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To: All general practices in England
Cc: Regional Directors of Public Health and Primary Care
CCG Accountable Officers and Clinical Leads
CCG Chief Pharmacists/Heads of Medicines Optimisation
Regional Chief Pharmacists

7 January 2021

Dear Colleague,

COVID-19 Vaccine Oxford AstraZeneca – movement of vaccine

Further to the temporary Authorisation of the COVID-19 Vaccine Oxford AstraZeneca (“AZ vaccine”) by the UK Department of Health and Social Care and Medicines and Healthcare products Regulatory Agency (MHRA) on 30 December 2020 – details of which can be found [here](#) – I am writing to draw your attention to additional operational flexibilities offered by the introduction of the AZ vaccine.

It is important to note that the priority setting for AZ vaccine delivery at present is in care homes; all PCNs should maximise use of AZ in their care homes as it arrives.

The characteristics of the AZ vaccine make it comparatively easier to deploy and handle. Providing the cold chain of 2-8°C and other conditions as set out in the relevant Standard Operating Procedures are maintained at all times prior to administration, it is permissible in principle for PCN groupings to transport the AZ vaccine flexibly between practice sites within the PCN grouping as well as to care homes and to those patients who are housebound and require vaccination at home. PCN groupings should only administer vaccines from sites other than those which have been specifically designated for COVID-19 vaccination where it is considered that this will improve patient access or increase vaccination capacity which remains a prime consideration. AZ vaccine must be used as soon as it is received rather than being stored. Vaccination capacity at the PCN grouping’s designated site must also be maintained and this is especially important as both the Pfizer and AZ available vaccines will continue to be supplied to sites.

Practices/PCN groupings must continue to meet all of the requirements within the COVID-19 Vaccination Programme 2020/21 Enhanced Service Specification and there will be no change to current PCN grouping set-up and supply arrangements as a consequence of flexibilities offered by the AZ vaccine outlined above. All vaccines and vaccine-related consumables will continue to be delivered to PCN designated sites only and will not be delivered to alternative premises. PCN groupings will need to transport the AZ vaccine, consumables and equipment from the designated site to the alternative vaccination premises. Any vaccinations administered at alternative premises should be recorded via Pinnacle/Outcomes for Health against the existing lead practice ODS code of the PCN grouping e.g. new accounts will not be set up. PCN groupings will need to ensure that the alternative vaccination premises support compliance with any requirements in relation to

the storage, preparation, administration and disposal of the vaccine and associated consumables as well as relevant guidance e.g. in relation to social distancing or security.

Greater flexibility in transportation does not mean that the relevant aspects of the Human Medicines Regulations 2012 do not apply. There are regulatory flexibilities that allow some sharing of vaccines between different end users without precipitating the need for a wholesale dealer's licence, and for allowing participants in PCN groupings to vaccinate patients who are not the patients of their own practice, but these are subject to compliance with the requirements of the COVID-19 Vaccination Programme 2020/21 Enhanced Service Specification, which must be followed at all times.

Under the Enhanced Service, the GP practice, together with the other GP practices in the PCN grouping are considered as if they are joint and several owners of the vaccine. Where any sub-contracting arrangement is in place, it must be clear that the PCN grouping that is sub-contracting delivery will at all times retain responsibility for governance and control of the vaccines to be administered. These arrangements are required to avoid a situation where it could be deemed that there had been a transfer of responsibility and control of the vaccine to a party outside of the PCN grouping (which is not permitted).

It is also possible, provided the cold chain of 2-8°C is assured and maintained, to move the AZ vaccine several times. For example, the vaccine could be transported from the PCN designated site to Care Home A, then Care Home B and on to Care Home C. However, the vaccine should not be transported once the first dose has been removed from the vial. There should be no returns to stock and the vaccine must never be returned to the PCN refrigerator after it has left the PCN site for administration elsewhere (where it must either be administered or destroyed). Note that this movement flexibility does not apply in the same manner to the Pfizer/BioNTech Vaccine BNT162b2 and the specific conditions pertaining to that vaccine should be followed.

The PCN grouping should ensure that it has a robust system in place for maintaining the cold chain, recording any movement of the AZ vaccine from designated sites and vaccine wastage. PCN groupings are also expected to follow Standard Operating Procedures as set out by the Specialist Pharmacy Service (www.sps.nhs.uk) which [have been updated to cover the transport of AZ vaccine to end user locations as well as to GP practices within the PCN grouping](#). I hope that the information in this letter is helpful and thank you for your continued efforts as part of this crucial vaccination programme.

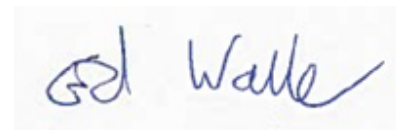
Yours sincerely



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