Medicines & Healthcare products Regulatory Agency

Mr Wynne Jones
By Email: cj-editor@biggeesblog.cymru

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

**gov.uk/mhra**

12 February 2021

Dear Wynne Jones

**Covid-19 Vaccines- Adverse Drug Reaction**

Thank you for your enquiry dated 24 January 2021.

I can confirm that the Artificial Intelligence (AI) tool you enquired about has been successfully deployed into the MHRA's pharmacovigilance system for to support the processing of cases of suspected adverse reactions we receive for COVID-19 vaccines.

All medicines and vaccines have the potential to cause side effects and the MHRA are responsible for monitoring the safety of all medicines and vaccines as well as medical devices and other healthcare products in the UK. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected safety concerns or incidents involving medicines and medical devices. The scheme is run by the MHRA and currently relies on voluntary reporting of suspected ADRs by health professionals and patients. The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation. Reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market.

With any major new vaccination campaign we always develop a proactive vigilance strategy, and COVID-19 vaccines are no exception. You can find our published strategy here with a further link to the ADR data we have received up to 24th January 2021 and our assessment of the data, these pages will be regularly updated. https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance

We have a range of resources and technology to support the proactive vigilance of any COVID-19 vaccination programme. The use of AI is one element of that. We take every report of a suspected side effect seriously and we combine the review of these individual reports with statistical analysis of clinical records.

This specific AI tool is for the surveillance of COVID-19 vaccines due to the potential size and scale of the vaccination campaign.

CPRD NIBSC MHRA

The AI tool we have introduced helps us by reducing the amount of manual coding 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.

Yours sincerely

Dr June Raine
Interim Chief Executive
Medicines and Healthcare products Regulatory Agency