Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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www.gov.uk/mhra

15th March 2021

Dear [redacted]

Our Ref: FOI 21/180

Thank you for your email dated 13th February 2021, where you asked:

"1. Given that the long term side effects are unknown what have you identified as potential risks e.g an increase in autoimmune conditions/diseases/negative health outcomes?
2. How likely are each of the risks you've identified and what (if any) is the confidence score?
3. What side effects/diseases/negative health outcomes are seen in animals after 12 and 24 months that have received mRNA treatment?
4. How many yellow card incidents have you received by vaccine and severity?"

The MHRA collects reports of suspected adverse reactions to all medicines and vaccines via the Yellow Card scheme. All reports are continually reviewed to detect possible new side effects that may require regulatory action, and to differentiate these from things that would have happened regardless of the vaccine or medicine being administered, for instance due to underlying or undiagnosed illness. Our adverse reaction assessment report can be found here:
https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

I can confirm that to date, our safety surveillance has not identified any new safety concerns regarding long term side effects such as autoimmune conditions or of an unexpected adverse impact in those with pre-existing medical conditions.

Please be assured that the MHRA continuously monitors the safety of COVID-19 vaccines through a variety of proactive pharmacovigilance processes, ensuring that any potential safety issues are promptly and adequately evaluated. Any information indicating a possible new safety concern will be evaluated, and updated advice for healthcare professionals and patients will be issued as appropriate.

With regards to the animal studies performed on the vaccines, the non-clinical assessments (composed of studies performed on animals) have been provided in the Public Assessment Report (PAR) for each vaccine. Additionally, Section 5.3 of the Information for Healthcare Professionals has updated information concerning reproductive toxicity, based on the non-clinical assessments

performed to date. Links to the PARs and Information for Healthcare Professionals for each vaccine 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

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.

Yours sincerely,

FOI Team
Vigilance and Risk Management of Medicines Division