FOI 23/442

Dear

Thank you for your email.

> *Thank you for that detailed response.*
>
> *Just to clarify, the COVID-19 vaccines began to be administered in the UK Dec 8th 2020 starting with Pfizer/Biontech (Comirnaty). I presume PRIOR TO the approval dates (below) the product listed would be considered experimental or under development or an investigational medicinal product ?*
>
> *Pfizer/BioNTech vaccine(Comirnaty) vaccine Dec 21st 2020.*
> *Moderna vaccine on 31 March 2021*
> *Janssen Covid-19 vaccine on 28 May 2021*
> *Oxford/AstraZeneca vaccine on 24 June 2021*

Prior to the marketing authorisation dates provided, the COVID-19 Vaccines for Pfizer/BioNTech, Oxford/AstraZeneca and Moderna were granted under Regulation 174. These temporary authorisations under Regulation 174 do not constitute a marketing authorisation, but permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to the MHRA. As previously stated, from the date of initial authorisation under Regulation 174 of each vaccine, they were no longer considered to be 'experimental' for the indications that had been authorised.

The dates of the Regulation 174 temporary authorisations and the later marketing authorisations are listed below:

COVID-19 Vaccine	Temporary Authorisation (Regulation 174)	Marketing Authorisation
Pfizer/BioNTech	2 December 2020	21 December 2020
AstraZeneca	30 December 2020	24 June 2021
Moderna	8 January 2021	31 March 2021
Janssen	-	28 May 2021

The temporary authorisations for use of the COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). 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 decision was made with advice from the Commission on Human Medicines (CHM), the government's independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech, Moderna and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. Links to these are provided below:

https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

The Janssen COVID-19 Vaccine was not licensed via Regulation 174 and instead received a marketing authorisation. The Public Assessment Report is available on the MHRA website here:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen

Considering the entirety of our correspondence, the heart of the matter you appear to be raising concentrates on the language used to describe the vaccines. Freedom of Information regime exists in order for members of the public to request information and documentation.

Therefore, it is unclear if your questions meet the criteria of an FOI request, you may be better served by raising this matter as a general enquiry.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out. Please remember to quote the reference number above in any future communications. If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted by writing to: Information Commissioner’s Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF Yours sincerely MHRA Customer Service Centre Medicines and Healthcare products Regulatory Agency 10 South Colonnade, Canary Wharf, London E14 4PU