Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

[redacted]

Our Ref: **FOI2026/00816**

13 August 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 24 July 2026. You wrote:

Under the Freedom of Information Act 2000, I am requesting the following information held by the MHRA.

1. The number of adverse incident reports received by the MHRA relating to continuous subcutaneous insulin infusion (CSII) pumps or automated insulin delivery (AID) / hybrid closed loop systems, where the reporting organisation or patient location was in Northern Ireland, for the period 1 January 2019 to the date of this request, broken down by year and by outcome severity (death, serious harm, other).
2. Where the outcome was recorded as death, whether the report identifies the suspected cause as device malfunction, software/algorithm fault, or user error, where this classification is recorded.
3. Whether any of these reports relate to devices also the subject of a Field Safety Notice or recall during the same period, and if so, please identify which notice(s).

MHRA Response

We confirm that we hold the information you have requested.

The MHRA codes medical devices within adverse incident reports using the Global Medical Device Nomenclature (GMDN). GMDN is a system of internationally agreed generic descriptors used to identify medical device products. We used the below Global Medical Device Nomenclature (GMDN) and Collective Term (CT) codes to query our database for the devices requested:

CT1822 – Ambulatory insulin infusion pumps

I can confirm that between 1 January 2019 and 24 July 2026, we received 17 adverse incident reports from Northern Ireland concerning the above CT code. None of these reports involve a fatal outcome.
We have provided a breakdown of these data in Table 1. Adverse incident reports concerning Ambulatory insulin infusion pumps received between 1st January 2019 and 24 July 2026, broken down by year.

We use the International Medical Device Regulators Forum (IMDRF) codes to classify adverse event terminology including terms for patient/user outcome. The Annex F code is used to classify the health impact of a medical device adverse event. We have provided a breakdown of these data in Table 2. Adverse incident reports from Northern Ireland concerning Ambulatory insulin infusion pumps received between 1st January 2019 and 24 July 2026, broken down by incident (Annex F).

Regarding the third request concerning if any of these reports relate to devices also the subject of a Field Safety Notice (FSN) or recall, a search was conducted across the aforementioned device type for the same period of 1 January 2019 to 24 July 2026. Three FSNs have been identified as follows:

- Omnipod 5 Automated Insulin Delivery System – 30 November 2023 – Regarding the Omnipod 5 Controller with software version 1.2.0 – Issue with Insulet Omnipod 5 insulin pumps means that device will not register a bolus entry entered with a decimal point. A software update was rolled out to correct this issue, and users were recommended to input doses with a decimal by using a '0.' Before entering the required dose.
- MyLife YpsoPump Orbit micro 2.0 infusion sets – 6 June 2024 – Regarding skin irritation associated with a new adhesive patch introduced in 2023. Users were recommended to discuss their concerns with their healthcare provider.
- Omnipod 5 Automated Insulin Delivery System and Omnipod Insulin Management System (Omnipod Eros) – 27 May 2026 – Recall of two lots due to tear in external soft cannula. Users were asked to check their pods and discontinue impacted lots, and replacement was provided.

When reviewing adverse incident data please note:

- 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 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.
- 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.
- 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. The data provided, therefore, is not a summary of known or proven adverse reactions to the device and must not be interpreted and used as such.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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