Title: Decision to amend Regulations 3A, 19 and 247A of the Human Medicines Regulations 2012. **IA No: 9605** **RPC Reference No: TBD** **Lead department or agency:** Department of Health & Social Care **Other departments or agencies: N/A**	**Impact Assessment (IA)** **Date:** 04/08/23 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** HMR.Consultation@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

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** Qualifying provision
-£1,740m	£0m	£0m	

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

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (HMRs) provided greater flexibilities for the movement and supply of certain types of vaccines, in light of the COVID-19 pandemic. The aim of this proposal is to ensure that the flexibilities established by Regulation 3A (R3A), Regulation 19 (R19) and Regulation 247A (R247A) are maintained for a further time-limited period to support the continuing supply, distribution and administration of COVID-19 and Influenza vaccines as we transition out of the pandemic. R3A and R19 have sunset provisions which mean they will be repealed on 1 April 2024 unless extended and R247A is only permitted for use during a pandemic.

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

The policy objective is to enable the continued deployment of safe and effective COVID-19 and Influenza vaccines to the pace and scale required, both now and in the future, whilst maintaining public safety. If the provisions provided for under R3A and R19 lapse (which will happen if we do nothing), and/or if the provisions in R247A are unable to be drawn on due to the ending of the pandemic, certain NHS vaccination activities would need to cease. This is likely to negatively impact on provision and uptake of these vaccinations.

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

Do nothing (Option 0): Once a pandemic is declared over, the NHS will be unable to use the expanded workforce to administer a COVID-19 or Influenza vaccine. This would jeopardise the ability for the NHS to deliver future COVID-19 and Influenza vaccine campaigns. Allowing R3A and R19 to lapse would mean that certain NHS vaccination activities would need to cease.

Option 1: Remove Condition A of R247A and extend the existing sunset provisions in R3A and R19 until 1 April 2026. This would mean the NHS can continue to use the expanded workforce to deliver the COVID-19 and Influenza programmes when COVID-19 is no longer considered to be a pandemic. It will also ensure continuation of the current flexibilities such as those that allow the assembly of a COVID-19 vaccine to be undertaken by or under the supervision of a healthcare professional, without precipitating the need for a manufacturer's licence or marketing authorisation and, the ability to move COVID-19 and Influenza vaccines between premises with a wholesaler dealer's licence.

Will the policy be reviewed? It be reviewed. **If applicable, set review date:** 09/23

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:** N/A	**Non-traded:** 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:  Date: 07/08/2023

Summary: Analysis & Evidence

Policy Option 0

Description: Do nothing- make no change to the Human Medicines Regulations 2012 (HMRs)

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	**PV Base Year** 2023	**Time Period Years** 2	Net Benefit (Present Value (PV))		
			Low: N/A	High: N/A	Best Estimate: -£1,740m

COSTS (£m)	**Total Transition** (Constant Price) Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	0	2	0	0
High	0		0	0
Best Estimate	0		0	0

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

Option 0 is modelled to have no monetised costs as it represents "do nothing" and would not require any specific action.

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

In practice, the registered workforce may increase their hours on the COVID-19 and Influenza vaccination campaigns to mitigate the impact of being unable to utilise the unregistered workforce. This would have an opportunity cost on other forms of healthcare when more registered staff time is spent delivering vaccines. This could deteriorate health outcomes elsewhere in the healthcare system.

BENEFITS (£m)	**Total Transition** (Constant Price) Years		**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	0	2	N/A	N/A
High	0		N/A	N/A
Best Estimate	0		-£205m	-£1,740m

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

The 'Do Nothing' Option 0 is modelled to have a disbenefit. We have modelled that Option 0 would lead to a 50% reduction in staff capacity, leading to a reduction in administered COVID-19 and Influenza doses. In the central scenario we estimate that this would have a health disbenefit of -£1,740m. These foregone benefits are the standard health benefits of vaccination, from averted mortality and morbidity, which accrue to the vaccinated individual and savings to the NHS from preventing hospitalisations. The latter arises because vaccines reduce the risk of hospitalisation due to COVID-19 or Influenza. Affected groups are those eligible for upcoming COVID-19 and Influenza vaccination campaigns - primarily individuals who are at risk from these diseases.

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

Option 0 has no non-monetised benefits.

Discount rate (%)	3.5

Key assumptions/sensitivities/risks

We assume the end of the COVID-19 pandemic will be announced by the WHO before April 2026.The quantification of benefits is approximate and is included as an "order of magnitude" estimate of the potential impacts. In the circumstances modelled, there are many plausible compensatory policy responses aimed to reduce the negative consequences, which the NHS may adapt. However, given the difficulty in predicting this response, we have taken a simpler approach of estimation. A key risk is epidemiological uncertainty in COVID-19 and/or Influenza. The emergence of a variant of concern, after a potential reclassification of COVID-19 as endemic could lead to significant negative health impacts for individuals who were unable to receive their COVID-19 and/or Influenza vaccine.

BUSINESS ASSESSMENT (Option 0)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: N/A	**Benefits: N/A**	**Net: N/A**	Not Applicable

Summary: Analysis & Evidence

Policy Option 1

Description: Make amendments to the Human Medicines Regulations 2012 (HMRs)

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 2	Net Benefit (Present Value (PV))		
			Low: £0	High: £0	Best Estimate: £0

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0	2	0	0
High	0		0	0
Best Estimate	0		0	0

Description and scale of key monetised costs by 'main affected groups'
Option 1 is modelled to have no monetised costs, as disruption of the vaccine programmes is averted by making the proposed amendments.

Other key non-monetised costs by 'main affected groups'
Option 1 has no non-monetised costs, as disruption of the vaccine programmes is averted by making the proposed amendments.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0	2	0	0
High	0		0	0
Best Estimate	0		0	0

Description and scale of key monetised benefits by 'main affected groups'
Option 1 has no benefits assigned to this policy since it is based on the policy avoiding potential disruption to the deployment of vaccines which proceeds as planned. Instead, Option 1 means benefits appraised in prior DHSC impact assessments will remain feasible for upcoming COVID-19 and Influenza vaccination campaigns.

Other key non-monetised benefits by 'main affected groups'
Since the vaccination programme began and the HMR amendments came into effect, the NHS in England has recruited almost 55,000 unregistered paid staff and 28,000 of these have been retained into wider careers across the health and social care sector, closing vacancy gaps elsewhere in the sector. If there is a continued cycle of staff being recruited for the vaccination campaigns and then going on to fill in gaps across the sector, this will continue to bring operational benefits for the NHS.

Considered on their own, the time-limited extension of R3A and R19 is not considered sufficient to warrant an impact assessment; they are covered here for completeness as they are included in the consultation alongside R247A and because the regulations work together towards the same objectives. R3A allows healthcare professionals to prepare and assemble COVID-19 vaccines for patients, regardless of location or where the patients are registered. R19 enables safe and appropriate vaccine movement between GP practices in the same PCN grouping to support the delivery of the NHS COVID-19 and Influenza vaccination programmes and provision in places where they could be used best and/or had the greatest need.

Discount rate (%)	3.5

Key assumptions/sensitivities/risks
Moving forward the delivery of vaccination campaigns is moving away from the use of mass vaccination centres to a much lesser extent, and to higher use of pharmacy settings. Currently it is unknown how many new pharmacies will be involved in future campaigns. As a result, the assumption is made that the proportion of unregistered healthcare workers administering the vaccines will continue to be the same as in previous years, despite the changes in delivery model.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: N/A	**Benefits: N/A**	**Net: N/A**	Not Applicable

Evidence Base

Introduction of Regulation 247A:

1. The COVID-19 pandemic to date has had substantial direct and indirect health impacts on the entire UK population, including over 22.2 million confirmed cases and 227,000 deaths with COVID-19 on the death certificate, as of 15 June 2023[1]. The pandemic has also had considerable impact on the economy, both globally and domestically, with GDP falling by a record 19.4% during the first national lockdown[2] and a large increase in unemployment and economic inactivity[3]. While non-pharmaceutical interventions (NPIs) reduce exposure to and the transmission of COVID-19, effective and timely vaccines have been shown to be an integral part of addressing the pandemic by saving tens of thousands of lives across the UK.

2. In advance of the COVID-19 vaccine programme, it was recognised that an expanded workforce would be required to deliver vaccines at the pace and scale required without significant impact to the delivery of wider health services. Additionally, as eligibility for Influenza vaccination was first expanded for autumn 2020, an expanded workforce eligible for administering Influenza vaccination was required to ensure the workforce comprised enough people to deliver the additional vaccinations, especially during the periods when the two vaccination programmes overlapped.

3. As part of a package of amendments to the Human Medicines Regulations 2012 (HMRs), Regulation 247A (R247A) was laid in Parliament on 16 October 2020. This introduced a new national protocol to be prepared by each of the four nations and authorised by their ministers to expand the workforce able to administer a COVID-19 or Influenza vaccine. Changes to the UK-wide Human Medicines Regulations 2012 are made by the UK and Northern Ireland Ministers jointly because medicines regulation is a devolved matter in relation to Northern Ireland and a reserved matter (to the UK Parliament) in relation to Scotland and Wales.

4. Under R247A, the use of a national protocol allows classes of persons designated in the protocol to safely administer a COVID-19 or Influenza vaccine. This includes those who are registered health care professionals who cannot ordinarily administer medicines or vaccines without the input of a prescriber (such as nursing associates, pharmacy technicians, operating department practitioners) and non-registered healthcare workers (such as assistant practitioners, healthcare assistants or maternity support workers).

5. The first national protocol for the COVID-19 vaccination programme was issued on 18 December 2020 in England for the first COVID-19 vaccine deployed in the UK. Since then, national protocols have been approved by Ministers and issued for multiple COVID-19 and inactivated Influenza vaccines for the national COVID-19 and Influenza vaccination programmes.

6. The initial consultation response to the amendments to the HMRs in 2020 included a commitment to formally review the operation of R247A following one year of use, to evaluate whether there had been adverse effects on patient safety. The review was published in April 2022 and highlighted that the regulation was being used widely across the UK and that stakeholders were positive about the impact the regulation was having on their ability to effectively deliver the COVID-19 and Influenza vaccine programmes. No adverse consequences for patient safety were identified by those responding to the review. Subsequent engagement with each nation has indicated that the regulation is still

[1] England Summary | Coronavirus (COVID-19) in the UK (data.gov.uk)

[2] GDP and events in history: how the COVID-19 pandemic shocked the UK economy - Office for National Statistics (ons.gov.uk)

[3] CBP-8898.pdf (parliament.uk)

being utilised to support the COVID-19 and Influenza programmes and that all nations' plans for COVID-19 and Influenza programmes would be negatively impacted if they were no longer able to rely on R247A.

Proposal to amend R247A:

7. Condition A of R247A specifies that medicinal products used for vaccination or immunisation against COVID-19 or Influenza can only be supplied under a national protocol when a disease:

   "is, or is in anticipation of a disease being imminently; a pandemic, and a serious risk or potentially serious risk to human health."

8. Although COVID-19 related deaths and hospitalisations have declined, largely due to the continued effectiveness of vaccines and improved treatments, COVID-19 continues to be recognised as a pandemic, which has enabled the continued use of R247A to develop national protocols for the administration of COVID-19 and Influenza vaccines. However, it is not clear when COVID-19 might transition from pandemic to endemic status, and this uncertainty causes a significant risk for the NHS across the United Kingdom regarding appropriate workforce planning for future COVID-19 and Influenza vaccine programmes.

9. At present, R247A will continue to be used to deliver the 2023 autumn COVID-19 vaccination programme, however the uncertainty as to how long R247A can continue to be used causes a significant risk for the NHS in all four nations. If Condition A remains in place and COVID-19 is no longer considered a pandemic or serious risk to health, then there would be a significant impact on the availability of an appropriate workforce to deliver the vaccines.

10. Therefore, recognising that we have transitioned to living with COVID-19 and in anticipation of COVID-19 no longer being nationally and/or internationally considered a pandemic, DHSC is looking to amend R247A to remove Condition A from the regulation. This is to allow the continued use of the national protocol model for COVID-19 and Influenza vaccines outside of pandemic status for COVID-19.

11. This amendment to R247A will be time limited, to 1 April 2026, in recognition that this mechanism may not be the most appropriate model for the ongoing use of an expanded workforce outside of pandemic response. During the period in which this amended regulation will operate, it is expected that there will be fuller consideration, and potential introduction (where agreed to be beneficial and subject to consultation) of an alternative longer-term mechanism which can be deployed to better support the use of an extended vaccination workforce.

12. This impact assessment (IA) will consider the impact of an amendment to the HMR where Condition A of R247A would be removed. Under an approved protocol within a set period, there would be continued use of the expanded workforce legally and safely able to administer a COVID-19 and Influenza vaccination as the country transitions out of the pandemic. This would mean planned vaccination campaigns could be delivered efficiently, with minimal disruption to wider health care services.

13. In the week commencing 7August (as of 12th July 2023), the Department of Health and Social Care will launch a consultation to gather the views of stakeholders, organisations, and members of the public on the proposed amendment to R247A, as well as two other regulations of the HMR, detailed below. This will provide additional opportunity to gather evidence, which will inform a final stage impact assessment.

Proposal for other amendments of HMRs:

14. In autumn 2020, as well as the introduction of R247A, other temporary amendments were made to the HMRs to support the deployment of COVID-19 and Influenza vaccines. These amendments included Regulations 3A and 19.

15. Regulation 3A (R3A) allows for the final stage of the preparation of COVID-19 vaccine to be conducted by suitably qualified healthcare professionals without the need for manufacturing licences or marketing authorisations. The COVID-19 vaccinations are still not available as a pre-filled syringe, and as a result they continue to require preparation before administration to patients.

16. Regulation 19 (R19) allows COVID-19 and Influenza vaccines to be moved between premises at the end of the supply chain by providers operating under NHS arrangements and the medical services of His Majesty's Forces without the need for a wholesaler dealer's licence. The provisions enable the safe and appropriate vaccine movement between GP practices within a Primary Care Network (PCN) Grouping to support delivery of the NHS COVID-19 and Influenza vaccination programmes and provision in places where they could be used best and/or had the greatest need.

17. Unlike R247A, R3A and R19 are not affected by Condition A, meaning COVID-19 does not need to be considered a pandemic. However, both R3A and R19 have sunset provisions and will be repealed on 1 April 2024, unless extended.

18. It is proposed that R3A and R19 are extended until 1 April 2026 to preserve the existing flexibilities while planning for a longer-term solution continues. Aside from the time extension, R3A and R19 would not change in any other way. There is no direct cost associated with extending these two regulations.

19. Both amendments have brought significant operational benefits to the COVID-19 and Influenza vaccination programmes, as well as benefits to staff, patients and service users. R3A allows for preparation and assembly of a COVID-19 vaccine to be undertaken by or under the supervision of a doctor, nurse, or pharmacist, at any location, without precipitating the need for a manufacturer's licence or marketing authorisation. R19 removed the requirement for providers operating under NHS to hold a wholesaler dealer's licence when moving COVID-19 and Influenza vaccines between premises. In these ways, both regulations reduce pressures on other NHS services.

20. A time-limited extension of R3A and R19 is not considered explicitly in the analysis in this impact assessment. The extension will allow the operational flexibility described above to continue in the short term, while a longer-term solution is developed. If these regulations were to lapse, this would contribute to disruption in delivering the vaccine programme. Considered on their own, the extension of these regulations is not considered sufficient to warrant an impact assessment. However, both regulations work towards the same objectives as R247 and we anticipate that there would be considerable disbenefit if the regulations were to lapse, particularly in relation to the increased wastage of vaccine stocks and in the time required to prepare vaccines for administration.

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

21. This IA demonstrates the potential costs, benefits and risks averted by removing Condition A from R247A of the HMRs, to enable an expanded workforce to administer a COVID-19 or Influenza vaccine when COVID-19 is no longer considered to be a pandemic. There are not expected to be any direct cost impacts, but the benefits of the

vaccines themselves, in terms of the doses that are unable to be deployed (option 0), are factored in.

22. There is vast epidemiological uncertainty associated with the characteristics of a future COVID-19 pandemic. Furthermore, COVID-19 and Influenza have different vaccine uptakes therefore different models to illustrate the impact of an extended and expanded workforce to deliver the vaccines.

23. There is a high level of uncertainty when predicting the future of the COVID-19 and flu vaccination programmes and their delivery models at this point in time when they are both subject to regular policy review. Of the 33 million COVID booster jabs delivered between September 2021 and September 2022, over 5 million were delivered in mass vaccination centres, such as conference centres and sporting venues[4]. However, for the autumn 2023 vaccination campaigns, the NHS will be using mass vaccination centres to a much lesser extent. Instead, the NHS will be expanding their community pharmacy network, and are anticipating for the network of pharmacies delivering vaccinations to double in size. At present, we do not have reliable estimates of how the delivery model will be split. Eligibility for COVID-19 vaccines will be reviewed for a potential spring and autumn programme for the foreseeable future, and Influenza cohorts may not have fully settled as, for example, new Influenza vaccines may come to market.

24. This creates challenges when analysing the future costs and benefits of amending R247A.

25. The analysis should therefore be seen as an illustrative estimate, based upon a range of plausible scenarios that reflect the different degrees of disruption which could occur, using the most up-to-date COVID-19 and Influenza vaccination data available.

26. It is also plausible that there would be minimum or no disruption, in the event COVID-19 is not reclassified as an endemic before a new permanent workforce plan is in place to deliver vaccines without relying on Condition A.

27. We welcome comments on any of the assumptions and parameters used in this impact assessment via the public consultation, and we will review the responses to the consultation and incorporate new evidence where appropriate to produce the Final Stage Impact Assessment.

Description of options considered

28. The options considered are as follows:

29. Option 0 “Do nothing” – Condition A remains in R247A, reverting to ‘business as usual’ governance for COVID-19 and Influenza vaccine deployment. This would mean that health services can only use unregistered staff to administer vaccines whilst COVID-19 is considered a pandemic and serious risk to human health. R3A and R19 would lapse on 1 April 2024.

30. Option 1 – Remove Condition A of R247A and give R247A a sunset clause of 1 April 2026. This gives time for establishment of more permanent workforce solutions for the continued delivery of the COVID-19 and Influenza vaccination programmes, which sit outside of emergency powers. A time-limited amendment would ensure there is no disruption to upcoming vaccination programmes. In addition, R3A and R19 to be temporarily extended for a further two years until 1 April 2026.

[4] COVID-19-monthly-announced-vaccinations-8-September-2022.xlsx (live.com)

Other policy options

31. There has been consideration for whether the amendments should be temporarily extended or made permanent. At this stage, a permanent extension is not considered for any of the three amendments. R247A has advantages but is a pandemic-specific measure. R3A and R19 are not pandemic specific but a permanent extension may be controversial without an overall long-term strategy and time to make sure sufficient safeguards are in place.

32. Over the summer of 2021 DHSC held initial conversations with external stakeholders 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.

33. The upcoming consultation with the public will seek views on whether stakeholders agree with the current proposal of setting a two-year time limited period on the continued operation of these regulations, while longer-term, sustainable options are explored.

34. Once the consultation closes and responses have been analysed, officials will prepare a consultation response, to be shared with the updated Statutory Instrument and accompanying materials in mid-September, subject to minister approval. This timeline will ensure the NHS can plan for ongoing use of the non-registered workforce beyond the end of the calendar year.

35. During the period in which this amended regulation will operate, it is expected that there will fuller consideration, and the potential introduction (where agreed to be beneficial) of an alternative longer-term mechanism which can be deployed to better support the use of an extended vaccination workforce. It is expected these options will be informed by the recently published NHS Long Term Workforce Plan.

36. In the event R247A can no longer be used, the alternative mechanism for using unregistered staff requires patients to be reviewed by a prescribing professional who issues a written instruction for the vaccination, which means the vaccine can be administered by unregistered staff. This would require significantly increased input from prescribing professionals. This option has not been modelled.

Policy objective

37. The overarching policy objective is to enable the continued deployment of safe and effective COVID-19 and Influenza vaccines to the pace and scale required both now and in the future, whilst maintaining public safety. If the provisions provided for under R3A and R19 lapse (which will happen if we do nothing) and/or if the provisions in R247A are unable to be drawn on due to the ending of the pandemic, certain NHS vaccination activities would need to cease. This is likely to negatively impact on provision and uptake of these vaccinations.

38. The proposed amendments to R3A and R19 will allow for continued flexibility for vaccine administration and support collaboration across the system. The proposed amendment to R247A will ensure that the current workforce administering COVID-19 and Influenza vaccines under an approved national protocol may continue to do so in order to provide sufficient workforce as we transition out of a pandemic.

Summary and preferred option with description of implementation plan

39. All three amendments have been in place since the end of 2020. Sunset clauses are being extended or added to provide clarity to the NHS in all four nations as to how long the current arrangements will remain in place, to avoid future disruption.

40. There is no expected need for further experimentation, piloting or training due to the current arrangements already being in place and no foreseen changes to how the vaccinations are administered.

Amendments to R247A (expanding the vaccination workforce)

41. The eligible workforce for vaccinations was expanded to support the deployment of the COVID-19 and Influenza vaccination programmes. As the autumn COVID-19 booster vaccination programme takes place simultaneously with the Influenza winter vaccination programme , it is important to have a sufficient workforce to deliver both vaccine programmes effectively.

42. It is assumed that the amendments to HMRs have led to more vaccines being delivered and have made the deployment of vaccines faster. This is because more of the workforce are eligible to administer the vaccine, reducing the burden on the previous pool of vaccinators. This also reduces the impact of potential de-prioritisation of other healthcare services to allow time for vaccinations.

43. An expanded workforce eligible to administer the Influenza vaccine is still required. The continued use of this mechanism to enable optimisation of the expanded workforce is essential to ensure the NHS across the four nations can have certainty in their workforce plans, whilst maintaining capacity and flexibility during the transition out of the pandemic.

44. If the vaccine workforce amendment was unable to be drawn on due to the ending of the pandemic, only specific appropriate practitioners would be able to administer medicinal products used for vaccination against coronavirus or Influenza virus (of any type). R247A introduced that medicinal produced used for vaccination or immunisation against COVID-19 or Influenza can be supplied under a national protocol when a disease:

    "…is, or in anticipation of a disease being imminently (a) pandemic, and (b) a serious risk or potentially serious risk to human health."

    The protocol allows those who are registered health care professionals who cannot ordinarily administer medicines or vaccines without the input of a prescriber (such as nursing associates, pharmacy technicians, operating department practitioners) and non-registered healthcare workers (such as assistant practitioners, healthcare assistants or maternity support workers) to administer the COVID-19 and Influenza vaccines.

45. Extending the provision, and removing the requirement for there to be a pandemic, until 1 April 2026 would ensure the workforce needed for mass vaccination programmes remain available and prevent vaccines from being missed or delayed for health and social care staff, and the public. Therefore, the amendment supports the policy objective.

Amendments to R3A (easing final preparation)

46. An amendment to R3A was made to allow for the final stage of preparation of the COVID-19 vaccine to be carried out by suitably qualified healthcare professionals without the need for manufacturing licenses and marketing authorisations. COVID-19 vaccinations are not available as a pre-filled syringe and continue to require preparation before administration. R3A allows healthcare professionals to prepare and assemble

COVID-19 vaccines for patients, regardless of location or where the patients are registered.

47. Currently, the provision has a sunset provision of 1 April 2024. By extending the provision until 1 April 2026, NHS teams can use the skills and expertise of staff in appropriate areas more effectively, enabling safer systems of working, particularly at larger sites.

Amendments to R19 (wholesale dealing of vaccines)

48. R19 allows for COVID-19 and Influenza vaccines to be moved between premises at the end of the supply chain by providers operating under NHS arrangements or arrangements as part of the medical services of His Majesty's Forces. This enables safe and appropriate vaccine movement between GP practices in the same PCN grouping to support the delivery of the NHS COVID-19 and Influenza vaccination programmes and provision in places where they could be used best and/or had the greatest need.

49. Currently, the provision has a sunset provision of 1 April 2024. Should the provision lapse, the supply of COVID-19 and Influenza vaccines from one healthcare organisation to another is subject to having a wholesale dealer license. If organisations must return surplus COVID-19 and Influenza vaccines to a wholesaler before being redistributed to an organisation where there was demand, this could lead to delays and reduce access to vaccine.

50. By extending the provision until 1 April 2026, COVID-19 and Influenza vaccines can be transferred swiftly and safely, meeting patient needs and avoiding wastage.

Appraisal methodology

Summary

51. This IA presents an illustrative model of the costs and benefits associated with the amendment of R247A, where Condition A is removed. The ''Do Nothing'' Option 0 is modelled to have a disbenefit that is appraised below. The analysis explores the impact for upcoming COVID-19 autumn and spring vaccination campaigns, and upcoming Influenza winter campaigns.

52. There was an approximate 50:50 split in the time spent vaccinating in 2022 to 2023 between registered and unregistered workers responsible for the delivery of vaccinations in vaccination centres and hospital hubs in England. **We assume the end of the COVID-19 pandemic will be announced by the WHO before April 2026,** and at this point the unregistered workers will be unable to deploy vaccines. When this occurs, it reduces staff capacity to deploy vaccines to 50% of the 2022 to 2023 baseline.

53. We model the 50% loss of staff capacity to result in a reduction in the number of doses that can be delivered going forward (see paragraph 85). Some eligible individuals who would demand a COVID-19 or Influenza vaccine will no longer receive their vaccine.

54. In practice, NHS England may take compensatory actions to mitigate the impact of the WHO announcement. The shortfall in demand is therefore modelled to decline over time owing to NHS England's compensatory actions.

55. Under Option 0, the inability to fully meet vaccine demand will result in a loss of health benefits. These include QALYs monetised at £70,000, which would have been realised by preventing hospitalisations and deaths through vaccination. There are also NHS savings from prevented hospitalisations, some of which are foregone in Option 0. These

are also treated as a disbenefit of Option 0, i.e. a negative benefit, rather than a financial cost, to avoid the suggestion that Option 0 incurs a financial outlay.

56. Option 0 is known as the ‘do nothing’ or ‘business as usual’ option. It involves continuing with the current arrangements in place. Common practice in impact assessments, as outlined in the HMT Green Book, is for other options to be compared to Option 0. This means Option 0 is typically modelled to have zero costs and benefits. However, in this instance we have presented Option 0 as having a disbenefit, since in this scenario ‘business as usual’ is the option which will cause significant disruption once the WHO announces the end of the COVID-19 pandemic. This atypical approach enables decision makers to clearly see the additional costs and benefits of proceeding with ‘business as usual’.

57. The timing of when the WHO will make their announcement is unknown. Therefore, it is unknown which, if any, COVID-19 and Influenza vaccine campaigns will be affected going forward. Instead, we model six illustrative and plausible scenarios for when the WHO announcement is made. We then apply a likelihood to each scenario to calculate the expected disbenefit of Option 0 from July 2023 to April 2026.

58. Whilst Option 0 incurs a disbenefit, Option 1, of amending the regulations, is assumed to have zero monetised costs and benefits. This is on the basis that this option maintains staff capacity to ensure demand for vaccines is met. Therefore, the benefits of Option 1 are primarily in enabling government to achieve the benefits outlined in prior DHSC impact assessments. This appraisal approach avoids the misattribution and double counting of benefits between DHSC impact assessments.

59. We do not factor in any costs or benefits of changing the sunsetting of regulations 3A and 19. Unlike R247A, R3A and R19 are not affected by Condition A, meaning COVID-19 does not need to be considered a pandemic. However, both R3A and R19 have sunset provisions and will be repealed on 1 April 2024, unless extended. Aside from the time extension, R3A and R19 would not change in any other way. There is no direct cost associated with extending these two regulations. As a result, time-limited extension of R3A and R19 is not considered explicitly in the analysis in this impact assessment.

Assessment period

60. This analysis assesses over the period from July 2023 to 1 April 2026. This is on the basis that Option 1 has a sunset clause of 1 April 2026. If Option 1 is not accepted, we anticipate NHS England may resolve its COVID-19 and Influenza capacity challenges by 1 April 2026. NHS England is consequently modelled to fully meet demand for vaccine campaigns post 1 April 2026, that is for the COVID-19 spring 2026, autumn 2026 and Influenza winter 2026 campaigns.

61. This means there are potentially eight vaccine campaigns under scope of this analysis. They are:
    a. COVID-19 autumn 2023
    b. Influenza winter 2023
    c. COVID-19 spring 2024
    d. COVID-19 autumn 2024
    e. Influenza winter 2024
    f. COVID-19 spring 2025
    g. COVID-19 autumn 2025
    h. Influenza winter 2025

62. This analysis assumes that all of these campaigns will go forward, noting that the Joint Committee on Vaccination and Immunisation (JCVI) have not yet advised on eligible cohorts for these campaigns, apart from the Influenza winter 2023 campaign.

63. The benefits are based on hypothetical scenarios of varying plausible levels of outbreak of COVID-19 or Influenza on the population, and the number of vaccines which would be missed due to having a reduced workforce. The levels of outbreak considered are the same rates as 2022 to 2023. Outbreaks to the level seen at the earlier stages of the COVID-19 pandemic are not considered, as the focus of the impact assessment is the impact of the amendments where levels of COVID-19 are still not high enough to be considered a pandemic.

64. The possibility remains that there would be minimum or no disruption where COVID-19 remains to be considered a pandemic until 1 April 2026 or earlier, and a new workforce plan to deliver both vaccination programmes is created and implemented without the need for R247A to be amended. The timing and probability of outbreaks of COVID-19 and Influenza are unknown. Therefore, benefits are estimated to occur within one season of vaccination campaigns.

65. 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 and Influenza infections are estimated within a one-year time horizon.

Future demand for doses 2023 to 2026

66. The analysis compares future demand for COVID-19 and Influenza vaccine doses against the capacity NHS England has to deliver these doses.

67. Upcoming 2023 to 2026 demand for doses is based on 2022 to 2023 demand, from three completed vaccination programmes:
    a. Influenza 2022 winter programme for adults and pre-schoolers (including ‘at-risk’ of all ages but excluding ‘not-at-risk’ 50–64-year-olds and children aged 4-14).
    b. COVID-19 autumn 2022 booster campaign
    c. COVID-19 spring 2023 booster campaign.

68. Demand from these campaigns is then extended over the period from July 2023 to 1 April 2026.

Table 1: Future demand for doses 2023 to 2026.

Campaign	Eligible cohort size	Uptake %	Forecast Demand
COVID-19 autumn 2023	31.6m	64%	20.2m
Influenza winter 2023	20.9m	64%	13.4m
COVID-19 spring 2024	6.6m	69%	4.5m
COVID-19 autumn 2024	31.6m	64%	20.2m
Influenza winter 2024	20.9m	64%	13.4m
COVID-19 spring 2025	6.6m	69%	4.5m
COVID-19 autumn 2025	31.6m	64%	20.2m
Influenza winter 2025	20.9m	64%	13.4m

69. Table 1 shows the demand profile for vaccine doses over the next two years. Eligible cohort sizes and uptake are assumed to repeat across future vaccination campaigns over the next two years. This is because JCVI has not yet offered advice on who would be eligible for upcoming COVID-19 and Influenza campaigns.

70. Table 1 suggests approximately 38.2m COVID-19 and Influenza vaccine doses will be demanded annually from eligible individuals. Whether this demand can be met will depend on when the WHO makes their announcement, and how much capacity the system will retain.

71. The upcoming COVID-19 autumn 2023 booster programme is assumed to offer a booster dose to the same cohorts as autumn 2022, since JCVI advice on autumn 2023 has not yet been announced. Eligible cohorts are assumed to be individuals aged 50 and above; individuals in a clinical risk group; frontline health and social care workers; household contacts of people with immunosuppression; residents in a care home for older adults and staff working in care homes for older adults. Since the autumn 2023 programme has not commenced, uptake figures are based on uptake for the autumn 2022 programme. Eligible cohort sizes are based on the National Immunisation Management System (NIMS) data. Autumn 2023 uptake is based on autumn 2022 uptake from UKHSA's national Influenza and COVID-19 surveillance reports. We have utilised UKHSA data over NHS England data, on the basis that UKHSA data provides a more granular age breakdown. Doses delivered in autumn 2023 are assumed to repeat for upcoming COVID-19 autumn programmes from 2023 to 2026.

72. The upcoming COVID-19 spring 2024 booster programme is assumed to offer doses to the same cohorts as the spring 2023 programme. The spring 2023 booster programme offered a booster dose to adults aged 75 years and over; residents in a care home for older adults and individuals aged 5 years and over who are immunosuppressed. The number of spring 2023 doses delivered are from published NHS England data[5]. Doses delivered in spring 2023 are assumed to repeat for upcoming COVID-19 spring programmes from 2023 to 2026.

73. The upcoming Influenza programme of winter 2023 is to offer a vaccine to individuals aged 65 years and over, children aged 2 to under 4, people aged 6 months to under 49 years who are in an Influenza at-risk cohort, and pregnant women. Future Influenza demand is based on 2022 to 2023 Influenza vaccine uptake figures. These were sourced from UKHSA's seasonal Influenza vaccine uptake reports[6]. UKHSA data was used so that we could adjust cohort sizes and uptake figures to remove people aged 50 to 64 years, who may no longer be eligible for upcoming Influenza campaigns. We assume this on the basis that this was a one-off government decision. Children aged 4-14 are excluded based on Influenza vaccines being delivered in a school setting for this cohort, a delivery model which is well established, and where there is less reliance on R247a.

Staff capacity for vaccine doses

74. Demand for vaccination of 38.2m annual doses, modelled above, is compared to modelled staff capacity under Option 0.

75. From April 2022 to March 2023 (12 months of data), there was an approximate 50:50 full-time equivalent (FTE) split between the immuniser role (non-registered) and Band 5 role

[5] Weekly announced vaccinations 6 July 2023 https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/

[6] https://www.gov.uk/government/statistics/seasonal-influenza-vaccine-uptake-in-gp-patients-monthly-data-2022-to-2023

(registered worker). These are the two roles responsible for the delivery of vaccinations in vaccination centres and hospital hubs.

76. This data covers England only and does not cover all nations for which the regulations apply. In Scotland, 44% of the vaccination workforce are estimated to be unregistered healthcare workers. In Wales, 45% are unregistered workers, though in areas, at certain times, this can be as high as 75%. The scope of this IA is England only, with healthcare a devolved matter in the UK.

77. Knowing there is an approximate 50:50 split in the hours worked between the unregistered and registered healthcare workers in the 2022 to 2023 programmes, it is assumed that the annual proportion of unregistered and registered workers will remain the same in 2023 to 2026 under Option 1. Option 1 therefore has no monetised cost or benefit because with full staff capacity, the demand for vaccines can be fully met going forward.

78. The current 50:50 split between registered and unregistered workers means that under Option 0, the prohibition towards unregistered workers administering vaccines reduces staff capacity by 50% when the WHO makes their announcement. Without data on the productivity differential between registered and unregistered workers, we assume registered and unregistered workers are equally productive. NHS England's delivery approach may differ from autumn 2023, although indicative and unpublished NHS England analysis suggests that a 50% loss of staff capacity is still a reasonable assumption up to April 2026.

79. Future annual staff capacity is based on the doses delivered in the completed 2022 and 2023 vaccination campaigns. These are presented below in Table 2.

Table 2: Historical staff capacity 2022 to 2023

Campaign	Doses delivered
COVID-19 autumn 2022	20.2m
Influenza winter 2022	16.5m
COVID-19 spring 2023	4.5m
Total	41.3m

80. For the COVID-19 autumn 2022 booster programme, a booster dose was offered to: individuals aged 50 and above; individuals in a clinical risk group; frontline health and social care workers; household contacts of people with immunosuppression; residents in a care home for older adults and staff working in care homes for older adults. Total uptake figures for the COVID-19 autumn 2022 programme were retrieved from published NHS England operational data[7] and include any vaccination with a dose number greater than or equal to 3, delivered in England on or after 5 September 2022. NHS England data has been used over published UKHSA data on the basis that UKHSA data does not include total uptake including eligible individuals below 50 years old who are at-risk.

81. For the COVID-19 spring 2023 booster programme a booster dose was offered to: adults aged 75 years and over; residents in a care home for older adults and individuals aged 5 years and over who are immunosuppressed. The number of spring doses delivered are taken from UKHSA's national Influenza and COVID-19 surveillance reports.

82. For the Influenza winter 2022 programme, a vaccine was offered to: individuals aged 50 years and over, children aged 2 to 3, school children aged 4-14, people aged 6 months

[7] Link to NHS E data

to under 49 years who are in an Influenza at-risk cohort, and pregnant women. 50 to 64-year-olds who are not in an Influenza at-risk cohort were eligible in 2022 and therefore included in this figure. Influenza vaccine uptake figures were sourced from UKHSA's seasonal Influenza vaccine uptake reports. In Table 2, school children aged 4-14 are excluded from this uptake figure because the Influenza vaccine tends to be administered in a school setting for this cohort and therefore may be less affected or unaffected under Option 0.

83. Table 2 shows that 41.3m doses were delivered in the three COVID-19 and Influenza vaccination campaigns from 2022 to 2023. We assume this represented the English vaccination workforce at full capacity. This means that with 100% staff capacity, 41.3m doses can be delivered annually in future COVID-19 and Influenza vaccination campaigns. This capacity exceeds the annual demand of 38.2m doses, from Table 1 above. In other words, supply can fully meet vaccine demand. Vaccinating all eligible individuals who come forward is only feasible under Option 1.

Staff capacity for vaccine doses when the WHO announcement is made

84. Under Option 0, when the WHO announcement is made, 50% of staff capacity is lost. This means only 50% of the total 41.3m annual doses can be delivered. This is a value of 20.6m doses.

85. This 20.6m annual staff capacity for COVID-19 and Influenza doses falls short of annual demand of 38.2m doses. There is a shortfall of 17.6m doses, whereby 17.6m eligible individuals who demand a vaccine, are unable to receive a vaccine. Equivalently, in percentage terms, this is a shortfall of approximately 45% in the number of doses delivered.

86. This means under Option 0, with 50% staff capacity, 45% of the 38.2m annual doses demanded cannot be met. Without any mitigating actions, 45% of eligible individuals who demand a vaccine may not receive one.

Adjustment for compensatory actions by NHS England

87. In practice, under Option 0, NHS England are likely to make compensatory actions to mitigate the shortfall of doses delivered. This could include utilising more registered staff, increasing the frequency of vaccine appointments and more. The exact compensatory actions are currently unknown but modelled to mitigate the 45% shortfall of doses delivered. We do not model compensatory actions incurring an additional financial cost in this consultation IA.

88. In the baseline scenario we model the compensatory actions as such:
    a. In 2023, we assume there is insufficient time to implement any effective compensatory actions. Therefore, there is no mitigation and 45% of demand would be unmet.
    b. In 2024, we assume NHS England's compensatory actions mitigate the shortfall by 33%. Put another way, a smaller 30% of COVID-19 and Influenza vaccine demand would be unmet.
    c. In 2025, NHS England make further actions which mitigate the shortfall by 67%. Consequently, 15% of vaccine demand would be unmet.

89. This is summarised below in Table 3. These percentages are unevidenced estimates, noting NHS England has not yet analysed compensatory actions and their impact. Engagement with NHS England colleagues suggest this is a reasonable approach.

Table 3: Impact of compensating actions by NHS England

	2023	2024	2025
Campaigns	N/A	COVID-19 spring 2024	COVID-19 spring 2025
	COVID-19 autumn 2023	COVID-19 autumn 2024	COVID-19 autumn 2025
	Influenza winter 2023	Influenza winter 2024	Influenza winter 2025
Compensatory action impact by NHS E	0%	33%	67%
Unmet demand[8]	45%	30%	15%

90. Unmet demand proportionately reduces the health benefits of vaccination. This means under Option 0 In 2023, 45% unmet demand results in 45% of the health benefits from COVID-19 and Influenza vaccinations being foregone. This reduces to 30% and 15% of health benefits foregone in 2024 and 2025 respectively.

Benefits realisable with full staff capacity 2023 to 2026

91. To determine the quantified amount of benefits foregone, we must first determine the current forecasted benefits of the upcoming COVID-19 and Influenza vaccine campaigns. The monetised benefits of upcoming COVID-19 and Influenza campaigns are presented below in Table 4. These benefits are only feasible under Option 1, with full staff capacity, where supply meets demand.

Table 4: Benefits feasible with full staff capacity 2023 to 2026.

Year	Campaign	Averted hospitalisations	Averted deaths	Benefits (discounted)
2023	COVID-19 autumn 2023	15,900	4,100	£ 2,940m
	Influenza winter 2023	5,900	1,200	
2024	COVID-19 spring 2024	12,600	3,700	£ 3,850m
	COVID-19 autumn 2024	15,900	4,100	
	Influenza winter 2024	5,900	1,200	
2025	COVID-19 spring 2025	12,600	3,700	£ 3,720m
	COVID-19 autumn 2025	15,900	4,100	

[8] For 2024, calculated by (100%-33%) *45% = 30%; in 2025 calculated by (100%-67%)*45%= 15%

	Influenza winter 2025	5,900	1,200	
Total		90,800	23,400	£ 10,500m

Numbers may not sum due to rounding

92. Monetised benefits for upcoming COVID-19 autumn vaccination campaigns are based on a DHSC COVID-19 autumn model. The benefits of this campaign consist of QALYs monetised at £70,000 per QALY, and savings to the NHS from averted hospitalisations. These QALYs benefit the vaccinated individual who would no longer suffer from the adverse mortality and morbidity impacts of a COVID-19 infection. Additionally, preventing hospitalisations due to COVID-19 avoid NHS England expenditure on treating COVID-19 patients, saving money for the NHS. The QALY benefits and NHS savings are summed to determine total benefits. Modelling is adjusted to ensure it reflects benefits primarily due to COVID-19 hospitalisations and deaths, rather than incidental hospitalisations and deaths.

93. The COVID-19 spring 2024 benefits remodels the COVID-19 autumn model for the smaller eligible cohort size in the spring programme.

94. Influenza benefits are based on analysis by Baguelin et al. (2015) ‘‘Extending the elderly- and risk-group programme of vaccination against seasonal Influenza in England and Wales: a cost-effectiveness study[9]'. JCVI used this modelling as the basis for its advice on eligible cohorts for Influenza vaccination. This recommendation still applies to the winter 2023 cohorts as set out by the National flu immunisation programme 2023 to 2024 letter[10].

95. The Influenza programme in general practice (65 years and over, at risk, pregnant women, and 2-to 3-year-olds) is estimated to prevent mortality and morbidity impacts from Influenza, measured in QALYs monetised at £70,000 per QALY. Additionally, by preventing Influenza hospitalisations and corresponding expenditure on these patients, the programme is expected to save money for the NHS.

96. We assume upcoming vaccine campaigns retain the same benefits as historical campaigns. For example, the undiscounted benefits of the COVID-19 autumn 2024 campaign are the same as in the COVID-19 autumn 2023 campaign. This is on the basis that future epidemiology is uncertain and therefore we assume that with the same cohort size and uptake, the same benefits are realisable. This means we do not model, nor account for, COVID-19 and/or Influenza becoming more or less severe over time. Rather, COVID-19 and Influenza impose the same health burden over time as they did from 2022 to 2023.

97. These are the standard health benefits appraised in DHSC vaccine IAs and aligned with the JCVI cost-effectiveness methodology, outlined in its 2013 Code of Practice[11]. The clinical outcome measures assessed relate to impacts of the vaccine on mortality and morbidity, typically measured in quality of life (QoL) and adjusted by the duration of the

[9] Extending the elderly- and risk-group programme of vaccination against seasonal influenza in England and Wales: a cost-effectiveness study | SpringerLink

[10] https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/national-flu-immunisation-programme-2023-to-2024-letter

[11] Link to JCVI Code of Practice 2013

outcome to determine quality adjusted life years (QALYs). One QALY represents a year of perfect health, and QALYs are valued equally. That is, they are not weighted depending on to whom they accrue. By measuring the difference in the health and life expectancy, from those who suffer the illness and those who do not, we can estimate the QALYs gained from vaccination. QALYs are used as a standardised measure to compare the severity of different diseases and the benefits of health interventions.

98. QALYs are then valued at £70,000 per QALY. This is the monetary willingness-to-pay of a QALY, known as the societal value of a QALY. It is the value recommended by HMT's Green Book[12]. This value is based on Department for Transport and academic analysis of the value of a prevented fatality in a road traffic accident. The value has since been inflated to 2020/2021 prices and rounded to £70,000 by government.

99. Wider economic and societal impacts are not considered as part of the modelling, though it is expected that a higher proportion of the population-in-need being vaccinated would have a substantial benefit.

100. Since the benefits of upcoming vaccination campaigns occur further ahead in time, their monetised benefits are discounted. For example, the COVID-19 autumn 2024 vaccination programme is assumed to have the same monetised benefits as the COVID-19 autumn 2023 programme. However, since the 2024 campaign's benefits occur one year ahead, the 2024 campaign's benefits are discounted.

101. Discounting is applied to future costs and benefits to convert them into a present value. This is important because costs and benefits can occur at different points in the future, and therefore discounting enables a fair comparison of costs and benefits. A discount rate of 3.5% is used. This rate differs from the 1.5% discount rate used for health appraisals that DHSC applies to most health interventions when following standard evaluation methods, in line with HMT Green Book's recommendations. The 3.5% discount rate has been used out of necessity because published benefits of the Influenza vaccine were discounted at 3.5%, and the breakdown of benefits by year is not available to re-calculate it with a different discount rate.

102. Further information on discounting can be found in HMT's Green Book, Annex A6.

103. This analysis does not factor in the deployment nor purchase cost of COVID-19 and Influenza vaccines. This is because these costs have been assessed in prior impact assessments. Further, there is uncertainty over to what extent these costs are recoverable in the event of the loss of staff capacity. Therefore, the analysis here is restricted to the gross discounted benefits of vaccination.

Timing scenarios

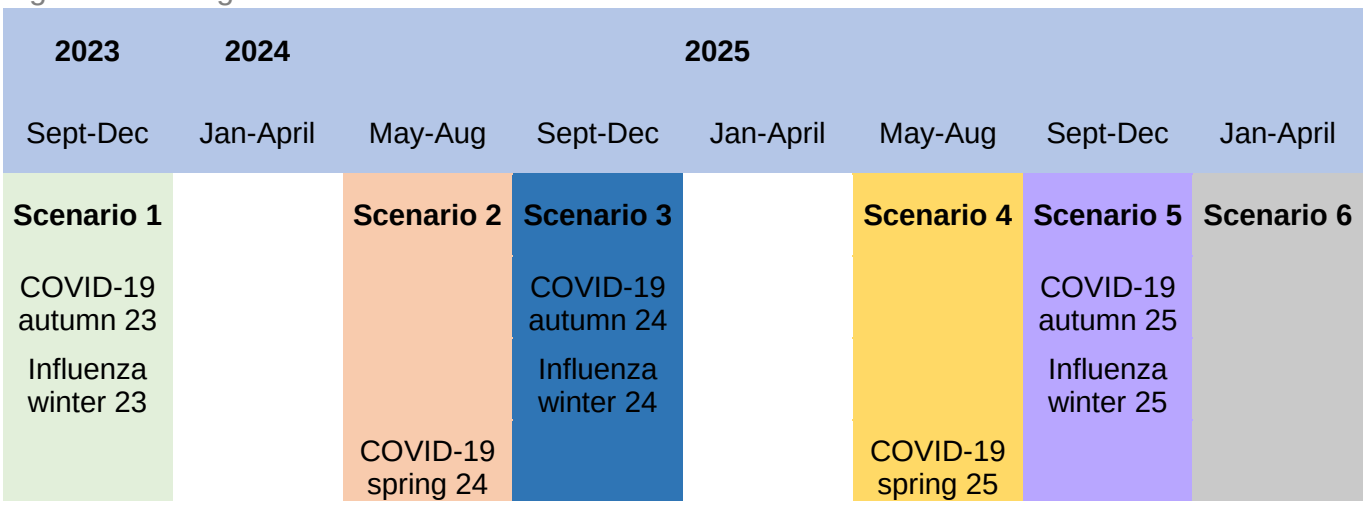
104. Based on Table 4 above, a total of approximately £11 billion of health benefits could be realised under Option 1 from July 2023 to April 2026. Under Option 0, lower staff capacity will mean only a proportion of the £11 billion of health benefits can be realised. Some health benefits will be foregone.

[12] A1.64, page 87
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063330/Green_Book_2022.pdf

105. This disbenefit of Option 0 depends on when then WHO makes their announcement. When this occurs, as modelled in Table 3, 45% of the health benefits are foregone in 2023, declining to 30% and 15% of benefits foregone in 2024 and 2025 respectively. For simplicity we assume there is no time lag between when the WHO announcement occurs and the prohibition of using the unregistered workforce.

106. However, there is uncertainty over when the WHO will announce the end of the COVID-19 pandemic. Without knowing when this announcement will occur, we model six discrete timing scenarios shown below in Figure 1.

Figure 1: Timing of WHO announcement.



107. The timing of the WHO announcement will therefore determine which vaccination campaigns are affected going forward.

108. For example, if the WHO announcement is in May-Aug 2024, we are in Scenario 2. Here we model six vaccination campaigns being affected going forward. These six affected campaigns, up to April 2026, would be:

a. COVID-19 spring 2024
b. COVID-19 autumn 2024
c. Influenza winter 2024
d. COVID-19 spring 2025
e. COVID-19 autumn 2025
f. Influenza winter 2025

109. For these six campaigns, under Option 0 there is 50% lower staff capacity than otherwise. For vaccine campaigns in 2024, this is modelled to result in 30% of individuals being unable to receive their vaccine because staff supply is unable to meet demand. The impact is assumed to fall on the average eligible individual. This therefore leads to 30% of health benefits foregone from 2024 campaigns under Option 0. For vaccine campaigns in 2025, 15% of individuals are unable to receive their vaccine and hence 15% of the health benefits from 2025 campaigns are foregone. In other words, the COVID-19 spring and autumn 2024 campaigns and Influenza winter 2024 campaign forego 30% of their benefits. In 2025, under Scenario 2, the COVID-19 spring and autumn 2025 campaigns and Influenza winter 2025 campaign forego 15% of their benefits.

110. In Scenario 2, since the announcement occurs after the COVID-19 2023 and Influenza winter 2023 campaigns, these campaigns are unaffected. Full staff capacity, of registered and unregistered workers, is available to meet 100% of the demand for vaccines in these campaigns. Hence, these two campaigns are unaffected, and no benefits are foregone for them.

111. Figure 2 presents the six scenarios of WHO timing and their impact of the COVID-19 and Influenza vaccination campaigns going forwards. The colour coding in Figure 2 corresponds to the colour coding in Figure 1. As the timing of the announcement moves further ahead in future, the scenario number increases, and fewer vaccination campaigns are affected.

Figure 2: Scenarios of the different timings the WHO announcement is made.

	Scenario 1	**Scenario 2**	**Scenario 3**	**Scenario 4**	**Scenario 5**	**Scenario 6**
When announcement occurs (50% drop in staff capacity)	Announcement before autumn 2023 programme commences	Announcement after autumn 23 campaigns have finished	Announcement after spring 24 campaigns complete	Announcement after autumn 24 campaigns complete	Announcement after spring 25 campaigns complete	Announcement after autumn/winter 25 campaigns complete
Affected campaigns (for these, with 50% capacity, some health benefits are foregone)	All -COVID-19 autumn 23 -Influenza winter 23 -COVID-19 spring 24 -COVID-19 autumn 24 -Influenza winter 24 -COVID-19 spring 25 -COVID-19 autumn 25 -Influenza winter 25	-COVID-19 spring 24 -COVID-19 autumn 24 -Influenza winter 24 -COVID-19 spring 25 -COVID-19 autumn 25 -Influenza winter 25	-COVID-19 autumn 24 -Influenza winter 24 -COVID-19 spring 25 -COVID-19 autumn 25 -Influenza winter 25	-COVID-19 spring 25 -COVID-19 autumn 25 -Influenza winter 25	-COVID-19 autumn 25 -Influenza winter 25	No campaign affected at all
Unaffected campaigns (100% benefits retained because WHO announcement was after these campaigns completed)	None- all affected until April 2026	-COVID-19 autumn 23 -Influenza winter 23	-COVID-19 autumn 23 -Influenza winter 23 -COVID-19 spring 24	-COVID-19 autumn 23 -Influenza winter 23 -COVID-19 spring 24 -COVID-19 autumn 24 -Influenza winter 24	-COVID-19 autumn 23 -Influenza winter 23 -COVID-19 spring 24 -COVID-19 autumn 24 -Influenza winter 24 -COVID-19 spring 25	-COVID-19 autumn 23 -Influenza winter 23 -COVID-19 spring 24 -COVID-19 autumn 24 -Influenza winter 24 -COVID-19 spring 25 -COVID-19 autumn 25 -Influenza winter 25

Option 0 cost modelling: loss of benefits from 2023-2026

112. Using the six scenarios from Figure 2 above, we model the foregone health benefits under Option 0 from July 2023 to April 2026. The percentage of benefits foregone is based on Table 3 above, reflecting the baseline assumptions about compensatory actions by NHS England. The health benefits with full capacity are taken from Table 4 above.

Table 5: Loss of benefits for Scenario 1-6.

			Scenario 1		Scenario 2		Scenario 3		Scenario 4		Scenario 5		Scenario 6	
Year	Campaign	Benefits realisable with full capacity	Benefits foregone	Disbenefit	Benefits foregone	Disbenefit	Benefits foregone	Disbenefit	Benefits foregone	Disbenefit	Benefits foregone	Disbenefit	Benefits foregone	Disbenefit
2023	COVID-19 autumn	£ 2940m	45%	£ 1320m	0%	£ 0m	0%	£ 0m	0%	£ 0m	0%	£ 0m	0%	£ 0m
	Influenza winter		45%		0%		0%		0%		0%		0%	
2024	COVID-19 spring	£ 3850m	30%	£ 1150m	30%	£ 1150m	0%	£ 850m	0%	£ 0m	0%	£ 0m	0%	£ 0m
	COVID-19 autumn		30%		30%		30%		0%		0%		0%	
	Influenza winter		30%		30%		30%		0%		0%		0%	
2025	COVID-19 spring	£ 3720m	15%	£ 560m	15%	£ 560m	15%	£ 560m	15%	£ 560m	0%	£ 410m	0%	£ 0m
	COVID-19 autumn		15%		15%		15%		15%		15%		0%	
	Influenza winter		15%		15%		15%		15%		15%		0%	
Total		**£10,500m**	**£ 3030m**		**£ 1710m**		**£ 1410m**		**£ 560m**		**£ 410m**		**£ 0m**	

Numbers may not sum due to rounding

113. The quantity of benefits lost will depend on when WHO makes the endemic announcement and the number of campaigns remaining between the announcement date and 1 April 2026. Each scenario models a potential timepoint when the WHO announces COVID-19 as endemic between July 2023 and April 2026. For each scenario, when the WHO makes their announcement, 15% to 45% of total health benefits are foregone. This is reflected as a disbenefit.

114. Table 6 below summarises the bottom row results in Table 5. The increased hospitalisations and deaths form the disbenefit. As the WHO announcement is delayed further ahead in time, the foregone benefits of Option 0 decline. As the converse, the earlier the WHO make an announcement, the greater the negative impact of Option 0. For example, in Scenario 1, where the WHO make an announcement before autumn 2023, all eight upcoming COVID-19 and Influenza campaigns will forego health benefits under Option 0, totalling a disbenefit of £3030m.

Table 6: Summary of Scenarios 1-6.

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6
Monetised Disbenefit	£ 3,030m	£ 1,710m	£ 1,410m	£ 560m	£ 410m	£ 0m
Increased hospitalisations	40,800	31,000	25,300	15,500	9,800	0
Increased deaths	10,500	8,100	6,500	4,100	2,400	0

Likelihood of each scenario

115. The modelling above develops six scenarios. There is uncertainty over when the WHO will make their announcement and therefore all scenarios are considered plausible. However, they are not all equally likely to occur. It is possible to assign probabilities to each scenario occurring. These are presented in Table 7 below.

116. The likelihoods of each scenario are unevidenced estimates based on current COVID-19 and Influenza epidemiology and a consideration of the impacts the infectious diseases continue to have. Our estimate is that the WHO are likely to make an announcement earlier on, before the NHS has the ability to reconsider its strategy for the vaccine workforce. These probabilities are tested in the sensitivity analysis below.

Table 7: Likelihood of each scenario.

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6
When announcement occurs (50% drop in staff capacity)	Announcement before autumn 2023 programme commences	Announcement after autumn/winter 23 campaigns have finished	Announcement after spring 24 campaigns complete	Announcement after autumn/winter 24 campaigns complete	Announcement after spring 25 campaigns complete	Announcement after autumn/winter 25 campaigns complete
Likelihood of scenario	20%	50%	15%	10%	3%	2%

Expected Value

117. The probabilities in Table 7 are applied to the disbenefit values in Table 6. This is to determine the total expected value of Option 0. We expect that Option 0 will result in a total expected disbenefit, of approximately £1,740 million over 2023-2026. This expected value accounts for the uncertainty of when the WHO will make their announcement, through the use of probabilities. Option 0 is expected to result in approximately 29,300 more hospitalisations and 7,600 more deaths up to April 2026, compared to Option 1.

Table 8: expected disbenefit of Option 0

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6	Total Expected value
Likelihood	20%	50%	15%	10%	3%	2%	**100%**

Expected Disbenefit	£ 610m	£ 860m	£ 210m	£ 60m	£ 10m	£ 0m	£ 1,740m
Expected Increased hospitalisations	8,200	15,500	3,800	1,600	300	0	29,300
Expected Increased deaths	2,100	4,100	1,000	400	100	0	7,600

Numbers may not sum due to rounding

Option 0 Results

Option 0 monetised benefits

118. As shown in Table 8 above, Option 0 has an expected monetised benefit of -£1,740 million up to April 2026. This is referred to as an expected disbenefit of £1,740m. This disbenefit consists of foregone health benefits, from averted mortality and morbidity, and foregone NHS savings from averted hospitalisations.

Option 0 non-monetised benefits

119. With fewer vaccines deployed, Option 0 may result in a lower total cost of deployment through avoiding payment of the item of service fee. This fee of £10.06 is paid for each dose of a COVID-19 and Influenza vaccine. Owing to uncertainty over the timing of WHO's announcement and whether deployment savings are recoverable, we do not model a saving. Any saving will be greatly outweighed by the loss of health benefits under Option 0.

Option 0 monetised costs

120. Option 0 does not have any monetised costs.

Option 0 non-monetised costs

121. The primary non-monetised cost is the opportunity cost of requiring additional time from the registered workforce to mitigate the impact of the WHO announcement. NHS England may need the current registered workforce to commit more time to vaccination and/or increase the size of the registered workforce. As a result, other forms of healthcare may be displaced when staff resource is redirected to vaccination. Health outcomes may then worsen elsewhere in the healthcare system. This is currently an unquantified opportunity cost, given the uncertainty over how NHS England may respond.

122. R247A enables the flexibility for the vaccination workforce to provide more bespoke services which target smaller groups. Through outreach vaccination services, which are usually made up of unregistered healthcare workers, the workforce has previously been able to increase uptake particularly for those in deprived communities where ethnic minority groups tend to be concentrated.

123. Registered healthcare workers would not make up the shortfall to continue the outreach work. As a result, the NHS would be more limited in being able to increase

uptake in groups where current uptake is low, particularly for underserved and marginalised groups, or groups where vaccine hesitancy may be stronger. This means some groups, with protected characteristics, may face a disproportionate impact under Option 0.

124. Retaining use of the extended workforce allows the vaccinations to be deployed in time before expiry. If Condition A lapses there will be an additional cost to safely dispose of excess vaccines. Alternatively, if the policy decision was made to extend the vaccination programme to use up the excess vaccines, there would be an associated cost of storing the vaccines.

125. The duration of the vaccination campaign is assumed to be unchanged under Option 0 and 1, and we assume once the campaign is over, the unregistered workforce will then return to other duties. Scenarios where the vaccination programme would run for a longer period are possible, but this cost has not been monetised in this impact assessment on the basis of this scenario's uncertainty.

Option 0 net present value

126. The net present value (NPV) for Option 0 has been calculated by subtracting the costs from the benefits. With no monetised costs, Option 0 results in a NPV of -£1,740 million from July 2023 to 1 April 2026.

Option 1 Results

Option 1 monetised benefits

127. This option is assumed to have no monetised benefits. Instead, this option will enable government to realise the benefits of vaccination that have been appraised in prior DHSC impact assessments for the COVID-19 and Influenza campaigns.

Option 1 non-monetised benefits

128. Since the vaccination programme began and the HMR amendments came into effect, the NHS in England has recruited almost 55,000 unregistered paid staff and 28,000 of these have been retained into wider careers across the health and social care sector. This has helped create a new workforce which has been important for closing vacancy gaps elsewhere in the sector. If there is a continued cycle of staff being recruited for the vaccination campaigns and then going on to fill in gaps across the sector, this will bring operational benefits for the NHS.

Option 1 monetised costs

129. This IA does not appraise the cost of using COVID-19 or Influenza vaccines, nor procuring the vaccines themselves. These costs have already been assessed and accounted for in prior DHSC impact assessments. Instead, the focus is on the costs of facilitating mass deployment. In this illustrative scenario, we assume there to be no additional costs. We assume no training costs as the expanded workforce has already been trained.

Option 1 non-monetised costs

130. Given the large, unregistered workforce that has been employed to achieve the faster rollout, there could be an opportunity cost on other areas in the healthcare system where the unregistered workers may be required. There is the potential that these sectors will continue to have fewer unregistered workers, which will go on to impact the efficiency of healthcare services.

Option 1 net present value

131. Option 1 has an NPV of £0 up to 1 April 2026.

Sensitivity analysis for Option 0

132. It is not possible to estimate any future wave of COVID-19 or Influenza with any certainty, given uncertainties on the rate of infection, disease severity and for COVID-19, the extent of non-pharmaceutical interventions implemented by the government.

133. Since the analysis models up to April 2026, and models six scenarios, we do not model a low/high scenario of COVID-19 and Influenza incidence and/or severity. A high incidence and/or severity of COVID-19 would decrease the likelihood of an early WHO announcement. Instead, we model sensitivities for when the WHO are to make their announcement, and sensitivity on how the loss of staff capacity affects the deployment of doses.

Sensitivity A: likelihood changes

134. In Table 9 below, we change the baseline likelihood assumptions on when the WHO will make their announcement. The current baseline estimate is an expected disbenefit of £1,740m.

135. We model three further likelihood scenarios:

a. If the WHO make the announcement immediately, that is before the autumn 2023 campaigns can commence, the expected disbenefit of Option 0 is £920m. In other words, Option 0 results in £3,030m of benefits being foregone.
b. If the WHO make an earlier than expected announcement, the expected disbenefit of Option 0 is £2,340m.
c. If the WHO make a later than expected announcement, the expected disbenefit of Option 0 is £1,120m.

Table 9: Sensitivity A modelling.

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5	Scenario 6	Expected Disbenefit
When announcement occurs (50% drop in staff capacity)	Announcement before autumn 2023 programme commences	Announcement after autumn 23 campaigns have finished	Announcement after spring 24 campaign complete	Announcement after autumn 24 campaigns complete	Announcement after spring 25 campaign complete	Announcement after autumn/winter 25 campaigns complete	

Baseline likelihood of scenario	20%	50%	15%	10%	3%	2%	**£1,740m**
Immediate	100%	0%	0%	0%	0%	0%	**£3,030m**
Earlier WHO announcement	50%	40%	10%	0%	0%	0%	**£2,340m**
Later WHO announcement	5%	15%	40%	20%	10%	10%	**£1,120m**

136. This sensitivity analysis shows that there is a significant change in the expected disbenefit of Option 0, depending on when the WHO makes an announcement. Nevertheless, each sensitivity shows that Option 0 results in a significant disbenefit up to April 2026.

Sensitivity B: compensatory response impact

137. The loss of the unregistered workforce (who constitute 50% of the total workforce) would lead to a reduction of staff capacity by 50%. The analysis above models this to mean the number of doses that could be deployed would fall between 15% to 45% and therefore the benefits of vaccination would fall equivalently.

138. In this sensitivity, we change this assumption from Table 3. We model a smaller and greater compensatory response, shown in Table 10 below.

Table 10: Sensitivity B modelling.

Sensitivity approach		**2023**	**2024**	**2025**
	Campaigns		COVID-19 spring 2024	COVID-19 spring 2025
		COVID-19 autumn 2023	COVID-19 autumn 2024	COVID-19 autumn 2025
		Influenza winter 2023	Influenza winter 2024	Influenza winter 2025
Baseline	**Compensatory response impact**	0%	33%	67%
	Benefits foregone	45%	30%	15%
No compensatory response	**Compensatory response impact**	0%	0%	0%
	Benefits foregone	45%	45%	45%
Smaller compensatory response	**Compensatory response impact**	0%	15%	30%
	Benefits foregone	45%	38%	32%

Greater compensatory response	**Compensatory response impact**	25%	50%	75%
	Benefits foregone	34%	17%	8%

139. In this sensitivity analysis, we retain the baseline likelihood assumptions from Table 7. Instead, we evaluate the expected value. These results are presented in Table 11 below.

Table 11: Sensitivity B results.

Assumption: benefits foregone with 50% fewer staff	Expected value of benefits foregone
Baseline	£1,740m
No compensatory response	£3,300m
Smaller compensatory response	£2,600m
Greater compensatory response	£1,030m

140. Table 11 highlights the uncertainty in the impact of Option 0. There is a wide range of foregone benefits due to uncertainty in the extent to which NHS England can mitigate the impact of the prohibition of the unregistered workforce in administering vaccines.

Summary of analysis

141. Analysis shows that Option 0 will result in some health benefits of upcoming COVID-19 and Influenza vaccination campaigns no longer being realisable. The shortfall of capacity means some eligible individuals would be unable to receive a vaccine dose that they demand. Overall, we estimate £1,740m of health benefits foregone from July 2023 to April 2026.

Direct costs and benefits to business calculations

142. There is no direct regulatory benefit or burden associated with this policy. There is a possibility of indirect costs to businesses, due to the pressure which may be placed on pharmacists to deliver the vaccines, without the support of pharmacy technicians.

143. The consultation with the general public will provide the opportunity for the Department to understand if there are any other costs or benefits we have not yet considered, which can be incorporated into the final impact assessment.

Risks and assumptions

Assumptions made in the modelling:

144. There have been changes in the vaccine delivery model from the 2022 to 2023 vaccination campaigns to the 2023 to 2024 campaign. Previously, as well as being delivered in hospital hubs and pharmacies, a significant number of vaccines were

delivered in mass vaccination centres (large scale venues, such as conference centres or sporting venues). These mass vaccination centres are being significantly scaled back and for 2023 to 2024, the community pharmacy network is being expanded and expected to double in size for the autumn vaccination programme. Despite these changes, we have made three assumptions:

a. *The change in vaccine delivery model will not impact the uptake of vaccines.*
b. *We assume a 50% reduction in staff capacity when the WHO announcement occurs, up to April 2026. This assumption is supported by indicative and unpublished NHS England analysis on changes to the vaccine delivery approach.*
c. *Secondly, as the data is not available on whether unregistered workers are more likely to be used in mass vaccination centres, we have assumed there will be the same proportion (50:50 split) of registered and unregistered healthcare workers across each setting covered by the new delivery model, such as community pharmacies.*
d. *The same proportion of both COVID-19 and Influenza vaccines would be missed if Condition A of R247A remains.*

145. JCVI is yet to make an official announcement on which cohorts would be eligible for future COVID-19 and Influenza vaccination campaigns.

a. *We have assumed that the same cohorts that are eligible in the 2023 COVID-19 spring and 2022 autumn, and Influenza winter 2022 campaigns would be offered the vaccine in future campaigns, with the same level of benefits accruing from the vaccination campaign. For Influenza, we have excluded individuals aged 50-64 from eligible future Influenza cohorts because they were included in the 2022 to 2023 vaccination campaign as a one-off cohort.*
b. *Vaccine uptake rates are assumed to be the same as in 2022 to 2023 for future campaigns.*

146. Outbreaks to the level seen at the earlier stages of the COVID-19 pandemic have not been considered. Although future COVID-19 and Influenza variants may be different than the current variant in circulation, for simplicity in the modelling we assume:

a. *Future (undiscounted) benefits of vaccination are the same as the 2022 to 2023 campaigns*

147. Due to the complexity and uncertainty involved, the modelling assumes that any impact of disruption under Option 0 would equally affect each of the eligible cohorts in every campaign. We assume:

a. *There would be no reprioritisation of eligibility or vaccine access. This means the estimates of impact of Option 0 are based on average impact per person missing a vaccination, rather than singling out cohorts to miss out on vaccination. Therefore, the loss of benefits has been averaged over the entire eligible cohort. Although some cohorts may have a disproportionately higher risk from COVID-19 or Influenza and therefore face greater loss of health from the disruption.*

148. In practice, it is likely that the loss of the unregistered workforce will impact harder-to-reach communities as the unregistered workforce are responsible for completing much of the outreach work. Whilst this is a very pertinent point, for the purpose of the modelling this was felt to be too complex to incorporate into the model.

a. *Any disruption to the vaccination programme, impacts the entire vaccination cohort equally, and that there is no time for reprioritisation of who should be vaccinated. This means the impact of the reduced workforce is for the 'average' adult who is eligible for either of the vaccinations, rather than a specific community which is harder-to-reach.*

149. The nasal Influenza vaccine which children receive is not licensed for adults and the workforce is separate. The nasal Influenza vaccination programme is delivered by an NHS commissioned school aged immunisation service team, with appropriate qualifications and training, including safeguarding training.

   a. *Under the economic model in this IA, the Influenza vaccination programme for children in school (aged 4 to 14 years-old) will not be affected.*

Risks associated with the amendments:

150. The key risks to the conclusions of the IA are the high level of epidemiological uncertainty associated with the future of the COVID-19 pandemic and Influenza outbreaks. The estimates contained in the different scenarios were made to consider this uncertainty and the range in disruption we could expect to see.

151. All three amendments were made in the exceptional circumstances of the COVID-19 pandemic, and in particular R247A is outside the norm of healthcare delivery. The amendments to R3A and R19 have already been extended once. So far, this has not been raised as an issue by stakeholders, however, is a factor to be considered in the longer-term.

152. The risks listed are a working list. Members of the public, stakeholders and organisations are able to provide their views in the current consultation.

Risks associated with the amendment to R247A

153. A downside on having the wider workforce administer vaccines is that more staff groups will focus on this work, to the detriment of other duties. In practice however, an expanded workforce allows for greater flexibility and for staff to rotate their duties, as it is likely that not all priorities will occur at the same time. Without the amendment, the registered staff has no support for administering the vaccine, creating additional pressures on the workforce.

154. As there are many unregistered healthcare workers who support the vaccination programmes, there is a potential risk of other areas where unregistered healthcare workers are likely to help having fewer workers to complete certain duties.

155. In the previous IA on making the amendments to HMR, individuals had raised concerns about staff who were not doctors or nurses being the ones to deliver injectable vaccinations, due to lack of training and qualifications. Since then, there have been no concerns around patient safety when receiving vaccinations from medical professionals who are not doctors or nurses.

Risks associated with the amendment of R3A (final stage of preparation) and R19 (wholesalers license)

156. The requirement for the assembly, preparation and labelling of the COVID-19 vaccination without a manufacturing license was to enable offsite administration of the COVID-19 vaccine via mobile delivery models. The professionals who undertake these responsibilities are working within their core competencies. There has been no evidence of safety breaches so far, and rather the amendment has allowed for NHS staff to not spend their time applying for manufacturing licenses for every centre, but using their capacity for vaccine delivery to patients.

157. The requirement for wholesaler dealer licenses is an important safeguard within the medicine regulation system. The exceptional circumstances of the pandemic, and the

need to minimise any waste, continues to provide the justification of sharing vaccine stocks between centres. There has been no evidence of safety breaches so far, and the system of mutual aid between centres has provided flexibility, which would not have been the case if wholesale dealer licenses were required at every point.

Summary of risks and assumptions

158. At this point in time, we therefore are of the view that the benefits of continuing to extend these provisions until 1 April 2026 outweigh the risks. This should be extended whilst longer-term solutions are sought, and to prevent any current vaccination services inadvertently operating unlawfully.

Impact on small and micro businesses

159. COVID-19 and Influenza vaccines are predominately administered through community pharmacies and primary care networks who have entered into voluntary contracts to deliver NHS services. Option 0 would bring a negative impact to pharmacies which are a small business because if Condition A was not to be removed then it would remove the ability to delegate to a pharmacy technician to prepare and administer a COVID-19/Influenza vaccine. In the event Condition A was to be removed, in a pharmacy setting, then a pharmacy technician would also be able to administer a vaccine, providing an overall larger workforce to deliver the vaccines and reducing pressure on the pharmacists' workloads[13]. Vaccinations are services that no private company are under obligation to provide.

Wider impacts (consider the impacts of your proposals)

160. Along with the impact assessment, a Public Sector Equality Duty report has been completed examining the impact of the amendments to the HMR on equality. The report summarises that the amendments were an intrinsic part of supporting the national vaccination programmes and targeting areas of low vaccine uptake or areas of high infection, supporting equity of access for underserved communities.

161. Furthermore, the NHS has been able to safely vaccinate staff and deliver the vaccine campaigns and to do so with minimal disruption to normal GP and hospital services using these provisions. By helping to achieve high vaccination coverage across at-risk groups, these regulations have also contributed to reducing the overall burden on the NHS, to the benefit of all service users.

162. Reducing the prevalence of these illnesses is of great benefit to UK patients and the NHS. As both illnesses disproportionately impact negatively on people with protected characteristics, maintaining a regulatory framework that safely and efficiently supports these vaccination programmes is also of particular benefit to these groups.

163. On a wider scale, more vaccinations can prevent productivity loss through illness and absence from work, increasing economic productivity.

A summary of the potential trade implications of measure

164. We do not expect that extending these provisions are likely to impact trade or investment.

[13] Assessment and consent of the patient and providing post-vaccination advice would still have to be conducted by the pharmacist or other registered healthcare professional

Monitoring and Evaluation

165. The amendments to all three regulations will be time limited, to 1 April 2026 in recognition that this model of vaccination delivery may not be the most appropriate model for the ongoing use of an expanded workforce outside of a pandemic response. During the period in which these amended regulations will operate, it is expected that there will be fuller consideration, and potential introduction (where agreed to be beneficial) of an alternative longer-term mechanism which can be deployed to better support the use of an extended vaccination workforce.

166. Additionally, as part of R247A was a commitment to formally review the operation of R247A following one year of use to evaluate whether there had been any adverse effects on patient safety. The review was published in April 2022[14] and stakeholders were positive about the impact of R247A and did not raise any adverse consequences for patient safety.

[14] https://www.gov.uk/government/publications/changes-to-human-medicine-regulations-to-support-the-rollout-of-vaccines-one-year-review/regulations-174a-and-247a-one-year-review