



Department
of Health &
Social Care

Department of Health and Social Care
39 Victoria Street
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17. November 2020

Dear Dr Raine,

As you will be 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 seeking to deploy a safe and effective vaccination as soon as possible.

One of the leading vaccine candidates is advanced enough for the Department to realistically plan for deployment before the end of the year. This is the COVID-19 vaccine being developed by Pfizer and BioNTech, the interim results of which indicated it was 90% effective in protecting people from symptomatic infection in global trials¹. There is a reasonable expectation that there will be a Phase III readout on a second vaccine this month.

Whilst acknowledging that full trial data are yet to be published, and peer reviewed (and subject to the MHRA receiving the information it needs to provide an assessment), the Department wishes to supply this vaccine in response to the COVID-19 pandemic. We therefore seek your views on its suitability for temporary authorisation under Regulation 174 of The Human Medicines Regulations 2012, so that we may promptly and safely deploy the vaccine, beginning with cohorts as set out by the final advice from the Joint Committee on Vaccination and Immunisation (JCVI).

As you will know, the UK has an agreement with Pfizer to supply 40 million doses of the vaccine. We are in the middle of the second pandemic wave of COVID-19, emphasising the urgent public health need for COVID-19 vaccines. We would like to be able to distribute this vaccine as part of the public health response to this pandemic as quickly as possible once it has been appropriately assessed for safety and efficacy. This vaccine, along with other future vaccines, will form a crucial role in helping this country, as well as other countries, recover from this devastating global pandemic, which has already claimed over 1 million lives worldwide. The virus continues to circulate meaning lives continue to be lost, and so the sooner vaccination can begin the better.

¹ <https://www.pfizer.co.uk/update-albert-bourla-discusses-covid-19-vaccine-efficacy-results>

There are clear public health benefits and needs met by vaccinating against COVID-19. Therapeutic treatments, and non-pharmaceutical interventions, will form key parts of the recovery from this outbreak. However, a safe and effective vaccine is crucial to save lives, and possibly to reduce the likelihood and size of future outbreak waves, and we believe there is a clear public health justification for making a vaccine available as soon as possible.

Whilst the final advice on prioritisation has not yet been provided by JCVI, and the content of the advice will depend on the exact characteristics of the vaccine, JCVI is likely to advise the prioritising of those most vulnerable to COVID-19, predominantly by age. We will seek JCVI's advice once further data from clinical trials are made available and present it to the Secretary of State for Health for a decision on prioritisation as soon as it is available.

We seek approval for the supply of 40 million doses of the vaccine by the NHS as part of the UK's public health response to the pandemic. You will wish to refer to Pfizer/BioNTech for the full description of the exact doses which would be covered by the authorisation.

BEIS and PHE are putting in place tailor made supply and distribution arrangements for the supply of this vaccine, which you will want to consider as part of your approval of the proposed supply. Full details of the proposed supply arrangements will be provided by PHE and BEIS.

Additionally, any authorisations will require specific guidance on administration for:

1. Those with a clinical history of COVID-19 infection (in the absence of any Polymerase Chain Reaction (PCR) confirmation) i.e. supposition/assumption
2. Those with a clinical history of COVID-19, as confirmed by PCR
3. Those with no history of disease but at least one assay showing the presence of COVID-19 antibodies.

Until the final clinical trial data is received, we will not know precisely when we will be in a position to proceed through the regulatory approvals process. However, we are aware that MHRA has been conducting a rolling review of various elements of the vaccine throughout its development, and we know upon receipt of this request will come to a view as soon as it is able to do so. The Department is grateful for the ongoing work of the MHRA in this regard.

Whilst the availability of the vaccine also depends on the manufacturer and timings of supply, the Government continues to work closely with the manufacturers to mitigate against any possible delays.

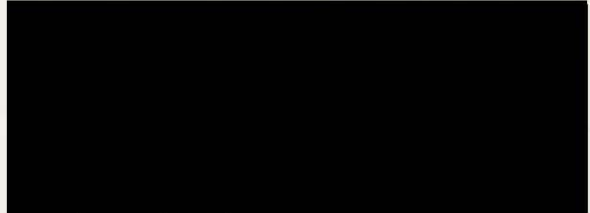
For the reasons above, we seek your views on its suitability for authorisation the under Regulation 174 of The Human Medicines Regulations 2012 for the proposed supply of the vaccine being developed by Pfizer and BioNTech as soon as possible. This is in order to prevent the spread of COVID-19 primarily in the most clinically vulnerable, 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 Director, [REDACTED]

Yours sincerely,



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