FOI 23/818

Dear

Thank you for your request under the Freedom of Information Act, we apologise for the delay in response. You requested:

> *"The information I'd like to request is in 4 parts:*
>
> *1. How many Yellow Card reports for Diazepam were submitted, broken down into the following categories and broken down by year for at least the past 10 years (2013 -> 2023), but if possible since the start of the yellow card scheme (01/07/1963)*
>
> *a) Suspected Defective Product*
>
> *b) Suspected Fake Product*
>
> *c) Suspected Side Effect*
>
> *2. For the reports for a) "Suspected Defective Product" and b) "Suspected Fake Product", how many of these reports resulted in a sample being analysed - again broken down by year, with statistics listed separately for the a) and b) categories.*
>
> *3. For the reports for which a sample was collected and analysed, how many resulted in a defective product or fake product being identified? - again broken down by year with statistics listed separately for the a) and b) categories.*
>
> *4. I was looking at the FOI request listed at this url: https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-26-july-2021/freedom-of-information-request-on-adverse-reactions-following-co-administration-of-opioid-and-benzodiazepine-foi-21743*
>
> *In the response, there is a quote:*
>
> *"Further to your request please find attached the relevant Drug Analysis Prints (DAPs). The prints contain information on all the UK spontaneous Adverse Drug Reaction (ADR) reports received where an opioid and benzodiazepine have been reported as suspect medications received since the start of the Yellow Card scheme, 01/07/1963 until 13/07/2021."*
>
> *However I cannot see the attached Drug Analysis Prints (DAPs). Would you be able to let me know how I can access these?"*

We confirm that we do hold information in scope of your request. However, we need to seek some clarification from you before we can proceed. Could you please consider and respond to us on the following points:

- In point 1) you have asked specifically about reports via the Yellow Card Scheme. However, reports we receive from Marketing Authorisation Holders (licence holders of medicines) are made outside of Yellow Card. Would you like us to consider these reports as part of your request?
- Also, regarding point 1), could we check our understanding of the timeframe you specify. Is it the case that you are seeking for us to breakdown reports into categories a, b, and c for as far back as our data allows? We will be happy to proceed on that basis, noting that some of these terms may not appear as categories in our data as far back as 1963.
- The way our data is structured means that some of our searches will need to be against the licensed product name (which in some cases will be a brand). We attach a list of all Diazepam marketing authorisations that have ever been granted in the UK (noting the current status alongside each). Could you confirm whether your request covers all of these products? i.e. any and every Diazepam product that we have received a report against. If it is something different then please let us know by reply.

We apologise for the delay in responding to you and seeking this clarification.

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU