Clearance checklist

*Inclusion of this checklist is **mandatory**. Please complete the whole list and private office will remove before putting submission in the box. A submission without it will be sent back.*

***Note**: Contact names provided must have seen and approved the submission.*

Finance	Does this involve any spending or affect existing budgets?	☐ If yes, named official ☐ No
Legal	Does this include legal risk, a court case or decisions that can be challenged in court?	☒ If yes, named official **NR** ☐ No
Communications	Could this generate media coverage, or a response from the health sector?	☒ If yes, named official **NR** ☐ No
Analysis and fact-checking	Does this include complex data, statistics or analysis?	☐ If yes, named official ☒ No
Devolved Administrations and the Union	Does this promote union wide policies, or will it affect Wales, Scotland or Northern Ireland?	☐ If yes, named official ☒ No
Legislation	Does this include options that may require or impact primary or secondary legislation/regulations? If yes, please discuss with the DHSC Legislation Team.	☐ If yes, named official ☒ No
Parliamentary Handling	Does this require engagement with parliamentarians or a statement in Parliament? If so, please discuss with the Parliamentary Affairs Team, and Intelligence, Insight and Engagement Team.	☒ If yes, named official **NR** ☐ No
Fraud	Have you considered fraud risks?	☐ If yes, named official ☒ No
Commercial	Does this include commercial or contractual implications?	☐ If yes, named official ☒ No
Technology, digital & data	Does this rely on or have crossover with a tech/digital/data solution?	☐ If yes, named NHSX official ☒ No
Health Data/Personal data use	Does this involve the use of sensitive health/care data? Discuss with the SIRO team. Could this require the processing of Personal Data (Data Protection Act 2018)? Discuss with the Data Protection Officer team.	☐ If yes, named SIRO/DPO official ☒ No
Strategy and Implementation Unit	Does this relate to cross-cutting or longer-term implications for wider DHSC strategy? Does this relate to one of the Secretary of State priorities or a manifesto commitment?	☐ If yes, named official ☒ No
Duties, Tests and Appraisals	Do the following tests apply and have they been considered; • Secretary of State Statutory Duties including on health inequalities • Public Sector Equality Duty • Family Test • Other (please specify)	☒ If yes, which test? • Secretary of State Statutory Duties including on health inequalities • Public Sector Equality Duty • Family Test

To:	**PS Matt Hancock**	**From:**	**NR**
	Minister Zahawi	**Clearance:**	**Julie Alexander, Prioritisation & Uptake Deputy Director, Emily Lawson SRO, COVID-19 Vaccines Programme & Jonathan Van-Tam, DCMO**
		Date:	**12th April 2021**
		Copy:	**NR**
			Private Office Submissions Copy List

JCVI Statement on Phase 2 of the COVID-19 vaccination programme

Issue	The Joint Committee on Vaccination and Immunisation (JCVI) has now provided final advice on Phase 2 **(Annex A).** This submission sets out the policy advice for Phase 2 deployment and seeks your agreement to accept the JCVI's final Phase 2 advice and handling ahead of publication.
Date a response is needed by Reason	Urgent (two working days) To allow the publication of the advice on 13th April. The vaccination programme needs to move on to Cohort 10 (40-49 year olds) by mid-April to deliver Phase 2 by the end of July.
Recommendation	We recommend that you: • **Agree** the final Phase 2 prioritisation of Covid-19 vaccines at Paragraphs 3 - 10**,** in line with final JCVI advice. • **Agree** the proposed timing of publication and handling arrangements for the **JCVI Statement on Phase 2 of the COVID-19 vaccination programme** set out at paragraphs 22-27. • **Agree** the statutory products (Annex B - Annex E). • **Agree** the parliamentary products and UK-wide Statement (Annex F- J). • **Note** the SPI-B paper at Annex K.

Background

1. At a COVID(O) meeting, on 9 February 2021, Ministers agreed that the Government's priority for Phase 2 of the COVID-19 vaccine deployment programme **should be to further reduce mortality, morbidity and hospitalisations**[1] and that the Government should seek advice from the Joint Committee on Vaccination and Immunisation (JCVI) on how best to achieve

[1] New admissions and duration of bed stay

this objective. On 26 February, JCVI published interim advice on Phase 2 of the COVID-19 vaccination programme advising an age-based approach which the government accepted in principle.

2. The JCVI's interim advice recommended an age-based approach to prioritisation. As expected, their final advice confirms this approach. It also includes a recommendation to use flexibility in operational delivery where this will help maximise uptake in areas of lower uptake. It also reflects the steer they gave in their statement, alongside MHRA on 7th April, on the use of AstraZeneca in healthy adults under 30.

Advice

3. On 12th April JCVI set out its **final advice** for Phase 2 (at Annex A) – to be published on 13th April. In line with the interim advice, the JCVI has recommended an age-based approach with adults aged 18-49 prioritised in descending age order as follows:

    - All those aged 40-49 years
    - All those aged 30-39 years
    - All those aged 18-29 years

4. This age-based approach is based on strong evidence that hospitalisations and risk of critical care admissions increase with age, including for individuals who are under 50 years of age. Mathematical modelling of vaccination strategies indicate that rapid vaccine deployment is the most important means to maximise public health benefits against severe outcomes from COVID-19. JCVI also advises that deployment teams should actively promote vaccination uptake for individuals who are: **male,** from **BAME** groups**,** have **a BMI of 30 or more**, and those **from areas of high socio-economic deprivation** given the heightened risk of hospitalisation for these groups.

Vaccine choice for those under 30

5. In line with the JCVI advice on use of AstraZeneca for those aged under 30 who have no underlying health conditions in Phase 1 (announced on 7th April), the JCVI recommend that in Phase 2 those aged between 18 and 29 are, if possible, offered either Pfizer or Moderna (the other two currently authorised vaccines).

Pregnant and breastfeeding women

6. The JCVI originally expected to use their Phase 2 final advice as the point at which they would update their advice on COVID-19 vaccines use in pregnant women to recommend routine vaccination rather than the current position (see para 7 below). The work was separate to their work on Phase 2, but the timing reflected the fact that most women who are pregnant will be in the 18-49 age group. The committee's final decision was that this was not the appropriate moment to recommend changes which are not directly linked to Phase 2 prioritisation.

7. Their final Phase 2 advice therefore leaves their existing advice on pregnancy and breastfeeding unaltered, pending further consideration. The existing guidance is that while the available data does not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend

routine use of COVID-19 vaccines during pregnancy. JCVI therefore advises that for authorised COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to COVID-19 infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women.

8. To date, the JCVI does not believe on current evidence there is a link between pregnancy and risk of the rare side effect of AstraZeneca. So, has made no pregnancy specific recommendation in respect of the use of this vaccine. The MHRA have stated that 'Pregnancy predisposes to thrombosis, therefore women should discuss with their healthcare professional whether the benefits of having [Astra-Zeneca] outweigh the risks for them.' JCVI and MHRA are in urgent discussion this week to reach a common position on this.

Operational flexibility

9. Phase 2 will continue to bring challenges for the deployment programme to address, including expected greater levels of vaccine hesitancy as Phase 2 is made up of younger and healthy adults. There is a need for a more flexible and targeted approach to communication and engagement, and a need to encourage all those eligible in Phase 1 to be vaccinated if they haven't already taken up the offer. The JCVI support operational flexibility (to vaccinate in scenarios such as multi-generational households out of age order) if this will increase uptake. **We recommend you accept this advice.**

10. The advice emphasises that when exercising operational flexibility in Phase 2, every opportunity should continue to be seized to extend coverage amongst any of those prioritised in Phase 1 who remain unvaccinated. The Programme is currently evaluating pilots that makes use of this operational flexibility for driving uptake.

Vaccine uptake and behavioural insights ahead of Phase 2 deployment

11. As of 11 April, c. 32 million[2] people across the UK had received their first dose of the COVID-19 vaccination. Over 7.6 million[3] people have now received their second dose of the vaccine. However, we are seeing variation across in uptake amongst different demographics.

12. To support JCVI's discussions and wider work on uptake, SPI-B's rapid evidence analysis was presented to JCVI on 16 March 2021. The SPI-B paper, including recommendations, is at Annex K. The paper highlights substantial variation in vaccine uptake as of 24 February 2021 by key socio-demographic factors. A graph of this data is available in Annex K. In summary:

    a. Amongst ethnic groups, the report demonstrates that compared to 'White' there is low uptake amongst Black, followed by Mixed and Other ethnic groups, and then South Asian groups.

[2] https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/
[3] https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-vaccinations/

b. There is substantially lower uptake in the shielding group for those under 49 years.[4]

c. In addition to age and ethnicity, there are socio-economic gradients, with those in the most deprived circumstances having the lowest uptake.

13. A range of work is underway to support uptake in groups and areas identified as having to date lower uptake or expressing vaccine hesitancy. In addition to this, urgent work is in hand to understand any impact of the recent advice on use of AstraZeneca on vaccine uptake. It has been suggested, based on previous incidents that rolling out a vaccine which may be followed by announcements of adverse risks can damage confidence[5]. It has also been highlighted that the use of messaging that is directly 'reactive' to new challenges to vaccination can be futile and has the potential to create a backlash[6]. Instead the focus should be placed on maintaining ongoing engagement via public dialogues and conversations.

14. Officials are working with the Programme on weekly reports for Minister Zahawi, using the Equalities Tool. This is so that insight driven changes to the Programme, if required, can be implemented at pace during Phase 2.

Ethical Considerations

15. On 3 March, officials presented to the Moral Ethical Advisory Group (MEAG). The committee noted the solid evidence that the risks of serious outcomes from COVID-19 increase with age, and that therefore in occupations where the risk of exposure to COVID-19 is potentially higher, the older workers are most at risk of serious illness if they do contract the disease. Therefore, MEAG members agreed prioritising on the basis of age was ethical.

16. In light of the public's concerns regarding prioritising the vaccine for certain occupations such as teachers, police officers and other key workers; members considered the ethical risks of *not* prioritising vaccine by occupation. Members noted that the more complicated the approach, including by occupation, the longer the vaccination programme would be likely to take.

17. MEAG noted that an age-based approach is the best way to facilitate rapid deployment, and this alone may significantly mitigate other moral concerns that may arise in relation to unfair or inequitable distribution of the COVID-19 vaccine. Therefore, **MEAG supported the age-based approach recommended by the JCVI.**

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[4] Particularly in certain areas of deprivation (NB; Cohort 6 and 10 tail). Considering this is a highly vulnerable group, operational efforts could be made to actively target and contact particularly the younger shielding group (and those in areas of social deprivation) more directly via particular services, channels or mobile units.

[5] Royal Society: COVID-19 vaccine deployment: Behaviour, ethics, misinformation and policy strategies https://royalsociety.org/-/media/policy/projects/set-c/set-c-vaccine-deployment.pdf

[6] Royal Society: COVID-19 vaccine deployment: Behaviour, ethics, misinformation and policy strategies https://royalsociety.org/-/media/policy/projects/set-c/set-c-vaccine-deployment.pdf

Phase 2 supply

18. In addition to Pfizer and AZ, Moderna is now being deployed in the vaccine programme. Two further vaccines (Jade and Nickel) may be available for deployment during the later stages of Phase 2 noting both have yet to be authorised by MHRA, we expect Jade authorisation by early May and Nickel in July. The current operational supply forecast will deliver sufficient volume of supply from the 3 currently authorised vaccines by the end of July to complete phase 1 & 2 vaccination (both doses). This forecast is updated weekly in detail as part of routine SofS briefing.

19. This advice covers Phase 2 prioritisation advice for all three authorised vaccines, AstraZeneca, Pfizer and Moderna. **We will write to you separately on prioritisation advice for Nickel and Jade later when they are due for authorisation.**

20. Moderna is being deployed under a GB Conditional Market Authorisation (CMA) from the MHRA. The vaccine is authorised for a 28 day dose interval however, the JCVI advised in a submission of 7th April that it may be deployed 'off label' at a 4-12-week dose interval (and you accepted this advice). The dosing interval for Moderna will therefore be consistent with those adopted for AstraZeneca and Pfizer in the UK.

21. Jade and Nickel are also likely to be authorised through the CMA process. Jade received a CMA from the European Medicines Agency (EMA) on 11 March and the vaccine is therefore authorised for use in Northern Ireland. This vaccine is not currently authorised for use in Great Britain, but we understand that the company now plans to approach the MHRA imminently to seek a GB CMA. Supply of Jade is contracted to commence from July. Jade is a single dose vaccine and contractual conditions limit its use to first vaccination only, it is therefore not deployable beyond phase 2 as a revaccination candidate vaccine.

Parliamentary Engagement

22. BEIS, DHSC and HMT ministers have collectively agreed to the inclusion of an indemnity clause in contracts with COVID-19 vaccine suppliers. Irrelevant & Sensitive

    Irrelevant & Sensitive

    Deployment to the next phase of the population increases the statutory contingent liability of the COVID-19 vaccination programme. We are required to notify Parliament of the increased contingent liability (and update it as things change over time) through the formal laying of a Departmental Minute (Annex G) and Written Ministerial Statement (Annex H). This is planned for 13 April. For confidential issues DHSC and BEIS Permanent Secretaries will also write to the Chairs of the Public Accounts Committee (PAC), Health and Social Care Select Committee and Business, Energy and Industrial Strategy Committee with details of the 'in confidence' material, which is included in Annex I.

23. The WMS, Departmental Minute and Letters to Chairs have been shared and cleared at official level with HMT and BEIS/VTF.

24. The maximum liability estimates presented in Annex I are based on the number of people vaccinated and therefore not which vaccines are deployed. As a result, the liability risk will be split between all deployed vaccines including, but not limited to AstraZeneca, Pfizer and Moderna, proportionate

to how much of the population received each vaccine. As the groups to be vaccinated either in or alongside Cohort 6 expanded following further advice from the JCVI, the estimate for Phase 1 liability has been updated to reflect those additions to the maximum liability set out in Annex J, along with the maximum contingent liability for Phase 2 for those aged 49-18.

25. A grid slot has been secured for [13 April] to the Written Ministerial Statement on the Phase 2 announcement and liabilities.

Parliamentary and Wider Handling

26. The JCVI final advice is ready for publication. Once you are content with the advice and have agreed the approach, DHSC officials will work with the Cabinet Office Taskforce to notify the Prime Minister of the final JCVI Phase 2 advice and your decision through a box note. Your private office will notify counterpart private offices to sight Ministers across Whitehall of the final JCVI advice. We also recommend you support notifying SROs from the 4 nations in parallel.

27. The intention is to issue an oral statement alongside the publication of the final Phase 2 advice, welcoming the advice and setting out the Government's intention to follow JCVI's recommended approach to prioritisation in Phase 2. This will be accompanied by a Dear Colleague letter alerting colleagues of the final Phase 2 advice (at Annex F). No10 are seeking a grid slot for publication on 13 April.

DA considerations & UK alignment

28. Alignment on JCVI interim advice was agreed by the four health ministers on 25/02. As discussed at the Four Nations Health Ministers meeting on 11 March, the intention is for the UK response to the final advice to be aligned with Devolved Administrations through a joint statement.
29. A draft statement was circulated to the DAs containing wording from the JCVI Statement of 07/04 and the interim advice on Phase 2. An updated statement (Annex J) will be circulated. We will work with your office to get final sign off for the government statement across the four nations.

Impact Assessment to demonstrate cost effectiveness of deploying the AstraZeneca, Pfizer and Magenta vaccines in Phase 2 cohorts – Gbemi Babalola

30. The attached Impact Assessment (IA) demonstrates that the decision at this stage to deploy the AstraZeneca, Pfizer and Moderna vaccines for the Phase 2 cohorts is cost effective at the £20,000 per QALY threshold. This assessment considers the deployment costs not yet committed (central estimate I&S , and the vaccine price per dose in the pre-purchase agreements.

31. The analysis shows the most significant benefit from this stage of vaccination is likely to be from protecting the group eligible in Phase 1 and therefore at higher clinical risk, but who either did not take up the vaccine or are not protected with the vaccine as it is does not provide 100% protection. This is because Phase 2 is expected to significantly reduce levels of infections across all society. They will also benefit directly from reduced levels of infections themselves, and hence avoiding acute covid-19, hospitalisations,

post- acute Covid-19 syndrome. There are also significant cost savings to the NHS from avoided hospitalisations. This assessment supports the JCVI advice and demonstrates that following it will deliver very large health benefits to the population and a cost-effective price-point.

32. This assessment excludes economic benefits, in line with other vaccine cost-effectiveness analyses, although significant economic savings are expected. Our assessment is that the JCVI advice is sound based on the evidence available and following it will deliver very large health benefits to the population and a cost-effective price-point.

33. The Moderna vaccine has been pre-purchased, and doses will become available during Phase 2 roll-out. It has been authorised by MHRA. We have also assessed it against Phase 2 benefits and shown it to be cost effective to deploy. Given the benefits from Phase 2 are greater the faster the roll-out, deploying Moderna alongside the AstraZeneca and Pfizer vaccines is desirable to avoid more COVID-19 deaths and hospital admissions.

Finance

34. Funding of £1.65bn was provided at Budget 21 to enable the vaccine deployment programme to continue administering in FY 21-22. As such, funding is not a barrier to progress nor a major factor in determining the Phase 2 rollout approach.

35. However, a significant change in scope or timescale may have a consequential impact on cost and funding needs above that already provided in Budget 21.

Vaccine Damage Payment Scheme (VDPS) / Indemnities

36. The VDPS has already been extended to include COVID-19 vaccines, to ensure that, in the very rare circumstance where someone is severely injured as a result of being vaccinated, those individuals can access financial assistance.

37. There is no confirmed evidence to suggest that any of the vaccines HMG has purchased will present severe adverse reactions. The MHRA reported on 7 April on their ongoing review of UK reports of extremely rare blood clots, occurring with lowered platelets in patients who have received the COVID-19 Vaccine AstraZeneca. More work is still needed by CHM and MHRA. We will update Ministers on effects to contingent liabilities relating to the indemnity contracts if any new information from CHM is provided to Ministers by MHRA. The Government is following the independent advice of the JCVI which on 7 April published new advice setting out that, as a precaution, it is preferable for people under the age of 30 with no underlying health conditions to be offered an alternative vaccine where possible once they are eligible. This is because the available data suggests there is a slightly higher incidence of this extremely rare condition in the younger adult age groups.

38. The number and nature of suspected adverse reactions reported so far are not unusual in comparison to other types of routinely used vaccines in line with *Managing Public Money guidance*. HMG is required to set out its best estimate for the potential value of the liability it has as a result of the indemnities.

39. HMG aims to represent a worst-case figure rather than a 'best estimate' because there is no available methodology to arrive at a best estimate figure. This does not mean we can assume that there will never be any future claims. The best available evidence to inform a worst-case scenario is therefore the incidence and cost of adverse reactions and liabilities associated with previous large-scale (non-Covid) vaccinations which did involve rare cases of severe adverse reactions.

40. The aim of the analysis is to fully capture a worst-case scenario. The data used therefore represents the most extreme situations for which there is an evidence precedent. This involves taking the 'worst of all worlds' approach, combining the higher risk of a comparatively milder adverse reaction with the high pay-outs of a more severe (but rarer) adverse reaction. Phase 2 of the rollout is expected to include the total of 19,381,930 people, with an estimated 'worst-case' maximum liability of Irrelevant & Sensitive

41. DWP has currently paused processing Covid VDPS claims as there is insufficient literature to identify causal links between the disabilities claimed by the claimants and the COVID vaccine. DHSC are working with DWP to provide support to procure causation expertise, to inform claimants of the wait and identify a solution.

LPP/LAP

LPP/LAP

Communications – cleared by NR

NR

49 The publication of the JCVI interim advice received widespread coverage, and we can anticipate the final advice will get some pick-up too. While the final advice for Phase 2 is unchanged from the interim advice, we anticipate some further criticism from groups that haven't been added into the advice – teachers and police officers for example.

50 PHE/JCVI will lead on the comms and will adopt a low-key approach, publishing the final advice on gov.uk without further proactive comms. PHE and DHSC will handle media queries reactively.

51 DHSC is working on comms plans to announce tomorrow that the 1-9 vaccination target has been met and Phase 2 will begin from this week. The Plan will be sent up separately in due course and cleared through No10/CO propriety teams and the Permanent Secretary.

Conclusion & Recommendation

We recommend that you:

52 **Agree the final Phase 2 prioritisation of Covid-19 vaccines at paras 3 to 10,** in line with JCVI final advice (at Annex A);

53 **Agree** the proposed timing of publication and handling arrangements for the **JCVI Statement on Phase 2 of the COVID-19 vaccination programme** set out at paragraphs 22-27;

54 **Agree** the statutory products (Annex B- Annex E).

55 **Agree** the parliamentary products and DAs Statement (Annex F-J).

56 **Note** the SPI-B paper at Annex K.

NR COVID-19 Vaccine Team I&S

I&S COVID-19 Vaccine Team I&S

Annexes

ANNEX A –JCVI Final Phase 2 advice

ANNEX B – Public Sector Equalities Duties

ANNEX C – Impact Assessment

ANNEX D – Families Test

ANNEX E – Statutory Duties, under part 1 of the NHS Act 2006

ANNEX F – Dear Colleague Letter

ANNEX G – Departmental Minute, Notification of Liability for Phase 2

ANNEX H – Written Ministerial Statement, Notification of Liability for Phase 2

ANNEX I – Letter to Select Committee

Annex J – DAs Statement

Annex K - SPI-B: Behavioural considerations for vaccine uptake in Phase 2 and beyond, introduction and executive summary