Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
www.gov.uk/mhra

[redacted]

20th December 2023

Dear [redacted]

FOI 23/919 – Media or FOI request

Thank you for your Freedom of Information (FOI) request dated 24th November 2023 where you asked:

- **Can you please let me know how many yellow card reports you have received in each of the previous five years related to herbal and homeopathic medicines.**
- **Please provide a break down of the medicines and adverse effects and comments received for each.**
- **The MHRA website below suggests you have an existing definition of what constitutes a herbal or homeopathic medicine.**

Further to your first request please see table 1 detailing the number of UK spontaneous suspected Adverse Drug Reaction (ADR) reports for herbal and homeopathic products received between 2018-2022

Table 1: Number of UK suspected spontaneous adverse reaction reports associated with medicinal herbal or homeopathic products between 1st January 2018-31st December 2022.

Year	Medicinal herbal product reports	Homeopathic product reports
2018	**92**	**1**
2019	**80**	**2**
2020	**72**	**4**
2021	**173**	**0**
2022	**165**	**2**

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

- The inclusion of a particular reaction on our system does not necessarily mean that it has been caused by the suspect drug. Many factors must be considered in assessing causal relationships, including temporal association, the possible contribution of concomitant medication, and the underlying disease. We encourage reporters to report suspected ADRs i.e., the reporter does not have to be sure of a causal association between the drug and the reactions – a suspicion will suffice.
- It is 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 to drugs for several reasons. 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.
- The number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known.

In terms of your second request it may be of interest that the Medicines and Healthcare products Regulatory Agency (MHRA) publishes interactive Drug Analysis Profiles (iDAPs) containing complete data for all spontaneous suspected adverse drug reactions, or side effects, which have been reported for medicines including herbal and homeopathic substances. This information can be accessed by following the link: https://yellowcard.mhra.gov.uk/idaps. Here you can choose the drug of interest by searching for a particular active substance. Plant based herbal or homeopathic products are listed by the botanical name rather than the common name e.g. St John's wort is Hypericum. This includes all reports received from healthcare professionals, members of the public, and pharmaceutical companies. The iDAPs allow you to filter to display subsets of the data, such as limiting to just males or females or by particular date ranges.

With regards to the request for comments received for each suspected adverse reaction, unfortunately, this information is exempt from release under sections Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

Further to your final request the definition of a herbal product and a link to a list of herbal products currently holding a traditional herbal registration (THR) granted by the MHRA can be found via Apply for a traditional herbal registration (THR) - GOV.UK (www.gov.uk). Similarly, the definition and list of registered and authorised homeopathic products can be found via Register a homeopathic medicine - GOV.UK (www.gov.uk).

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

Medicines & Healthcare products Regulatory Agency

Wilmslow
Cheshire
SK9 5AF