

EXPLANATORY MEMORANDUM TO
THE HUMAN MEDICINES (CORONAVIRUS AND INFLUENZA) (AMENDMENT)
REGULATIONS 2020

2020 No. 1125

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (“the Department”) 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 The instrument amends the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended) (“the HMRs”) to strengthen existing regulations that allow for the temporary authorisation of the supply of unlicensed medicines, including vaccines, in response to certain public health threats.
- 2.2 The instrument allows for the expansion of workforce able to administer COVID-19 and influenza vaccines.
- 2.3 The instrument extends the partial immunity from civil liability already given to registered healthcare professionals and manufacturers of temporarily authorised products to pharmaceutical companies placing such products on the market and people who are not registered health care professionals but who are administering immunisations under new protocols that are part of the workforce expansion proposals.
- 2.4 The instrument ensures that the treatments used in response to certain specific types of public health threat, such as COVID-19, can where appropriate be promoted by limited forms of advertisements.
- 2.5 The instrument also provides an exemption from the need for wholesale dealer’s licence to allow for a swift and safe transfer of COVID-19 and flu vaccines, and other medicines for treatment of pandemic disease, in response to patient need, by NHS providers and providers of armed forces medical services at the end of the medicines supply chain.

3. Matters of special interest to Parliament

- 3.1 The Department regrets that unfortunately some of 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”).
- 3.2 At date time of signing, there is no immediate prospect, within the 21 day period, of the deployment of a medicine temporarily authorised under the revised powers to do so (i.e. under regulation 174 and the new regulation 174A of the HMRs). However, it is possible that regulatory decisions may need to be taken, within the 21-day period, in anticipation of such deployment. Also, the provisions that allow for additional

vaccinators to administer COVID-19 and flu vaccines as part of NHS and local authority occupational health services may need to be relied upon within the 21 day period – in order to administer flu vaccines – because of the considerable expansion of the annual flu vaccination programme as part of the pandemic response. Similarly, the new flexibility around NHS and armed forces providers at the end of the supply chain being able to move some medicinal products between each other without a wholesale dealer’s licence may be needed within the 21 day period as part of the annual flu vaccination programme.

- 3.3 Viewed as a package, the measures that are being brought into force in breach of the 21-day rule are essentially permissive and enabling. To the extent that they support the annual flu vaccination programme, delaying their implementation could increase the incidence of seasonal influenza in the UK, as well as hampering an important aspect of the COVID-19 fightback.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is for 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 the 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 (“the Directive”).
- 6.2 The general presumption on which that regime is predicated is that products placed in the market in the United Kingdom will be covered by a product licence known as a “marketing authorisation”. However, the Directive does provide for exceptions to this principle – including, in Article 5(2) of the Directive, arrangements for the temporary authorisation of the sale or supply of unlicensed medicines in response to certain public health threats. Where the supply of products is temporarily authorised as mentioned in Article 5(2), some of those in the supply chain are to be given partial immunity from civil liability (Article 5(3) and (4)). The implementation to date of Article 5(2) to (4) of the Directive has been set out in regulations 174 and 345 of the HMRs.
- 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 includes the ability to supply under patient group directions, or pandemic treatment protocols, and arrangements for the supply of prescription only medicines as part of an occupational health scheme.

7. Policy background

What is being done and why?

Why are measures needed?

- 7.1 The primary purposes of the policy reflected in this instrument are that it seeks to support the expansion of the annual seasonal flu vaccination campaign, happening now, and in due course to support the successful roll-out of a safe and effective COVID-19 vaccine, to bolster the related safeguards, and to ultimately reduce mortality.
- 7.2 Until the end of the transition period, the licensing of some medicinal products in the UK, including a potential COVID-19 vaccine, still needs to be undertaken by the European Medicines Agency (“EMA”). Pending the grant of an EMA licence for a COVID-19 vaccine, each Member State of the EU, and separately now the United Kingdom, has the option of temporarily authorising an unlicensed vaccine’s sale or supply in their territory (as provided for in Article 5(2) of the Directive), if they consider this to be justified on public health grounds. The preferred route to enable deployment of any vaccine, including new vaccines for COVID-19, remains through the usual marketing authorisation (product licensing) processes. The independent Commission on Human Medicines (CHM) will advise the UK government on the safety, quality and efficacy of such vaccines. No vaccine will be deployed unless the stringent standards have been met through a comprehensive clinical trial programme.
- 7.3 The option of temporarily authorising an unlicensed vaccine has led the Department to consider its implementation of Article 5(2) to (4) of the Directive to see if it is fit for purpose. Two important sets of changes to the HMRs are being made in the light of that consideration.
- 7.4 Firstly, this instrument makes clear the licensing authority’s power to impose conditions in relation to the temporary authorisation. This will provide certainty for both the licensing authority and those in the supply chain about the nature of the licensing authority’s power in this area. Imposing conditions is central to having an effective system of regulatory control, and that is in the interests of everyone in the supply chain. Provision is also made to deal with the consequences of breach of those conditions.
- 7.5 Secondly, the instrument also clarifies the scope of the partial immunity from civil liability which regulation 345 of the HMRs (based on Article 5(3) and (4) of the Directive) gives to some of those in the supply chain in relation to products whose unlicensed use is recommended by the licensing authority in response to certain specific types of public health threat. Up until now, manufacturers of a recommended product have been given that partial immunity, but not pharmaceutical companies placing a product on the market who outsource manufacture of their products. The Department considers this to be anomalous, and that the partial immunity should fairly and properly extend to both pharmaceutical companies that do their own manufacturing, and those that don’t. Similarly, partial immunity is already given to registered health care professionals who treat patients with temporarily authorised products, and the Department considers that this should fairly and properly be extended to people who are not registered health care professionals but who may be asked to administer COVID-19 or influenza vaccines under the new immunisation protocols that are also created by this instrument.

- 7.6 The Instrument also makes three key changes to ensure that the UK has the available workforce to administer the COVID-19 and influenza vaccines:
- i. Expanding the scope of patient group directions to allow for them to be issued for the administration of any medicine, including COVID-19 vaccines and flu vaccines, the supply of which has been temporarily authorised under regulation 174;
 - ii. Introducing a new type of national immunisation protocol (regulation 247A), to be authorised by UK ministers and the Devolved Administrations, which will allow those who are registered healthcare professionals who do not normally vaccinate, and people who are not registered health care professionals, to safely administer a licensed or temporarily authorised COVID-19 or influenza vaccine;
 - iii. Expand the workforce legally allowed to administer vaccines under National Health Service (NHS) and local authority occupational health schemes, so that additional health care professionals in the occupational health workforce will be able to administer these particular vaccines.
- 7.7 The instrument ensures that unlicensed vaccines temporarily authorised under regulation 174 are treated, for the purposes of advertising to the public, in the same way as licensed products, and that treatments used in response to certain specific types of public health threat, such as influenza and COVID-19 treatments, can be promoted by advertisements, healthcare professionals and to the public, subject to Ministerial approval. This approval provision is based on an equivalent provision that already exists for vaccination campaigns. Government and NHS information campaigns, such as those for the national flu immunisation programme, are not considered to be “advertisements” for the purpose of the HMRs, so the easements largely relate to advertising material put out by suppliers as part of such campaigns.
- 7.8 The instrument also provides an exemption from the need for a wholesale dealer’s licence to allow for the swift and safe transfer of COVID-19 and flu vaccines, and other medicines for treatment of pandemic disease, in response to patient need. This exception is available for NHS organisations, NHS contracted service providers, and the medical services of the armed forces only – and it only applies to providers of services at the end of the supply chain (e.g. community pharmacies and GP practices) who find that they are unable to supply or administer all the vaccines etc. that they have sourced.
- 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 The government hosted a public and targeted consultation on the changes to HMRs to support the rollout of COVID-19 and Influenza vaccines from 28 August to 18 September.

- 10.2 The consultation received 188,036 consultation responses, from a range of stakeholders including individual members of the public, NHS and health service delivery bodies, organisations representing health care professionals, pharmaceutical companies and patient groups.
- 10.3 As part of the consultation process, the Department, in collaboration with the Medicines and Healthcare products Regulatory Agency (“MHRA”), held a number of meetings with health and social care professional bodies and pharmaceutical industry representatives.
- 10.4 Following considerations on the feedback received, the Department is making three key changes to the proposals set out in the original consultation document. These changes will:
- i. Ensure robust scrutiny of the impact of regulation 174A takes place by making it a requirement that regulation 174A, which allows the licensing authority to attach conditions to a temporary authorisation for the supply of an unlicensed medicinal product for use in response to certain specific types of public health threat, and provides for the consequences of the breach of those conditions, will be formally reviewed a year after first use.
 - ii. Promote objectivity by changing the test for when the partial immunity from civil liability is lost, if the conditions for the temporary authorisation are breached. Immunity is only lost if the breach is “sufficiently serious”, and the “objective bystander” who notionally determines this has been changed from a reasonable person with an interest in placing medicinal products on the market (and so a reasonable pharmaceutical company) to a reasonable person “...with relevant expertise in the subject matter of the breach...”.
 - iii. Create an additional level of assurance in relation to the expanded workforce by making it clear that the new national protocol should include, where appropriate, the requirements for the supervision of an additional vaccinator.
- 10.5 The consultation and the summary of responses can be found at the following link: <https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments-for-covid-19-and-flu/outcome/government-response-consultation-on-changes-to-the-human-medicines-regulations-to-support-the-rollout-of-covid-19-vaccines>

11. Guidance

- 11.1 It is anticipated that resources, including guidance, will be made available to support the roll-out and distribution of COVID-19 vaccines and treatments, and influenza vaccine, by the NHS in each country, as appropriate. It is anticipated that those resources will also deal with matters such as who are able to administer vaccines and training requirements.

12. Impact

- 12.1 The impact on business, charities or voluntary bodies can be considered significant.
- 12.2 The instrument clarifies the scope of immunity from civil liability to apply to companies that placing an unlicensed medicine, such as a vaccine, on the market without the approval of the licensing authority.
- 12.3 There will also be an impact on the public sector as the instrument will facilitate the expansion of the workforce legally allowed to administer vaccines under NHS and

local authority occupational health schemes. Additional healthcare professionals in the occupational health workforce will therefore be able to administer vaccines.

- 12.4 In most cases, there are no additional costs under the Business as Usual scenario. There are likely to be costs associated with training existing vaccinators to administer a new COVID-19 vaccine, as well as in terms of the scale and pace at which we may aim to administer vaccines; however it is difficult to be certain about the costs of training for an as yet unknown vaccine.
- 12.5 Under a Business as Usual scenario, it could take longer to bring a product to market and deploy it within the population; as such, benefits to health, society and economy would not be realised – for example, fewer deaths related to COVID-19.
- 12.6 The main monetised costs relate to training the expanded workforce; we estimate this would cost an additional £7.9-9.3m from delivering the training and £36.2-£42.3m in training the new vaccinators, compared to the BAU scenario.
- 12.7 There is also likely to be costs of administering any vaccine, estimated by NHSEI at £1,765.1m; in the absence of evidence, we assume this is a similar cost under the BAU scenario because the same number of vaccines would need to be administered, and therefore not an additional cost.
- 12.8 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the [legislation.gov.uk](https://www.legislation.gov.uk) website.

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 the Department believes they will want to support as well as tackling seasonal influenza.

14. Monitoring & review

- 14.1 The effect of the legislation will be monitored alongside consideration of the regular scientific advice on the safety and efficacy of any successful COVID-19 vaccine, and the Department will work closely with the MHRA on these issues.

15. Contact

- 15.1 Navneet Bal at the Department of Health and Social Care Telephone: 02079723022 or email: Navneet.bal@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Julie Alexander, Deputy Director for the COVID-19 Vaccines Team, at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.
- 15.3 Jo Churchill, Parliamentary Under Secretary of State for Prevention, Public Health and Primary Care at the Department for Health and Social Care can confirm that this explanatory memorandum meets the required standard.