Department of Health and Social Care
39 Victoria Street
London
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24 December 2020

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 seeking to deploy a safe and effective vaccination as soon as possible.

We wrote to you on 24 November regarding the vaccine candidate developed by Oxford University/Vaccitech and AstraZeneca (AZD1222). In addition to this vaccine, a third vaccine candidate is now advanced enough for the Department to realistically plan for its deployment, potentially starting in January 2021. This is the COVID-19 vaccine being developed by Moderna (mRNA-1273), the interim results of which indicated it was 94% effective overall in protecting people from COVID-19 in trials[1].

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 Moderna to supply 7 million doses of the vaccine. You will be aware that a new SARS-CoV-2 strain has arisen and is now becoming dominant in London and wider South-East England. Initial scientific analysis suggests this new variant appears to be more transmissible than the predecessor strain, 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 quality, safety and efficacy, particularly given our understanding of its relatively undemanding logistics and cold chain requirements. We refer you to the manufacturer so that you may obtain full information and description of the product that we seek to have approved as part of our proposed supply.

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[1] https://investors.modernatx.com/node/10446/pdf

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 greatest extent to which we can upscale our vaccination programme, the better.

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 as many vaccines available as soon as possible.

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.

The Department for Business, Energy & Industrial Strategy (BEIS) and Public Health England (PHE) are putting in place appropriate 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 BEIS and PHE.

Additionally, to dovetail with the programme already underway, any authorisation will require specific guidance on approved supply 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.
4. Administration during pregnancy and breast feeding

And:

5. Whether, and to what extent, an extended interval between first and second doses can be allowed, giving operational flexibility and potentially allowing increased prioritisation of the first dose for as many people as possible.

We are aware that MHRA has been conducting a rolling review of various elements of the vaccine throughout its development, and will reach a view on regulatory approval as soon as it is able to. 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 manufacturer to mitigate against any possible delays.

For the reasons above, we seek your views on the suitability of mRNA-1273 for authorisation under Regulation 174 of The Human Medicines Regulations 2012. 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, Julie Alexander.

Yours sincerely,

[redacted]

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