Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00738**

10 August 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 9 July. You wrote:

> *I am writing to request information under the Freedom of Information Act (2000).*
>
> *I understand that the MHRA has said that doctors should report all suspected inaccuracies caused by AI tools used in clinical practice to the regulator's yellow card scheme.*
>
> *I would like to know:*
>
> *1. To date, how many times the MHRA has been made aware of inaccuracies or concerns caused by AI tools used in clinical practice.*
>
> *2. How many of these (issues flagged) were related to AI-enabled ambient scribing products*
>
> *3. Please give the details of each issue flagged - including the name of the product used, the details of who contacted the MHRA (e.g. GP surgery name or Trust) and details of what the concern was.*
>
> *4. Is the MHRA sent hazard reports related to AI-enabled ambient scribing products, collated by medical practices? If so, please supply all the hazard reports which have been received since April 2025.*
>
> *If you are unable to answer any part of this request please move on to the next question and provide as much information as you can.*
>
> *I would like to receive this information in the form of an email reply.*
>
> *If this request is too wide or unclear, I would be grateful if you could contact me as I understand that under the Act you are required to advise and assist requesters. If any of this information is already in the public domain, please can you direct me to it, with page references and URLs if necessary. I understand that you are required to respond to my request within the 20 working days after you receive this letter. I would be grateful if you could confirm in writing that you have received this request.*

[redacted]

MHRA Response

Regarding the first part of your request, medical device registration data does not look at whether a device is Artificial Intelligence (AI) enabled. Devices are registered under a Global Medical Device Nomenclature (GMDN) code and there is no one specific GMDN code or term that covers all AI products. Qualification and classification of devices is based on intended use/purpose. Therefore, we are unfortunately unable to answer this part of your request without further clarification of the specific AI enabled devices you are seeking information for.

Regarding the second part of your request, we can confirm that we hold the information you requested. As of 30th July 2026, the MHRA has received a total of 5 reports for Ambient Voice Technology (AVT) products. The search was conducted using the GMDN Collective Term (CT) codes specified below, which correspond to the description of these products, and the supplier names listed on the NHS England AVT Self-Certified Supplier Registry: Ambient Voice Technology Self-Certified Supplier Registry - NHS England Digital.

GMDN CT codes:

- CT1629 - Dictation systems and associated devices
- CT1630 - Dictation systems

Regarding part 3 of your request, please see below aggregated tables containing the information on the role of the initial reporter, and the IMDRF Annex E, A and F terms reported in these cases. We are not able to disclose individual case level details or information on the location of the reporter. This information is exempt from release under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOI Act.

Supplying you with this information could lead to patient or reporter identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme.

The MHRA now adopts International Medical Device Regulators Forum codes for Health Effects (IMDRF https://www.imdrf.org/working-groups/adverse-event-terminology/annex-e-health-effects-clinical-signs-and-symptoms-or-conditions). As such, Tables 2-4 provide the breakdown of the 5 reports by Annex A, E and F codes. Please be aware that a single report may also contain more than one Annex A/E/F code, and code-level counts should therefore not be added together and interpreted as the number of individual patients or distinct events.

Table 1: role of initial reporter

Role of initial reporter	Number of reports
Patient	1
Healthcare professional	4
Total reports	5

Table 2: IMDRF Annex A terms reported

IMDRF Annex E term	Number of reports
A09 - Output Problem	1
A23 - Use of Device Problem	2
A26 - Insufficient Device Problem Information	1
A27 - Appropriate Device Problem Term/Code not Available	1
A0203 - Defective Device	1
A1107 - Data Problem	1
A210103 – Inaccurate Information	1
Total reports	5

Table 3: IMDRF Annex E terms reported

IMDRF Annex E term	Number of reports
E24 - Other Terms/codes Related to Clinical Signs and Symptoms or Conditions	1
E0202 – Emotional Changes	1
E2403 – No Clinical Signs, Symptoms or Conditions	2
E2401 – Insufficient Information	1
Total reports	5

Table 4: IMDRF Annex F terms reported

IMDRF Annex F term	Number of reports
F11 - Non-Serious Injury/ Illness/ Impairment	1
F12 - Serious Injury/ Illness/ Impairment	1
F24 – Insufficient Health Impact Information	1
F26 - No Health Consequences or Impact	2
F28 – Appropriate Health Impact Term/Code not Available	1
Total reports	5

To provide you with some further information, these five reports report a range of issues relating to the system capturing incorrect information; file save errors; and concerns relating to patient consent of use of the product.

You asked for the name of the products used. This information is being withheld under section 43 of the Freedom of Information Act 2000. This exemption applies where disclosure would, or would be likely to, prejudice the commercial interests of any person or organisation, including a third-party supplier, manufacturer, or the public authority itself. We are unable to provide information on which companies the reports relate to for commercial confidentiality reasons.

Disclosure could reasonably be expected to prejudice the commercial interests of the manufacturer and/or other relevant organisations by revealing information that is not otherwise publicly available and which could be used by competitors to gain a commercial advantage. We recognise the public interest in promoting transparency and accountability regarding medical devices and the activities of public authorities. However, we consider that there is a stronger public interest in protecting legitimate commercial interests where

disclosure would be likely to cause commercial harm and could undermine the ability of organisations to participate openly and effectively in regulatory and commercial processes.

When reviewing this 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 report.

- 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 incidents related to the device and must not be interpreted or used as such.

Regarding the last part of your request, if you are referring to adverse incident reports submitted via the Yellow Card scheme, we can confirm that we accept reports from all healthcare professionals including those identified at medical practices. Submitted reports are device and case specific, with the reporter being guided to provide a description. The reporting form is dynamic and changes depending on the product type selected (medicine, vaccine, medical device, software/app/AI, blood product, e-cigarette) and the answers given during the report.

The Yellow Card scheme currently relies on voluntary reporting of suspected adverse effects associated with medicine and medical device use by healthcare professionals, patients and lay stakeholders. Therefore, healthcare professionals are not legally obliged to submit all adverse incident reports for all patients. However, the ability to report a Yellow Card is required to be and is included within nearly all GP clinical IT systems facilitating and making it easier to report suspected side effects to the MHRA by doctors. Please see the following press release for further information: Integrated Yellow Card reporting now available in 93% of GP practices in the UK - GOV.UK.

We can confirm that the 5 adverse incident reports for Ambient Voice Technology (AVT) products held by the MHRA were all received after April 2025.

If you are referring to hazards that have occurred in a medical practice related to the delivery of care, not product specific though may be involved in the care pathway, then that would be

under the remit of the Care Quality Commission (CQC), who regulate and monitor health and adult social care services in England.

If you plan to use this information for media publication purposes, you should contact our news centre who can provide any additional context or comment. You can contact them on 020 3080 7651 or by email at newscentre@mhra.gov.uk. For clarification on the recently published guidance, please reach out to our press office.

We hope this information is helpful. 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.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/