FOI 23/042

8th February

Dear

iDAPs reports for pethidine

Thank you for your email dated 17 January 2023 regarding whether it is possible to obtain data on the time frame of when reports were received for a specific adverse effect and drug substance combination from the interactive Drug Analysis Profiles (iDAPs) available on our website.

I can confirm it is possible to filter by year received by the MHRA on the iDAPs using the option on the left-hand side. Using the example given in your email of pethidine and neonatal respiratory disorders, you can filter on year received to determine that 5 reactions within the neonatal respiratory disorders grouping were reported in association with pethidine during the years shown in Table 1.

Table 1: The total number of reactions within the neonatal respiratory disorders HLGT reported within UK spontaneous ADR reports in association with pethidine broken down by year received

Year received	Number of reactions
1964	2
1968	1
2017	1
2018	1

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

• A reported reaction does not necessarily mean it has been caused by the suspect drug, only that the reporter had a suspicion it may have been. When any medicine is given to patients, some recipients will inevitably experience illness following its use. 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular vaccine, and may be stimulated by promotion and publicity about a vaccine. 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.

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 Group