FOI 22/1170 – qualitative risk assessment data

REQUEST
25 November 2022

In accordance to the Freedom of Information Act 2000 you are required to provide the following:

1. Does the Medicines and Healthcare Products Regulatory Authority hold a quantitative risk assessment data and report which demonstrates that the MHRA Yellow Card Vaccine Adverse Reaction reports are NOT the results of vaccine adverse reaction(s) and /or effects exist? Please answer YES or NO only. If YES please supply the full document.

2. Does the Medicines and Healthcare Products Regulatory Authority hold a quantitative risk assessment data and report by june: raine: acting as the Chief Executive, Medicines and Healthcare Products Regulatory Authority which demonstrates that the MHRA Yellow Card Vaccine Adverse Reaction reports are NOT the results of vaccine adverse reaction(s) and /or effects exist? Please answer YES or NO only. If YES please supply the full document.

3. Does the Medicines and Healthcare Products Regulatory Authority hold a UK Government quantitative risk assessment data and report which demonstrates that the MHRA Yellow Card COVID-19 Vaccine Adverse Reaction are NOT the results of COVID-19 vaccine adverse reaction(s) and /or effects exist? Please answer YES or NO only. If YES please supply the full document.

4. Does the Medicines and Healthcare Products Regulatory Authority hold a quantitative risk assessment data and report by the DEPARTMENT-OF-HEALTH-NORTHERN-IRELAND which demonstrates that the MHRA Yellow Card Vaccine Adverse Reaction reports are NOT the results of vaccine adverse reaction(s) and /or effects exist? Please answer YES or NO only. If YES please supply the full document.

5. Does the Medicines and Healthcare Products Regulatory Authority hold a a quantitative risk assessment data and report by the NORTHERN-IRELAND-EXECUTIVE which demonstrates that the MHRA Yellow Card Vaccine Adverse Reaction reports are NOT the results of vaccine adverse reaction(s) and /or effects exist? Please answer YES or NO only. If YES please supply the full document.

6. As the harms and potential harms to children aged 12 years - 18 years who are injected with the experimental COVID-19 gene therapy/vaccination/injection /jab including, but not limited to, death, myocarditis also known as inflammatory cardiomyopathy, pericarditis, blood clots, etc. are documented, does the Medicines and Healthcare Products Regulatory Authority hold a medical quantitative risk assessment for children and young people from 12 years old to 18 years for the experimental Covid-19 gene therapy/vaccination/jab injection authorised by Michael Mc Bride, acting as Chief Medical Officer, Department of Health Northern Ireland? Please answer YES or NO only. If YES please supply the full document.

7. As the harms and potential harms to children aged 12 years - 18 years who are injected with the experimental COVID-19 gene therapy/vaccination/injection /jab including, but not limited to, death, myocarditis also known as inflammatory cardiomyopathy, pericarditis, blood clots, etc. are documented, does a Risk- Benefit Analysis between the harms and potential harms of children aged 12 - 18yrs taking the experimental COVID-19 gene therapy/vaccination/injection and children aged 12 years to 18 years acquiring a natural COVID-19 infection exist? Please answer YES or NO only. If YES please supply the full document. "

8. As the harms and potential harms to children aged 12 years - 18 years who are injected with the experimental COVID-19 gene therapy/vaccination/injection /jab including, but not limited to, death, myocarditis also known as inflammatory cardiomyopathy, pericarditis, blood clots, etc. are documented, does the Medicines and Healthcare Products Regulatory Authority hold a quantitative Risk- Benefit Analysis between the harms and potential harms of children aged 12 - 18yrs taking the experimental COVID-19 gene therapy/vaccination/injection and children aged 12 years to 18 years acquiring a natural COVID-19 infection exist? Please answer YES or NO only. If YES please supply the full document. "

9. As the harms and potential harms to a pregnant woman and her unborn baby's health and wellbeing by taking the experimental Covid-19 gene therapy/vaccination/injection short term, medium and long term are unknown as "…large clinical trials of COVID-19 vaccine in pregnancy have not been carried out."* does a medical risk assessment for pregnant woman who take the Covid-19 gene therapy/vaccination/injection authored by Michael McBride acting as Chief Medical Officer for Northern Ireland exist? Please answer YES or NO only. If YES please supply the full document.

*'The Immunisation against infectious disease' also known as the 'Green Book'
 Source: The Immunisation against infectious disease' also known as 'The Green Book':
- https://bit.ly/3pGsosK

10. As FOI 25378 to the Belfast Health and Social Care Trust states that from 1st January 2021 - 31st May 2021: zero (0) i.e. no pregnant women were admitted to hospital for treatment Covid-19; zero (0) i.e. no pregnant women were regarded as seriously ill with Covid-19; zero (0) i.e. no pregnant women were admitted to ICU for treatment of Covid-19; zero (0) i.e. no pregnant women needed a ventilator for treatment of Covid-19; does the Medicines and Healthcare Products Regulatory Authority hold a a Risk- Benefit Analysis between the harms and potential harms of pregnant woman taking and her unborn baby being exposed to the experimental COVID-19 gene therapy / vaccination / injection /jab and a pregnant woman and her unborn baby not exposed to receiving acquiring a natural COVID-19 infection exist? Please answer YES or NO only. If YES please supply the full document.

11. Does the Medicines and Healthcare Products Regulatory Authority hold copies of the licenses for all Covid-19 vaccination(s) /gene therapy(s)/injection(s) administered in Northern Ireland since January 2021. Please answer YES or NO only. If YES, please supply the full licenses.

12. Does the Medicines and Healthcare Products Regulatory Authority hold copies of the full, unredacted list of ingredients of all of the Covid-19 vaccination(s)/gene therapy(s) administered in Northern Ireland since January 2021. Please answer yes or no only. If YES, please supply the full unredacted lists of ingredients.

MHRA RESPONSE
8 March 2023

FOI 22/1170

Dear

Thank you for your email and we apologise for delay in response.

For Questions 1- 9 we confirm that the information you have requested is not held by the MHRA. The assessment of benefits and risks of a medicinal product is conducted qualitatively on an ongoing basis.

The MHRA has in place a comprehensive strategy to monitor the safety of the COVID-19 vaccines authorised in the UK. This monitoring strategy is continuous, proactive and based on a wide range of information sources. The Yellow Card scheme is one of the sources of information used in the monitoring strategy and is the UK system for healthcare professionals and patients to report suspected side effects or adverse reactions to medicines and vaccines. Further details on the monitoring strategy including the Yellow Card Scheme can be found here: https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance#proactive-vigilance-for-covid-19-vaccines

The MHRA's view is that the benefits of the vaccines in preventing serious complications associated with COVID-19 far outweigh any currently known side effects in the majority of patients. The MHRA will continue to carefully review and monitor all reports of suspected side effects submitted to us following COVID-19 vaccination. When a safety issue is confirmed the MHRA will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk.

You asked about the safety of Covid-19 vaccines in pregnancy. We recommend as a starting point that you review our 'Coronavirus vaccine - summary of Yellow Card reporting', which has a section entitled 'Safety of COVID-19 vaccines in pregnancy'.

For Question 11 - Firstly, the COVID-19 vaccinations are not classified as gene therapy. Secondly, Northern Ireland licences are determined by the European Medicines Agency and not MHRA.
Please see below links to the European Public Assessment Reports (EPARS) for these products.

https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna
https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-janssen
https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca
https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca
https://mhraproducts4853.blob.core.windows.net/docs/27680d2f701880f90f62740cab6adb4d939b54b4
https://mhraproducts4853.blob.core.windows.net/docs/27680d2f701880f90f62740cab6adb4d939b54b4

Question 12 – We confirm that this information available in the public domain

If you have a query about the information provided, please reply to this email.

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 at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Experience Centre

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