FOI 22/1201

[PREVIOUS REQUEST/RESPONSE FOI 22/1169]

16 November 2022

> i still request data showing the annual occurrence of myocarditis, arrythmias & any other heart issues amongst the UK cohort as a baseline comparison from 2010 onwards & also following any Covid-19 vaccination.

MHRA RESPONSE

> Regarding the first part of your request "annual occurrence of myocarditis, arrythmias & any other heart issues amongst the UK cohort as a baseline comparison from 2010 onwards" We confirm that the MHRA does not hold this information.
>
> Regarding the second part of your request, please refer to the link below where we have published information on the Yellow Card reports we have received and our analysis of those:
> https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

REQUEST FOI 22/1201
15 December 2022

> thank you. where can i get this information from? i'm shocked that your newly installed £1 million plus artificial intelligence system has not been used to collate this information on such a large national vaccination experiment.

MHRA RESPONSE
20 January 2023

Dear

Thank you for your email dated 15th December 2022.

It may be helpful if I firstly describe the role of the Medicines and Healthcare products Regulatory Agency (MHRA) and the work that we do. The MHRA is a government agency that has responsibility for the regulation of medicines and medical devices. The MHRA, together with independent expert advice from the Commission on Human Medicines (CHM), is responsible for ensuring that the overall balance of benefits in terms of effectiveness, and risks of medicines is positive at the time of licensing and remains so thereafter.

The Yellow Card Scheme, which is run by the MHRA, is the UK program for

collecting experiences of side effects from healthcare professionals and patients and is used to monitor the safety profile of all medicines, including those from prescriptions, over-the-counter or general retail sales. It is a voluntary scheme for healthcare professionals and members of the public; however there is a legal requirement for pharmaceutical companies to report side effects that they have received to the scheme. It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines or medicines which is why we do not hold the data you requested. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug.

We have a range of resources and technology to support the proactive vigilance of COVID-19 vaccination programmes. The use of artificial intelligence (AI) is just one element of that. We take every report of a suspected side effect seriously and combine the review of these individual reports with statistical analysis of anonymised clinical records. The specific AI tool is for the surveillance of COVID-19 vaccines due to the size and scale of the vaccination campaign. The AI tool we introduced has helped us by reducing the amount of manual coding required for each report, thereby saving resource in processing cases and ensuring they are rapidly available for scientific analysis. The tool is not used for assessment of data, but to help ensure that all the information from the reporter is well structured to support analysis and subject to robust quality assessment.

You may be able to obtain the information you requested from the Office for National Statistics.

Kind regards,

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