Medicines & Healthcare products Regulatory Agency

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

[redacted]

30th April 2024

FOI 24/315

Dear [redacted]

Thank you for your Freedom of Information request dated 2nd April 2024, where you stated: *"I have received news from some colleagues detailing dosing issues during the injection of insulin when using BD AutoShield Duo Safety pen needles (see copy of this below) due to the needle not being visible to the healthcare professional. I do not have much more information about this and I was, in fact, surprised to hear it as errors likely respond to the wrong injection technique, rather than the device itself. Would you be able to share any reports on this? The Drug Analysis Profiles (iDAPs) only include medicinal agents, do you have a similar source for medical devices? Or shall I request this differently?"*

Further to your request, I can confirm that while we do hold information on failure reports regarding the above device, this information is exempt from disclosure under Section 44 of the Freedom of Information Act 2000 (FOIA).

Section 44 – Prohibitions on disclosure: the release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions, and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002 and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.

Whilst we cannot provide information for a specific device, we are able to provide higher level information. For instance, we are able provide the medical device problems reported for pen needles generally. If this would be appropriate, please can you state this in a reply, and we will be able to deal with this as a new request.

As with all medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.

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

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, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF