Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

7th March 2021

Dear [redacted]

Our Ref: FOI 21/186

Thank you for your email dated 16th February 2021.

The authorisation of the Pfizer/BioNTech and the Oxford/AstraZeneca vaccines was done through an expedited 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 temporary authorisation under Regulation 174 permits the supply of identified vaccine batches, based on the safety, quality and efficacy data submitted to MHRA. These authorisations do not constitute a marketing authorisation. The conditions of authorisation are provided via the links for each vaccine below.

All vaccines are tested through three phases of clinical trials to ensure they meet the gold standard. Phase 1 trials are with a small group of people to make sure there are no safety concerns and determines the appropriate dosage for the best immune response. Phase 2 trials are conducted on a larger group of people to check the vaccine works consistently and that the immune response is sufficient. Phase 3 trials test the vaccines on thousands of people for scientists to assess if the vaccine is producing immunity that will prevent disease. Usually, these phases are run in sequence, but in an effort to find a safe and effective Covid-19 vaccine as quickly as possible, once safety has been ascertained through Phase 1, Phases 2 and 3 are being run in parallel. Extensive checks and balances are required at every stage of the development of a vaccine, and this is no different for a Covid-19 vaccine. No stages in the vaccine development processes were bypassed.

Information on the study conducted using the Pfizer/BioNTech vaccine and its results are available in a peer-reviewed journal, the New England Journal of Medicine. A link to this is provided below:
https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=featured_home

The approval for use of the Pfizer/BioNTech and Oxford/AstraZeneca 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 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

Further to the above, the Moderna vaccine has also recently been authorised for use. Further information on this is provided below:
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Throughout this global pandemic, we have always been guided by the latest scientific advice. Having studied evidence on both the Pfizer/BioNTech and Oxford/AstraZeneca vaccines, the Joint Committee on Vaccination and Immunisation (JCVI) has advised that we should prioritise giving as many people in at-risk groups their first dose, rather than providing two doses in as short a time as possible.

The four UK Chief Medical Officers agree with JCVI that at this stage of the pandemic prioritising the first doses of vaccine for as many people as possible on the priority list will protect the greatest number of at risk people overall in the shortest possible time and will have the greatest impact on reducing mortality, severe disease and hospitalisations and in protecting the NHS and equivalent health services.

This is because the evidence shows that one dose of either vaccine provides a high level of protection from Covid-19.

For both vaccines, data provided to MHRA demonstrate that whilst efficacy is optimised when a second dose is administered both offer considerable protection after a single dose, at least in the short term. For both vaccines the second dose completes the course and is likely to be important for longer term protection.

The NHS across the UK will prioritise giving the first dose of the vaccine to those in the most high-risk groups. Everyone will still receive their second dose and this will be within 12 weeks of their first. The second dose completes the course and is important for longer-term protection.

The JCVI's independent advice is that this approach will maximise the benefits of both vaccines allowing the NHS to help the greatest number of people in the shortest possible time. It will ensure that more at-risk people are able to get meaningful protection from a vaccine in the coming weeks and months, reducing deaths and starting to ease pressure on our NHS.

The following Department of Health and Social Care (DHSC) webpage for the independent report 'Optimising the COVID-19 vaccination programme for maximum short-term impact' from the Joint Committee on Vaccination and Immunisation (JCVI) provides the rationale for the government's implemented dosing strategy:

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https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement/optimising-the-covid-19-vaccination-programme-for-maximum-short-term-impact

Further, the scientific basis from the JCVI concerning the current evidence on efficacy after single doses of the Pfizer/BioNTech, Oxford/AstraZeneca and Moderna vaccines is available in the public domain and is provided below:
https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement

Regarding your specific questions:

1. The demographics of the recipients of the vaccines in the clinical trials (including age) are presented in the PAR for that vaccine. The PAR for each vaccine is accessible via the links we have provided above.
2. The MHRA's assessment of the safety of each vaccine is presented in the PAR for that vaccine. Any precautions, warnings or contraindications are available in the Information for Healthcare Professionals for each vaccine. Both of these documents are available for each vaccine via the links we have provided above.
3. A full list of ingredients for each vaccine is available in Section 2 (Qualitative and Quantitative Composition) and Section 6.1 (List of Excipients) of the Information for Healthcare Professionals for each vaccine.

In response to your request for information about adverse reactions (ADR) reports to Covid-19 vaccines for your age group, we can confirm that the MHRA does hold this data.

We intend to publish all suspected reactions reported in association with available COVID-19 vaccines in an interactive format as iDAPs, along with our ADR summary that is published each week. The use of iDAPs will enable users to view the data by categories of their choice such as age, sex and seriousness of reports.

As we plan to publish the data, we consider that your request is covered by section 22 of the Freedom of Information Act (information intended for future publication) and the information you have asked for is therefore exempt from disclosure.

Section 22 is a qualified exemption which means we have considered whether there is a greater public interest in releasing the information requested or withholding it. We recognise there is strong interest in seeing this data and accept it should not be withheld.

We will send you a link to the iDAPs once they are published.

We hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

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The Information Commissioner's Office
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