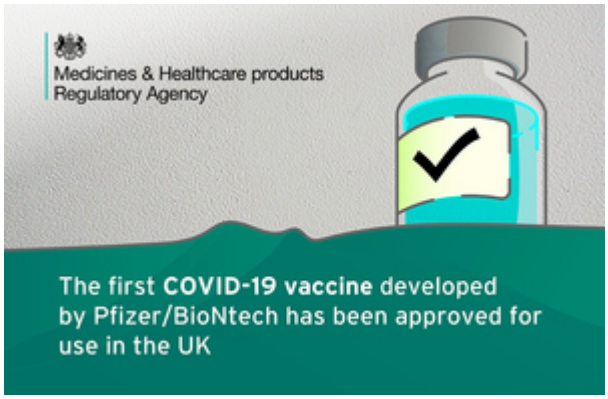
UK medicines regulator gives approval for first UK COVID-19 vaccine



The decision by the UK regulatory authority was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body. A dedicated team of MHRA scientists and clinicians carried out a rigorous, scientific and detailed review of all the available data, starting in October 2020.

This was done using a regulatory process known as a 'rolling review'. A 'rolling review' can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis.

The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine and also considered the conditions for its safe supply and distribution.

The National Institute for Biological Standards and Control, part of the agency, has been and will continue doing, independent laboratory testing so that every batch of the vaccine meets the expected standards of safety and quality.

MHRA Chief Executive, Dr June Raine said:

> We have carried out a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness. The public's safety has always been at the forefront of our minds – safety is our watchword.
>
> I'm really pleased to say that the UK is now one step closer to providing a safe and effective vaccine to help in the fight against COVID-19 – a virus that has affected each and every one of us in some way – and in helping to save lives.
>
> We are globally recognised for requiring high standards of safety,

quality and effectiveness for any vaccine. Our expert scientists and clinicians worked tirelessly, around the clock, carefully, scientifically, robustly and rigorously poring over hundreds of pages and tables of data, methodically reviewing the data.

Vaccines are the most effective way to prevent infectious diseases. They save millions of lives worldwide.

See Information for Healthcare Professionals, and Information for UK recipients.

Dr June Raine discusses how COVID-19 vaccines are approved by the MHRA

Notes to Editor

1. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
2. The decision to approve the supply of this vaccine was taken under Regulation 174 of the Human Medicine Regulations 2012, which enables rapid temporary regulatory approvals to address significant public health issues such as a pandemic.
3. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care.
4. The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care.

Published 2 December 2020
Last updated 2 December 2020 + show all updates

1. 2 December 2020

   Added link to page containing Information for Healthcare Professionals, and Information for UK recipients on the vaccine.

2. 2 December 2020

   First published.