



Medicines & Healthcare products
Regulatory Agency

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Our Ref: **FOI2026/01032**

13 October 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 10 September. You wrote:

Under the Freedom of Information Act 2000, I request the following recorded information concerning how MHRA receives, records, assesses and uses evidence arising from coroners and inquests concerning deaths involving medicinal products.

The period of this request is 1 January 2018 to the date of this request.

This request is limited to existing centrally held policies, procedures, datasets, aggregate information, audits, reports and governance records.

I am not requesting individual patient records, individual Yellow Card reports, a manual review of individual inquests or the creation of new statistics.

Sources of coronial information

1) Please provide copies of any policies, procedures, standard operating procedures, guidance or other recorded arrangements governing MHRA's receipt or acquisition of information from:

- a) Prevention of Future Death reports issued under Regulation 28;*
- b) coroners or coroners' offices outside the Regulation 28 process;*
- c) inquest conclusions or narrative conclusions;*
- d) post-mortem or toxicology findings supplied following an inquest;*
- e) the Chief Coroner or Office of the Chief Coroner;*
- f) Ministry of Justice;*
- g) Medical Examiner offices or NHS England;*
- h) police or other public bodies following medication-related deaths.*

Deaths where no Regulation 28 report is issued

2) Please provide any recorded policy, procedure or guidance addressing how MHRA can become aware of, or obtain information from, an inquest involving a medicinal product where the coroner does not issue a Regulation 28 Prevention of Future Death report to MHRA.

3) Please include any recorded consideration of whether reliance on Regulation 28 reports alone would fail to identify medication-related deaths relevant to pharmacovigilance.

Systematic data feeds or information-sharing arrangements

Please provide copies or descriptions of any existing:

- a) information-sharing agreements;*
- b) memoranda of understanding;*
- c) routine data feeds;*
- d) notification arrangements;*
- e) database links;*
- f) periodic reports;*

between MHRA and any of the following concerning medication-related deaths:

- * coroners;*
- * the Chief Coroner;*
- * Ministry of Justice;*
- * Office for National Statistics;*
- * NHS England;*
- * Medical Examiner offices;*
- * toxicology services.*

Recording and Coding

4) Please provide any existing data dictionary, coding guidance or list of database fields used by MHRA to identify that safety information originated from:

- a) a coroner;*
- b) an inquest;*
- c) a Regulation 28 report;*
- d) a post-mortem;*
- e) toxicology;*
- f) a Medical Examiner;*
- g) a death involving suspected overdose or poisoning.*

Please also indicate through disclosure of the relevant recorded material whether such information can be searched or retrieved according to medicinal product.

Aggregate information

5) *Where already centrally held, please provide for each calendar year from 2018 onwards:*

- a) the number of Regulation 28 reports received by MHRA concerning medicinal products;*
- b) the number of other coronial or inquest notifications received which were not Regulation 28 reports;*
- c) the number of safety reports or pharmacovigilance cases identified as having originated from coronial or inquest information;*
- d) the number of cases where post-mortem or toxicology findings supplied by a coroner contributed to a pharmacovigilance assessment;*
- e) the number of Yellow Card reports, if separately identifiable, generated from or linked to coronial information.*

I am requesting these figures only where they already exist. I am not requesting MHRA to perform a retrospective review of individual records to create them.

Signal detection and regulatory assessment

6) *Please provide any policy, procedure, guidance or governance document describing how information arising from coroners, inquests, post-mortems or toxicology is incorporated into:*

- a) signal detection;*
- b) signal validation;*
- c) signal assessment;*
- d) periodic safety review;*
- e) benefit-risk assessment;*
- f) regulatory action concerning a medicinal product.*

Audits and gap analyses

7) *Please provide copies of any audits, reviews, reports, committee papers, risk assessments or gap analyses since 1 January 2018 considering:*

- a) whether MHRA receives sufficient information from coroners concerning medication-related deaths;*
- b) possible under-reporting of medication-related deaths identified at inquest;*
- c) limitations arising where no Regulation 28 report is issued;*

d) barriers to linking coronial, toxicological or mortality information with pharmacovigilance data;

e) proposals to improve such information flows.

Suicide, poisoning and medication-related deaths

8) *Please provide any national policy, guidance or governance record specifically concerning the use of coronial or toxicological information in MHRA surveillance where death involves:*

a) suicide;

b) intentional or suspected intentional overdose;

c) accidental poisoning;

d) prescribed-drug toxicity;

e) a combination of prescribed medicinal products.

For avoidance of doubt, I am seeking the systems by which MHRA learns from these deaths, not details of individual deceased persons.

If any part would exceed the appropriate cost limit, please provide the information which can be supplied within the limit and provide section 16 advice and assistance concerning any part requiring refinement.

Please provide the information electronically.

MHRA Response

We confirm that we hold some of the information you have requested. For ease of reference, we have numbered your questions above and corresponding answers can be found below.

Question 1

Please find attached our Standard Operating Procedure (SOP) "Responding to requests from Coroners and the Police".

Question 2

The MHRA has undertaken searches for recorded policy, procedure or guidance addressing how the Agency may become aware of, or obtain information from, an inquest involving a medicinal product where the coroner does not issue a Regulation 28 Prevention of Future Death report to the MHRA.

We have not identified any specific recorded policy, procedure or guidance that addresses this scenario.

In practice, the MHRA may become aware of information arising from an inquest through a variety of routes, including information provided by coroners, healthcare professionals, marketing authorisation holders, members of the public, Prevention of Future Death reports, or other regulatory and safety-monitoring activities. However, we do not hold any recorded

guidance that specifically sets out a process for obtaining information from an inquest where the coroner has not issued a Regulation 28 report to the MHRA.

Accordingly, under section 1(1)(a) of the Freedom of Information Act 2000, the MHRA can confirm that it does not hold recorded information falling within the scope of your request.

Question 3

The MHRA has interpreted your request as seeking recorded information on any current formal arrangements for the routine sharing of information relating to medication-related deaths between the MHRA and:

- coroners;
- the Chief Coroner;
- Ministry of Justice;
- Office for National Statistics (ONS);
- NHS England;
- Medical Examiner offices; and
- toxicology services.

The MHRA has conducted searches for recorded information within the scope of your request. We have not identified any information-sharing agreements, memoranda of understanding, routine data feeds, database links or equivalent standing arrangements specifically relating to the systematic provision of information on medication-related deaths between the MHRA and the organisations listed above.

The MHRA does not receive routine data feeds of coroner inquest outcomes or medication-related deaths from coroners, the Chief Coroner, the Ministry of Justice, Medical Examiner offices or toxicology services.

The MHRA may receive information relevant to medication-related deaths through a variety of mechanisms, including Yellow Card reporting, direct correspondence from coroners or healthcare professionals, published Prevention of Future Death reports, information provided by marketing authorisation holders, and other pharmacovigilance and regulatory activities. However, these do not constitute systematic data feeds or formal information-sharing arrangements of the type described in your request.

The MHRA also receives and uses mortality statistics and other publicly available health data published by external organisations, including the Office for National Statistics, where relevant to its public health functions. However, we have not identified any recorded information describing a dedicated routine data feed or information-sharing arrangement specifically concerning medication-related deaths between the MHRA and the organisations listed in your request.

Accordingly, to the extent set out above, the MHRA can confirm that it does not hold recorded information describing information-sharing agreements, memoranda of understanding, routine data feeds, notification arrangements, database links or periodic reports within the scope of your request.

Question 4

Within MHRA's Individual Case Safety Report (ICSR) database, Coroner is available as a specific Reporter Qualification value and may therefore be used to identify cases reported by a coroner.

MHRA does not hold dedicated database fields, code lists or coding guidance specifically for identifying information originating from:

- an inquest;
- a Regulation 28 (Prevention of Future Deaths) report; or
- a Medical Examiner.

Where such information is received, it may be contained within case documentation, attachments, correspondence and/or free-text narrative fields associated with an individual case.

For post-mortem examinations, MHRA holds structured ICSR fields relating to deaths, including:

- whether an autopsy/post-mortem was performed;
- reported cause(s) of death; and
- autopsy-determined cause(s) of death.

Additional post-mortem information may also be recorded within attached documentation and free-text case narratives.

MHRA does not hold a dedicated database field specifically identifying toxicology reports. Where toxicology information is provided, it may be recorded within results of tests and procedures, attached documentation and/or free-text narrative fields.

Deaths involving suspected overdose or poisoning are not identified through a dedicated database field. However, such cases may be identifiable through adverse reaction coding using the Medical Dictionary for Regulatory Activities (MedDRA), reported cause(s) of death, or autopsy-determined cause(s) of death.

Other than the Reporter Qualification value of "Coroner" and the structured death-related fields described above, MHRA does not hold a separate data dictionary, coding guidance document or list of database fields specifically designed to identify safety information as originating from each of the categories listed in parts (a) to (g) of your request.

MHRA has also considered whether information falling within categories (a) to (g) can be searched for or retrieved according to medicinal product. Where the information is recorded within structured ICSR data fields, such as Reporter Qualification, adverse reaction coding, reported cause(s) of death, autopsy status, autopsy-determined cause(s) of death, and product information, it may be possible to search for and retrieve cases by medicinal product and the relevant field value. However, where information is contained solely within free-text narratives, correspondence, attachments or other unstructured case documentation, retrieval according to medicinal product may require manual review of case records and may not be achievable through a specific database field or standard search parameter.

The extent to which information can be retrieved by medicinal product therefore depends on how the information has been recorded within the individual case record.

Question 5

MHRA has considered whether the following aggregate information could be extracted from its ICSR systems:

- a) The number of Regulation 28 reports received by MHRA concerning medicinal products

The MHRA has identified 110 Regulation 28 (Prevention of Future Death) reports concerning medicinal products received between 01/01/2018 and 17/09/2026. The annual breakdown is provided in the table below.

Year	Regulation 28 Reports
2018	14
2019	12
2020	11
2021	17
2022	9
2023	12
2024	19
2025	11
2026	5
Total	110

b) The number of other coronial or inquest notifications received which were not Regulation 28 reports

MHRA can identify ICSRs where the reporter qualification is recorded as Coroner, as this is a structured field within the ICSR database. However, MHRA does not hold dedicated fields identifying inquest notifications or other coronial communications. As a result, any count derived from the Reporter Qualification field would identify reports submitted by a coroner, but would not necessarily identify all coronial or inquest-related information held by MHRA. Yellow Cards are created for Regulation 28 Prevention of Future Death reports where the incident has not been reported by a third party.

c) The number of safety reports or pharmacovigilance cases identified as having originated from coronial or inquest information

MHRA does not hold a dedicated field recording whether a case originated from coronial or inquest information. Other than cases where the reporter qualification is recorded as Coroner. The annual breakdown of these is provided in the table below.

Year	Number of reports
2018	7
2019	13
2020	14
2021	37
2022	14
2023	6
2024	5
2025	3
2026	4
Total	103

d) The number of cases where post-mortem or toxicology findings supplied by a coroner contributed to a pharmacovigilance assessment

MHRA holds structured fields relating to autopsy status, reported cause(s) of death and autopsy-determined cause(s) of death. Information on post-mortem examinations and

toxicology findings may also be contained within test results, attached documentation and free-text case information.

However, MHRA does not hold a dedicated database field indicating that post-mortem or toxicology information was supplied by a coroner, nor a field recording whether specific information contributed to a pharmacovigilance assessment. Consequently, this information cannot be retrieved through a standard database query.

Where post-mortem or toxicology findings are available, they may be considered alongside all other relevant information during routine pharmacovigilance activities, including individual case assessment, signal management and signal detection. The contribution of such information to an assessment is not routinely recorded in a structured manner that would allow cases to be identified or counted through a standard search of the database.

e) The number of Yellow Card reports, if separately identifiable, generated from or linked to coronial information

Yellow Card reports submitted by individuals with the reporter qualification of Coroner may be identifiable through a database query. However, MHRA does not hold a dedicated field indicating that a Yellow Card report was generated from or linked to coronial information. Cases containing coronial information received through other routes are not separately identifiable through a standard database search.

Question 6

The MHRA has interpreted your request as seeking recorded policy, procedure, guidance or governance documents describing how information arising from coroners, inquests, post-mortems or toxicology is incorporated into:

- a) signal detection;
- b) signal validation;
- c) signal assessment;
- d) periodic safety review;
- e) benefit-risk assessment; and
- f) regulatory action concerning a medicinal product.

The MHRA has conducted searches for recorded information within the scope of your request.

The MHRA holds operational guidance relating to interactions with coroners and the police, including procedures for responding to requests for information or evidence, attending inquests where required, and responding to Regulation 28 Prevention of Future Death reports. For example, BRE SOP 004-04 Responding to requests from Coroners and the Police describes the Agency's processes for handling coroners' requests and Regulation 28 reports.

The MHRA does not, however, hold a separate policy, procedure, guidance or governance document specifically describing how information arising from coroners, inquests, post-mortems or toxicology is incorporated into signal detection, signal validation, signal assessment, periodic safety review, benefit-risk assessment or regulatory action for medicinal products.

More generally, the MHRA's pharmacovigilance activities consider safety information from a wide range of sources. These may include Individual Case Safety Reports (ICSRs), clinical studies, medical literature, information supplied by marketing authorisation holders,

information received from healthcare professionals and members of the public, and information obtained from other regulatory or public sources. Where relevant, information arising from coroners, inquests, post-mortems or toxicology may form part of the body of evidence available for consideration alongside these other sources.

Potential safety signals are assessed using the totality of the available evidence. Where a signal is validated and subsequently assessed, all relevant information available to the MHRA may be considered as part of the evaluation of a medicinal product's benefit-risk balance and whether any regulatory action is required.

Accordingly, whilst the MHRA may consider information originating from coroners, inquests, post-mortems or toxicology where it is relevant to a safety concern, we have not identified any recorded document that prescribes a distinct process for incorporating information from those sources into the specific pharmacovigilance activities listed in your request.

Therefore, the MHRA can confirm that it does not hold recorded information of the specific description requested.

Question 7

We have conducted searches for any audits, reviews, reports, committee papers, risk assessments or gap analyses relating to the scenarios described in your question and have not identified any recorded documents to address this question. All Coroner's reports with actions for MHRA to prevent further death are taken forward with independent committee advice in line with the SOP.

Question 8

As noted in response to Question 6, whilst as part of our surveillance activities the MHRA may consider coronial or toxicology information where it is relevant to a safety concern, we have not identified any recorded document describing national policy, guidance or governance record specific to the situations specified in your question.

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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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>