Medicines & Healthcare products Regulatory Agency

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[redacted]

28th April 2023

Dear [redacted]

FOI 23/253 – Vitamin K injections

Thank you for your email dated 05 April 2023 where you requested the interactive Drug Analysis Prints (iDAPs) for all the current brands for the vitamin K injections given to new-borns in the UK. Unfortunately, iDAPs are only available by substance so we are unable to provide you with an iDAP for each brand of vitamin K injection as requested, however we have provided a PDF Product Analysis Print (PAP) which I hope will meet your request.

Please find attached two PAPs; one for the Konakion brand of vitamin K injection and one for reports concerning a vitamin K injection in which the brand of injection was not reported. The prints contain information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received through the Yellow Card scheme up to and including 25/04/2023.

Please note the following points regarding the data provided:

- The PAPs include Yellow Card reports whereby the patient was reported either be 1 years old or younger, have an age group of neonate/infant or where the age of the patient is unknown.
- Reports in which the vitamin K was reported to be given orally have been excluded.
- Reports in which the dose given did not correspond to that given to a paediatric patient have also been excluded.
- 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 vitamin K injection, only that the reporter had a suspicion it may have. 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 products. 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 medicines and 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 these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: MHRA Products | Home for details on the possible side effects of vitamin K injections.

We 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