authorisations for veterinary medicines are able to support an application for an SPC.

5.8 This instrument ensures that SPCs can be obtained based on authorisations granted in NI under the EU Veterinary Medicine Regulation. Transitional provisions enable SPC applications which have already been filed on the basis of such authorisations to be granted, provided they meet the substantive criteria.

Agrochemicals

5.9 This instrument does not change the law relating to SPCs for agrochemical products as agrochemicals are not impacted by the changes agreed to the Windsor Framework. Separate legislation provides for SPCs for medicines (human and veterinary) and SPCs for agrochemicals. Therefore, the agrochemical SPC legislation is not affected by this instrument.

What was the previous policy, how is this different?

5.10 SPCs will continue to provide up to five years of additional protection for patented medicines and agrochemicals, to compensate for the patent holder being delayed from using their patent (bringing the product to market) until a marketing authorisation is granted from the relevant regulatory authority. Paediatric extensions will similarly remain available for medicines that have completed the relevant studies into the use of a product as a paediatric medicine.

5.11 This instrument will ensure SPCs remain available for eligible products that have obtained the relevant regulatory approval to allow them to be placed on the market in NI, GB or UK as appropriate, subject to meeting the substantive requirements in the SPC Regulation.

6. Legislative and Legal Context

How has the law changed?

6.1 The SPC Regulation is assimilated direct legislation, incorporated into domestic law under section 3(1) of the European Union (Withdrawal) Act 2018. It provides for SPCs for medicinal products, covering both products for human use and products for veterinary use (separate legislation provides for SPCs for agrochemicals; as agrochemicals are not impacted by the changes agreed to the Windsor Framework, that legislation is not affected by this instrument.)

Human medicines

6.2 Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 (on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC) implements the arrangements for human medicines under the Windsor Framework in EU law. The Human Medicines Regulations 2012, as amended by the Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (S.I. 2024/832) ("the 2012 Regulations"), amend UK law relating to the authorisation of human medicines to do the same. Both pieces of legislation will become applicable from 1 January 2025.

6.3 The changes made to the SPC Regulation by this instrument are centred around three key effects arising from the Windsor Framework as implemented by these two pieces of legislation.

6.4 Firstly, UK-wide authorisations will likely be the main authorisation route for novel SPC eligible medicinal products approved in the future. Some existing provisions will need to recognise them alongside GB and NI authorisations. For example, under the current law, an SPC application filed based on an NI authorisation can be supplemented by providing notification of a GB authorisation granted for the same product. In future, that notification may need to be affected using a UK authorisation.

6.5 Secondly, on and after 1 January 2025, current marketing authorisations which have effect in Great Britain are treated by the 2012 Regulations as having effect across the whole of the UK. These authorisations will have changed from being GB authorisations to being UK authorisations. This category of UK authorisations is defined as "transitioned-UK authorisations". From an SPC perspective, the change of authorisation type may affect the territory in which an SPC provides protection; provisions in the instrument therefore set out how the protection conferred by that SPC will extend when the authorisation falls within that category.

6.6 Thirdly, when Regulation (EU) 2023/1182 becomes applicable, any medicinal products that are subject to authorisations granted under the centralised procedure (whether before or after that point) will be prohibited from being placed on the market in Northern Ireland. Any such NI authorisations granted before 1 January 2025 would therefore no longer be valid for the purpose of applying for SPC protection, unless specifically recognised in legislation. Where that recognition is required to deal with transitional effects, the instrument therefore refers to a "former NI authorisation". As there is a six-month period for filing an SPC application once an authorisation is granted, the instrument will allow applications to be filed using former NI authorisations where that period commenced before 1 January 2025, otherwise prospective applicants may be prevented from seeking an SPC entirely on the basis of these authorisations.

6.7 Most of the provisions dealing with these transitional effects are found in a new Annex III inserted by this instrument. There are around 300 SPCs or SPC applications that will be live on 1 January 2025, at various stages in the process. The arrangements in Annex III are intended to ensure that these continue to be valid and do not become open to challenge solely as a result of the regulatory changes. They also deal with circumstances where certain pre-2025 authorisations will remain relevant for future applications, either allowing their use or exempting them from various statutory requirements.

Veterinary medicines

6.8 As discussed in paragraphs 4.4 and 5.7 above, in terms of the law which applies to NI, Directive 2001/82/EC has been replaced with the EU Veterinary Medicine Regulation. References to that Directive in the SPC Regulation are replaced with references to the EU Veterinary Medicine Regulation.

6.9 Some applications for SPCs based on authorisations for medicinal products for veterinary use granted in accordance with the EU Veterinary Medicine Regulation have already been filed at the IPO. To ensure that such applications are not unfairly disadvantaged, the instrument provides that, going forward, they are to be treated as being valid for assessing them against the statutory requirements for granting an SPC.

Why was this approach taken to change the law?

6.10 This approach is necessary to bring SPC legislation into line with the new arrangements for authorising medicinal products for human and veterinary use in the UK under the Windsor Framework. Without these changes, uncertainty would have been created regarding the status of existing SPC rights and whether new innovative medicines could still be protected by SPCs. Non-legislative alternatives, such as guidance or advice on interpretation, would not have addressed the identified issues or deterred litigation to resolve any ambiguities in which individual rights would have been at risk. Legislative change was therefore considered the best option.

7. Consultation

Summary of consultation outcome and methodology

7.1 A consultation has not been carried out for this instrument, as the policy approach was necessitated by the new arrangements for authorising medicinal products in the UK agreed under the Windsor Framework, making the need for consequential changes to adapt the SPC system to those new arrangements unavoidable.

7.2 However, the IPO conducted a technical review of the proposed drafting of the instrument with key stakeholder groups with a known interest in SPCs. These groups represent the innovative/originator pharmaceutical sector, generic pharmaceutical sector, and the patent attorney profession. Given that affected SPCs apply to products in just two specific fields of technology (human and veterinary medicines), this was considered a fair and appropriate approach.

7.3 IPO officials set out the issues to be addressed in the legislation and shared a draft of the instrument, inviting feedback on the proposed drafting. This feedback was considered and used to finalise the text of this instrument, as well as to help draft the business guidance discussed below.

8. Applicable Guidance

8.1 The IPO will be providing guidance to businesses who use the SPC system to explain the changes that will result from this legislation and the indirect effects of the Windsor Framework. This is expected to be published on gov.uk at www.gov.uk/government/publications/changes-to-supplementary-protection-certificates-on-1-january-2025 on the date this instrument is laid.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the impacts are expected to be minimal and are expected to fall below the de minimis threshold.

Impact on businesses, charities and voluntary bodies

9.2 There is no significant impact on business, charities or voluntary bodies. These changes make the necessary changes to the SPC system to account for the new authorisation arrangements for medicinal products in the UK under the Windsor Framework. This instrument will preserve existing SPCs and applications for SPCs and enable innovative businesses to continue to obtain SPC protection for eligible products based on the new authorisations that apply in the UK.

9.3 The Government believes that the impact of the changes made by this instrument is low, as it is limited mainly to administrative costs arising from the need to supply evidence of new marketing authorisations to the IPO following an initial SPC application.

9.4 On average, the IPO receives around 70 applications for SPC protection annually[1], meaning that the number of applications made by businesses per year is relatively small. Administrative costs will be reduced for some future and existing SPC applicants that no longer need to notify the IPO of a later marketing authorisation. There could be some costs for businesses applying for SPCs to adapt to the new administrative processes. Competing businesses could face some administrative costs in order to check the territorial scope of the SPC impacted by the transitional provisions. However, these impacts are expected to be minimal. The IPO is not adjusting fees for SPCs as a consequence of this instrument.

9.5 The legislation does impact small or micro businesses. No specific action is proposed to minimise the impact of the requirements on small or micro businesses because the impact of the instrument on such businesses is expected to be minimal.

9.6 There is no, or no significant, impact on the public sector for the same reasons as set out in paragraphs 9.2 and 9.3.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation is to assess the effect of the changes being made as part of the course of normal departmental business. In particular, as the authority responsible for the SPC application, examination, and granting process, the IPO will closely monitor how it operates and whether any practical issues arise.

[1] IPO internal statistics. Median for the years 2010-2019 (inclusive).

10.2 No review clause is required as this instrument is made under the European Union (Withdrawal) Act 2018. In particular, Paragraph 27 of Schedule 7 of the European Union (Withdrawal) Act 2018 disapplies Section 28 of the Small Business, Enterprise and Employment Act 2015 (duty to review regulatory provisions in secondary legislation).

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Secretary of State for Science, Innovation and Technology has made the following statement regarding Human Rights:

"In my view the provisions of the Supplementary Protection Certificates (Amendments Relating to the Windsor Framework) Regulations 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is made under section 8C(1) of and paragraph 21(a)(ii) and (b) of Schedule 7 to the European Union (Withdrawal) Act 2018 and therefore relates to the withdrawal of the United Kingdom from the European Union. The changes to supplementary protection certificate legislation arise out of the new arrangements for the authorisation of human and veterinary medicines under the Windsor Framework in the EU Withdrawal Agreement.