EXPLANATORY MEMORANDUM TO

THE BLOOD SAFETY AND QUALITY (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Act.

2. Purpose of the instrument

2.1 This instrument amends the Blood Safety and Quality Regulations 2005 (S.I.2005/50) which operates in the field of blood and blood component safety and quality. It is made in exercise of the powers in the European Union (Withdrawal) Act 2018 to ensure the Blood Safety and Quality Regulations 2005 operate as intended following the withdrawal of the United Kingdom (UK) from the European Union (EU), if the UK leaves the EU in March 2019 with no agreement in place.

Withdrawal from the EU without a deal would mean that the law in this area will no longer work as it is intended to. This is because it contains a number of references that will no longer be appropriate, such as references to obligations that UK is required to comply with as an EU Member State.

As blood is a devolved competence, the legislation is being made on a UK-wide basis with the agreement of each of the Devolved Administrations (DAs) and will ensure continuity of the UK regulatory framework for the safety and quality of blood.

2.2 Explanations

What did any relevant EU law do before exit day?

The main piece of EU legislation in relation to blood and blood components is Directive 2002/98/EC (the 'EU Blood Directive') which sets the quality and safety standards in relation to blood and blood components. It sets the standards for the collection and testing of human blood and blood components and covers all steps in the transfusion process from donation, collection, testing, processing, and storage to distribution. The EU Blood Directive was implemented in UK law (under section 2(2) of the European Community Act 1972) in the Blood Safety and Quality Regulations 2005.

The Commission has also made the following additional directives to implement the EU Blood Directive:

- Commission Directive 2004/33/EC as regards certain technical requirements for blood and blood components;
- Commission Directive 2005/61/EC as regards traceability requirements and notification responsibilities in case of serious adverse reactions and events;
- Commission Directive 2005/62/EC as regards European Union standards and specifications relating to the quality system for blood establishments; and

- Commission Directive 2009/135/EC which allows for temporary exemptions from the requirements set out in Commission Directive 2004/33/EC in light of a risk of shortage of blood and blood components caused by the Influenza A (H1N1) pandemic; and
- Commission Directives 2011/38/EU, 2014/110/EU and 2016/1214 which make amendments to the implementing directives referred to above.

Why is it being changed?

2.3 As noted above, the amendments contained in this instrument are intended to ensure that blood safety and quality legislation will continue to function after exit day in the event that the UK leaves with EU without a deal in place.

2.4 The legislation being amended also contains references that will no longer be appropriate once the UK withdraws from the EU, such as references to obligations which the UK must comply with as an EU Member State, and some references to the European Union (EU), the European Economic Area (EEA), the Commission and EU law. The European Commission also has powers under the EU Blood Directive (such as the ability to update technical requirements, for example, requirements to ensure traceability in line with scientific and technical developments), which it will no longer exercise on the UK's behalf following exit. Amendments have been made to take account of this.

What will it now do?

2.5 The amendments made by this instrument will ensure that there is minimal disruption to blood safety and quality policy as a result of the UK's withdrawal from the EU. The detailed breakdown of the various types of changes which this instrument will bring about is included in section 7. It will make the following changes to recognise that the UK is no longer a Member State and eliminate any ambiguity:

- Amend or omit EU/EEA/Member State/third country references;
- Omit provisions relating to EU obligations that will no longer be relevant to the UK;
- Transfer relevant Commission powers under the EU Blood Directive to the Secretary of State in relation to England and to the devolved ministers in relation to the devolved areas (which is detailed in paragraphs 7.12 to 7.15); and
- Modify how the Annex to the Commission Directive 2005/62/EC (the 'Annex') is to be read after exit. As noted above, the directives referred to in paragraph 2.2 ('the Directives') will not form part of domestic law after exit. However, blood establishments, hospital blood banks and importers of blood from third countries will continue to be required to comply with the requirements set out in the Annex, in the same way as they would prior to exit.

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 is the United Kingdom.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Mental Health, Inequalities, and Suicide Prevention, Jackie Doyle-Price MP has made the following statement regarding Human Rights:

"In my view the provisions of the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 As stated in paragraph 2.5, this instrument is being made to ensure that legislation in relation to blood safety and quality continues to function in the event that the UK leaves the EU without a deal in place.

6.2 The Blood Safety and Quality Regulations 2005 and the relevant amendments were made under section 2(2) of the European Communities Act 1972 to implement the EU Blood Directive, which governs the safety and quality of blood and blood components (see paragraph 2.2 for more information).

6.3 The European Communities Act 1972 will be repealed by the European Union (Withdrawal) Act 2018, however section 2 of the European Union (Withdrawal) Act 2018 saves EU-derived domestic legislation so that it continues to have effect in domestic law on and after exit day. The Blood Safety and Quality Regulations 2005 will therefore be preserved, but will require amendment in order to function effectively after exit day. It is therefore being amended pursuant to the power in section 8 of the European Union (Withdrawal) Act 2018. The purpose of these regulations (as outlined in paragraph 2.1) is to ensure that domestic legislation continues to function in the event that the United Kingdom leaves the EU with no deal.

7. Policy background

7.1 The EU blood legislation referenced in section 2.2 sets the policy and legal framework for the quality and safety standards for blood and blood components.

7.2 The donation of blood and blood components (red cells, platelets, and plasma) facilitate a wide range of essential, and often life-saving treatments. Blood transfusions are vital when dealing with major surgery or trauma, (often) in cancer management, or to treat inherited chronic blood diseases (e.g. Thalassaemia).

7.3 Donated plasma is a component of blood that can be used to manufacture medicinal products such as clotting factors and immunoglobulins. The manufacture of these products is subject to pharmaceutical legislation, while the donation, collection and testing of plasma is regulated by blood legislation. The UK is largely self-sufficient in the supply of blood and blood components. The UK occasionally exports rare frozen

red blood cells (usually fewer than 10 units a year) to EU and non-EU countries, and imports from the EU per year around 6.5% of plasma units (an average of figures over 3 years) issued in the UK.

What is being done and why?

7.4 As stated in sections 2 and 6 of this memorandum, this instrument is being made to enable the Blood Safety and Quality Regulations 2005, to continue to function as intended after the UK leaves the EU. This instrument does not introduce new policy changes but instead amends provisions arising as a result of the UK's withdrawal from the EU to ensure that the current high standards of quality and safety for human blood collection, storage, testing and processing are maintained.

7.5 Examples of changes made by these amendments are listed below.

Competent Authority references

7.6 The reference to the "competent authority" in regulation 2(1) has been omitted. This is an EU term and regulation 2 designated the Secretary of State as the competent authority for the purpose of the EU Blood Directive. As the EU Blood Directive will not form part of domestic law after exit, it is appropriate to omit this paragraph.

EU obligations that will no longer be relevant

7.7 Regulation 16A of the Blood Safety and Quality Regulations 2005 is being omitted. This regulation requires the maintenance of communication of serious adverse events or reactions (SAERs) between the Secretary of State and other blood regulatory authorities in EU Member States. However, once the UK leaves the EU, it will no longer be an EU Member State and therefore there will no longer be an obligation on the Secretary of State to communicate with the blood regulatory authorities in EU member states.

EU references which are redundant or inappropriate

7.8 Minor changes are being made by the instrument to take account of EU references which will be redundant or inaccurate. For example, the Blood Safety and Quality Regulations 2005 includes references to the "EU", "Union" and "the Commission". These have been amended and, where appropriate, replaced with "the United Kingdom" and "the Secretary of State," as they will not function correctly as, after exit, the UK will no longer be an EU Member State.

Exchange of blood and blood components with EU countries as third countries.

7.9 Once the UK has left the EU, the UK will be classified as a third country under the Directives. The Directives allow for the exchange of blood and blood components between Member States and third countries. EU countries and Gibraltar will also be considered as third countries by the UK in a no deal scenario. Amendments have been made to reflect this. For example, the definition of a "third country" has been changed from "a country other than a Member State" to "a country other than the United Kingdom".

Modifications to the Annex to Commission Directive 2005/62/EC

7.10 The Blood Safety and Quality Regulations 2005 implement the Directives in part by way of cross-reference to the Directives. After exit, the Directives will no longer impose requirements on the UK. However, references to the requirements of the Annex will be retained in regulations 7, 9 and 13 of the Blood Quality and Safety

Regulations 2005. This instrument amends the Blood Quality and Safety Regulations 2005 to clarify that the requirements set out in the Annex will still apply after exit in the same way that they do prior to exit.

7.11 In order to ensure that the provisions in the Annex continue to function correctly after exit, it is necessary to modify how some of the paragraphs in the Annex are to be read. For example, where specific provisions have been implemented in UK legislation, instead of referring to the relevant article in the directives, amendments have been made to refer to the specific requirements in the Blood Safety and Quality Regulations 2005. In addition, specific glosses have been included so that where there are references to the competent authority or competent authorities in the Annex, this is to be read as a reference to the Secretary of State.

Transfer of Commission Powers

7.12 The European Commission currently holds a power in Article 29 of the EU Blood Directive to update technical requirements relating to blood and blood components in light of scientific developments. This power is being conferred on the Secretary of State in relation to England, and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in respect of Northern Ireland, the Department of Health).

7.13 To date, amendments to the Blood Safety and Quality Regulations 2005 have been made under section 2(2) of the European Communities Act 1972. After exit section 2(2) of the European Communities Act 1972 will be repealed. Similarly, the Commission will no longer have any functions in respect of the UK. The conferral of the power in Article 29 of the EU Blood Directive will therefore enable the UK to respond to respond to emerging threats, such as infectious disease outbreaks; changing safety and quality standards; and technological advances.

7.14 The powers that the draft SI confers are in the new regulation 23A of the Blood Safety and Quality Regulations 2005. This will enable regulations to be made in respect of the same technical requirements that are listed in Article 29 of the EU Blood Directive. Regulation 23A will therefore enable provision to be made in relation to:

- standards and requirements relating to a quality system for blood establishments;
- information to be provided to donors;
- information to be obtained from donors;
- blood quality and safety requirements;
- storage, transport and distribution requirements;
- quality and safety requirements;
- traceability requirements;
- deferral criteria for donors of blood and blood components. Deferral is defined in the Blood Safety and Quality Regulations 2005 and refers to the suspension (either permanent or temporary) of the eligibility of an individual to donate blood or blood components.

- requirements applicable to autologous transfusions; and
- the procedure for notifying serious adverse reactions and events.

7.15 The technical requirements which currently apply in domestic law are set out in regulations 7, 8, 12B and 13(a) and parts 2 to 8 of the Schedule, in the Blood Safety and Quality Regulations 2005. These provisions implement the requirements set out in the implementing Directives referred to in paragraph 2.2. The power to make regulations to make provision in respect of the technical requirements referred to in the new regulation 23A would allow both the existing relevant provisions in the Blood Safety and Quality Regulations 2005 to be amended and new provisions to be made in relation to those requirements.

7.16 With the exception of the power to make provision in relation to deferral criteria for donors of blood or blood components (in regulation 23A(1)(h)) all the powers in regulation 23A will be subject to the negative scrutiny procedure. The powers allow for the amendment of technical requirements, which are very unlikely to be controversial and will be needed to be in place quickly in order to respond to emerging threats and technological advances so as to maintain appropriate quality and safety standards. The power to amend the deferral criteria for donors of blood and blood components may in some circumstances be more controversial and, as such, it is right that regulations made under this power should be afforded greater scrutiny by Parliament, so this power will be subject to the affirmative scrutiny procedure.

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

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to ensure retained EU law operates effectively following withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum (Annex A).

9. Consolidation

9.1 This Statutory Instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 A formal consultation was not considered necessary as the instrument makes minor amendments and it is not anticipated that the quality and safety of blood and blood components will change as a result.

10.2 Stakeholders, hospital blood banks, blood product manufacturers, representative groups and blood establishments were informed of the changes being made to the legislation.

10.3 Northern Ireland, Scotland and Wales have been engaged in ongoing consultation in relation to the changes included in this instrument. This instrument has been adapted to incorporate changes and comments that Devolved Administrations have proposed.

11. Guidance

11.1 The changes brought about by this Regulation will be publicised widely so that all who may be affected may be made aware of their effects. The Department of Health and Social Care has also issued a blood technical notice which sets out information to allow businesses and citizens to understand what they would need to do in a 'no deal' scenario, so they can make informed plans and preparations.

12. Impact

12.1 There is no, significant, impact on business, charities or voluntary bodies.

12.2 There is no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because the direct cost impact has been assessed as lower than the £5 million threshold in any one year and the policy is not considered novel or contentious. The impact of this instrument on businesses will be low.

12.4 Blood establishments and blood banks will need to ensure that blood and blood components from the UK continue to conform to the current EU testing requirements (Directive 2002/98/EC4), as well as meet with the equivalent standards (Directive 2004/33/EC5) of quality and safety as implemented by the UK Blood Safety and Quality Regulations 2005.

12.5 Manufacturers of blood products should comply with Directive 2002/98/EC for the testing of imported human blood and blood components for use in the manufacture of blood products

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The SIs are intended to ensure that quality and safety standards for human blood and blood components are maintained once the UK leaves the EU. The effectiveness of the SIs doing so will be regularly evaluated as part of a programme of accountability meetings between the Department of Health and Social Care and NHS Blood and Transplant (NHSBT).

14.2 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Trudy Netherwood at the Department of Health and Social Care Telephone: 020 7972 3255 or email: Trudy.Netherwood@dh.gsi.gov.uk can be contacted with any queries regarding the instrument.

15.2 Ailsa Wight at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention, at the Department of Health and Social Care 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 clauses 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/ESIC
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 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 clauses 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 clauses 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 77	Ministers of the Crown exercising clauses 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 clauses 8(1), 9, and 23(1) or jointly exercising	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising clauses 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, Sch 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 13, 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 16, 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.~~ Appropriateness statement

1.1 The Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention, Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

1.2 "In my view the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 does no more than is appropriate". This is the case because the instrument only amends blood safety and quality legislation to ensure it operates as intended following the withdrawal of the United Kingdom from the European Union or to correct blood safety and quality legislation where it would otherwise fail to operate effectively. This includes amending references to obligations or the UK must comply with as an EU member state that will no longer exist and transferring appropriate Commission functions to the Secretary of State in relation to England and on devolved ministers in relation to devolved areas. Further details, including examples of the changes included in the instrument, are detailed in Section 7 of the main body of this explanatory memorandum. It also ensures that the UK continues to maintain the current high standards of quality and safety for human blood and blood components (as outlined in Section 6).

2. Good reasons

2.1 The Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention, Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

2.2 "In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.3 Following exit day, without amendments to the relevant legislation, blood safety and quality policy would cease to function effectively. This instrument seeks to remove or amend provisions in UK legislation and EU legislation saved by the EU (Withdrawal) Act 2018, in order to ensure that blood safety and quality policy will continue to function at the same level as prior to EU exit. The instrument provides the Secretary of State and devolved ministers with powers previously held by the EU Commission. These powers will allow the Secretary of State to update blood safety and quality legislation in relation to England and, Devolved Ministers in relation to devolved areas in response to emerging threats, changing safety and quality standards, and technological advances. Further details, including examples of the amendments made and reasons for making them, are set out in Section 7 of the main body of this explanatory memorandum.

3. Equalities

3.1 The Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention, Jackie Doyle-Price MP has made the following statement "The draft instrument does not amend, repeal or revoke a provision or provisions in the

Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts".

3.2 The Parliamentary Under Secretary of State for Mental Health, Inequalities and Suicide Prevention, Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

3.3 "In relation to the draft instrument, I, Jackie Doyle-Price MP have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

4. Explanations

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