FOI 23/124

13th March 2023

Dear

Thank you for your Freedom of Information (FOI) request dated 11th February 2023 where you asked for the Vaccine Analysis Print (VAP) for the swine flu vaccine Pandemrix.

It may be first useful to provide some background on the Pandemrix vaccine and the MHRA's involvement. In October 2009, a mass immunisation campaign with the pandemic H1N1v influenza (swine flu) vaccines, Pandemrix and Celvapan, started across the UK to help prevent future cases of swine flu. These vaccines were offered to all frontline health and social care workers, people at increased risk of influenza complications, and healthy children. The MHRA conducted a comprehensive post-pandemic safety review of the swine flu vaccines and antiviral medicines used to manage swine flu symptoms in the UK during 2009 - 2010 swine flu pandemic. From this review it was concluded by the Commission on Human Medicines (CHM) that no new risks had been identified with the extensive use of the swine flu vaccines in the UK during the pandemic, and that a positive balance of benefits to risks remains. The report summary of the review can be found here.

Further to your request, please find attached a VAP for the Pandemrix vaccine. The prints contain information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme up to and including 24/02/2023 for the vaccine Pandemrix. The attached guidance sheet provides you with further information on how to interpret the print.

When considering the attached spontaneous data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- 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. 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. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

The MHRA continuously monitors the safety of vaccines through a variety of pharmacovigilance processes including the Yellow Card scheme. As part of our signal detection processes all adverse reaction reports received by the Yellow Card scheme are individually assessed and cumulative information reviewed at regular intervals. If appropriate, regulatory action would be taken if any serious risks were confirmed.

As this data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: Pandemrix, INN-Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted) product information for details on the possible side effects of this vaccine.

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,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency