FOI 23/461

Dear

Thank you for your Freedom of Information request dated 27th June 2023, where you requested MHRA data regarding ***adverse incident reports associated with the use of dermal fillers as well as botulinum toxin used for cosmetic purposes***.

Further to your request, I can confirm that we have received a total of **1,323** UK, spontaneous adverse incident reports for dermal fillers, including both hyaluronic acid and non-hyaluronic acid based products up to and including 27/07/2023. The inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. In addition, details of the reports may have changed since the report was submitted. When incidents are recorded on MHRA's adverse incidents database, each incident is reviewed and then the reported clinical effects are recorded by selecting the respective term from a list of predetermined clinical effects.

The data must be read together with the following explanations:

- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues.
- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time after the use of dermal fillers and on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- When interpreting the above data it is important to note that 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 dermal filler is known.
- The numbers may include reports where the incident has been taken from published literature.
- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.
- Adverse incident reports by members of the public are voluntary but play a substantial part in the successful operation of the vigilance system. All reports received via Yellow Card are sent to the relevant manufacturer (if known and anonymised as appropriate) to feed into the vigilance system.
- Adverse incident reports include mandatory reporting by manufacturers to MHRA for certain types of incidents that occurred in the UK as part of the regulatory post market surveillance 'vigilance' system. The principal purpose of this system is to improve the protection of health and safety of patients. This is

to be achieved by the evaluation of reported AIRs and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such adverse events.

Additionally, I can confirm that the MHRA has received a total of **396** UK spontaneous suspect adverse drug reaction (ADR) reports concerning botulinum toxin indicated for cosmetic purposes such as skin wrinkling, up to and including 27/07/2023. Individual reports can contain more than one reported reaction. It is important to note that indication is not a mandatory field when completing a Yellow Card report and so this is not always provided. Therefore, the true number of cases where botulinum toxin is used for cosmetic purposes could be higher. The cumulative adverse reactions can be located in the drug analysis profile (DAP) attached. Please also see the DAP interpretation guide for your reference.

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.

Please be aware that the DAP provided should not be used as a list of side effects to botulinum toxin products. All established undesirable effects for licensed botulinum toxin medicines can be found at the Electronic Medicines Compendium (EMC) website. These are listed in section 4.8 of the Summary of Product Characteristics (SmPC) and section 4 of the Patient Information Leaflet (PIL). Please see the following link for your reference: Home - electronic medicines compendium (emc).

I hope the information provided is helpful. The MHRA encourages the use of Yellow Card data however wishes to ensure that the data is studied and applied appropriately, and any conclusions/interpretations take into account the above information. For this reason, if you wish to use this information for a publication, we request that you engage with the MHRA during this process and provide a copy of the report.

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,
Vigilance and Risk Management of Medicines Division