EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES AND MEDICAL DEVICES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 1385

1. Introduction

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

2. Purpose of the instrument

2.1 These Regulations (which come into force immediately before exit day) are made to correct drafting defects and omissions in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791). This is to ensure that the published policy in relation to the regulation of human medicines and medical devices in a no deal EU exit scenario is properly reflected in those instruments. Those instruments, which come into force on exit day, amend the Human Medicines Regulations 2012 (S.I. 2012/1916 – "HMRs"), associated Medicines (Fees) Regulations 2016 and the Medical Devices Regulations 2002 (S.I. 2002/618 – "MDRs") to ensure they are fit for purpose in a no deal EU exit.

Explanations

What did any relevant EU law do before exit day?

2.2 EU law provided for the EU medicines regulatory system of which the UK is a part before exit day. This includes licensing routes for the UK market, through the European Medicines Agency (EMA), joint Member State assessment or mutual recognition procedures, enabling recognition of prescriptions across the EU/EEA, providing networks and processes for monitoring the safety of medicines and incentivising the development of medicines to treat rare diseases and children.

2.3 EU law also provided for the EU regulatory system for medical devices and in vitro diagnostic devices (IVDs) of which the UK is a part before exit day. This includes the system of conformity assessment which is required for all medical devices and IVDs before these can be placed on the EU market. As explained further in section 6 below the current EU regime consists of three EU Directives and a number of pieces of EU tertiary legislation. The new Medical Devices Regulations (MDR) and in-vitro Diagnostics Regulations (IVDR) have been applied directly in UK law since May 2017 and will be fully implemented in the EU from May 2020 and May 2022 respectively.

Why is it being changed?

2.4 In a no deal EU Exit scenario the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), needs to operate outside of the EU medicines regulatory network and take on the responsibilities currently undertaken through the EU regulatory network for medical devices. The required changes have been made through the Human Medicines (Amendment etc.) (EU Exit) Regulations

2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019. The Explanatory Memoranda to those Regulations explained the changes in detail.

What will it now do?

2.5 The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 allow the MHRA to take on the required roles to regulate medicines effectively and to conduct effective market surveillance and assurance in relation to medical devices in the UK from exit day. These Regulations make technical corrections to those instruments to ensure their proper functioning at exit day, but do not represent a change of any underlying policy.

3. Matters of special interest to Parliament

Matters of special interest to the Sifting Committees

3.1 This instrument was laid in draft for sifting as an instrument subject to the negative procedure. It was considered by the Secondary Legislation Scrutiny Committee and European Statutory Instruments Committee at their meetings on 2nd July. Both Committees recommended that this instrument should be upgraded to the affirmative resolution procedure. As such the Department of Health and Social Care is laying the instrument in draft under the affirmative resolution procedure.

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 8(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 effect of this instrument is the same as the instruments it amends, namely all of the United Kingdom.

4.2 The territorial application of this instrument is the same as the instruments it amends, that is, it applies to all of the United Kingdom.

5. European Convention on Human Rights

5.1 Nicola Blackwood has made the following statement regarding Human Rights:

5.2 "In my view the provisions of The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 These Regulations are made to correct the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, which in turn amend the HMRs, associated Medicines (Fees) Regulations 2016 and the MDRs to ensure that the human medicines and medical devices legislation continues to operate effectively post-exit.

6.2 The regulation of human medicines and medical devices is an area of shared competence between the EU and Member States under article 4 of the Treaty on the Functioning of the EU (TFEU); but in light of the EU's comprehensive exercise of the competence, Member States are precluded from exercising the competence nationally.

Medicines:

6.3 The EU has created a comprehensive code for the marketing, manufacturing, packaging, distribution, advertising and monitoring of human medicines. The framework for this is set out in Directive 2001/83/EC and Regulation (EC) No. 726/2004. There are also multiple pieces of Commission-made EU tertiary legislation - both Directives and Regulations –largely made under Directive 2001/83/EEC or Regulation (EC) No 726/2004 as well as some further EU Regulations that supplement the EU legislative framework on human medicines.

6.4 Directive 2001/83/EEC and the tertiary Directives on human medicines have all been transposed into UK law by the HMRs. The HMRs are made under section 2(2) of the European Communities Act 1972 (ECA).

6.5 Regulation (EC) No 726/2004 and the tertiary and other EU Regulations on human medicines take direct effect in UK law by virtue of section 2(1) ECA.

6.6 The EU (Withdrawal) Act 2018 (EUWA) provides at section 2 that domestic legislation made under section 2(2) ECA continues to have effect in domestic law on or after exit day (notwithstanding that the ECA is repealed by virtue of section 1). "Exit day" is defined at section 20 to mean 11pm on 31st October 2019. By virtue of being saved under section 2 EUWA, the HMRs form part of "retained EU law" as defined in section 6(7) EUWA.

6.7 Section 3 of the EUWA provides that EU Regulations and tertiary Regulations also continue to form part of domestic law on or after exit day and these also form part of retained EU law. The approach taken in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 was to revoke and restate in the HMRs, with modifications, all the relevant EU and tertiary Regulations, in order to place the law governing the regulation of medicinal products for human use in one domestic instrument.

6.8 Section 8 of the EUWA provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy or mitigate (a) any failure of retained EU law to operate effectively; or (b) any other deficiency in retained EU law arising from the withdrawal of the UK from the EU.

6.9 The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 relied on the power at section 8 of the EUWA to amend the HMRs, and modify the effect of the re-stated EU regulations, to ensure that all aspects of retained EU law in relation to human medicines operate effectively and are not deficient after exit day as a result of the UK's withdrawal from the EU. This instrument corrects some errors and omissions in those amendments.

Medical Devices:

6.10 The EU regulatory framework for medical devices is set out in three Directives: Directive 90/385/EEC on Active Implantable Medical Devices; Directive 93/42/EEC on Medical Devices; and Directive 98/79 /EC on In Vitro Diagnostic Medical

Devices. In addition, there is EU tertiary legislation which supplements the framework.

6.11 The three EU Directives have been transposed into UK law by the Medical Devices Regulations 2002 SI 2002/618 (the 2002 Regulations) which are mostly made under section 2(2) of the European Communities Act 1972 (ECA). The EU tertiary legislation, made under the three EU Directives, takes direct effect in the UK by virtue of section 2(1) ECA.

6.12 On 5 April 2017, two new EU Regulations on medical devices were adopted and they subsequently entered into force on 25 May 2017: Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (the MDR); and Regulation (EU) 2017/746 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (the IVDR).

6.13 These two new EU Regulations replace the three EU Directives but they will only fully apply from 26 May 2020 in the case of the MDR and 26 May 2022 in the case of the IVDR.

6.14 The EU (Withdrawal) Act 2018 (EUWA) provides at section 2 that domestic legislation made under section 2(2) ECA continues to have effect in domestic law on or after exit day notwithstanding that the ECA is repealed by virtue of section 1. "Exit day" is defined at section 20 to mean 11pm on 31st October 2019. By virtue of being saved under section 2 EUWA, the 2002 Regulations form part of "retained EU law" as defined in section 6(7) EUWA.

7. Policy background

What is being done and why?

7.1 The policy reflected in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 seeks to ensure:

- that the regulation of medicines in the UK continues to be effective to safeguard public health and to allow the MHRA to operate as the regulator in this sector; and
- that the obligations on manufacturers to ensure that medical devices placed on the market in the UK are safe and fit for their intended purpose continue and to allow the MHRA to take on the roles and responsibilities for oversight and market surveillance for medical devices.

7.2 This instrument makes a number of changes to the above Regulations to ensure that the UK legislation accurately reflects published policy, correct drafting errors and omissions and reflect technical updates at EU level. Examples of the corrections include:

- Correcting the misspelling of an acronym of a standard setting body, adding some wording which was inadvertently missed from the provisions governing applications for biosimilar medicinal products, and including a definition of signal and signal evaluation in relation to pharmacovigilance;

- Correcting grammatical errors caused by amendments, eg. ‘an CAB’ being changed to ‘a CAB’ (original being ‘an EC Conformity Assessment Body (CAB)’).
- Correcting a missed definition: ‘authorised representative’ in one place where that should be ‘UK responsible person’
- Correcting some cross-referencing errors in the MDRs.

7.3 The instrument also makes clear that the requirements for a wholesaler’s licence (and in turn a responsible person for import (RPI)) apply to hospitals importing human medicine directly from a country on an approved list for their own use, and that medicinal products with EU marketing authorisations which were cancelled pre-exit on grounds not relating to safety, quality and efficacy can be reference products for applications for marketing authorisations in the UK for generic medicinal products. Marketing authorisations may be cancelled by the holder for commercial or strategic reasons which are unrelated to the safety or efficacy of product itself. It is those products which this provision brings into the scope of reference products for UK applications for generic medicines post exit.

7.4 There are also some amendments made in relation to Commission on Human Medicines (CHM) review of licensing authority decisions on rare diseases medicines (orphan) and paediatric matters. Certain functions in relation to the authorisation of medicinal products are currently carried out by the European Medicines Agency and the European Commission. After EU exit, the licensing authority will be responsible for carrying out those functions, and the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 put in place the changes to achieve that.

7.5 An example of these transferred functions in relation to paediatric and orphan matters includes that the licensing authority will agree paediatric investigation plans (i.e. agreements between the licensing authority and the company concerned to study a medicine in children before obtaining a marketing authorisation) and any modifications or waivers of the need for such a plan. It will also be able to decide that the orphan criteria (criteria demonstrating that a product is for a rare disease and should qualify for certain rewards) are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.

7.6 The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 added these decisions to the list of decisions which should in principle be subject to CHM review, but omitted the necessary detail in relation to the procedure for this. This instrument therefore provides for a mechanism for companies affected by proposed decisions in relation to orphan and paediatric matters to have those decisions, in the same way as already exists for other licensing authority decisions, reviewed by the CHM, which is the scientific advisory body which provides advice to the licensing authority.

7.7 This instrument provides clarification that the temporary exemption as to the location of an appropriately qualified person for pharmacovigilance (QPPV) applies to a holder of a UK marketing authorisation or traditional herbal registration granted before exit day, in respect of all UK marketing authorisations they hold, that are covered by a single pharmacovigilance system in respect of which there is the same QPPV who, immediately before exit day, resided and operated in an EEA State.

7.8 This instrument also inserts a transitional provision in relation to the pharmacovigilance system master file (PSMF). This provision provides a temporary exemption regarding the obligation to maintain and make available on request of the

licensing authority a PSMF covering all medicinal products for which the holder obtained a UK marketing authorisation in accordance with the HMRs, subject to specified statutory conditions. The transitional period begins with exit day and ends on the day on which the holder's QPPV resides and operates in the United Kingdom. This transitional provision corrects a potential conflict concerning locating a UKPSMF at a single point in the United Kingdom in instances where the QPPV is not established in the United Kingdom on exit day, and ensures that businesses have time to comply with the PSMF content and format requirements outlined in Schedule 12A to the HMRs (inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019).

7.9 The addition of the Republic of Korea to the approved list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day reflects the update to the EU list since the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 were made.

7.10 This instrument also makes amendments which result from amendments made by the EU to the underlying medical devices EU Regulations since the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 were made via the recently published corrigendum. The changes range from grammatical and reference corrections to amendments around what is included in the scope of the transitional provisions.

7.11 Two further minor changes to the devices regime:-

- ensure that products which are mainly used for cosmetic purposes are required to comply with Common Specifications (these are common EU rules made in situations where harmonized standards either do not exist or are inadequate, or where there is a need to address specific public health concerns. They are made through EU tertiary legislation and operate by modifying certain parts of the underlying EU Regulations);
- and require the information registered about medical devices with the MHRA to be updated by the manufacturer.

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 address failures of retained EU law to operate effectively or other deficiencies arising from the 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.

9. Consolidation

9.1 The majority of medicines legislation was consolidated in 2012 as the Human Medicines Regulations 2012. There are currently no plans to consolidate the legislation being amended by this statutory instrument.

9.2 The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 consolidated all the amendments to the Medical Devices Regulations 2002 in order to make the Regulations fit for purpose in a no deal EU exit scenario. There are currently no plans to consolidate the legislation being amended by this statutory instrument.

10. Consultation outcome

10.1 This instrument corrects technical and drafting errors in the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and does not represent changes of policy which has already been consulted on. No further consultation was necessary.

11. Guidance

11.1 The Government has committed to provide further guidance in advance of EU Exit day (when the legislation which this instrument amends comes into force).

12. Impact

12.1 This legislation will not have any significant impact on business, charities or voluntary bodies.

12.2 There is no significant impact on the public sector.

12.3 An impact assessment was produced for the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791). An impact assessment has not been prepared for this instrument as no significant changes to what businesses or the public sector will have to do under these regulations are envisaged.

13. Regulating small business

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

14. Monitoring & review

14.1 The Human Medicines Regulations 2012 are subject to a regular review by the Secretary of State. As this instrument is made under the EUWA, no review clause is required.

15. Contact

15.1 Bindiya Shah at the MHRA Telephone: 020 3080 6843 or email: Bindiya.shah@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Ian King at the MHRA can confirm that this Explanatory Memorandum meets the required standard.

15.3 Baroness Blackwood at the DHSC 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
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 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 Health, Baroness Blackwood, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018: "In my view the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 do no more than is appropriate".

1.2 This is the case because: the changes to the law made by these Regulations are limited to making technical amendments to earlier instruments without changing any underlying policy. Those earlier instruments made provision which was appropriate to prevent, remedy or mitigate deficiencies arising out of EU exit, and resulting from the UK no longer being part of the EU medicines and medical devices regulatory network, whilst maintaining, so far as possible, the existing regulatory position.

2. Good reasons

2.1 The Parliamentary Under Secretary of State for Health, Baroness Blackwood has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018: "In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These reasons are: ensuring that the earlier instruments which these Regulations amend function correctly. Those earlier instruments aimed at ensuring the protection of public health in the UK once the UK is no longer part of the EU medicines and medical devices regulatory network.

3. Equalities

3.1 The Parliamentary Under Secretary of State for Health, Baroness Blackwood 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 Health, Baroness Blackwood 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, Nicola Blackwood, Parliamentary Under Secretary of State for Health, 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 paragraph 2 of the main body of this explanatory memorandum.