EXPLANATORY MEMORANDUM TO

THE SUPPLEMENTARY PROTECTION CERTIFICATES (AMENDMENT) (EU EXIT) (REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Intellectual Property Office (IPO), an executive agency of the Department for Business, Energy & Industrial Strategy, and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument changes legislation concerning supplementary protection certificates (SPCs) which protect some patented medicines and agrochemicals. Specifically, it amends the Patents Rules 2007 (SI 2007/3291), the Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801), Regulation (EC) No 469/2009 in relation to supplementary protection certificates for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

2.2 The changes to the SPC system are needed to take account of changes to the regulation of medicines and agrochemicals when the Northern Ireland Protocol comes into effect. This will see the introduction of new marketing authorisations that will be valid for only part of the territory of the UK. A marketing authorisation is required for the grant of an SPC; an SPC has effect UK wide, but current legislation does not account for authorisations that are not valid UK wide. The amendments make only the changes which are necessary to provide certainty to users of the system when the Northern Ireland Protocol comes into effect.

2.3 The changes are intended to maintain the balance of interests between all users of the system; this includes patent holders and applicants for SPCs, third parties with an interest in SPC-protected products (such as generic medicine manufacturers) and consumers of medicines (including the NHS) or agrochemicals.

Explanations

What did any relevant EU law do before exit day?

2.4 The relevant EU law provided for an SPC system for patented medicines and agrochemicals, under which SPCs are granted nationally. SPCs are valuable intellectual property rights which take effect when a patent expires. SPCs are granted when a patent holder is delayed from using their patent (bringing a product to market) until a marketing authorisation is granted from the relevant regulatory authority.

2.5 Under the EU Regulations, an SPC can be granted for a product which is protected by a patent and which has a valid authorisation to place that product on the market. One of the qualifying criteria for an SPC is therefore to have a valid marketing authorisation (MA) for the UK.

Why is it being changed?

2.6 Until the end of the transition period, the only MA valid in the UK is one which applies across the whole of the UK; this is irrespective of whether it has been granted by European agencies or domestic agencies. Following the transition period, under the Northern Ireland Protocol, Northern Ireland will still be bound by EU law for the authorisation of medicines and plant protection products, while Great Britain (GB) will not. This means there will be separate MAs for NI and GB alongside UK MAs, which SPC law will need to reflect so that SPCs can be granted and enforced with legal certainty in the UK.

What will it now do?

2.7 The aim is to provide SPC applicants and third parties with a system which is as similar as possible to the current regime, while adjusting for new MAs that will be valid in the UK.

2.8 The proposed change will allow an SPC to be granted based on whichever GB/UK/NI authorisation or combination of authorisations the applicant has at the point of application. If the SPC enters into force with an MA covering only one of GB or NI, the protection provided by the SPC extends only to that territory. Up until the SPC comes into force, an applicant can submit an additional MA, allowing protection to extend to the whole of the UK.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see section 24(1) of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is all of the United Kingdom.

4.2 The territorial application of this instrument is all of the United Kingdom.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Minister for Science, Research and Innovation), Amanda Solloway MP has made the following statement regarding Human Rights:

"In my view the provisions of the Supplementary Protection Certificate (Amendment) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 Section 8C(1) of the European Union (Withdrawal) Act 2018[1] provides Ministers with the power to make provision in connection with the Protocol. Although the changes to the SPC system are not required to fulfil obligations under the Protocol, they are matters arising out of the Protocol's obligations in respect of regulation of medicines and agrochemicals, and so the power is engaged.

6.2 Regulations 469/2009 and 1610/96 have previously been amended to resolve inoperabilities arising from the retention of EU law at the end of the transition period, using the powers in section 8 of the European Union (Withdrawal) Act 2018. The Patents (Amendment) (EU Exit) Regulations 2019 and the Intellectual Property (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1050) both made changes to the two SPC Regulations. These changes will come into effect on IP completion day. If approved, this instrument will supplement or replace those changes.

6.3 The substantive requirements for the six-month SPC term extension rewarding completion of paediatric testing, as discussed in paragraph 7.5, are provided by separate legislation – currently, this is Article 36 of Regulation (EC) No 1901/2006. At the end of the transition period, this will be replaced by regulation 58A of the Human Medicines Regulations 2012[2]. As the Protocol specifically excludes Article 36 from applying to Northern Ireland, the requirements for the extension will remain a matter for domestic law. Subject to Parliamentary approval, further amendments to regulation 58A will be made by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020[3]. The amendments in the present instrument make changes only to the administrative requirements for the grant of the extension which are set out in the SPC Regulations.

6.4 This instrument does not address the effects of the Protocol on the regulatory system itself. These will be dealt with by way of other statutory instruments coming before Parliament, namely:

- the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020;
- the Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020; and
- the Pesticides (Amendment) (EU Exit) Regulations 2020.

7. Policy background

What is being done and why?

How the SPC system currently works

7.1 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.

7.2 Supplementary protection certificates (SPCs) provide a period of additional protection for patented medicines and agrochemicals (referred to below as "products"), to reflect

[1] C.16; as inserted by section 21 of the European Union (Withdrawal Agreement) Act 2020 (c. 1).
[2] As inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/775).
[3] Laid in draft on [15 October 2020].

the need for such products to undergo lengthy regulatory approval procedures during the patent lifetime before they can be sold and research investment recouped. The SPC gives the approved product the same rights and protection as the original patent for up to five years after the patent expires. SPCs are provided by EU Regulations but operate as individual national rights.

7.3 For an SPC to be granted in the UK, there must be i) a patent which provides protection for the active ingredient of the product, and ii) regulatory approval for the product which allows it to be sold in the UK. This regulatory approval, in the form of a marketing authorisation (MA), may come from the UK regulator or, in the case of medicines, it may come from the European Medicines Agency, which grants approval EU-wide. The MA must be the first which allows the product to be sold in the UK.

7.4 An application for an SPC to be granted must be filed at the Intellectual Property Office. The application must be filed within six months of either the patent being granted or the MA being approved, whichever is later. The application is then examined against the statutory requirements and granted or refused.

7.5 The granted SPC takes effect at the end of the patent term for a maximum of five years, depending on how long it has taken for the MA to be granted. If the product is a medicine, and it has been tested for use in paediatric populations, a further six-month extension can be granted if the relevant requirements are met. This extension must be applied for no later than two years before the expiry of the SPC.

Why the Northern Ireland Protocol requires changes to be made

7.6 At the end of the transition period, the Northern Ireland Protocol takes effect as part of the Withdrawal Agreement. Article 5(4) of the Protocol states that the provisions of EU law which are listed in Annex 2 to the Protocol shall apply to, and in, Northern Ireland. The provisions which are listed largely relate to regulatory requirements for placing products on the market; these form part of ensuring there is no hard border between Northern Ireland and the Republic of Ireland.

7.7 Regulations 469/2009 and 1610/96 concerning SPCs are not included in the list of provisions. However, EU Directives and Regulations relating to the regulation of human and veterinary medicines and agrochemicals, and the Regulations relating to the operation of the European Medicines Agency, are included.

7.8 Products which are subject to regulatory approval before they can be placed on the market in Northern Ireland must therefore be assessed in accordance with EU law, to ensure that they are free to move between Northern Ireland and the Republic of Ireland. Approval may be given by the UK regulator acting on behalf of Northern Ireland or by the European Medicines Agency.

7.9 This means that products which can be sold in at least part of the UK may have a marketing authorisation granted under EU law.

7.10 A product may potentially be covered by a UK-wide marketing authorisation ("UK authorisation"), an authorisation allowing the product to be sold in England, Wales and Scotland only ("GB authorisation"), or an authorisation allowing the product to be sold only in Northern Ireland ("NI authorisation"). A specific product may have two authorisations relating to it covering different territories – in most cases, a GB authorisation and an NI authorisation.

7.11 The current SPC system is not designed to accommodate marketing authorisations which cover only part of the UK. It is therefore necessary to amend the existing legislation as an indirect effect of the regulatory arrangements established by the Protocol.

How the SPC system will change as a result

7.12 With the changes being made by this instrument, an SPC may be granted if there is a marketing authorisation which allows the product to be sold somewhere within the UK. This marketing authorisation must fulfil the same requirements as in the current system – it must be valid for placing the product on the market and must be the first such authorisation for its particular territory.

7.13 SPCs will remain a UK-wide right – there will not be separate SPCs for GB and NI. However, it is important to preserve the principle that an SPC must be underpinned by a marketing authorisation with effect in the relevant territory. So, the protection conferred by a granted SPC will extend only to the territory where that authorisation allows the product to be sold. For example, an SPC based solely on an NI authorisation would provide protection only in Northern Ireland.

7.14 That does not mean that the territory where protection applies is fixed at the point of applying for the SPC. The protection can be extended further if an authorisation for that product has been granted covering a different part of the UK, and the IPO is notified of it. This can be done either when making the initial application, if all the authorisations have been granted at that time, or at any time before the SPC comes into effect.

7.15 For the protection to extend to the additional territory, that authorisation must meet the same requirements – it must be a valid authorisation to place the product on the market in its particular territory, and must be the first authorisation to place the product on the market in that territory. The only difference is that those requirements must be met as of the date the additional authorisation was granted, rather than the date of the SPC application.

7.16 The ability to extend the territory will end at the point the SPC takes effect. The territory in which the protection of the SPC has effect will then be fixed for as long as the certificate lasts. This ensures that rightsholders and third parties have certainty about where protection applies. This deadline aligns with the last point at which an SPC application can be filed; this flexibility is therefore not expected to put third parties at any additional disadvantage in terms of transparency.

7.17 In relation to the six-month extension for paediatric testing, the territory in which the paediatric extension has effect will match that of the SPC, provided that the necessary requirements have been met for all authorisations within that territory, and the relevant applications have been made by the two-year deadline mentioned in paragraph 7.5. If the requirements have only been met for part of that territory, then the paediatric extension will only apply to that part. It will not be possible for the paediatric extension to provide protection in a part of the UK where the SPC does not.

7.18 Transitional arrangements mean that SPC applications pending at the end of the transition period will be considered based on the existing requirements. Changes that have previously been made to the SPC Regulations for the end of the transition

period[4] will still apply to these applications, as these ensure the existing requirements remain operable. Any SPC application filed after the end of the transition period will be considered based on the updated requirements. All granted SPCs will be subject to the updated requirements.

Changes to the SPC Regulations

7.19 This instrument amends Regulations 469/2009 and 1610/96 either directly, or indirectly by amending provisions of the Patents (Amendment) (EU Exit) Regulations 2019 which act on them.

7.20 Both Regulations have nearly identical numbering, so references to a particular Article in the following paragraphs are to the same Article in both Regulations unless otherwise indicated. References to a regulation are to those in this instrument; paragraphs refer to the Schedule.

7.21 Article 1 contains definitions which are used in the rest of the Regulation. Paragraphs 2 and 11 of the Schedule amend Article 1 to add definitions of GB authorisation and NI authorisation.

7.22 Articles 2 and 3 set out the key principles of the system which determine whether an SPC may be granted, as discussed in paragraph 7.3. Regulations 2(4), 2(5)(a), 3(4), and 3(5)(a) ensure that the MA on which an SPC may be based can be any of a UK, GB, or NI authorisation. Regulations 2(5)(b) and 3(5)(b) make it clear that the authorisation needs only to be the first authorisation in its particular territory.

7.23 Article 4 sets out that an SPC only protects the specific product which has been authorised for sale, as well as any further uses of that product which are authorised before the SPC expires. Paragraphs 3 and 12 of the Schedule amend this so that the SPC protects the product which has been authorised in any of the MAs associated with the SPC, and any further uses authorised in the UK. This scope of protection applies in all territories where SPC protection extends.

7.24 Article 5(1) establishes that a granted SPC provides the same protection as the patent on which it is based. Paragraphs 4 and 13 of the Schedule insert new paragraphs 2 and 3 to Reg 1610/96 and 1a and 1b to Reg 469/2009 respectively. These new paragraphs set out that this protection will only extend to territory within the UK where i) an MA has been granted for the product before the SPC takes effect, and ii) that MA meets the requirements set out in Article 3. The second new paragraph enables the protection to apply in additional territory if an MA for the product which meets the requirements set out in Article 3 is granted in that territory after an application for an SPC is filed. Because those requirements must normally be met as of the date the SPC application is filed, and a later MA will not have been granted at that time, the second new paragraph establishes that the later MA must meet them as of the date it is granted.

7.25 Article 7 sets the timescale for when an SPC application must be made (as discussed in paragraph 7.7). Paragraphs 5 and 14 of the Schedule amend the Article so that, if the applicant has multiple MAs granted before they file an application, the application must be filed within six months of the earliest of those MAs being granted for it to be accepted.

[4] As discussed in paragraph 6.2.

7.26 Articles 8, 9 and 11 set out the documentary requirements for an SPC application, and the information which the IPO is obliged to publish when the application is received and when the SPC is granted. Regulations 2(6), 2(7), 2(8), 3(6), 3(7), 3(8), and 3(10), and paragraph 6 of the Schedule, amend these Articles to require details on all MAs filed with the application to be provided and published. For applications for a paediatric extension, paragraphs 15-17 of the Schedule add requirements to provide and publish information on the territory where the conditions for the extension are met.

7.27 Article 13 defines the duration of an SPC, including when the six-month paediatric extension applies. To qualify for the paediatric extension, the MA for the product must contain a statement that the paediatric testing has been carried out in accordance with an agreed plan. This is usually done by updating the original authorisation used for the SPC application. Paragraph 18 of the Schedule adds a provision that the extension will provide protection in the territory of the updated authorisation, but only as far as the SPC itself provides protection. If only one MA associated with an SPC has been updated, the extension will only provide protection in its territory, even if the SPC is wider.

7.28 Paragraphs 7 and 19 of the Schedule insert new Article 13A. This new Article provides the mechanism by which information on additional MAs can be provided to the IPO. The applicant or SPC holder must provide this information within six months of the MA being granted and by the time the SPC takes effect; if the applicant fails to meet this deadline, the protection will not extend to the relevant territory. This information will be published by the IPO for the benefit of third parties.

7.29 Paragraph 19 of the Schedule also adds new Article 13B to Regulation 469/2009. Article 13B provides a mechanism by which a further application can be made for the paediatric extension to also provide protection in the territory of another MA associated with the SPC, if the conditions for granting the extension have been met for that MA. This application must still be filed by the two-year deadline.

7.30 Article 14 sets out when an SPC ceases to have effect or "lapses". An SPC can lapse if the MA underpinning the SPC is withdrawn. Regulations 2(12) and 3(11) modify this condition so that all the MAs associated with the SPC must have been withdrawn for this to happen. Those regulations also set out what happens if not all MAs are withdrawn – the SPC continues to have effect, but its protection will only extend to the territory where an MA remains valid. The IPO will publish a notification if it is made aware that this has happened; paragraph 8 of the Schedule amends Article 16 of Reg 1610/96, whilst paragraph 20 amends Article 17 of Reg 469/2009, to facilitate this.

7.31 Several of the new provisions require applicants or SPC holders to provide information to the IPO; to ensure that the information is provided consistently, a new statutory form will be created. Forms are prescribed in the Patents Rules 2007, and Regulation 6 makes the necessary amendments to add the form to the rules on SPCs.

7.32 Transitional provisions are set out in regulation 7. These establish that the new provisions will apply to all SPC applications filed after IP completion day; this includes applications based on MAs granted before that date. Applications which are pending on IP completion day will be determined based on the legislation as previously amended, in accordance with Article 60 of the Withdrawal Agreement. In addition, the regulatory changes arising from the Protocol may result in an MA which

underpins an existing SPC being replaced by authorisations covering separate territories; regulation 7(4), 7(7) and 7(8) ensure that, if this happens, it will not affect the continuing validity of the SPC.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is not being made to address a deficiency in retained EU law but relates to the withdrawal of the United Kingdom from the European Union because it is being made under Section 8C of the European Union (Withdrawal) Act 2018. The Minister has made any relevant statements in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 No consolidation of the relevant legislation is planned at present. Informal consolidated texts of domestic intellectual property legislation are publicly available for free on the gov.uk website[5].

9.2 The IPO has prepared, and will be making publicly available, informal consolidated texts of Regulations 469/2009 and 1610/96 which take into account all legislative changes for the end of the transition period. A draft of this material has been laid in the Libraries of both Houses to assist with Parliamentary scrutiny.

10. Consultation outcome

10.1 Consultation with stakeholders on the indirect effects of the Protocol on the SPC system began following publication of the Command Paper, "The UK's Approach to the Northern Ireland Protocol"[6]. There was also close collaboration with Government departments and regulatory bodies involved in the authorisation of medicines (veterinary and human) and agrochemicals - namely, Defra, MHRA and DHSC – to ensure that information on the interaction with the regulatory regime could be provided.

10.2 IPO officials contacted the presidents of key Intellectual Property stakeholder groups with a known interest in patents, IP professionals who had engaged with IPO previously on SPC matters, and businesses operating in the relevant industries based on contacts provided by the other Government departments. Given that SPCs apply to products in just two specific fields of technology, this was considered an appropriate approach. Officials set out the problem to be addressed and invited comments, in order to better understand potential impacts for users of the system.

10.3 Officials then met with representatives of those groups which had responded to this initial contact, to discuss the Government's proposed approach in more detail. These were: the Association of the British Pharmaceutical Industry; the Chartered Institute of Patent Attorneys; the British Generic Manufacturers' Association and the BioIndustry Association. These groups cover the innovative/originator pharmaceutical sector, generic pharmaceutical manufacturers and the patent attorney profession (which represents businesses in both the pharmaceutical and agrochemical fields).

[5] https://www.gov.uk/topic/intellectual-property/law-practice
[6] CP226, https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol

10.4 All those involved agreed that intervention would be appropriate and supported the approach proposed, describing it as "flexible" and "pragmatic". None identified clear winners or losers of the described process, although. concerns were raised that it should not be so flexible that applicants risked their applications being rejected on purely administrative grounds. Discussions also noted the need for third parties to have early certainty about the territorial scope of granted SPCs and the intent of the SPC applicant on that issue. Another area of concern raised was the interaction between the SPC legislation and the paediatric legislation in relation to the six-month paediatric extension; IPO officials have worked closely with DHSC on a coordinated approach to the extension.

10.5 Further dialogue between the IPO and stakeholders included the sharing of a draft of the legislation, inviting feedback on the proposed drafting. This feedback was considered and used to finalise the text of the legislation.

11. Guidance

11.1 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 Protocol. This is expected to be available, subject to when the instrument is approved, at the end of November 2020.

11.2 Any new or updated statutory forms will be made available on gov.uk for 1 January 2021.

12. Impact

12.1 The impact on business, charities or voluntary bodies is small.

12.2 The impact on the public sector is small.

12.3 An Impact Assessment has not been prepared for this instrument because the effect of the instrument is estimated to fall below the threshold for a formal assessment; a de minimis analysis has been conducted. The changes made by this SI are largely driven by the regulatory arrangements established in the Northern Ireland Protocol. The impacts of needing different authorisations for medicines and agrochemicals are therefore associated with the effects of the Protocol and do not fall within the scope of the assessment. Only the changes to fit those arrangements into the SPC system, set out in this SI, are applicable to the analysis.

12.4 The Government believes that the impact of the changes made by this SI 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.

12.5 On average, the IPO receives around 70 applications for SPC protection annually[7], meaning that the number of applications made by businesses per year is relatively small. There could be additional administrative costs for businesses applying for SPCs, as they may need to supply IPO with an additional marketing authorisation in comparison with the present system. However, businesses will not have to pay any statutory fees beyond what is currently required - the IPO is not adjusting fees for SPCs as a consequence of this SI or charging any additional fees for the work to be

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

undertaken. Competing businesses could face some administrative costs in order to check the territorial scope of the SPC when it comes into force.

12.6 There will be a small impact on the IPO in processing information about an additional MA for an SPC application. As the IPO operates as a Trading Fund, these costs are expected to be absorbed by existing fees and require no central government funding to accommodate.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

13.3 The basis for the final decision on what action to take to assist small businesses is that the statutory requirements that must be met for the grant of an SPC should be consistent for all applicants. In addition, SPCs are limited to specific technical fields; the small number of businesses which interact with the system are highly engaged with its operation. Whilst some familiarisation with the new processes may be required, this is not expected to provide any additional burden to small businesses operating in these technical fields over larger ones.

14. Monitoring & review

14.1 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.

14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Michael Warren or Richard Sewards at the Intellectual Property Office Telephone: 01633 813988 or 01633 813536 or email: michael.warren@ipo.gov.uk or richard.sewards@ipo.gov.uk can be contacted with any queries regarding the instrument.

15.2 James Porter, Divisional Director for Policy and Legal at the Intellectual Property Office can confirm that this Explanatory Memorandum meets the required standard.

15.3 Parliamentary Under Secretary of State (Minister for Science, Research and Innovation) Amanda Solloway MP at the Department for Business, Energy & Industrial Strategy can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Explanations

1.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.