Medicines & Healthcare products
Regulatory Agency

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[redacted]

15 April 2024

FOI 24/319

Dear [redacted],

Thank you for your email dated 13 March 2024, where you requested the following information on the reports in the iDAP for clostridium botulinum:

- Indication for the use of Botox; particular interest in cosmetic procedures
- Why have the most recent years have seen a dramatic increase?

The MHRA has received 644 spontaneous suspected adverse drug reaction (ADR) reports for the medicinal product Botox up to and including 9 April 2024. Please note this excludes ADR reports associated with alternative clostridium botulinum products. Within these reports 191 report a cosmetic indication. Attached is a Product Analysis Print containing a complete list of all suspected ADRs for the 191 reports.

The table below provides the number of reports for each cosmetic indication term.

Table 1. UK spontaneous suspected ADR reports for Botox with a cosmetic indication

Indication	Number of reports
Excessive gingival display	2
Face lift	3
Lip cosmetic procedure	2
Skin cosmetic procedure	42
Skin wrinkling	147

Please note that it is not mandatory to provide the indication when submitting a Yellow Card report. Furthermore, a suspect drug may have more than one indication associated with it.

The reporting rate for spontaneous ADRs can depend on lots of different factors and is influenced by public awareness and seriousness of the event. The MHRA has a Yellow Card Strategy to continually promote the scheme and raise awareness amongst healthcare professionals and patients. During the COVID-19 vaccine campaign in 2021, we worked with media outlets, ran a social media campaign and worked in close collaboration across the healthcare system to ensure healthcare professionals and patients were and still are aware of the Yellow Card scheme and how they can report to us. The success of these campaigns has resulted in an overall increase in the number of reports we receive across all medicines, vaccines and devices. In addition, the MHRA has observed an increase in reports from

marketing authorisation holders, who have a regulatory obligation to report all suspected ADRs to the MHRA.

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

- A reported reaction **does not** necessarily mean it has been caused by the vaccine, medicine, or device only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a vaccine, medicine, or device, 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 or compare the safety profile of different vaccines, medicines, or devices. ADR and Device incident reporting rates are influenced by the seriousness of adverse reactions, their ease of recognition, the extent of use of a particular medicine or device, and may be stimulated by promotion and publicity. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

I hope the information provided both here and in the iDAPs is helpful, however if you are interested in receiving any additional information outlined in the options above please let us know by return of this email. 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

Please remember to quote the reference number above in any future communications.

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

Information Commissioner's Office

Medicines & Healthcare products
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