EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

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

2. Purpose of the instrument

2.1 This instrument amends:

- The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) ("the 2019 Regulations");
- The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/1385) ("the Second 2019 Regulations")
- The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/744) ("the Clinical Trials 2019 Regulations"); and
- The Good Laboratory Practice Regulations 1999 (S.I. 1999/3106).

2.2 The 2019 Regulations and the Second 2019 Regulations (together "the 2019 SIs") and the Clinical Trials 2019 Regulations make significant amendments to the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the HMRs"), the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031) ("the Clinical Trials Regulations") and the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190) ("the Fees Regulations"). Those amendments were intended to ensure that the Regulations were fit for purpose in a no deal EU Exit scenario. The HMRs, the Clinical Trials Regulations and the Fees Regulations will remain the basis for the regulation of medicines and clinical trials in Great Britain ("GB") after 1 January 2021.

2.3 This instrument amends the Regulations set out above in order that the HMRs, the Clinical Trials Regulations and the Fees Regulations will continue to be effective at the end of the Implementation Period for the purposes set out below.

2.4 This instrument will amend how medicines and clinical trials will be regulated in Northern Ireland ("NI") and in GB at the end of the Implementation Period, taking account the Northern Ireland Protocol ("NIP").

Explanations

What did any relevant EU law do before exit day?

2.5 EU law provided for the EU medicines and clinical trials regulatory system of which the UK is a part until the end of the Implementation Period (11pm on 31 December 2020). 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 and regulating the conduct of clinical trials.

Why is it being changed?

2.6 The 2019 Regulations and the Clinical Trials 2019 Regulations amended retained EU law across the UK as a whole and they are due to come into force at the end of the Implementation Period. Following the conclusion of the Withdrawal Agreement, NI must continue to meet the requirements of the majority of the EU regulatory framework on medicinal products, for as long as the NIP is in force, whilst that framework will now no longer apply in GB. The MHRA needs to operate outside the EU regulatory network in respect of GB but will continue to regulate medicines in NI, largely on the basis of EU law. The HMRs, the Clinical Trials Regulations and the Fees Regulations were amended by the 2019 SIs and the Clinical Trials 2019 Regulations in anticipation of the UK leaving the EU and moving out of the EU regulatory regime in its entirety. The explanatory memoranda to those Regulations explained the changes in detail. Further amendments are now required to ensure that EU law continues to be implemented in Northern Ireland, to update the regulations in light of the Withdrawal Agreement and Implementation Period and to update, in GB, some aspects of the earlier provision that was made.

What will it now do?

2.7 This instrument will enable the effective ongoing regulation of medicinal products across the UK from the end of the Implementation Period. This instrument makes technical amendments to existing instruments to ensure their proper functioning. It also makes updates to some policy areas following industry feedback, and it ensures that NI continues to meet the provisions of applicable EU legislation. This instrument will ensure patient access to safe and effective medicines as well as enabling the MHRA to continue to monitor the ongoing safety of those medicines across the UK and where necessary take action to protect patients.

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 (sections 8(1) and 8C of, and paragraphs 1(1) and 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 ("EUWA")) cover the entire United Kingdom 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 Lord Bethell has made the following statement regarding Human Rights:

"In my view the provisions of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 The regulation of human medicines 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.

6.2 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.

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

6.4 Clinical trials included in applications for marketing authorisations ("MAs") for human medicines in the European Economic Area must be conducted in accordance with the requirements set out in Annex 1 of Directive 2001/83/EC. Clinical trials conducted in the EEA have to comply with Directive 2001/20/EC on the approximation of laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ("the Clinical Trials Directive"). The Clinical Trials Directive is implemented in the UK by the Clinical Trials Regulations.

6.5 Article 5(4) and Annex 2 to the NIP provide for the legislation listed in that Annex to apply to and in the United Kingdom in respect of Northern Ireland from the end of the Implementation Period. Paragraph 20 of the Annex sets out the applicable EU legislation relating to medicinal products; this list includes Directive 2001/83/EC, Regulation 726/2004 and Article 13 of the Clinical Trials Directive (which regulates the manufacture and importation of investigational medicinal products that are used in clinical trials).

6.6 Section 8 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.

6.7 Section 8C EUWA provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate (a) to implement the Northern Ireland Protocol on Ireland/Northern Ireland in the Withdrawal Agreement, (b) to supplement the effect of section 7A in relation to the NIP, or (c) otherwise for the purposes of dealing with matters arising out of, or related to, the NIP (including matters arising by virtue of section 7A and the NIP).

6.8 Section 2 of EUWA saves EU-derived domestic legislation so that it continues to have effect in domestic law, on and after IP completion day. The HMRs and Clinical Trials Regulations are retained EU law and the 2019 SIs and Clinical Trials 2019 Regulations will amend them from 1 January 2021 to ensure they function effectively once the UK is no longer subject to EU law, in reliance on section 8 of EUWA (power to remedy deficiencies in retained EU law arising from EU exit). As NI will need to remain subject to EU medicines legislation after the end of the Implementation Period, this instrument re-exercises the power in section 8 of EUWA to restrict the changes being made by the 2019 SIs and Clinical Trials 2019 Regulations to GB. This instrument also relies on the power in section 8C of EUWA (power to implement the Northern Ireland Protocol), for example by making provision for unfettered access, to ensure NI businesses can continue to trade EU-compliant goods on the GB market without facing new GB regulatory controls and checks.

6.9 The MHRA, an executive agency of DHSC, carries out the functions of competent authority in the UK in the area of human medicines on behalf of the "licensing authority", a body established under regulation 6 of the HMRs.

6.10 By virtue of the MHRA Trading Fund Order 2003 (S.I. 2003/1076), the MHRA operates as a trading fund and seeks to recover the cost of its work regulating human medicines through the charging of fees. The majority of the fees the MHRA charges are statutory and are set out in the Fees Regulations. This instrument relies on the powers at Schedule 4 EUWA to introduce new fees and amend existing fees in connection with functions conferred on the licensing authority under sections 8 and 8C EUWA. They do so by amending the Fees Regulations.

7. Policy background

What is being done and why?

7.1 The policy reflected in the 2019 SIs and the Clinical Trials 2019 Regulations sought to ensure that the regulation of medicines and clinical trials in the UK continues to be effective to safeguard public health and to allow the MHRA to operate as the regulator in this sector.

7.2 This instrument makes a number of changes to the above Regulations to:

- make technical updates to take into account the Implementation Period that was agreed under the WA. So, for example, they substitute references to 'exit day' with 'IP completion day';
- give effect to the NIP; they do this by reversing some of the changes made by the 2019 SIs and Clinical Trials 2019 Regulations, limiting those changes to GB so that EU law will continue to be implemented in NI; and
- implement a limited number of policy changes to the regulatory regime in GB.

Types of Marketing Authorisations ("MAs")

7.3 In their current form, the HMRs allow for both EU MAs and UK MAs to authorise medicines to be marketed in the UK. Regulation 8 defines "marketing authorisation" as either an EU or a UK marketing authorisation. It also defines both of those terms. An EU MA is one granted by the European Commission on a centralised basis. A UK MA is one granted by the MHRA under the HMRs. The key provision governing marketing is regulation 46, the effect of which, with regulation 47, is that it is a criminal offence to sell or supply a product without an MA or otherwise than in accordance with the terms of an MA.

7.4 There are two main changes to the HMRs in order to reflect the NIP's impact on MAs:

(1) EU MAs will authorise sale or supply in NI only; and

(2) UK MAs will not automatically apply on a UK-wide basis (as now), but instead may authorise sale or supply in the whole UK, in GB only or in NI only.

Reliance on EU Marketing Authorisations ("MAs")

7.5 At present, there are four routes by which a company can gain an MA to place a human medicine on the UK market, three of which involve the EU regulatory network:

- A centralised MA granted by the European Commission which is valid for the whole EU
- A national UK MA granted following either:
    a) a mutual recognition of a national MA granted by another EU member state. This is known as the mutual recognition procedure ("MRP"); or
    b) a collective assessment procedure by several member states, led by one of them. This is known as the Decentralised Procedure ("DCP").
- A purely national UK route, resulting in a national MA valid for the UK only. This does not involve the EU regulatory network.

7.6 After EU Exit, the UK will no longer be part of the EU licensing system in the way that it is now, but centralised MAs granted by the European Commission will continue to apply in NI. However, all medicines coming to GB will be required to be authorised via a UK national route. In order to facilitate continued patient access to a full range of available medicines as soon as they are available in the EU, the legislation includes a power enabling the regulatory authority to automatically recognise licensing decisions made by the EU (based on the scientific opinion of the EMA's Committee for Medicinal Products for Human Use ("CHMP")) in relation to medicines ("automatic recognition"). There will also be provision for the MHRA, when making licensing decisions, to have regard to decisions taken by EU Member States on products approved via decentralised and mutual recognition procedures. The MHRA will authorise products entering GB, even where relying on EU scientific assessments and decisions. This policy is to ensure that the UK can take effective regulatory and safety action on these products. Changes to regulation 58 of the HMRs and to the Fees Regulations have been made to achieve this. Further, non-legislative changes may also be implemented in order to ensure the continued attractiveness of the UK market.

Moving goods from NI to GB: Unfettered Access

7.7 The UK Government has committed to NI businesses having unfettered access to the GB market at the end of the implementation period. Unfettered access ensures NI businesses can continue to trade EU-compliant goods on the GB market without facing new GB regulatory controls and checks.

7.8 Medicines are defined as 'highly regulated goods' given the potential patient safety and public health risks associated with them. Therefore, these Regulations put in place transparency requirements and safety clauses for medicines being moved from NI to GB via this route. These requirements will allow the MHRA to maintain oversight of a product when it enters the GB market, and because licensing decisions made in the EU will apply in NI, allows the MHRA to take pre-emptive regulatory steps in relation to GB in the event of early concerns, rather than only being able to remove a product from the market. We have sought to balance keeping administrative burdens on industry to a minimum with mitigating the risks of a reduction in market oversight.

7.9 Specifically, this instrument provides powers for the MHRA to grant a MA for the GB market for medicines that have a valid MA for NI from one of the three EU routes, provided that the applicant produces specified information in support of their application. This route does not require the MHRA to evaluate the supporting scientific data, which has already been considered at EU level. Gaining such a GB MA would be reliant on:

a) providing MHRA with the same information and data provided to the EMA or EU Member State regulators for approval of the MA that applies in NI;

b) providing MHRA with the same post-MA information and data, on an on-going basis, as provided to the EMA or EU Member State regulators. This should also include reports of all serious suspected adverse reactions that occur in the UK and other countries, and all non-serious suspected adverse reactions that occur in the UK.

c) this MA only being applicable to medicines that are qualifying NI goods, as that term is defined in this instrument.

d) the GB MAH having at its disposal a UK or EU based QPPV who will be responsible for giving the MHRA access to the safety system for that medicine. If the QPPV is EU-based, a UK-based nominated contact person will be required.

7.10 To ensure unfettered access only benefits NI businesses, these regulations require that:

a) only an NI business should be able to apply for a licence from MHRA via this route; and

b) the market authorisation holder (MAH) will need to be located in NI. The NI business (who will be the MAH) providing the information and data takes on the legal responsibility for the medicine once on the GB market, including access to a suitably qualified person for UK regulators to interact with on ongoing safety monitoring (pharmacovigilance) related to those medicines.

7.11 The UK regulator will retain powers which include:

- The power not to grant an MA in relation to GB if there are concerns with regard to public safety and the power to withdraw a product from the GB market in exceptional circumstances, but the MHRA would retain its ability to work with manufacturers to address any safety concerns before resorting to taking the product off the market;

- The ability to re-test batches of biological medicines where it is deemed appropriate
- The power to carry out a targeted assessment of a medicinal product to provide assurances of its safety on the GB market.

Location of Qualified Person for import of investigational medicinal products (IMPs)

7.12 The products given to patients in a Clinical Trial are known as Investigational Medicinal Products (IMPs). Currently, for an IMP to be supplied in the EU or the UK, it must have been certified by a Qualified Person (QP certified). This is true whether the IMP is manufactured in the EU, the UK, or a third country.

7.13 For IMPs manufactured in a third country the importer must hold a Manufacturer's Authorisation for Import for IMPs (MIA(IMP)) and QP certify the product before supplying it in the EU. When GB becomes a third country to the EU, there will be no obligation under EU law that ensures IMPs coming from the EU into GB will have been QP-certified.

7.14 QP certification is a critical part of ensuring that an IMP has been manufactured to the correct standard. For this reason, this instrument will require the importation of IMPs from approved countries (which, at the end of the transition period, will encompass all EEA states) to be overseen by the holder of a UK MIA(IMP) licence to ensure that the IMP has been QP-certified within an approved country, by a Qualified Person (QP) based in any of the EU/EEA countries. This requirement will come into force 12 months after the end of the transition period to enable industry to implement these changes. In the interim, reliance will be placed on the clinical trial Sponsor to ensure that IMPs are supplied in accordance with the Clinical Trial Authorisation and manufactured according to EU good manufacturing practice.

7.15 It is this requirement for a second, UK based QP providing assurance which industry have strongly pushed back on, stating it is overly burdensome and would make the UK less attractive for Clinical Trials.

7.16 We have therefore revisited this requirement and identified a change that would continue to minimise public health risks while also ensuring a UK based person is legally responsible for the IMP. This change would remove this final requirement, and:

a) Require the QP named on the supplying EEA MIA(IMP) to continue to certify IMPs in line with the UK clinical trial authorisation.

b) Allow the QP named on the UK MIA(IMP) who is responsible for confirming that EEA certification has been done in the EEA to reside in the UK or in a country from an approved list of countries (initially the EU/EEA).

c) Continue to see the MIA(IMP) Holder be legally responsible for assuring QP certification has happened.

Qualified Person for Pharmacovigilance

7.17 The holder of a MA ("the MAH") must establish a pharmacovigilance system which is overseen and maintained by a named Qualified Person for Pharmacovigilance (QPPV).

7.18 The HMRs were previously amended to provide that, after EU exit, holders of UK MAs would have to have at their disposal a UK QPPV who resides and operates in the

UK. MAHs were to have 24 months to put this UK-based QPPV in place. This is because the QPPV is a specialist role and so it was expected to take time to recruit and train sufficient numbers.

7.19 However, relevant EU legislation, which will continue to apply in Northern Ireland, provides that the QPPV for MAs granted under EU law must reside and operate in the Union which, by virtue of the NIP, includes the UK in respect of Northern Ireland. Therefore, to best implement the NIP, this instrument makes amendments to allow a QPPV to reside and operate in the UK or the EU. This instrument also provides that if the QPPV is not based in the UK, the MAH must nominate a UK-based representative with the ability to provide the MHRA with access to the pharmacovigilance system as required (a national contact person for pharmacovigilance).

7.20 The Regulations introduce a 12-month transition period for industry to meet the requirement of having a national contact person for pharmacovigilance.

7.21 Overall this would ensure the UK retains the need for a named UK QPPV and the ability to access the pharmacovigilance system in all scenarios, and would remove the need for MAHs to maintain separate systems for NI and GB, which would be duplicative and expensive for no added value.

Data and Marketing Exclusivity

7.22 The applicant for an authorisation for an innovative medicine must provide information about the efficacy and safety of the product to the licensing authority. That data is then protected for a period of time, during which applicants for generic versions of the product are not permitted to refer to the information submitted by the innovator company. This is known as "data exclusivity". Once the innovative product is authorised, no generic version may be placed on the market until a period of "marketing exclusivity" has expired. These two types of protection are known as data and marketing exclusivity ("DME").

7.23 There will not be any changes as a result of EU exit to the DME periods enjoyed by the existing holders of UK national MAs or converted EU MAs.

7.24 While the MHRA has taken steps to significantly ease the process of licensing a new medicine for use in Great Britain where there is a parallel application in the EU, companies will still need to apply for a licence in GB and go through a simplified MHRA process to obtain the licence. This could lead to a small delay in some cases between when a new medicine receives an EU licence, which is valid in NI, and a GB licence.

7.25 This delay will be significantly minimised if a company submits their application for a GB MA as soon as they have received a positive scientific assessment on their application from the EU's Committee for Medicinal Products for Human Use ("CHMP"). The MHRA will then complete its licensing process in parallel to the EU licensing process which also follows CHMP's decision.

7.26 In the case of any potential delay between a company receiving an EU licence, which will be valid in NI, and going through the process to receive a GB licence, this could lead to a corresponding discrepancy in the period in which the medicine has DME protection in different parts of the UK. DME is a key intellectual property (IP) provision for new, branded medicines.

New/amended MHRA fees

7.27 The MHRA charges fees to recover the costs of statutory regulation of medicines. Changes are therefore required to reflect the costs of the new regulatory changes being introduced after the end of the Implementation Period. The Fees Regulations set out the fees which the Agency currently charges. The fees changes introduced in this instrument include new fees for MAs and renewals issued under automatic recognition or through the unfettered access route, the fees are set out below:

a) For an application for a New Active Substance, the fee will be £18,437

b) For a Complex Abridged application, the fee will be £10,443

c) For a Standard Abridged application, the fee will be £5,783

d) For a Simple Abridged application, the fee will be £2,564

e) For renewals, the fee will be £747

7.28 This instrument also introduces new fees for applications which will have regard for the EU scientific decision during the MRP/DCP approval process. These fees will be set at the same level as the existing fees for an equivalent MRP application.

7.29 This instrument also introduces a pharmacovigilance fee reduction to £734 for Post-authorisation Safety Study protocols (PASS) for MAs which are granted via automatic recognition and via unfettered access.

Implementing the Northern Ireland Protocol

7.30 This instrument makes a large number of changes to the 2019 SIs to make sure that applicable EU law will continue to be implemented in NI and the MHRA can continue to operate in NI after the end of the transition period; this will ensure continuity is provided for businesses and the public in NI. A description of these changes is set out below.

Packaging and leaflets

7.31 All medicines on the UK market that are the subject of a MA must comply with the provisions of Part 13 of the HMRs and the associated schedules with regards to labelling, packaging and patient information leaflets. This ensures a high degree of public safety on the basis of comprehensive information. The policy intention is to retain this level of information provision which is currently fully aligned with the EU acquis.

Falsified medicines

7.32 The requirements placed on all actors in the UK supply chain from 9 February 2019 by virtue of the Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regarding the safety features aspects of the Falsified Medicines Directive (2011/62/EU), will be amended by this instrument, because in GB companies will no longer be required to comply with the requirement to verify and authenticate all relevant medicines within the ambit of the Directive. For example, the unique identifier in a 2D data matrix code for products coming from the EU will have been decommissioned (made inactive) on export from the EU and before entry to GB as a third country. In NI, however, as a result of the NIP, the Falsified Medicines Directive will continue to apply.

7.33 Furthermore, this instrument ensures that there will be no obligations on the GB supply chain to affix the safety features or to scan packs of medicines. Packs already

affixed with FMD safety features will continue to be accepted in GB, provided that they are in line with other GB packaging requirements. In the interests of public safety, the Government will evaluate the options for a future GB falsified medicines framework, taking into account the investment already made by stakeholders.

Borderline Products

7.34 Borderline products are products where there is some question as to whether they constitute medicines (including herbal or homeopathic medicines) within the meaning of the regulations.

7.35 This Part of the Regulations was amended by the 2019 Regulations so no significant policy changes are required as a result of the NIP. There are, however, some small changes that will be needed as a result of the changes in the types of marketing authorisation (i.e. GB and NI authorisations now being available as well as UK authorisations).

7.36 Once the determination procedure for borderline products is triggered for a product being placed on the market anywhere in the UK, the procedure will determine whether the product should be treated as a "medicine" for the UK as whole, even if different types of authorisation might be applicable to the product in NI compared to GB. The tests at present for whether a product should be considered a medicine for the purposes of the HMR remain the same in NI and GB.

Manufacturing and Importation

7.37 Part 3 of the HMRs deals with manufacture, importation and distribution of medicinal products and active substances. The 2019 SIs amended this Part of the HMRs to reflect the UK's departure from the EU. They are now amended to reflect the fact that EU law, including the 2001 Directive, will continue to apply in NI. Therefore, authorisations will apply in GB (subject to GB regulations) or NI (subject to retained EU law), or both, in the case of UK wide authorisations.

Advertising

7.38 From 1 January 2021, some medicines may only be authorised for sale in some parts of the UK (i.e. either in NI or GB or both) and some medicines will have different product requirements in different parts of the UK.I It will therefore be important to be able to distinguish between which publications, websites etc. are UK-wide as opposed to those which can properly be viewed as GB or NI only to ensure that consumers are not misled.

7.39 This instrument states that an advert may not be published unless there is a valid MA in that country. As it is possible that an advert may be seen in both GB and NI, all adverts for products with a GB only MA must state this in the advert in order not to mislead NI customers.

Batch testing of biological medicines

7.40 Stringent regulators worldwide insist that biological medicines are tested by an independent laboratory prior to use, in addition to the manufacturer. The UK's National Institute for Biological Standards and Control (NIBSC) is currently a member of the EU's Official Control Authority Batch Release (OCABR) network for biological medicines. A feature of the system provided for in Directive 2001/83/EC (Article 114) is that there is mutual recognition of certificates across the EU/EEA,

which means that a batch certified by one independent laboratory will be accepted by the other states. When the UK is a third country from the EU's perspective, this system of mutual recognition will no longer be in place, but the UK will be required to recognise certificates for products that are for sale or supply in NI.

7.41 There will be several possible scenarios for manufacturers marketing biological medicines in the UK (see new regulations 60A and 60B of the HMRs). First, where the UK agrees with one or more countries to accept each other's independent test certificates for biological medicines, there will be little change from the current arrangements, except as agreed and set out in the formal mutual recognition agreement between the countries. A list of those countries with whom the UK has an agreement in place, together with any restrictions to the exemption to batch release, will be available.

7.42 Second, and subject to the scenario in the following paragraph, where there is no mutual recognition agreement in place, NIBSC will issue UK certificates for batches of biological medicines used in this country. Manufacturers will provide samples and documentation for each batch of biological medicine destined for the UK to NIBSC. It is anticipated that batches to be used only in the UK will usually be tested and certificated by NIBSC. Where a batch is destined for use in both the UK and another country, if it has already received independent certification in a country that is on the UK's approved country list, NIBSC will take a public health risk-based approach to deciding whether to rely on a paper assessment of that certification to issue the UK certificate or whether to carry out laboratory testing of the batch in the UK.

7.43 Thirdly, if the batch is of a medicinal product for sale or supply in Northern Ireland only, and it has already received independent certification from a relevant EEA state, that certificate will be recognised in the UK (unless it is issued by a state other than the state where the batch was manufactured).

7.44 This approach is designed to provide the UK with an appropriate level of safety oversight over batches of biological medicines, whilst minimising the impact on manufacturers.

7.45 Regulation 60A has been amended to provide for NIBSC testing of medicinal products authorised under a Parallel Import licence, and to provide for the recognition of OCABR certificates for products for sale or supply in NI. Regulation 60B has been inserted to provide for NIBSC testing of medicinal products for sale or supply in NI, that are authorised under an EU MA.

Good Laboratory Practice

7.46 The Good Laboratory Practice Regulations 1999 (S.I. 1999/3106) ("GLP Regulations") implement Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances and Directive 2004/9/EC on the inspection and verification of good laboratory practice (GLP). Under the GLP Regulations, there is a requirement that regulatory studies must only be conducted at test facilities which are part of the UK GLP compliance programme. Currently, one of the possible reasons for refusing a test facility operator's prospective membership into the UK GLP compliance programme, or immediately withdrawing a test facility operator's membership of the programme, without allowing the test facility operator an opportunity to make representations, is in order "to ensure fulfilment of an EU obligation". As there are

currently no other 'EU obligations' in the relevant directives that could apply in these circumstances, it is not necessary to retain this reference to 'EU obligation'.

Part 12 Dealings with Medicinal Products

7.47 Part 12 deals with the sale, supply and administration of medicinal products, including provisions on who can sell/supply prescription only medicines and medicines subject to general sale. The changes made to Part 12 are largely to reflect the wider changes being made to the licencing of medicines in the UK and the subsequent amendments to reflect the introduction of different MA processes in NI and GB as part of the implementation of the NIP.

7.48 This instrument also makes changes to Regulation 251. Regulation 251 provides that a person must not sell or supply a medicinal product that is subject to a monograph in the British Pharmacopeia ("the BP") unless the product complies with the standard specified in that monograph. An exemption has been inserted for EU MAs, or MAs obtained through an EU procedure (MRP or DCP), which authorise sale or supply of medicinal products in NI; the exemption applies to products that do not comply with the relevant monograph in the BP, but do comply with their authorisations.

Part 12A - Sale of Medicines to the Public at a Distance

7.49 Part 12a of the HMRs deals with the online sale of medicinal products to the public. This originally implemented provisions in Directive 2001/83/EC by requiring online sellers to comply with relevant requirements and display the EU distance selling logo on their website. This Part of the Regulations was revoked by Regulation 197 of the 2019 Regulations to reflect the UK's departure from the EU so that UK-based online sellers no longer had to comply with the requirements. To give effect to the NIP Part 12a has been amended to apply to NI only. Therefore, from 1 January 2021, the requirements in Part 12a, including the online seller's scheme, will not apply to online sellers established in GB, but will apply to online sellers established in NI.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the powers in sections 8 and 8C of EUWA in order to update amendments made 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 and to implement the Northern Ireland Protocol. The instrument is also made under the powers in paragraph 21of Schedule 7 of EUWA and in Schedule 4 to introduce new and amend existing fees in connection with functions conferred on the MHRA under section 8. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of Annex 2 to this explanatory memorandum.

9. Consolidation

9.1 The majority of human 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 instrument.

10. Consultation outcome

10.1 The amendments introduced by this instrument are largely technical in nature and their primary purpose is to give effect to the Northern Ireland Protocol by restricting the changes made by the 2019 SIs and Clinical Trials 2019 Regulations to GB and ensuring that the current law will remain in place for NI. Therefore, there was no public consultation. Guidance has been published in advance of laying this SI and industry has had the chance to consider and comment on key changes.

10.2 The proposed amendments have been shared with the NI devolved administration; this instrument is being made on a UK-wide basis with the agreement of the NI devolved administration.

11. Guidance

11.1 Guidance relating to this instrument has already been published and the Government has committed to provide further guidance in advance of the end of Implementation Period (when this instrument comes into force).

11.2 Where guidance is referenced in EU legislation, the amendments to the HMRs generally state that the EU guidance on that topic applies until the MHRA amends or replaces it. The guidance may be accessed at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012

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 2019 Regulations. The Better Regulation Executive guidelines on EU exit impact assessments state that any analysis on EU Exit related instruments should focus on specific changes of individual pieces of legislation and should not include information or analysis that appears to be estimating the overall impact of leaving the EU, or what the UK's future relationship might look like with the EU. Analysis was undertaken to assess the impact of the amendments proposed against a baseline of the leaving the EU and implementing the NIP, as this remains the basis for legislation from the 1st of January 2021. As the impact to businesses was below the +/- £5 million threshold, a full Impact Assessment would not be proportionate and hence a more high-level Regulatory Triage Assessment was carried out.

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 Jack Turner at the MHRA Telephone: 020 3080 6743 or email: Jack.turner@mhra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jonathan Lepper at the MHRA can confirm that this explanatory memorandum meets the required standard.

15.3 Lord Bethell 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 Equality 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 s. 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 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA 1972, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under s. 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 1972.	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, Lord Bethell, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 do no more than is appropriate".

1.2 This is the case because: they do nothing more than amend legislation on medicinal products for human use to (a) give effect to the Ireland/NIP in the Withdrawal Agreement and; (b) update a limited number of provisions in respect of GB to prevent, remedy or mitigate deficiencies arising out of EU exit and (c) make technical amendments in light of the Implementation Period, such as substituting references to "exit day" with "IP completion day". The majority of the changes to the law made by these Regulations are limited to making technical amendments to earlier amending instruments without changing 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 clinical trial 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, Lord Bethell 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: the NIP sets out the EU law that will continue to apply to and in the UK in respect of NI, which includes relevant EU legislation on medicinal products for human use. NI must continue to meet the requirements of the relevant EU legislation for as long as the Northern Ireland Protocol is in force. These regulations make the changes needed to enable NI to meet these requirements. 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. The implementation of the NIP, together with updates to the regulatory regime in light of EU exit and the Implementation Period, are required to ensure the effective ongoing protection of public health across the UK.

3. Equalities

3.1 The Parliamentary Under Secretary of State for Health, Lord Bethell, 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, Lord Bethell, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Lord Bethell, 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 section 2 of the main body of this explanatory memorandum.