FOI 23/120

8th March 2023

Dear

Thank you for your FOI request dated 8th February. We can confirm that the MHRA has received a total of 9 UK spontaneous suspect adverse drug reaction (ADR) reports concerning codeine linctus preparations, between 01/01/2000 and 22/02/2023, containing a total of 16 adverse reactions. Individual reports can contain more than one reported reaction. To note, this data covers the current available codeine linctus preparations within the UK, where linctus preparation refers to viscous liquid preparations indicated for oral use. Brand name is not mandatory on a Yellow Card report and therefore is not always provided. Consequently, there may be reports which are only coded as codeine and occurred with linctus preparation but due to the lack of information we cannot determine this. The cumulative adverse reactions can be located in the drug analysis profile (DAP) attached. Please also see the DAP interpretation guide for your reference.

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 the vaccines.

When considering the provided spontaneous Adverse Drug Reaction (ADR) data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug. 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, 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. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

If you plan on sharing or publishing the data within this response more widely, please provide us with a copy beforehand so we can ensure correct interpretation.

Regarding your remaining questions, this information is not held by the MHRA and we would suggest that you contact DHSC and NHS England.

Kind regards,

FOI Team,
Vigilance and Risk Management of Medicines Division