Department of Health & Social Care

From the Lord Bethell
Parliamentary Under Secretary of State for Innovation (Lords)

39 Victoria Street
London
SW1H 0EU

Irrelevant & Sensitive

By email to: Jonathan.VanTam@dhsc.gov.uk
Antonia.Williams@dhsc.gov.uk

01 December 2020

Dear Professor Van-Tam and Ms Williams,

Thank you for your letter of 17 November, which sought the Licensing Authority's authorisation for the vaccine developed by Pfizer/BioNTech (Vaccine BNT162b2) to be supplied by the Department of Health and Social Care (the Department) under regulation 174 of The Human Medicines Regulations 2012 (Annex A).

After taking the advice of the Commission on Human Medicines, and considering the evidence on quality, efficacy and safety of this vaccine and the public health need to curb the spread of COVID-19, I have decided to approve the Department's proposed supply of the vaccine in response to the pandemic, pending the product obtaining a market authorisation.

My approval is subject to a number of conditions, which are annexed, and which will apply to all those involved in the supply and distribution of this product. This approval is not a market authorisation, and there is therefore no general authorisation to place this vaccine on the market.

The Department had asked, in particular, whether the authorisation would require specific guidance on administration of the vaccine for:

1. Those with a clinical history of COVID-19 infection (in the absence of any polymerase chain reaction (PCR) confirmation)

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.

Following the CHM's recommendation on these questions, I can confirm that no specific precautions have been suggested for the administration of this vaccine in any of the above three populations.

With my very best wishes,

Personal Data

LORD BETHELL