



Department
of Health &
Social Care

Department of Health and Social Care
39 Victoria Street
London
SW1H 0EU

3 February 2021

Dear Dr Raine,

As you are aware, the Department of Health and Social Care is leading the Government's deployment of vaccinations against COVID-19. In order to save lives, and to reduce the number of people who need hospital treatment due to COVID-19, we are currently deploying two highly effective vaccines against COVID-19 in the largest vaccination programme this country has ever seen.

We wrote to you on 24 November 2020 regarding the vaccine developed by Oxford University/Vaccitech and AstraZeneca (AZ). We also wrote to you on 22 December 2020 to consider whether the second dosing of this vaccine (and the Pfizer vaccine) could take place over an extended interval, to enable a larger proportion of the population to receive a first dose. So far, over 10 million doses of these two vaccines have been deployed in the UK.

As you will know, the UK has an agreement with AZ to supply 100 million doses of their COVID-19 vaccine. In addition to this agreed supply, the UK has the opportunity to acquire up to 15 million additional doses of this vaccine manufactured by the Serum Institute of India (SII) under technology transfer agreement with Oxford/AZ. It is this additional supply which is the subject of this request.

We are in the middle of the third pandemic wave of COVID-19, emphasising the urgent public health need for COVID-19 vaccines. With the continued emergence of new variants of SARS-CoV-2, there is a pressing need to vaccinate the most vulnerable as quickly as possible in order to save lives. If the SII vaccine can be appropriately assessed for safety, quality and efficacy and is authorisable for use, we would like to distribute this additional supply of this vaccine as part of the public health response to this pandemic as quickly as possible.

This vaccine, along with other future vaccines, forms a crucial role in helping this country recover from this devastating global pandemic, which has already claimed over 2 million lives worldwide. The virus continues to circulate, meaning lives continue to be lost, and so the sooner our vaccination programme can be accelerated by bringing additional supply into use, the better.

We are therefore writing to ask you to consider varying the temporary authorisation of the AZ COVID-19 vaccine, under Regulation 174 of The Human Medicines Regulations 2012, to include these additional doses on offer from SII. This will enable the NHS to deploy more doses of this vaccine sooner whilst adhering to the Government's prioritisation programme. The NHS has in place the appropriate distribution and administration procedures, making it very efficient to add additional supply of a vaccine we can deploy quickly and effectively.

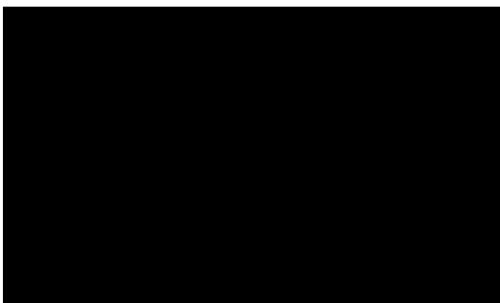
We refer you to our previous letters regarding authorisation of this vaccine for considerations on prioritisation and supply and distribution arrangements. We also refer you to the manufacturer and the companies that may stand in the place of the marketing authorisation holder so that you may obtain full information and description of the product that we seek to have approved as part of our proposed supply.

We seek approval to commence supply of the vaccine by the NHS as part of the UK's public health response to the pandemic as soon as we can access doses, should the MHRA's investigations and checks to the safety and quality of this specific supply of the vaccine prove satisfactory.

For the reasons above, we seek your views on the suitability of an additional supply of the AZ COVID-19 vaccine, manufactured by SII, for authorisation under Regulation 174 of The Human Medicines Regulations 2012. This is in order to protect the most clinically vulnerable from COVID-19, and in doing so preserve human life and promote public health.

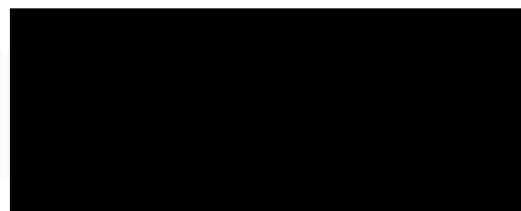
Please continue to direct policy and regulatory queries to our DHSC COVID-19 Vaccine Policy Deputy Directors, Julie Alexander and Laura Squire.

Yours sincerely,



Professor Jonathan Van-Tam

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FRCPath, FRSPH, FRSB, Hon FFPM, CBiol, CSci.
Deputy Chief Medical Officer
Department of Health and Social Care



Antonia Williams

Director
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