EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (CORONAVIRUS) (FURTHER AMENDMENTS) REGULATIONS 2020

2020 No. 1594

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.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument amends the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended) ("the HMRs") to deal with five legal issues that have emerged in the early stages of the mass vaccination campaign against COVID-19. These five changes are time limited so that they expire on 1st April 2022.

2.2 Firstly, this instrument enables certain providers of NHS and public health services, for example NHS trusts and foundation trusts, to issue Patient Group Directions (PGDs) in relation to parenterally administered medicinal products under powers that previously could only be used to issue PGDs in relation to medicinal products that are not parenterally administered.

2.3 Secondly, this instrument provides that the PGDs that allow retail pharmacy businesses to administer COVID-19 or influenza vaccines may be used at a location other than a registered pharmacy.

2.4 Thirdly, this instrument also allows doctors, nurses and pharmacists to prepare or assemble COVID-19 vaccinations, or supervise their preparation or assembly, in circumstances in which they were not previously permitted to do so without the appropriate licences.

2.5 Fourthly, it provides for authorised medicinal products which are to be used for the reformulation of COVID-19 vaccines, most commonly diluents, to be "assembled" into new products (for example by packing them down into different quantities and relabelling them), without those new products needing to be covered by new marketing authorisations.

2.6 Fifthly, it allows holders of a wholesale dealer's licence – without a manufacturer's licence – to relabel COVID-19 vaccines with a new shelf life to take account of the thawing of the product.

2.7 This instrument also corrects errors made by the Human Medicines (Amendments etc.) (EU Exit) Regulations (S.I. 2020/1488) ("the EU Exit Regulations") that arise out of a failure to take account of the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (S.I. 2020/1125) ("the C&I Regulations") to restore the effect of some of the changes made by the C&I Regulations.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 DHSC regrets that unfortunately the provisions of this instrument breach the rule that provisions of statutory instruments subject to the negative procedure should normally have been laid before Parliament 21 days before they come into force ("the 21-day rule"). The regulations in this instrument have been brought into force either on the day after the day on which this instrument is laid before Parliament or, in the case of the amendments made to correct errors made by the EU Exit Regulations, immediately after the amendments made by those Regulations take effect. They will take effect at the start of the Implementation Period completion day, which starts at 11pm on 31st December 2020.

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 C&I Regulations included all the changes to the HMRs that DHSC thought, at the time of the making of those Regulations, that it would need to support the roll-out of the mass vaccination campaign against COVID-19. The specific challenges of deployment of COVID-19 mRNA vaccine BNT162b2 have, however, brought to light or highlighted the need for five additional measures, which are all of relevance to the mass vaccination campaign which has now begun.

3.3 All these five changes are essentially permissive and enabling, and delaying their implementation could potentially hamper the mass vaccination campaign against COVID-19. The corrections to the errors made by the EU Exit Regulations also need to be made at the earliest opportunity, as they may impact upon the mass vaccination campaign.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

5.1 As this instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The HMRs establish a comprehensive regime for the authorisation of medicinal products for human use, and for their manufacture, distribution, sale, supply, labelling and advertising – and for pharmacovigilance. This comprehensive regime has to date been based largely on the implementation of EU legislation, most notably Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

6.2 Two of the general presumptions on which that regime is predicated are that products placed on the market in the United Kingdom will be covered by a product licence known as a “marketing authorisation”, and businesses that manufacture or assemble medicinal products have to have a “manufacturer’s licence”. However, there are exemptions in regulations 3 and 4 of the HMRs that relate to the final supply of

medicinal products which mean that manufacture, preparation and assembly of medicinal products at the end of the supply chain will not need a manufacturer's licence, and the products that result from the final processing will not need marketing authorisations. These exemptions relate to final processing done by or in the name of a doctor, dentist, nurse or midwife or by or under the supervision of a pharmacist. In the latter case, the final processing must take place at a specified range of premises.

6.3 There are also general presumptions in the HMRs restricting the supply of prescription only medicines. The relevant provisions restrict both who can prescribe or administer prescription only medicines and the locations where they can be supplied. However, there is a range of exceptions – in Part 12 of the HMRs and the related Schedules – which include the ability to supply under PGDs.

7. Policy background

What is being done and why?

7.1 The primary purposes of the policy reflected in this instrument are that it seeks to support the successful roll-out of a safe and effective COVID-19 vaccine, ultimately to reduce mortality. As is noted in paragraph 3.2 above, the mass vaccination programme using COVID-19 mRNA vaccine BNT162b2 has brought to light or highlighted the need for five changes to the HMRs which, it is considered, could not be dealt with for any reasonable length of time by enforcement policies, pending later changes to the HMRs. After the end of 2020, changes to the HMRs cannot be made until new powers being included in the Medicines and Medical Devices Bill currently before Parliament come into force.

First change

7.2 One of the challenges of deploying COVID-19 mRNA vaccine BNT162b2 is that it is relatively complicated to prepare the vaccine for final administration. A vial containing the vaccine is first diluted and then five doses for individual patients are drawn up from that vial. Different health care professionals, working in teams, may undertake the final preparation of the vaccine and the administration of it.

7.3 The HMRs do not provide clarity on whether or not this type of final dilution and drawing up is a regulated activity. However, if it is a regulated activity, and the final supply is by a doctor or nurse, it is also not clear from the relevant exemption in the HMRs (regulation 3) whether the final preparation or, in this context, "assembly" needs to be done by the doctor or nurse or whether they could take responsibility for someone else doing it, for example a pharmacy technician. Also, regulation 3 presupposes that this assembly will be done by a doctor or nurse for someone who is their own patient, which may not be the case in a mass vaccination programme. Pharmacists, on the other hand, are entitled to supervise others undertaking this assembly, and need not do it just for their own patients, but the assembly they undertake must take place at a registered pharmacy, a hospital, a health centre or in Scotland a care home service (section 10(1) of the Medicines Act 1968 (c. 67), which is incorporated by regulation 4 of the HMRs). This would preclude a pharmacist from being responsible, for example, for assembling the vaccine, or supervising someone else from doing it, in a care home in England.

7.4 To ensure that there is robust legal cover for nurses, doctors and pharmacists preparing or assembling COVID-19 vaccines or supervising others doing it – at any

location and regardless of whether or not the patients were their own patients – DHSC has created a bespoke provision that does not include the normal restrictions in regulations 3 and 4 of the HMRs, but does require these healthcare professionals to be acting under NHS arrangements or arrangements as part of the medical services of Her Majesty's Forces. The new regulation 3A(1) of the HMRs accordingly prevents artificial legal barriers determining the make-up of COVID-19 vaccination teams and how they operate, rather than professional standards and competencies.

Second change

7.5 As noted in paragraph 6.2 above, these exemptions in regulations 3 and 4 function in law as exemptions from the requirements to hold marketing authorisations and manufacturers licences – and an additional change is required in relation to what is known as the "packing down" of the diluent that is mixed with the COVID-19 mRNA vaccine BNT162b2. This vaccine comes in trays of 195 vials of five doses, and the trays sometimes need "packing down" into smaller quantities of vials when teams of health care professionals are administering the vaccines at locations that could not use up that amount of vaccine within its shelf life, e.g. care homes. The diluent that needs to travel with the vials may also need packing down, but ordinarily that would create a "new" medicinal product, and so would normally trigger separate authorisation or compliance with the strict rules of supply of "specials" in regulation 167 of the HMRs. Regulation 3A(2) allows this type of packing down of products such as diluents needed for the administration of COVID-19 vaccines without triggering either of these legal outcomes.

Third change

7.6 COVID-19 mRNA vaccine BNT162b2 has to be kept at ultra low temperatures and, when it leaves an ultra low temperature environment, the trays of vials need to be labelled with the time the product started thawing, because the vaccines must be used within a specified window period after that. This instrument allows wholesale dealers without manufacturers' licences to label the trays with the revised shelf life of the product.This is a procedure that would normally precipitate the need for a manufacturer's licence if it wasn't conducted at the very end of the medicines supply chain. In relation to this change and the other two changes in the new regulation 3A of the 2012 Regulations, a consequential change is also made in relation to the labelling provisions of the 2012 Regulations. This is to take account of the changes to the presentation of the products that will result from the permitted processing.

Fourth change

7.7 In the early phase of the mass vaccination campaign against COVID-19, it is likely that most of the vaccinating will be done in hospitals, at sites attached to hospitals or by teams based at hospitals but going out, for example, into care homes. Where administration of the vaccines is not done by "appropriate practitioners" (i.e. health care professionals with prescribing rights), hospitals are accustomed to developing PGDs for other health care professionals to administer the vaccines. Some of the powers in Part 12 of the HMRs to issue PGDs already permit the issuing of PGDs in respect of parenteral products (for example, the powers of independent hospitals to issue PGDs in regulation 231 of the HMRs), but the powers relied on by NHS hospitals to issue PGDs (regulation 229 of the HMRs) do not.

7.8 It has become apparent that the limitation in regulation 229 that precludes the issuing of PGDs in relation to parenteral products has not been understood by at least some of the NHS bodies empowered to issue PGDs under that regulation. It is also unclear why this limitation exists – certainly in relation to NHS hospitals, given the powers given to independent hospitals. Furthermore, it appears that the limitation did not exist in the provisions from which regulation 229 was derived. DHSC has temporarily reverted to the position that existed prior to the coming into force of the HMRs, in order to support the COVID-19 vaccination campaign but also potentially to the broader benefit to the NHS, with a view to consulting on potentially making the change permanent in 2021.

7.9 An additional amendment is made to ensure that this change cannot be construed as adding to the prescribing rights of appropriate practitioners who could not otherwise prescribe medicinal products for parenteral administration. This is relevant to optometrist independent prescribers, whose prescribing rights do not cover products for parenteral administration by virtue of regulation 214(5)(b) of the HMRs.

Fifth change

7.10 Retail pharmacy businesses are already accustomed to using PGDs and to supporting national vaccination campaigns – they are involved in the annual seasonal influenza immunisation campaign, which they participate in on the basis of a national PGD under regulation 233 of the HMRs. However, regulation 233, unlike some powers to issue PGDs (for example regulation 229) does not provide an exemption from the general requirement that prescription only medicines must be sold or supplied on premises that are a registered pharmacy. Pharmacy led vaccination services in respect of both COVID-19 and influenza may need to be undertaken elsewhere, for example in care homes or community halls, so this restriction has been temporarily removed for these types of vaccination.

Correction of errors

7.11 The C&I Regulations made wide ranging provision in relation to the powers of the licensing authority under the 2012 Regulations to temporarily authorise the supply of a medicinal product that does not have a marketing authorisation – and use has been made of these powers with the temporary authorisation of the supply of COVID-19 mRNA vaccine BNT162b2. Some of the changes made by the C&I Regulations made adaptations to the provisions of the 2012 Regulations relating to the use of PGDs and to the advertising of medicinal products in order to accommodate temporary authorisations of supply. Without those changes PGDs could not be used for such products and they could not be appropriately advertised. Very regrettably, the EU Exit Regulations did not take these changes into account. This instrument therefore makes a number of consequential amendments to preserve the effect of the changes made by the C&I Regulations in relation to PGDs and medicines advertising that were not reflected in the changes made by the EU Exit Regulations.

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

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 The instrument does not consolidate any legislation. There are no plans to consolidate the HMRs.

10. Consultation outcome

10.1 DHSC has not had an opportunity to consult on the provisions given the urgency of needing to avoid potentially hampering the vaccination campaign against COVID-19. It has, however, alerted the Chief Pharmaceutical Officers of England, Scotland, Northern Ireland and Wales to the proposals and they are supportive of them.

10.2 The lack of an opportunity to consult, and the speed with which the provisions have been brought into force are fundamental to the decision to time limit these proposals, apart from the correction of the errors made by the EU Exit Regulations, until 1st April 2022. This date was selected as it is the expiry date for some of the vaccine related provisions included in the HMRs by the C&I Regulations. Accordingly, a suite of vaccine related provisions can be reviewed together with a view to either making them permanent or allowing them to expire.

11. Guidance

11.1 The Medicines and Healthcare products Regulatory Agency, an Agency of the DHSC, has been supporting the NHS in each of the four countries with guidance on the interpretation of the HMRs in relation to deployment of COVID-19 vaccines, and will continue to do so.

12. Impact

12.1 The impact on business, charities or voluntary bodies can be considered significant.

12.2 This instrument will make it easier for non-NHS bodies to support deployment of the COVID-19 vaccines – in particular, the removal of the restriction on pharmacists only being able to supervise "assembly" at registered pharmacies and other specified premises, and retail pharmacy businesses only being allowed to administer vaccines under PGDs at registered premises. It will allow retail pharmacy businesses potentially to provide COVID-19 and influenza vaccination services at other locations, for example in other parts of retail premises that are not part of a registered pharmacy in those premises, in community halls and in care homes. It will also enable non-NHS manufacturing licence holders to assist the NHS in packing down diluents to support smaller scale vaccination operations.

12.3 There will also be an impact on the public sector, as this instrument will facilitate the NHS's mass vaccination programmes in each of the four countries.

12.4 In most cases, there are no specific additional costs under the Business as Usual scenario, although any hampering of the national vaccination programme could mean anticipated benefits to health, society and economy would not be realised. These benefits include, notably,– fewer deaths related to COVID-19.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses. However, the changes are essentially enabling, and it would not be appropriate to exclude small

and micro businesses from facilitating the fightback against COVID-19, which DHSC believes they want to support.

14. Monitoring & review

14.1 All the changes, apart from those correcting the errors made by the EU Exit Regulations, are time limited and will expire on 1st April 2022. They will accordingly be subject to review in 2021 with a view to making them permanent in their current or an amended form, or allowing them to expire.

15. Contact

15.1 Katie Driver at the Department of Health and Social Care Telephone: 02072105687 or email: katie.driver@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jeannette Howe, Deputy Director for Pharmacy, 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 Lord Bethell at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.