Title: Decision to change temporary provisions in the Human Medicines Regulations 2012 to support COVID-19 and influenza vaccination campaigns by making some or all permanent and/or adding a time limited extension. **IA No: 9684** **RPC Reference No:** N/A **Lead department or agency:** Department of Health & Social Care **Other departments or agencies:** MHRA and NHSEI	Impact Assessment (IA) **Date:** 04/01/2022 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Thomas.Rowland@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£0m	£m N/A	£m N/A	Qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

Vaccines have been proven to be a crucial line of defence against the ongoing COVID-19 pandemic and for the prevention of seasonal influenza In the case of COVID-19, vaccines have helped to minimise the harmful impacts of the disease on the nation's health and economy. As part of its response to the COVID-19 pandemic, the Government needed to ensure that the regulatory framework could support vaccines being brought to the market and deployed as quickly as possible to ensure the direct impacts of COVID-19 on mortality and morbidity, as well as indirect impacts on health, society and the economy were minimised as far as possible. In October and December 2020, the Human Medicines Regulations 2012 (HMRs) were amended (amongst other things) to facilitate the continued deployment of safe and effective COVID-19 (including any future booster doses) and influenza vaccines at the pace and scale required both now and, in the future, whilst maintaining public safety. Certain amendments have an end date of 1 April 2022. We assess the impact of new UK-wide regulatory changes designed to achieve similar benefits for the longer term. **We do not put a figure on the costs and benefits due to the intrinsic uncertainty of future COVID-19 and influenza outbreaks, but we include a single illustrative scenario based on evaluating the impact of the temporary regulatory changes to date. We discuss the costs and benefits of making the amendments under consultation for future emergency circumstances: permanent; temporarily extending them to 1st April 2024; or allowing them to lapse.**

What are the policy objectives of the action or intervention and the intended effects?

The policy objective is to maintain flexibility in the NHS to deploy COVID-19 and influenza vaccines at pace, should that need to continue beyond March 2022. The HMRs were amended in 2020 to add flexibility to some of the governance around vaccine supply to patients as part of the response to the COVID-19 pandemic. Due to the considerable expansion of the annual influenza vaccination programme as part of the COVID-19 pandemic response, the amendments in question applied to the influenza vaccine as well. The overarching policy objective is to facilitate the continued safe and effective deployment of COVID-19 and influenza vaccines. The legislation governing the regulation of medicines may benefit from other changes to support other mass vaccination campaigns that arise from future pandemics other than COVID-19 or influenza, but this assessment focuses on its primary purpose of supporting delivery of COVID-19 and influenza vaccines.

In the interests of pandemic preparedness, the consultation also sought views on whether these provisions should be extended so that they may apply to any future pandemic.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

This IA considers making amendments to HMRs, in order to facilitate mass vaccination campaigns for COVID-19 and influenza specifically, beyond March 2022. Currently the HMR provisions being considered will cease to have legal effect on 1 April 2022. Recommendations will be made to make three permanent, and temporarily extend two.

To be made permanent:

a) Retain the provisions that expand the workforce for NHS bodies or local authorities operating an occupational health scheme who can administer COVID-19 and influenza vaccinations
b) Retain the provision to enable parenteral administration of medicines under a Patient Group Direction (PGD)
c) Retain the provision which enables providers of community pharmacies who are providing vaccinations for COVID-19 or influenza under a PGD to provide that service away from their normal registered premises.

To be temporarily extended to 31 March 2024:

d) The provision to enable providers of NHS services and medical services to HM Forces to distribute medicinal products used for vaccination or immunisation against COVID -19or influenza between vaccination centres without the need for a wholesale dealer licence.
e) The provision to enable the final preparation of COVID-19 vaccination without the need for manufacturers' licences and marketing authorisations (i.e. relaxation of rules around packaging and labelling)

Option 0- Do not retain the temporary amendments to HMRs and allow them to lapse in 2022.
Option 1 – Retain the amendments to HMRs (some permanent and some temporarily extended, as outlined above) so the provisions support any further mass vaccination with COVID-19 and influenza vaccines, either by making permanent or extending for a further time limited period.

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro**No	**Small** No	**Medium** No	**Large**No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	
Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A				

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister
Parliamentary Under Secretary of State Lord Syed Kamall Date: 4 February 2022

Summary: Analysis & Evidence

Policy Option 0

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2020	PV Base Year 2021	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

No anticipated additional costs

Other key non-monetised costs by 'main affected groups'

No anticipated additional costs

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

No anticipated additional benefits under option 0 (business as usual).

Other key non-monetised benefits by 'main affected groups'

No anticipated additional benefits under option 0 (business as usual).

Key assumptions/sensitivities/risks	Discount rate (%)
A large-scale vaccination rollout without the amendments in place would take additional time relative to a vaccination programme with the amendments in place.	

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** No estimate available

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				**No estimate available**

Description and scale of key monetised costs by 'main affected groups'

No quantified estimates available due to intrinsic uncertainty in the future events that would make use of these amendments.

Other key non-monetised costs by 'main affected groups'

We include an illustrative scenario in which we assume additional costs from training the workforce based upon previous figures for training costs and the potential for this to be required again. Note the costs for a future vaccinator workforce are highly uncertain due to unknowns around the scale of a future vaccine rollout, i.e. whether the current workforce will be an adequate number to support future rollout decisions. We assume no additional vaccine administration costs, as the same number of vaccines are expected to be ultimately delivered with or without the amendments, albeit with a slower roll-out.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	
High	Optional		Optional	
Best Estimate				**No estimate available**

Description and scale of key monetised benefits by 'main affected groups'

No quantified estimates available due to intrinsic uncertainty in the future events that would make use of these amendments.

Other key non-monetised benefits by 'main affected groups'

We include an illustrative scenario in which the primary benefits would be health benefits from a faster vaccine roll-out . This estimates the amendments resulted in the faster total rollout of the first phase of vaccinations of 2-10 days. We estimate this averted 700-3,000 deaths and 2,000-10,000 hospitalisations, amounting to 5,000-13,000 saved mortality QALYs and 200-1,000 saved morbidity QALYs. This has an equivalent societal value of £300m-£900m. There are also indirect benefits to the health and social care system, wider society, and the economy from faster vaccine deployment. This is due to bringing the UK closer to pre-pandemic life in a shorter time span. Estimates from the OBR suggest the UK GDP fell by 9.9% in 2020[1], suggesting there are great benefits from avoiding the economic slump seen in the first wave of the pandemic.

Key assumptions/sensitivities/risks	**Discount rate (%)**	1.5%

The illustrative scenario is based on the average number of infections, hospitalisations and deaths per day. Estimates are made for a wave without vaccination, between 01/09/2020 and 19/03/2021, and with vaccination between 20/03/2021 and 31/08/2021. The number of days saved in the vaccination rollout by having the regulatory options available is assumed to be between 2 and 10 days.

[1] https://obr.uk/overview-of-the-march-2021-economic-and-fiscal-outlook/

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Evidence Base

Problem under consideration and rationale for intervention

1. The COVID-19 pandemic to date has had substantial direct and indirect health impacts on the entire UK population, including over 17.5 million confirmed cases and more than 157,409 deaths within 28 days of a positive COVID-19 test reported on 2 February 2022[1]. The economic impacts have been vast globally and domestically, with large increases to the unemployment rate, and Government borrowing in the UK continuing to rise to the highest cash deficit on record[2]. While non-pharmaceutical interventions (NPIs) reduce exposure and spread to COVID-19, effective and timely vaccines have been shown to be an integral part of addressing the pandemic.
2. Any vaccine must first go through the usual rigorous testing and development process and be shown to meet the expected high standards of safety, quality, and efficacy before it can be deployed. The independent Joint Committee on Vaccination and Immunisation (JCVI) then advise the UK government on which COVID-19 vaccine/s the UK should use, and on the priority groups to receive the vaccine based on the best available clinical, modelling, and epidemiological data.
3. There are currently four COVID-19 vaccines that have been authorised for use in the UK: Pfizer-BioNTech (Comirnaty), Oxford/AstraZeneca, Moderna (Spikevax) and Janssen. Pfizer-BioNTech (Comirnaty) was the first vaccine authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) in December 2020. Following this, the JCVI advised the Government to vaccinate nine key groups in priority order, ultimately covering all adults aged 50 years and over, frontline health and care workers and younger adults, including those with underlying health conditions putting them at specific risk from COVID-19. The AstraZeneca vaccine was authorised by the MHRA on the 30th December 2020, with roll out as advised by the JCVI to phase 1 priority groups from the 4th January. All of the 12+ population have now been offered 2 doses of a COVID-19 vaccine, and all 18+ have been offered a third booster dose. Severely immunosuppressed individuals have also been offered a fourth dose.
4. The Human Medicines Regulations 2012 (HMRs) were amended in October and December 2020 to add flexibility to the regulatory scheme to facilitate rapid COVID-19 and influenza vaccine deployment, supporting the successful delivery of the vaccine programme to date. As of 27 December 2021, 89.9% of the UK 12+ population has had a first dose, 82.2% have had a second dose, and 56.9% have had a booster or a third dose[31] above. The 2020 changes were to facilitate the mass vaccination campaigns for COVID-19 and influenza once vaccines became available. Some of these provisions will cease to have effect on 1 April 2022, therefore it must be decided whether they should be made permanent, extended for a further limited period, or allowed to lapse.
5. The provisions under consideration are:

   To be made permanent:
   a) Retain the provisions that expand the workforce for NHS bodies or local authorities operating an occupational health scheme who can administer COVID-19 and influenza vaccinations
   b) Retain the provision to enable parenteral administration of COVID-19 and influenza vaccinations under a Patient Group Direction (PGD)

[1] UK Summary | Coronavirus (COVID-19) in the UK (data.gov.uk)
[2] https://obr.uk/coronavirus-analysis/
[3] Severely immunosuppressed individuals were recommended a third primary dose of a COVID-19 vaccine.

c) Retain the provision which enables providers of community pharmacies who are providing vaccinations for COVID-19 or influenza under a PGD to provide that service away from their normal registered premises

To be temporarily extended to 31 March 2024:

d) The provision to enable providers of NHS services and medical services to HM Forces to distribute medicinal products to be used for vaccination or immunisation against COVID-19 or influenza between vaccination centres without the need for a wholesale dealer licence
e) The provision to enable the final preparation of COVID-19 vaccination without the need for manufacturers' licences and marketing authorisations (i.e. relaxation of rules around packaging and labelling)

6. These changes were given an end date of 1 April 2022, because they were considered exceptions to the business as usual model, which under normal circumstances, we would not want to retain, or because due to being new would require a review of practical implications and safeguards following implementation. These are UK wide provisions.
7. The COVID-19 pandemic led to an increase in eligibility and overall demand for influenza vaccinations in a time where there was already significant work delivering COVID-19 vaccinations. It is anticipated that increased demand for influenza vaccination could continue beyond winter 2021-2022 and with the possibility of competing priorities of the COVID-19 vaccinations, there is a need to ensure the workforce that can administer vaccines, is of sufficient size, and has the flexibility allowed by the provisions.
8. With the amendments in place, it would be possible to use the increase in vaccinator workforce to address possible future influenza pandemics as well as future COVID-19 outbreaks.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

9. This IA aims to demonstrate the potential costs, benefits and risks associated with maintaining the HMR amendments that add operational flexibility to the NHS, in order to enable a COVID-19 or influenza vaccine to be deployed (should need arise), safely, at pace and at scale, for now and in the future.
10. There is vast epidemiological uncertainty associated with the future of the COVID-19 pandemic. Factors including social mixing patterns, and the duration of vaccine protection (waning immunity) form uncertainties on the future trajectory of the pandemic.
11. This means we are unable to provide analysis on the future costs and benefits of the evolving pandemic. We therefore take a retrospective look at the costs and benefits associated with the initial wave of the COVID-19 pandemic, and estimate the benefits generated from faster vaccine deployment. We compare scenarios before and after COVID-19 vaccines were available, and estimate the health impacts that would have incurred, should deployment have slowed down in the absence of the HMR amendments made in October and December 2020.
12. It is not possible to distinguish between each individual provision's contribution to the speed of deployment, therefore we assume that they collectively have an impact on the speed of deployment. We provide a qualitative discussion on the likely impact of each amendment.
13. It is important to note that the costs and benefits of vaccines themselves are not included, rather the costs and benefits of legislative change are what is demonstrated here.

14. It is uncertain about how the amendments will continue to be used in future vaccine rollouts, but the indicative scenario shows a clear net benefit with the ratio of costs to benefits. If there is a need for future rounds of COVID-19 vaccines, the workforce costs would be those in the illustrative scenario, scaled linearly by the number of doses needed.; However, the benefits will depend on many factors and could be very different from the illustrative scenario. If there are no future requirements for these amendments, no additional workforce will need to be trained and we will not see the benefits of a faster emergency vaccination programme, as there would not be one.

15. **The analysis in the IA should therefore be seen as an illustrative scenario, based upon a retrospective analysis of what occurred previously within the COVID-19 pandemic.**

16. The characteristics of a future influenza pandemic are also highly uncertain. The illustrative example of the COVID-19 pandemic could equally be applied to a future influenza pandemic scenario given that the illustrative scenario is also a plausible pandemic influenza scenario in terms of the potential for vaccines to reduce harm.

Description of options considered

17. Several issues were identified that were deemed to inhibit the policy aim of enabling the deployment of a safe and effective COVID-19 vaccine at pace and scale. These were:

    - Workforce: With the existing workforce at the outset of the pandemic, a COVID-19 vaccine programme would have been undeliverable at pace on a population wide scale, therefore severely hampering the Government's response to COVID-19. In particular, healthcare workers (who are prioritised for the COVID-19 vaccine under JCVI guidance), are usually immunised via Occupational Health (OH) schemes; if the workforce that administered vaccines under an OH scheme was not expanded, there would have been delays in vaccinating healthcare workers.
    - Promotion: At present there is a prohibition on promoting via an advertisement an unlicensed medicine to healthcare professionals and the public. The UK Government is proposing that this prohibition is disapplied to allow advertising of any temporarily authorised products under regulation 174, including a COVID-19 vaccine. Without the provision, an unlicensed, but temporarily authorised, vaccine could not be promoted as part of normal business advertising arrangements within the four nations; this could have implications for the take-up of the vaccine which is essential for life to return to normal as much as possible.3
    - Wholesale dealing: Prior to amendments, if a COVID-19 vaccine was available there would be delays in moving around a vaccine between premises at the very end of the supply chain as it is the case that the providers in question (such as GP practices and community pharmacies) did not have wholesaler dealer licences. The solution would have been to return any excess vaccines in one organisation to the wholesale supplier who would then dispatch them to the organization with too few vaccines. This would have been time consuming and inefficient, leading to delays in getting the vaccine to the public.

18. As a result, the Government consulted on amending the HMRs- some to be made permanent, and some on a temporary basis- to resolve these issues, set to lapse on 1 April 2022. The consultation closed on 29 December 2021, with 125 responses received. This will be discussed further below and is described in further detail in the separate Consultation Report document.

19. The decision to temporarily authorise a COVID-19 vaccine is separate to the amendments to the HMRs subject to the December 2021 consultation. The amendments related to conditions, immunity and promotion are not proposed to make it more likely that a temporarily authorised COVID-19 vaccine will be used; instead, they aim to

facilitate the rapid administration process if a temporarily authorised vaccine is to be used. While speedier deployment may encourage a faster decision-making process for eligible vaccines, the MHRA process for vaccine approval is maintained.

20. The MHRA, an Executive Agency of the Department of Health and Social Care, is the independent body that performs the functions of the UK's 'licensing authority' under the HMRs across the whole of the UK, acting on the authority of the Minister of Health in Northern Ireland and the Secretary of State for Health and Social Care. The MHRA undertakes a robust assessment of evidence relating to vaccine authorisation (including safety and vaccine efficacy), whether that is through the temporary authorisation of an unlicensed vaccine, or the normal licensing process.

21. The options considered are as follows:

22. Option 0 "Business as usual" – allow the amendments to lapse, reverting to business as usual governance for COVID-19 and influenza vaccine deployment.

23. Option 1- Make amendments to HMRs, to facilitate future mass vaccination campaigns of COVID-19 and influenza. Recommendations will be made to make some permanent, and some temporarily extended:

To be made permanent:

a) Retain the provisions that expand the workforce for NHS bodies or local authorities operating an occupational health scheme who can administer coronavirus and influenza vaccinations
b) Retain the provision to enable parenteral administration of medicines under a Patient Group Directive (PGD)
c) Retain the provision which enables providers of retail pharmacies who are providing vaccinations for COVID-19 or influenza under a PGD to provide that service away from their normal registered premises.

To be temporarily extended to 31 March 2024:

d) The provision to enable providers of NHS services and medical services to HM Forces to distribute medicinal products to be used for vaccination or immunisation against COVID-19 or influenza between vaccination centres without the need for a wholesale dealer licence.
e) The provision to enable the final preparation of COVID-19 vaccination without the need for manufacturers' licences and marketing authorisations (i.e. relaxation of rules around packaging and labelling)

Other policy options

24. Future pandemics may arise from illnesses other thanCOVID-19 or influenza but may still lead to a requirement for a mass vaccination campaign. It may therefore be beneficial to enable the provisions to be applicable in all pandemic scenarios. Views on this were sought in the consultation.

25. The consultation also sought views on the decision between temporary extension of the provisions to 1 April 2024 or making them permanent. Proposals were made for each provision. The split between what amendments are made permanent and what amendments are continued temporarily could happen in any permutation. This does not impact the illustrative scenario analysis in this IA as it explores an example where all the amendments were in place.

26. There is also the option of only including certain amendments and letting the others lapse. The illustrative example retrospectively analyses the amendments that were made in October and December 2020 as one collective set; and it has not been possible to

provide illustrative scenarios of any other combinations of the regulations being taken forward.

27. Following the analysis of consultation responses and considering the continuing need for mass vaccination, the Government will prioritise implementation of those provisions that will lapse on 1 April 2022, to enable health services to continue to plan and operate mass vaccinations. The next steps for these and the other proposals are as follows:

    a) Tranche 1, to be laid before Parliament in early 2022: those regulations that are currently due to lapse on 1 April 2022. This will give health services the certainty they need to be able to continue to plan and operate mass vaccination programmes on the same basis as now.

    b) Tranche 2, clinical supervision within vaccine centres: This received broad support and will be taken forward at the next legislative opportunity:

    c) Tranche 3, provisions relating to extending workforce flexibilities to Occupational Health Schemes in the private sector and adding professional groups to those who can already vaccinate under Occupational Health Schemes. Limited evidence was received through this consultation on these provisions. We will undertake further targeted evidence gathering before making a final decision.

    d) Tranche 4, extension of all of the arrangements to any future pandemic, not limited to COVID-19 or influenza: This will be considered further and subject to further public consultation, as indicated previously.

Temporary versus permanent

28. As outlined in detail above, for tranche 1 provisions, some are be extended permanently, while others will be extended for a further limited time period during which we will come to understand more about the UK's future vaccination requirements. This further evidence and detail will help inform another review of these particular provisions before 1 April 2024.

29. Over the summer of 2021 DHSC held initial conversations with external stakeholder organisations to determine their views on how the provisions have been used and the direction they would like to see them take from 1 April 2022. These discussions informed which provisions should be proposed as being made permanent and which should be proposed as temporary extensions.

30. The provisions that have been made permanent have been done so as they are considered low risk and likely to be beneficial under almost any circumstances. The provisions which have been extended on a temporary basis, may present slightly higher risk or are more relevant to current circumstances. At this point in time, we are of the view that for these two provisions the benefits substantially outweigh the risks, but this should be further reviewed in 2 years given the likelihood of different vaccines with different requirements becoming available in that time. Risks associated with both the permanent and temporary provisions are discussed in more detail in the risk section.

Policy objective

31. The overarching policy objective is to enable the continued deployment of safe and effective COVID-19 (including any necessary booster doses) and influenza vaccination at the pace and scale required now and in the future.

Overview of HMR Amendments

32. Here we detail the time limited amendments that were made in October and December 2020 for the purpose of the illustrative scenario. These may not necessarily map directly to the proposed amendments to be carried forward post-consultation.

Amendments 1) and 2) expanding the vaccination workforce

Summary and preferred option

33. The eligible workforce for vaccinations was expanded to ensure the UK has available workforce eligible to administer COVID-19 vaccines and influenza vaccines. Provisions for this expansion included enabling additional healthcare professional groups to vaccinate health and social care workers in occupational health services and the public under Patient Group Directions (PGD). This included a clarification that this also applied to injected medicines. This provision was set to lapse on 1 April 2020. We also introduced the national COVID_19?? and influenza vaccination and immunisation protocol, which enables a wider range of staff to administer COVID-19 and influenza vaccines after appropriate training and, where appropriate, under supervision. This provision was not sunset to lapse on 1 April 2022.
34. It is assumed that these amendments have made deployment faster since more vaccinators are eligible to administer vaccines, reducing the burden on the previous pool of vaccinators. This means a reduced impact on potential de-prioritisation of other healthcare services to allow time for vaccination.
35. An expanded workforce eligible to administer the influenza vaccine is still required, as demonstrated by the expanded influenza vaccination programme this winter. Thousands more received the influenza vaccine last year than received it the year before and we anticipate that this trend will continue beyond winter 2021/2022, so there is a need to ensure the workforce that can administer vaccines is of sufficient size. There is a possibility that both the COVID-19 and influenza vaccines will be delivered at the same time, and we need to make sure that in this scenario there is sufficient workforce to allow for this.
36. If the vaccine workforce amendment was to lapse, only specific 'appropriate practitioners' would be eligible to administer 'prescription only medicines' (including vaccines) under a PGD. Appropriate practitioners are defined in the HMRs as:
    - A doctor
    - A dentist
    - A supplementary prescriber
    - A nurse independent prescriber
    - A pharmacist independent prescriber
    - In special circumstances, a community practitioner nurse, optometrist independent prescriber, podiatrist independent prescriber, physiotherapist independent prescriber, therapeutic radiographer independent prescriber, paramedic independent prescriber is an appropriate practitioner and a European Economic Area health professional

37. Under these amendments, healthcare professionals who are able to administer a vaccine under a PGD[4] (signed by an appropriate practitioner – see above) include: chiropodists, podiatrists, dental hygienists and therapists, dieticians, midwives, nurses, occupational therapists, optometrists, orthotists and prosthetists, paramedics, pharmacists, physiotherapists, radiographers, and speech and language therapists. In NHS and local authority Occupational Health Schemes, the changes permanently add midwives, nursing associates (England only), operating department practitioners, paramedics, physiotherapists and pharmacists to the workforce which can administer COVID-19 and influenza vaccines and/or immunisation medicines.
38. Making the workforce provision permanent would ensure the workforce needed for mass vaccination programmes (COVID-19 and influenza) are available and prevent delays in vaccinating health and social care workers and the public. This will therefore support the policy objective.

Amendment 3) provisions for wholesale dealing and end stage preparation of vaccines

Summary and preferred option

39. In the business as usual scenario, should the provision lapse, the supply of vaccines from one healthcare organisation to another is subject to having a wholesale dealer licence. If there is a surplus in one organisation and a lack of vaccine in another, the first organisation would have to return the surplus to the wholesaler before the product could be redistributed to where there was demand. This could lead to problems and delays with moving vaccines between service providers and runs the risk that patients cannot access the vaccine.
40. By maintaining the provision, either through making it permanent or extending, the system would have the flexibility to move vaccines quickly and safely within the healthcare system between NHS providers (and between the suppliers of medical services to the armed forces), meeting patient needs and avoiding wastage. Medicines that treat COVID-19 and influenza also benefit from this provision.

Amendment 4) easing final preparation of coronavirus

Summary and preferred option

41. An amendment was made in order to relax some of the governance rules on the assembly, preparation and labelling of medicinal products and the need for manufacturers' licences and marketing authorisations to enable the necessary actions taken by pharmaceutical companies and healthcare professionals to specifically prepare coronavirus vaccines for administration to the public. These relaxations were under the proviso that the actions were done under NHS arrangements or arrangements as part of the medical services of Her Majesty's Forces.

42. By maintaining the provision, either through making it permanent or extending, NHS teams can continue to use the skills and expertise of their staff in appropriate areas much more effectively and for various professions to focus on their areas of speciality, enabling

[4] NHS England and NHS Improvement South West » Patient Group Directions (PGDs)

safer systems of working, particularly at larger sites. The ability to prepare vaccines for administration flexibly at a range of sites within a safe system has proven to be very useful.

Amendment 5) Supply of COVID-19 or influenza vaccines by a pharmacy

Summary and preferred option

43. Currently the temporary provision allows providers of community pharmacies who are providing a COVID-19 or influenza vaccination or immunisation service under a PGD to provide that service away from their normal registered premises
44. This flexibility was used on a regular basis by the majority of community pharmacy run COVID-19 vaccination sites, where the main site was located away from their normal registered premises. It also allowed many hundreds of community pharmacies to offer pop-up clinics, in particular supporting groups of patients where bookings were not able to be made on the health service booking system of the relevant country (for example, 16 and 17 year olds), where there were particular infection clusters or in locations where there were clusters of unvaccinated patients. Additionally, this flexibility allowed teams to vaccinate residents and carers in care homes.
45. This flexibility was also used in the 2020-21 seasonal influenza programme to support an increase in vaccinations from the previous year and is expected to be used more widely in 2021-22 season.

Monetised and non-monetised costs and benefits of option 1

Scope of costs and benefits considered

46. This IA presents an illustrative example of the costs and benefits associated with the HMR amendments present during this time period, using a retrospective analysis of the impact of the amendments on the COVID-19 vaccine rollout. It is not possible to estimate any future wave of COVID-19 with any certainty, given uncertainties on the rate of infection, disease severity, vaccine escape and the extent of non-pharmaceutical interventions implemented by government.
47. While the sunset HMRs amendments will also impact influenza roll out, there is a lack of evidence to suggest what these impacts would be.
48. Therefore, the initial COVID-19 vaccination rollout will be used as an example to illustrate the potential benefits of the amendments. To achieve this, the waves pre and post the first phase of the vaccination rollout are compared. There will be unique aspects of these waves that will not be reflected in any future waves of the pandemic or any future influenza pandemic. In particular, there was a high level of non-pharmaceutical interventions (NPIs) that were in place in the pre-vaccination wave, it is unclear the extent of impact this had on the health impacts estimated. For example, due to high levels of NPIs in this wave, this would have supressed the number of infections we see in a ‘no-vaccine’ scenario, relative to the ‘with vaccine’ scenario. However, for this illustrative example these assumptions of a degree of NPIs have been built into the no-vaccine scenario versus a with-vaccine scenario.
49. Comparing the ‘no vaccine’ scenario with the ‘with vaccine’ scenario gives an overall average impact of the vaccination programme per day. Subsequently, by assuming a number of days saved through the amendments on the time taken for the vaccination rollout, the benefits can be estimated.

50. We expect the only costs associated with amending the HMRs further to the December 2021 consultation are the costs associated with training future staff. We use the initial costs from the amendments made in 2020 for the illustrative scenario, but this does not necessarily reflect any future costs, as it is assumed that the workforce needed for the amendments has already been trained. Any further costs associated with future deployment will be made as a separate decision at that point in time.
51. This illustrative scenario considers the benefits from reduced infections, hospitalisations, and deaths as a result of speeding up vaccine deployment, and therefore focuses on direct health impacts. Wider economic and societal impacts are not built into costs and benefits, although it is expected that speedy deployment of future vaccines would have a substantial benefit.
52. Due to the level of uncertainty a central net present value cannot be estimated. This illustrative example estimates whether the benefits of the amendments outweighed the costs in the initial vaccine rollout. These provide an illustrative example of the overall positive impact that the regulatory benefits have for future outbreaks of COVID-19 and influenza and subsequent vaccine rollout.

Assessment period

53. The benefits are based on a hypothetical scenario of another wave of COVID-19 on an unvaccinated population. The calculations are done in the same manner as if answering the question “what impact did the temporary HMR amendments have on COVID-19 outcomes?”.
54. The possibility remains that these temporary HMR amendments could have similar benefits in the future if, for example, a vaccine-escape variant of concern (VoC) evolves, and a new vaccine, effective against the VoC, is developed. Other scenarios, such as an entirely new pandemic, could also have a similar impact.
55. The timing and probability of such occurrences is unknown. Therefore, we estimate the benefits as if this occurrence is within the coming year. This means that future costs and benefits will only be discounted by this amount.
56. The health benefits, in terms of QALYs gained from averted deaths, are calculated over the lifetime of the individuals impacted, and the morbidity impacts from COVID-19 infections are estimated with a 1-year time horizon.
57. Ideally, a final adjustment would be made to the total benefits to represent the probability of these benefits occurring. As the pandemic is ongoing, it is hard to estimate the additional benefits that these amendments will have, given the deployment of COVID-19 vaccines continue and there is no certainty yet to the frequency of doses that will be recommended.

Monetised costs

58. As noted, this IA does not appraise the cost of using COVID-19 or influenza vaccines, nor procuring the vaccines themselves. Instead the focus is on costs of facilitating mass deployment. In this illustrative scenario, we assume the only costs incurred were for training the expanded workforce, as detailed below. For future scenarios, we assume there are no more additional costs associated with making some HMRs provisions permanent and extending some. Any funding needed related to use of these policies in the context of a future pandemic requirement would be covered as part of HMT engagement on funding requirements at that point.

59. Ahead of the COVID-19 vaccination programme, provisions were made to expand the workforce eligible to administer vaccines, to ensure that the UK had a sufficient workforce. These included enabling additional healthcare professional groups to vaccinate health and social care workers in occupational health services and the public under PGDs. Additionally, the national coronavirus and influenza vaccination and immunisation protocol, enabled a wider range of staff to administerCOVID-19 and influenza vaccines after appropriate training and, where appropriate, under supervision.

60. In the retrospective look at the COVID-19 vaccination programme, with or without the additional workforce there still would have been the demand for the same number of vaccinations. Therefore, costs such as wages of additional staff are not estimated, based on an assumption that in the counterfactual, at least equivalent hours of work would have been done by existing staff, if not more. It is probable that this would have also not been done with the same level of efficiency as seen in vaccination locations such as mass vaccination centres.

61. By estimating the costs of the additional trained workforce in a retrospective look at the first phase of vaccinations, this would give insight into the potential future costs, if another large-scale vaccination programme is needed. The same number of staff may not be needed to be trained.

62. Staff levels were coordinated at trust level. It is unclear the total number of staff that would have been used as part of the vaccination programme, but there would have been an overall lower flexibility in the numbers of staff.

63. NHS Professionals, a flexible workforce provider looked to recruit an additional 10,000 vaccinator staff[5]. These roles include:
    - COVID-19 Vaccination Programme Registered Vaccinator
    - COVID-19 Vaccination Programme Registered Health Care Professional (RHCP) (Immunisations)
    - COVID-19 Vaccination Programme RHCP Clinical Supervisor (Immunisations)

64. To apply for RHCPI and Clinical Supervisor roles, a professional would have to be registered with the following bodies: General Medical Council (GMC), General Dental Council (GDC), Nursing and Midwifery Council (NMC), Health and Care Professionals Council (HCPC), General Pharmaceutical Council (GPhC), Pharmaceutical Society of Northern Ireland or pandemic temporary register (including Bring Back Staff) and to be trained to draw up and administer vaccination.

65. However, it is possible to apply for a vaccinator role for wider healthcare professionals even if they are not registered with any of these organisations. Additionally, higher education medical or healthcare related courses were eligible and those who have taken healthcare courses as part of their career training.

66. For these roles, we assume 2-3 days' worth of training to be required at a minimum. These would have been a mixture of online and in person training courses. For clinical supervisor and registered healthcare professional roles there are 8 e-learning training courses that reduce to 5 if they have had vaccinator experience in the last 12 months. Unregistered vaccinator roles require 11 additional, statutory, and mandatory e-learning training courses on top of the 8 courses required for registered healthcare professionals.

[5] https://www.nhsprofessionals.nhs.uk/Campaigns/Vaccine-boost

67. Additional volunteers to run the expanded programme have been recruited via St. John Ambulance, who have trained an additional 30,000 volunteers to help with the vaccination programme[6], and through NHS volunteer responders, who aimed to recruit 30,000 volunteers to work in stewarding roles. Overall, we estimate an additional 70,000 additional staff that have gone through between 2-3 days training to be part of the expanded vaccination programme.

68. In the central scenario we assume the costs to set up and run the training for the additional staff to be equal to approximately £59m. This figure is taken from an IA for the emergency implementation of the HMR amendments made prior to the rollout. Given the uncertainty of this figure combined with the uncertainty of whether or not the same number of vaccinators will need to be trained for any future vaccination rollout. The figure is varied by 10% across the scenarios.

Table 1: Scenario cost assumptions

Scenario assumptions	Costs associated with training
Central Estimate	£59m
Lower Estimate[7]	£53m
Upper Estimate	£64m

69. As this is based on a training programme that is at the same scale as the prior COVID-19 rollout, it is unlikely that this would be required once again, as the rollout may require lesser or fewer staff to be trained. However, these figures represent a useful upper bound to the cost estimate.

Monetised benefits

70. The primary benefits would be health benefits from a faster vaccine roll-out, though there will also be wider benefits, such as to the economy, from reducing the need for restrictions to slow down infections. Due to the intrinsic uncertainty in the frequency and nature of future pandemics, we do not provide an estimate of benefits. However, we include one plausible scenario for illustration purposes, which is based on a retrospective assessment of the 2020 temporary amendments in light of the threat of COVID-19.

71. This section provides the methodology for this illustrative scenario in terms of the health benefits (averted COVID-19 infections, hospitalisations, and deaths) due to these regulation changes. These health benefits are then monetised in terms of QALYs from avoided infections, hospitalisations, and deaths, plus savings to the NHS from avoided costs of hospitalisations. The methodology for this final step is given in Annex A.

72. A paper prepared by DHSC and in collaboration with the Office for National Statistics (ONS) for the SAGE, estimates the direct and indirect health impacts of COVID-19[8]. The paper summarised four routes through which COVID-19 had an impact on health:

- Category A. Direct impacts of COVID-19 such as mortality impacts and morbidity impacts.
- Category B. Impact of COVID-19 on NHS critical care capacity.

[6] https://www.sja.org.uk/what-we-do/Coronavirus-support/coronavirus-vaccine/

[7] *Later adjusted in NPV calculation

- Category C. Indirect impacts of COVID-19 on health-related behaviours and healthcare.
- Category D. Indirect impacts of COVID-19 on the wider population in the long-run such as impacts on the wider population through changes to employment and the wider economy.

73. Category A will be estimated within this IA, but as this analysis only considers the impact of the HMR regulations on the speed of the vaccination rollout, and with the assumption that this would save a magnitude of days, Categories B, C, D are not estimated in this benefits section as it will not be possible to have the precision to estimate the impact of saving a number of days on these categories. It is likely that there will be a positive impact on these categories from a faster rollout of the COVID-19 vaccination and therefore there will be a positive impact on these categories which the benefits estimate in the illustrative example may not fully reflect.

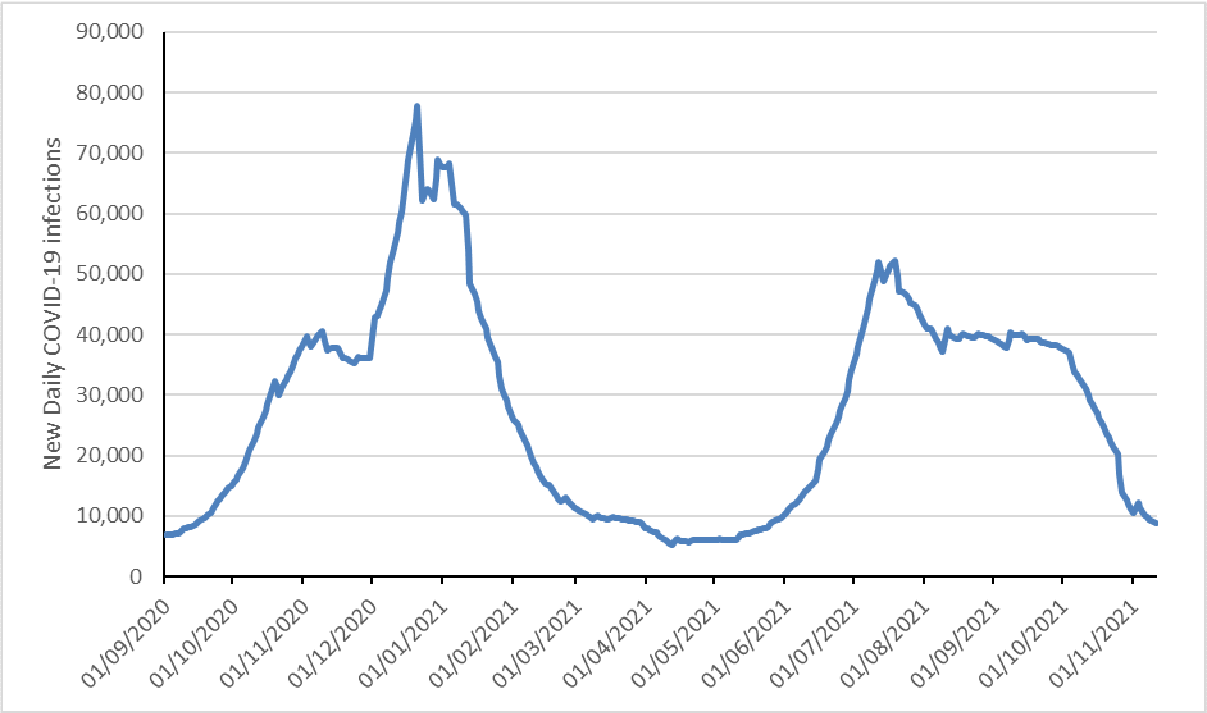
Methodology for monetising the direct health benefits

74. The analytical approach taken is a retrospective look at the previous waves of the COVID-19 pandemic and the impact of the vaccination programme on health outcomes, measured through infections, hospitalisations, and deaths. For estimating these outputs, we look at a scenario where the population is vaccinated and a counterfactual where the population is not vaccinated. To do this we look at two time periods from the COVID-19 pandemic.

75. Figure 1 shows two waves of COVID-19 according to an estimate of the total number of infections[9], not just cases reported. From the period of September 2020 to the end of August 2021 there are two clear examples of waves of infections, with the second wave in the graph happening within a time period where the vast majority of the population is vaccinated.

Figure 1: Estimated number of new daily COVID-19 infections in England

[9] https://www.mrc-bsu.cam.ac.uk/tackling-covid-19/nowcasting-and-forecasting-of-covid-19/



76. As well as vaccination, there are further variables that impacted these waves of infection, including the increased infectiousness of the Delta variant; differing levels of non-pharmaceutical interventions; and differences in the behaviour of the population. By using the two waves as a general example of a wave, pre and post vaccination will give us a scenario for the impact of the vaccination on health outcomes. The two scenarios are assumed to take place between the following dates:

Table 2:COVID-19 infection scenarios

	Counterfactual "No Vaccine" scenario	"With Vaccine" scenario
Start date of scenario	01/09/2020	21/03/2021
End date of scenario	20/03/2021	31/08/2021
Average daily infections	29k	20.8k
Average daily hospitalisations	654	234
Average daily deaths	373	41

77. Although the methodology requires a degree of simplification in the comparison between the waves, the aim of this analysis is to estimate the impact of a faster vaccination programme on a possible future breakthrough variant of COVID-19 or a influenza pandemic; with all the uncertainty that would come with possible outbreak, a general look at pre and post vaccination waves will still be applicable.

    By comparing pre and post vaccination waves it is possible to gain a generalised understanding of the average impact per day that the vaccine has had on the health

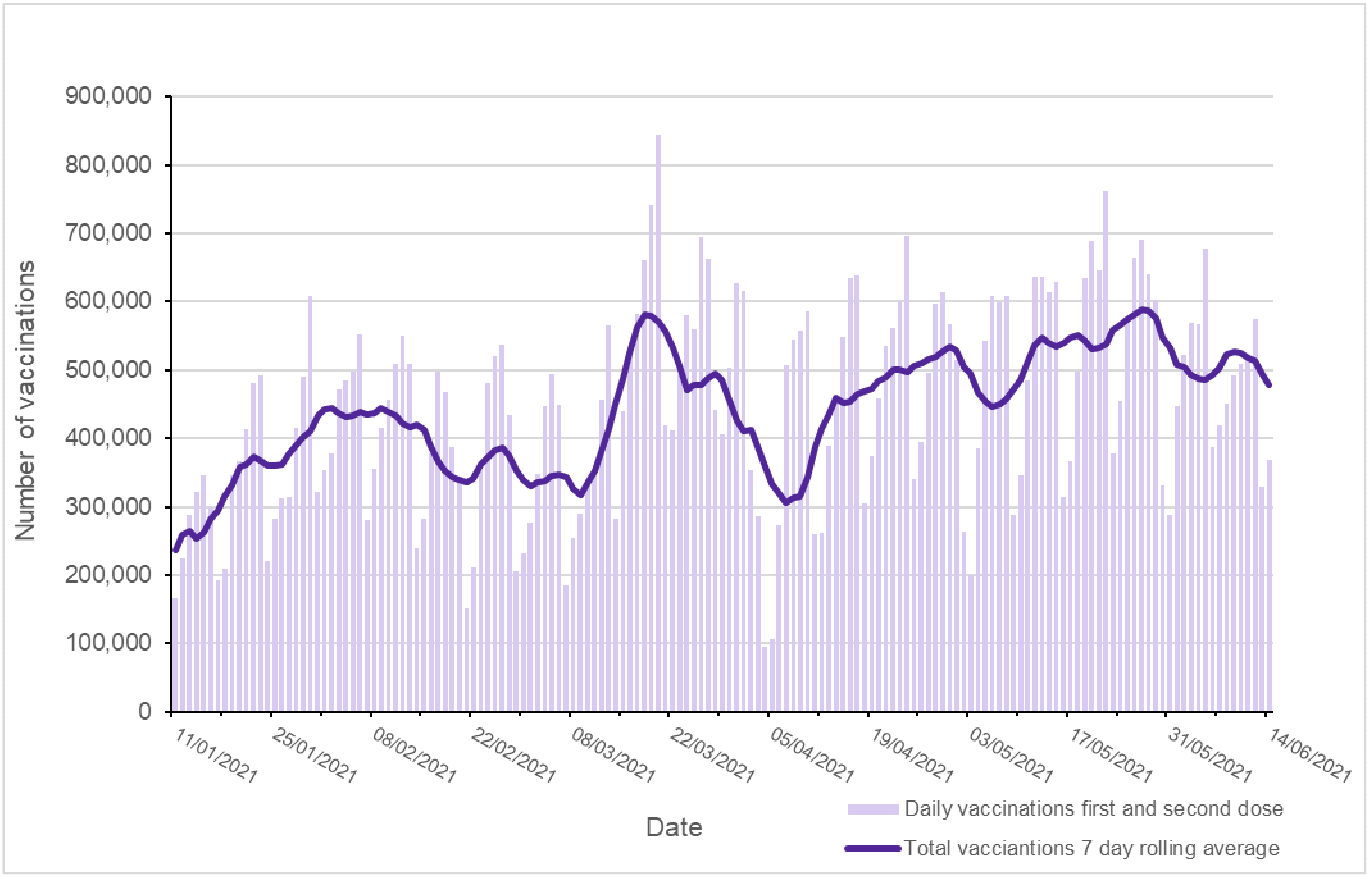
outcomes of the UK. The aim of this IA is to estimate the specific impacts that the regulations have had, this is approached by taking the average differences between the 'no vaccine' and 'with vaccine' scenario. An assumption is then made for the number of days saved through enabling a smoother and faster vaccination rollout.

Estimating additional time associated with regulations

78. A key assumption in this analysis, is the impact of the HMRs amendments from October and December 2020 on the speed of deployment of the vaccines. By assuming a set number of days difference with and without the regulations in place, this determines the length of time that we would compare the base and HMR changes scenario. Determining this length of time is not straightforward as there is not clear counterfactual to draw upon. Ahead of the rollout of the COVID-19 vaccinations, the HMRs were amended, to allow for a faster and smoother rollout. With the retrospective approach this analysis is taking to estimate future benefits of keeping the amendments, an assumption of the number of additional days associated with not having the regulations in place is required.

79. To inform these assumptions analysis be made based upon the rollout seen in early 2021.

Figure 2: Daily vaccination rate (7-day average)



80. There is a noisy but positive increase in the daily vaccination rate between January and late March, which could be defined as the UK getting up to speed with its vaccination programme, as it scales up the process. The rollout reaches two peaks in its 7 day rolling average, one at just under 580,000 vaccinations per day, in mid-March, comprising of mostly first doses and one on the end of May, made up of mostly second doses.

81. The peak level of daily vaccinations took place on the 20th March. This is used as a comparator from which the other scenarios are measured against.

82. If the impact of the regulations was to increase the Government's ability to scale up daily vaccinations, then by adjusting the rate of increase in vaccinations per day, this could represent the impact of the regulations on the overall speed of the rollout.

83. Assuming a constant rate of increase, by varying the gradient of the line we can change the date at which the UK will reach the first peak of 580,000 a day.

84. It is also possible to estimate the impact at limiting both the speed of scaling up the rollout and the peak level of vaccinations. HMR provisions such as increased workforce will increase the peak level of vaccinations per day, whereas changes that affect logistics such as the ability to use the army to label and transport the vaccinations could be seen as impacting the speed of the scaling up of rollout.

Table 3: Scenario assumptions

Scenario assumptions	Per day increase in vaccination rate	Maximum daily vaccination rate	New date	Days different between counterfactual and new scenarios
Counterfactual	4,800	580,000		
Central Estimate	3,000	450,000	27/03/2021	7
Lower Estimate	4,000	500,000	22/03/2021	2
Upper Estimate	2,500	400,000	30/03/2021	10

85. The scenarios are modelled through a constant rise in the daily vaccination rate until the maximum is reached, then it plateaus until the cumulative number of vaccinations is equal to that on the 20th March in the counterfactual, equal to 26,500,000.

Likelihood of the regulations being used

86. In the policy option where the regulations are extended. A true measure of the net present value associated with the policy needs to reflect the likelihood of the 2020 provisions of the HMRs being used and the extent to which they are used (i.e. whether the number of staff is the same as in the initial rollout). This is dependent on a highly uncertain epidemiological landscape, and both the likelihood and the extent that the regulations will be used is unclear.

Results

87. Through the additional time assumption associated with each of the scenarios, this is then multiplied to the average health impacts per day in the 'no vaccine' counterfactual and the 'with vaccine' scenario.

Avoided COVID-19 mortality

Table 4 – Averted deaths from HMR regs

		Averted deaths

	Without HMR amendments scenario	With HMR amendments scenario	
Central scenario deaths	2,590	288	2,302
Low scenario deaths	740	82	658
High scenario deaths	3,700	412	3,288

88. Applying the central scenario of an additional 7 days for the rollout, it is estimated that there may have been approximately 2,300 averted COVID-19 deaths as a result of vaccination. These results reflect the average level of deaths per day difference observed across the 'no vaccine scenario' and the 'with vaccine' scenario.

QALY impact from averted COVID-19 mortality

Table 5: Discounted Mortality QALYs

		1.5% discount rate	
	Averted deaths	**Mortality QALYs**	**Monetised QALYs**
Central scenario mortality QALYs	2,302	9,431	£566m
Low scenario mortality QALYs	658	5,389	£323m
High scenario mortality QALYs	3,288	13,473	£808m

89. We assume a breakdown of 2,300 deaths are equated to 9,400 QALYs (discounted at 1.5%), monetised at £60,000 per QALY to give a societal benefit of £566m.

Avoided COVID-19 morbidity

Table 6: Number of COVID-19 infections and hospitalisations averted

Transmission scenario	COVID-19 infections averted	COVID-19 total hospitalisations averted	COVID-19 ICU hospitalisations averted
Central scenario	67,426	6,932	455
Low Scenario	19,265	1,981	130
High Scenario	96,323	9,903	650

90. The overall morbidity QALYs associated with the number of infections, hospitalisations, and ICU admissions, see Annex A for more detail.

QALY impact from averted COVID-19 morbidity

Table 7: Discounted QALYs associated with morbidity

	1.5% discount rate	
Transmission scenario	**Morbidity QALYs**	**Monetised QALYs**
Central scenario	718	£43m
Lower estimate	205	£12m
Higher estimate	1,026	£62m

91. 67,400 infections averted and 6,900 hospitalisations averted are equated to 720 QALYs (discounted at 1.5%), monetised at £60,000 per QALY to give a societal benefit of £43m.

NHS savings

Table 8: NHS savings from fewer COVID-19 hospitalisations

Central estimate	£39,200,000
Lower estimate	£11,200,000
Upper estimate	£55,900,000

92. On top of the societal health benefits associated with fewer infections, hospitalisations and deaths that we see in the form of QALY gains, fewer admissions also lead to lower costs for the NHS. By preventing 6,900 hospital admissions and 450 ICU admissions in the central scenario the NHS would save an estimated £39m.

Total benefits

Table 9:Monetised benefits of the HMR regulations

	1.5% discount rate					
Transmission scenario	**Mortality QALYs**	**Morbidity QALYs**	**Total QALYs**	**Monetised QALYs**	**NHS Savings**	**Total Benefits**
Central scenario	9,431	718	10,149	£609m	£39m	£648m
Lower estimate	5,389	205	5,594	£336m	£11m	£347m
Higher estimate	13,473	1,026	14,499	£870m	£56m	£926m

93. The table shows the aggregated benefits of each scenario of the number of days saved as a result of the regulations. It should be noted that £566m of the total benefits of £648m are associated with the QALY gains from deaths prevented, that is by far the key benefit of the regulations. It reflects the high level of reduction in deaths we see across the two scenarios, with the counterfactual 'no vaccine' scenario averaging 373 deaths a day in comparison to 41 from the 'with vaccine' scenario.

94. The analysis of the QALY benefits associated with the faster rollout in the initial phase of vaccination show a scenario where the benefits far outweigh the costs associated with the amendments. This illustrative example shows that due to the possibility of deaths averted from a faster and smoother vaccination programme, as well as additional benefits in reduced morbidity and NHS savings, that the continued use of these amendments will likely have a net positive impact.

Sensitivity Analysis

3.5% discount rate

95. The table shows the aggregated benefits but this time future QALY benefits are discounted at 3.5%. Whilst guidance on evaluating the costs and benefits of health interventions, as specified by HMT's Green Book, typically uses 1.5% discount rates, there are examples in evaluating the impact of vaccines, such as when JCVI methodology is applied, where a 3.5% discount rate is used. In this case the overall net present value in all scenarios is still positive despite the higher discounting of future QALY benefits.

Table 10: Monetised benefits with a 3.5% discount rate applied

	3.5% discount rate					
Transmission scenario	**Mortality QALYs**	**Morbidity QALYs**	**Total QALYs**	**Monetised QALYs**	**NHS Savings**	**Total Benefits**
Central scenario	9,431	704	10,135	£608m	£39m	£647m
Lower estimate	5,389	201	5,590	£335m	£11m	£347m
Higher estimate	13,473	1,006	14,479	£869m	£56m	£925m

Break-even analysis with reduced health impacts

96. The break-even sensitivity analysis explores at what level the health benefits from a faster vaccination rollout would be outweighed by the costs of the implementation of these regulations. As mentioned, by applying an adjustment that would relate to the likelihood of the impacts of the regulations being used for COVID-19 and influenza would reduce both the impacts of COVID-19 and influenza proportionately. Therefore, in order to reach a break even point, the scenario would be based around a reduction of the impact of the regulations on the time saved in the rollout of the vaccine. If there are fewer days saved, then the ratio of costs to benefits would increase.
97. Table 9 shows the number of QALYs and the equivalent infections, hospitalisations and deaths needed to ensure that the net present value of the regulation changes matches the costs associated with the main policy option. As in the benefits section, we assume the societal value of a QALY of £60k.

Table 11: Number of QALYs required for the net present value to equal zero

	Central	Low	High
Averted infections needed	244,351	285,076	203,625
Averted hospitalisations needed	4,079	4,758	3,399
Averted number of deaths needed	59	29	52
Number of QALYs	449	524	374

98. Table 2 in the *Methodology for monetising benefits* section describes the difference between the number of infections, hospitalisations, and deaths in the 'no vaccine' scenario and the 'with vaccine' scenario.

99. The number of averted infections per day between the two scenarios is estimated to be 9,632 infections, 925 averted hospitalisations per day and 329 averted deaths per day. Therefore, in order to reach a break even point only 1 days increase in the speed of programme is required in order to justify the costs estimated within this IA.

Risks

100. The key risks to the conclusions of the overall IA are that the benefits reflected will not be outweighed by the costs of additional staff training. As explored in the sensitivity analysis only 1 day of additional days within the 'with vaccine' scenario is required to break even, so there is a low risk in overstating the time saved on the rollout, associated with the regulations.

101. To make use of the regulatory changes introduced in October and December 2020 and to see the benefits estimated within this IA, other elements of the comprehensive HMRs (which govern the entire medicines supply chain) need to be adhered to. For example, vaccination centres will only be able to carry out final preparation and labelling of COVID-19 vaccines where they are confident that they are covered by a marketing authorisation or manufacturers licence, vaccination venues will be unable to share surplus vaccines with venues where stocks are short without having a wholesaler dealer licence.

Risks associated with increased vaccinator workforce

102. With regards to the increased vaccinator workforce, there is some public perception that only doctors and nurses should be able to administer injectable vaccinations. This does not, however, reflect modern day practice in the health service. In responses to the public consultation, several individuals raised concerns about which staff groups should be vaccinating the public and whether they have adequate training and qualifications but no evidence to indicate what would constitute adequate training was provided.

103. Potentially another downside of having a wider workforce administer vaccines is that more staff groups will focus on this work to the detriment of other duties. In practice, however, the total workforce is used flexibly to deliver different priorities and those vaccinating can be rotated, or a particular staff group given these duties when their other, usual duties may not currently be a priority for the provider at a given point in time. In a counterfactual where the provisions laid out by this IA are not in place, there would still

be vaccination for COVID-19 and influenza, but the additional staff and flexibility would not be in place, leading to additional pressures on the current workforce.

104. Given the large volunteer workforce that has been employed to achieve the faster rollout. There is a potential that there is an opportunity cost in drawing volunteers away from other areas. Volunteers also support the wider NHS and social care sector, many through St. John's Ambulance who have trained an additional 30,000 volunteers. There is a potential risk that these sectors will have fewer volunteers in times of large vaccination rollout, but the exact relationship is unclear.

Risks associated with the provision which enables providers of retail pharmacies who are providing vaccinations for COVID-19 or influenza under PGD to provide that service away from their normal registered premises.

105. The public may also perceive this provision as perhaps not being necessary or as carrying more risk than being vaccinated in a community pharmacy premises. This, however, is not the case.

106. Community pharmacies are often small spaces which do not easily lend themselves to offering vaccination programmes at a large scale. All the necessary patient safety procedures and usual checks made by a pharmacist before vaccinating a patient will be carried out in exactly the same way, regardless of the location in which the physical vaccination of the patient takes place. Vaccinating outside of the registered pharmacy premises additionally allows the main pharmacy premises to continue their routine work of dispensing medicines and advising patients without disruption.

107. Similar to the concerns of the opportunity cost of volunteera being deployed to the vaccination programme and not other volunteering opportunities, within the NHS or elsewhere, there is also a potential that places used for the vaccination programme such as community centres and town halls are not used for other services that could benefit the wider community. However, the costs of this will be largely outweighed by the reduced workload for GP services as a result of the additional premises used for vaccination.

108. All provisions that are being taken forward at this time have been utilised for the past year or so and we have not collected any formal or informal consultation feedback to suggest that there are any major risks to moving forward with prioritising implementation of those provisions that will lapse on 1 April 2022, to enable health services to continue to plan and operate mass vaccinations.

Risks to extending the temporary provisions

109. The two provisions which are being extended temporarily for another two years to 1 April 2024 are: the provision to enable providers of NHS services and medical services to HM Forces to distribute medicinal products to be used for vaccination or immunisation against COVID-19 or influenza without the need for a wholesaler dealer licence and the provisions to enable the preparation of COVID-19 vaccinations without the need for manufacturers' licences and marketing authorisations (which, amongst other things, relax of the rules on packaging and labelling).

110. Licensing arrangements are important parts of the medicines regulation regime to assure patient safety. The exceptional circumstances of the pandemic, including the need to make best possible use of available vaccine and minimise the risk of wastage, continue to provide sufficient justification for sharing of COVID vaccine stocks between vaccination centres without the need for additional wholesaler dealer licences to continue

to be set aside temporarily for a further two years. In undertaking engagement with stakeholders about the operation of this easement to date there has been no evidence of safety breaches. In terms of benefit, this easement has enabled, for example, local providers to access additional stock so they can use their full capacity to deliver vaccinations.

111. The exceptional circumstances of the pandemic, and the particular requirements for the COVID-19 vaccines in use at this time, continue to provide sufficient justification for the final stage of preparation of COVID-19 vaccines before administration to patients to be carried out by qualified healthcare professionals without the need for additional manufacturing licences or marketing authorisations requirement, to be set aside temporarily at the present time, but maintaining the safeguard of only qualified healthcare professionals undertaking the final preparatory work. The professionals who are preparing the vaccines under these arrangements are working within their core competencies. In undertaking engagement with stakeholders about the operation of this easement to date there has been no evidence of safety breaches. In terms of benefit, this easement has meant that NHS professional staff are not having to spend their time applying for licences for each and every centre but use their full capacity for vaccine delivery to patients.

112. At this point in time, we therefore are of the view that for these two provisions the benefits substantially outweigh the risks, but this should be further reviewed in 2 years given the likelihood of different vaccines with different requirements becoming available in that time.

Wider impacts

113. We do not anticipate any further wider impacts as a result of the amendments being made permanent.

Impact tests

114. In line with Better Regulation Guidance[40], we have considered the following issues as part of this appraisal:

Trade impacts

115. We do not anticipate that extending these provisions are likely to impact trade or investment.

Legislation

116. The proposals are aligned with the Human Rights Act and should not infringe on any right included in the Act. The proposals should not contravene the Data Protection Act or Freedom of Information Act.

Competition test

117. The proposed amendments to the HMRs would affect the vaccine market, and indeed other markets which involve temporarily authorised products, supplied by private organisations. We do not expect the amendments to:

    a. directly or indirectly limit the number or range of suppliers

b. limit the ability of suppliers to compete
c. limit suppliers' incentives to compete vigorously
d. limit the choices and information available to consumers.

Rural issues

118. We do not expect specific direct impacts of amending the HMRs on rural areas. However, there may be indirect benefits for rural areas, due to their demographic characteristics since older people are more likely to live in rural areas and are likely to be prioritised for a COVID-19 vaccine.[10] There are higher rates of COVID-19 mortality amongst older people, so the expected benefit of lower mortality as a result of more rapid deployment of the vaccine may present a specific benefit for rural communities.

Monitoring and Evaluation

119. For amendments being extended until 31 March 2024, a review will be carried out prior to this end date to decide whether they will be made permanent, another temporary extension, or will lapse. There are no plans to review the permanent amendments at this time.

Annex A: Quantifying Benefits

Quantifying QALYs gained per death prevented

1. We calculate the expected years of life and quality of life in individuals who receive protection (individually or from others) from a COVID-19 fatality during the vaccine roll-out.

2. QALYs are used to measure the health state of an individual in terms of length of life, adjusted for the quality of life. One QALY represents one year of life in perfect health. When estimating QALYs from a direct COVID-19 death, we consider the expected years of life an individual would have remaining, and the quality of life they were expected to have lived. Certain co-morbidities are especially common in those who contract COVID-19, including heart disease and respiratory illnesses including asthma and diabetes. These diseases are chronic and have a significant effect on Quality of Life (QoL). In the absence of COVID-19, individuals with these conditions would not have experienced QoL of 1 corresponding to perfect health. The risk profile of individuals is therefore accounted for when estimating harms.

3. We assume the majority of individuals susceptible to a COVID-19 fatality on average during the vaccine rollout are at high risk of dying from COVID-19 due to pre-existing health conditions for a number of reasons:
    a. Internal analysis suggested 73% of deaths to date were in individuals with a pre-existing condition
    b. ONS analysis from March 2020 estimated the mean number of pre-existing conditions in individuals who died of COVID-19 was 2.7

4. To calculate the quality of life (QoL) aspect, we use data from the Health Survey for England (HSE) 2017. The HSE asked adults 16 and over to complete the EQ-5D-5L, a

[10] rural-proofing-guidance.pdf (publishing.service.gov.uk)

tool used to describe an individual's health state based on 5 dimensions; mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

5. To estimate the mortality impacts, we assume individuals susceptible to a COVID-19 fatality on average during this roll-out are at high risk of dying from COVID-19. This is because the majority of COVID-19 deaths are attributed to those prioritised in phase 1 of the vaccination programme. Individuals not protected by vaccination during phase 1 despite eligibility (i.e. did not take up or vaccine was not effective) will still be susceptible to harm at a higher risk.

6. We use the QoL estimate for individuals with at least 1 comorbidity to depict high risk individuals. The HSE data were grouped by age, sex and risk status, and the average health-related quality of life was calculated for each group, weighted by the survey weighting.

7. For the 2017 HSE cohort we generated a quadratic best-fit line to the average QoL by age (in single years).

8. QoL estimates have been discounted by 3.5% as per JCVI methodology.

9. Life expectancy data for individuals with 2 comorbidities is used for each age/sex group. Combining life expectancy data and the average QoL by age band, we estimate the average discounted QALYs for a COVID-19 death in each age and sex group.

10. We calculate the total QALYs that could be saved based on the outputs of the LSHTM model which summarises mortality by 5-year age bands.

11. For each age/sex group, we use the distribution of COVID-19 deaths by age and sex to estimate the distribution of QALYs saved by age and sex:

Total discounted QALY lost= Average discounted QALYS x averted deaths x Proportion of deaths by sex

Limitations

12. In this analysis we deem individuals at high risk to be those with at least one pre-existing health condition to determine the QoL score used in the QALYs calculation, as it was not possible to calculate the QoL for individuals with 2 conditions or 3+ conditions, due to a limited number of data points in the Health Survey for England (HSE) data. QoL scores could therefore be an overestimate.

13. Many deaths occur in care home residents, who will have a lower life expectancy and lower quality of life score. This has not been factored in, but we would expect this to reduce the average averted QALYs for a fatality.

14. The HSE 2017 does not provide quality of life scores for those under the age of 16, therefore we have assumed that those under 16 have a quality of life score equivalent to a 16-year-old. This is highly likely to be an underestimate and therefore not accurately depict QALY loss for children.

Quantifying morbidity QALYs gained

15. The morbidity impacts of COVID-19 were estimated and quantified using QALYs. The modelling was based on a model built by the Institute and Faculty of Actuaries[11].

16. We model the morbidity impacts of infected individuals in three groups:
    a. Infected and non-hospitalised individuals
    b. Infected and hospitalised ward patients
    c. Infected ICU patients

17. Hospitalised individuals will suffer greater morbidity impacts compared to those with milder COVID-19 infections who are not hospitalised.

18. Individuals infected with COVID-19 suffer symptoms for varying lengths of time. NICE defines 3 periods of disease:
    a. Acute COVID-19 is defined as signs and symptoms of COVID-19 for up to 4 weeks
    b. Ongoing symptomatic COVID-19 lasts between 4-12 weeks
    c. Post-COVID-19 syndrome- sometimes referred to as Long COVID-19 are signs and symptoms that continue for more than 12 weeks.[12]

19. For the non-hospitalised group, we use the ONS publication on the prevalence of ongoing symptoms following COVID-19 infection in the UK. They provide estimates of the proportion of people by age-band who continue to suffer symptoms 5- and 12-weeks post infection. We build an exponential curve for each age-band using these figures to estimate the duration of symptoms in infected non-hospitalised individuals. We assume that 50% of all infected non-hospitalised individuals are asymptomatic.

20. Exponential curves for the duration of symptoms in hospitalised ward and hospitalised ICU patients were based on figures given in the Halpin et al paper.[13] They followed COVID-19 infected patients in ward and ICU and found that 60% of ward patients and 72% of ICU patients were symptomatic 7-weeks post infection. We assume these proportions are true for all age groups in the model.

21. The Halpin et al paper measured the average change in EQ-5D-5L index in hospitalised ward and hospitalised ICU patients from their pre and post COVID-19 states. The average change in a hospitalised ward patient is -0.061 and for a hospitalised ICU patient is -0.155. These were used to estimate the QALY loss per day for infected individuals. The model assumes that the QALY loss for a non-hospitalised patient was the same as that for a hospitalised ward patient. The mean age for a ward patient was 70.5 years for the cohort of individuals that the Halpin paper surveyed. The mean age for ICU patients was 50.8 years. We adjusted the QALY loss created from the EQ-5D-5L index in the Halpin paper for other age-bands.

22. The model applied the duration exponential curves to the LSHTM estimates of averted infections and hospitalisations to estimate the number of days these individuals would

[11] https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bulletins/prevalenceofongoingsymptomsfollowingcoronaviruscovid19infectionintheuk/1july2021

[12] Overview | COVID-19 rapid guideline: managing the long-term effects of COVID-19 | Guidance | NICE

[13] https://onlinelibrary.wiley.com/doi/10.1002/jmv.26368

suffer symptoms for. It then applied the estimates of QALY per day to estimate the total morbidity QALY saved.

23. Note, the estimates relating to Post-COVID-19 syndrome (Long COVID) are particularly uncertain given the novel nature of this condition and the wide range of symptoms that it covers.

Quantifying NHS savings from fewer COVID-19 hospitalisations

1. In the absence of published data for the cost of a COVID-19 hospital admission, we use a proxy NHS unit cost for a hospital episode of viral pneumonia, using NHSE/I's national cost collection for 2019/20[14]. The symptoms from this illness resemble severe COVID-19 that are likely to result in hospitalisation. Additionally, we take a unit cost for critical care admissions.

2. We assume the cost of a COVID-19 admission to be £ 5,565 per patient, and £6,755 per patient if they are also admitted to a critical care ward. These costs include all expenses relating to the patient care during the admission such as medication, staffing costs and accommodation costs.

3. These costs are applied to avoided hospitalisations across the entire population, based on the modelled estimates.

[14] NHS England » National Cost Collection for the NHS