FOI 23/044 - Yellow card reports on Covid Vaccines

13 January 2023

> *I would be grateful if you could answer the following questions under the Freedom of Information Act.*
>
> *1. What form do your investigations take, eg do you contact patients or their GP's, coroner's etc*
>
> *2. What percentage of the reports on adverse reactions and deaths were established to be definitely caused by the vaccines.*
>
> *3. At what point do you consider withdrawing a medicine or vaccine. I note in the past some have been withdrawn after very few reports of harm. What level of harm would cause you to withdraw the vaccines.*
>
> *4. Given that there are many recorded yellow card reports what have you done to minimize harm for the future as described on your website.*
>
> *Finally, I note that you have described the agency now as an 'enabler'. As your role is supposed to be as a regulatory agency to protect the public, the change of description would suggest that you are now acting to help the pharmaceutical industry rather than preventing them harming patients. I would appreciate your comments.*
> *Has the change of emphasis been authorised by parliament?*

MHRA response

16 March 2023

Thank you for your email of 13 January 2023 where you requested the following information in relation to Yellow Card reports concerning COVID-19 vaccines:

1. What form do your investigations take, eg do you contact patients or their GP's, coroner's etc

2. What percentage of the reports on adverse reactions and deaths were established to be definitely caused by the vaccines.

3. At what point do you consider withdrawing a medicine or vaccine. I note in the past some have been withdrawn after very few reports of harm. What level of harm would cause you to withdraw the vaccines.

4. Given that there are many recorded yellow card reports what have you done to minimize harm for the future as described on your website.

For 1), since the start of the COVID-19 vaccine roll out, a team of scientists have continually reviewed the Yellow Card reports received, considering information such as the patient's medical history and the nature of the event, along with how many other similar reports have been received.

Where it is considered that additional information would aid our assessment of the case, the reporter is contacted to request these details. The reporter may be a healthcare professional or a patient reporting about someone else, or could be someone reporting for themselves.

In response to 2), this information is not held. For individual reports, the MHRA is most often not in a position to establish whether a suspected adverse reaction is definitely caused by a vaccine. The purpose of the Yellow Card scheme is to provide a system for the public and healthcare professionals to raise suspicions about possible side effects. The MHRA then considers information from the Yellow Card scheme alongside other information such as the likelihood of the event being caused by the medicinal product, and whether there is other evidence to support an association.

For vaccines, which are generally given as a one-off exposure to a wide range of people, many of whom are healthy, it is often challenging to assess whether there is a true link, and this is why data on how many people have been exposed to the vaccine, and what the background rate of the event is, is important, along with well-designed epidemiological studies.

In response to 3), there is no set number of suspected adverse reactions which would trigger the withdrawal of a medicinal product. Ultimately, if the known risks are considered by medicines regulators and/or the manufacturer to outweigh the benefits, or expected benefits of a medicinal product for all or the majority of people, then a product would be withdrawn. When considering the number of reported suspected adverse reactions, it is important to consider how many people have been exposed to the product and over what time period. Other considerations include the level of awareness of a particular product. The COVID-19 vaccination programme was the largest ever undertaken in the UK (over 93% of the UK population have received at least one vaccine since December 2020), and there was high awareness of the vaccines amongst the general public.

In response to 4), where new risks have been established through ongoing assessment by the MHRA or other regulators such as the European Medicines Agency as being linked to certain COVID-19 vaccines, we have ensured that these new risks are captured in the authorised product information (the summary of product characteristics and the patient leaflet), and where considered appropriate, communications have been issued to the pubic and healthcare professionals to raise awareness of the risk, the signs and symptoms to be aware of and what action should be taken. However it is unfortunately the case that it is often not possible to predict who may experience adverse effects following vaccination. However, the MHRA regularly provides information on the safety of the COVID-19 vaccines to the committee which makes recommendations on the roll out of the COVID-19 vaccines in the UK.

In response to your comments about MHRA as an ‘enabler’, the MHRA as the UK sovereign regulator of medicines and healthcare products works across the product life cycle to make sure that medicines and healthcare products available in the UK are safe and effective. As a sovereign regulator we also have the responsibility to enable innovation through supporting research and development that is beneficial to public health, as set out in our obligations under the Medicines and Medical Devices Act 2021. These two obligations to ensure safety and efficacy alongside attractiveness of the UK to undertake research and development, are complementary in nature as they provide MHRA access to data across all stages of development and supply of medicine and healthcare products. As a regulator, the MHRA must engage with all sources of innovation including for example UK academia, UK health services and commercial entities that whilst including Pharmaceutical companies, also encompasses the small and medium enterprise sector in the UK and globally. Through this we are made aware of opportunities to protect the health of the UK population and to monitor safety.

MHRA does this in a non-exclusive and unbiased fashion, maintaining an independence and rigour that is respected around the world. By engaging with all sectors we are able to better understand how me might regulate emerging technologies and modalities, enabling the UK population access to life changing and life saving technologies. In addition by enabling research and development we are also able, where appropriate and to the best of our ability, prevent harmful products reaching the patients and the public.

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,

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. After that, if you remain dissatisfied, you may ask the Information Commissioner at: The Information Commissioner’s Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF