FOI 23/052

24th February 2023

Dear

Thank you for your continued communication with the MHRA where you detail your ongoing concerns with regards to the function of the LibreLink alarms and sensor connectivity problems you have identified. Please accept our apologies for the delay in getting back to you.

In your enquiry, dated 22nd January 2023, you have asked the following questions under the Freedom of Information (FOI) act:

- 1) To be sent copies of all correspondence the MHRA have had so far with Abbott on this matter.
- 2) Have you also been in contact with other public sector bodies?

To address your first point, please see attached the email and associated attachments that document the correspondence the MHRA has had with Abbott on the matter of loss of sensor connection and software updates. Redactions have been made under Section 40 of the FOI Act, the names of employees below the grade of Senior Civil Servant (SCS) have been withheld. This is because they are normally not responsible for high profile work and would not reasonably expect their personal details to be in the public domain. As a result, the releasing of their names would not, in our view, be fair or reasonable. Similarly, names and personal identifiers of external stakeholder contacts have been redacted in line with the data protection. Where topics unrelated to your enquiry are present within the relevant documentation, these have also been redacted to ensure confidentiality.

It is important to note that further redactions within the associated email attachments have been made in line with the exemptions under section 43 (2) FOIA due to commercial sensitivities. This information is exempt information as it has been assessed that its disclosure would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

To address your second question, the MHRA has not been in contact with other public sector bodies. The issues you have raised have been addressed by Abbott and a Field Safety Notice (FSN) is available on this subject matter here: https://www.gov.uk/drug-device-alerts/field-safety-notices-6-to-10-february-2023

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