From the Chief Medical Officer
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HSS(MD)21/2022

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FOR ACTION
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Deputy Secretary SPPG
GP Medical Advisers, SPPG
All General Practitioners and GP Locums (for onward distribution to practice staff)
OOHs Medical Managers (for onward distribution to staff)

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Dear Colleague

PERMANENT SUSPENSION OF THE 15 MINUTE WITH COVID-19 VACCINES

1. Following on from our letter of 15th December (HSS(MD)82/2021) https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-82-2021.pdf , advising of the temporary suspension to the 15-minute observation requirement following Pfizer and Moderna COVID-19 vaccines, this letter is to advise that the suspension is to be made permanent, subject to certain conditions. This is based on the latest advice from the Commission on Human Medicines (CHM), following an expert review of the approach.

2. This decision has been approved by the Chief Executive of Medicines and Healthcare products Regulatory Agency (MHRA)., The 4 UK CMOs and the Joint Committee on Vaccination and Immunisation (JCVI) also support this approach.

Background

3. The 15-minute observation requirement is part of the conditions of authorisation of the Pfizer, Moderna and Novavax COVID-19 vaccines by the MHRA and European Medicines Agency (EMA). The observation period was recommended by the regulators due to reports of anaphylaxis following the administration of vaccines and the need for appropriate medical treatment and supervision to be readily available in case of an anaphylactic event.

4. Developments regarding the Omicron variant and concerns about waning vaccine effectiveness in December 2021 led to a strong public health imperative to increase the pace and scale of the COVID-19 booster vaccination programme. Following careful examination of the Yellow Card data, which suggested events of

anaphylaxis were very rare, on 13 December the CHM advised that the 15-minute observation requirement could be temporally suspended to aid acceleration of the response to the Omicron variant.

5. This advice was accepted by Ministers and the UK CMOs on the basis that maintaining the requirement for a 15 minute observation period post vaccination would cause more harm than it could avert by limiting the number of people who could be vaccinated over a short period of time. On 14 December the 15-minute observation requirement was temporarily suspended, with the UKHSA updating the 'Green Book' to reflect this change.

6. The MHRA and the COVID-19 Vaccines Benefit Risk Expert Working Group (EWG) have kept the reporting of anaphylaxis under close review following the temporary suspension. The EWG has reviewed Yellow Card reporting of anaphylaxis with the mRNA vaccines on 13 January, and on 19 January reviewed international data on anaphylaxis in children aged 5-11 years following administration of the Pfizer vaccine.

CHM Review and advice

7. The MHRA and the COVID-19 Vaccines Benefit Risk Expert Working Group (EWG) have kept the reporting of anaphylaxis under close review following the temporary suspension. The CHM and EWG recently reviewed the suspension of the observation requirement. This included analysis of reports of anaphylaxis by the UKHSA, NHS England, and devolved health bodies as well as reports from the MHRA's Yellow Card scheme.

8. A total of 73 reports of suspected anaphylaxis events have been reported since 14 December 2021 for the Pfizer vaccine and a total of 30 events have been reported for the Moderna vaccine. This is in the context of over 10 million boosters given in this period. There have been no fatal reports of anaphylaxis since the temporary suspension of the 15-minute observation period. The CHM concluded that reporting of suspected anaphylaxis following administration of all doses of the Pfizer and Moderna vaccines remains consistent with previous reviews and no new safety concerns had been identified.

9. In light of this, the CHM, in line with EWG's advice, recommended that the requirement be permanently lifted for all authorised COVID-19 vaccines (including the newly authorised Novavax vaccine, should it be deployed) **for those aged 12 and above.**

10. The CHM advised that the suspension should remain temporary and under review for the 5-11 year age group (and should be re-reviewed in two months' time when more data will be available).

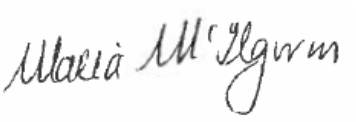
11. As a precaution, the CHM supported the EWG recommendation that the observation time should remain in place for a small proportion of individuals potentially at increased risk of anaphylaxis, such as those with a history of anaphylaxis as per the Green Book advice and that more communications could

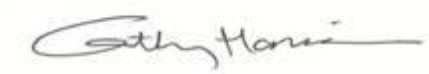
be issued to clarify this. It also remains that those who have previously had a hypersensitivity reaction to the vaccine should not receive that vaccine.

12. Based on the CHM's expert scientific advice, the MHRA is also content to support the permanent lifting of the 15-minute observation requirement for individuals aged 12 years and older, and the continued temporary suspension for those aged 5-11 years. This change will be enacted through extant vaccination policy and guidance which supports the off-label use of vaccines in the context of national expert recommendations for use, with no regulatory change proposed at this time.

13. The background to this decision is set out in Annex A for information.

Yours sincerely





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This letter is available on the Department of Health website at https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications

Annex A

CHM ADVICE ON 15 MINUTE OBSERVATION REQUIREMENT POST-VACCINATION

ISSUE

1. On 13 December 2021 the Commission on Human Medicines (CHM) reviewed data relating to reports of anaphylaxis following mRNA COVID-19 vaccination, along with evidence of the evolving threat of the Omicron variant and the emerging booster vaccine effectiveness data against Omicron. Following careful examination of the Yellow Card data, which suggested events of anaphylaxis were very rare, the CHM advised that the 15-minute observation requirement could be temporally suspended to aid acceleration of the response to the Omicron variant. You accepted the advice from DHSC on this issue and on 14 December the post-vaccination observation requirement was temporarily suspended.

2. The MHRA and the COVID-19 Vaccines Benefit Risk Expert Working Group (EWG) have kept the reporting of anaphylaxis under close review following the temporary suspension. The EWG has reviewed Yellow Card reporting of anaphylaxis with the mRNA vaccines on 13 January, and on 19 January reviewed international data on anaphylaxis in children aged 5-11 years following administration of the Pfizer vaccine.

EWG/CHM CONSIDERATION

3. On 4 February, the EWG reviewed an additional analysis of reports of anaphylaxis by the UK Health Security Agency (UKHSA), NHS England, and devolved health bodies. This analysis has not identified any change in the number of ambulance calls, emergency attendances or admissions since the temporary suspension was put in place and indicates that there have been no negative impacts on safety due to the temporary suspension.

4. The EWG was presented with a recent analysis of Yellow Card reports of suspected anaphylaxis following administration of all doses of the Pfizer and Moderna vaccines since the temporary suspension of the observation time. While there has been a steady increase in the number of anaphylaxis events reported in line with vaccine usage, there has not been a further increase in the number of reports of anaphylaxis following the temporary suspension of the 15-minute observation requirement. A total of 73 reports of suspected anaphylaxis events have been reported since 14 December 2021 for the Pfizer vaccine, and a total of 30 events have been reported for the Moderna vaccine, this is in the context of over 10 million boosters given in this period. There have been no fatal reports of anaphylaxis since the temporary suspension of the 15-minute observation period.

5. Where detail of onset times of anaphylaxis has been provided, the majority of events have occurred within 15 minutes of vaccination for both the Pfizer and Moderna vaccines. Many reports indicate that individuals were treated by healthcare professionals at vaccination sites or healthcare facilities, such as administering adrenaline or antihistamines, before symptoms progressed in severity. Approximately 40% of reports of suspected anaphylaxis received since 14 December 2021 indicate that adrenaline was administered.

6. Overall, analysis of Yellow Card data does not indicate that there are significant numbers of anaphylaxis events occurring post-vaccination, or that more serious consequences of anaphylaxis are occurring compared to when the 15-minute observation requirement was in place. Reporting remains consistent with previous reviews and no new safety concerns have been identified.

7. The EWG was asked to consider whether the temporary suspension of the 15-minute observation requirement could become permanent, or whether alternative action should be advised. The EWG advised that the 15-minute observation requirement can be lifted for all authorised COVID-19 vaccines, However, the suspension should remain temporary and under review for the 5-11 year age group where experience with the authorised Pfizer 5-11 year formulation is starting to accumulate in the at risk groups. The EWG advised that data on the 5-11 year age group should be re-reviewed in two months' time when more data will be available.

8. The EWG also advised that more communications could be issued to clarify the pre-existing advice that those with a history of allergies should be observed for at least 15 minutes, and for those of highest concern to be referred to specialist allergy clinics, via the Green Book. It also remains that those who have previously had a hypersensitivity reaction to the vaccine should not receive that vaccine.

9. The CHM was asked, via written comment, whether the EWG's recommendations could be endorsed and whether advice can be issued for the permanent suspension of the 15-minute observation time for those aged 12 years and over, and for the suspension to remain temporary and under review for those aged 5-11 years.

CHM ADVICE

10. The CHM endorsed the lifting of the 15-minute observation requirement for the vaccination of individuals aged 12 years and over, and the temporary suspension for those aged 5-11 years would remain under review.

11. However the CHM supported the recommendation that, as a precaution, the observation time will remain in place for a small proportion of individuals

potentially at increased risk of anaphylaxis, such as those with a history of anaphylaxis as per the Green Book advice. A contraindication for those with hypersensitivity to any of the vaccine ingredients remains in place.

12. The CHM's advice will be enacted through vaccination policy and guidance via UKHSA, NHS England, and devolved health authorities. No regulatory change is proposed at present.

NEXT STEPS

13. The MHRA will keep reports of anaphylaxis associated with the COVID-19 vaccines under close and continual review, in particular in those aged 5-11 years. We will seek further expert advice should any potential change in the risk benefit be detected.