



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](#)

Our Ref: **FOI2026/00395**

7 May 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 10 April 2026. You wrote:

I am writing following correspondence from the Office for Product Safety and Standards (OPSS), who have stated that MHRA was the lead regulator for the contaminated consumer wet wipes associated with Burkholderia stabilis and linked to fatalities.

OPSS has directed all questions of regulatory responsibility, enforcement, recall, and accountability to MHRA.

Accordingly, I now request the following information under the Freedom of Information Act 2000 and/or the Environmental Information Regulations 2004 (EIR).

If MHRA considers any part of this request to fall under EIR rather than FOIA, please process it under the correct regime without delay.

1. MHRA's role as "lead regulator"

Please provide:

- The date on which MHRA formally determined that these wipes were medical products.*
- Any classification documents, internal assessments, or regulatory determinations relating to these wipes.*
- Whether MHRA had classified these products as medical devices before the contamination incident.*
- Any pre-market or post-market surveillance undertaken by MHRA relating to these products.*
- Any concerns previously raised by MHRA about categorisation, labelling, or marketing.*

If MHRA did not classify these wipes as medical products until after the contamination was discovered, please confirm this explicitly.

2. Regulatory responsibility and potential regulatory gap

OPSS has stated that these contaminated wipes were outside their regulatory scope.

Please provide:

- MHRA's formal position on whether it understood itself to be the sole regulator responsible for these consumer-sold wipes.*
- Any internal MHRA documents assessing regulatory responsibility for these products.*

- Any MHRA assessments of whether a regulatory gap existed between MHRA and OPSS.
- Any internal reviews, lessons-learned documents, or evaluations of how contaminated wipes reached the market and remained on sale.

3. Investigation into manufacturer, supply chain, and production environment
OPSS states that MHRA was responsible for all investigations relating to the manufacturer and supply chain.

Please provide:

- All MHRA investigation reports relating to the manufacturer, supply chain, or production environment.
- Any findings relating to systemic failures in manufacturing or quality control.
- Any enforcement notices, sanctions, compliance actions, or regulatory decisions issued by MHRA.
- Any correspondence with manufacturers or distributors relating to contamination.

If MHRA took no enforcement action, please provide the reasoning and any internal decision records.

4. Product recall decisions

OPSS states that manufacturers undertook voluntary recalls and that MHRA did not mandate a recall.

Please provide:

- Any MHRA assessments of whether a mandatory recall was considered.
- Any risk assessments relating to the adequacy of voluntary recalls.
- Any MHRA verification that contaminated products were fully removed from the market.
- Any internal or external correspondence relating to recall decisions.

5. Coordination with UKHSA and OPSS

OPSS states that MHRA and UKHSA led the incident response.

Please provide:

- MHRA's role in the UKHSA incident management team.
- Any MHRA instructions, guidance, or risk assessments issued to OPSS.
- Any MHRA evaluations of cross-regulator coordination.
- Any minutes, notes, or records of meetings involving MHRA, UKHSA, and OPSS.

6. Accountability for regulatory failure

OPSS has stated that accountability for regulatory failure is a matter for MHRA.

Please provide:

- MHRA's formal position on whether contaminated consumer wipes reached the market under its regulatory oversight.
- Any MHRA internal reviews, investigations, or lessons-learned documents relating to fatalities.
- Any planned or completed regulatory reforms arising from this incident.
- Any documents assessing MHRA's own performance or regulatory effectiveness.

7. Documents requested under FOIA/EIR

To avoid ambiguity, I request disclosure of:

- Classification documents
- Risk assessments
- Incident reports
- Internal briefings
- Enforcement notices
- Recall assessments

- Correspondence between MHRA, OPSS, and UKHSA
- Any internal reviews or lessons-learned documents

MHRA Response

Please see our response to each of your questions below.

1. MHRA's role as "lead regulator"

Please provide:

- *The date on which MHRA formally determined that these wipes were medical products.* Products containing chlorhexidine and/or cetrime intended for topical use for a medical purpose on humans are classified as medicinal products. These specific products were formally determined as such in June/July 2025.

- *Any classification documents, internal assessments, or regulatory determinations relating to these wipes.*

We hold no documents on this matter.

- *Whether MHRA had classified these products as medical devices before the contamination incident.*

MHRA had not classified these products as medical devices before the incident.

- *Any pre-market or post-market surveillance undertaken by MHRA relating to these products.*

MHRA was not previously aware of these products.

- *Any concerns previously raised by MHRA about categorisation, labelling, or marketing.*

MHRA was not previously aware of these products.

If MHRA did not classify these wipes as medical products until after the contamination was discovered, please confirm this explicitly.

Products containing chlorhexidine and/or cetrime intended for topical use on humans are classified as medicinal products. These specific products came to MHRA's attention following the discovery of the contamination in June/July 2025.

2. Regulatory responsibility and potential regulatory gap

OPSS has stated that these contaminated wipes were outside their regulatory scope.

Please provide:

- *MHRA's formal position on whether it understood itself to be the sole regulator responsible for these consumer-sold wipes.*

Products containing chlorhexidine and/or cetrime intended for topical use on humans for a medical purpose are classified as medicinal products and, as such, the Human Medicines Regulations 2012 require that they hold appropriate MHRA authorisation to allow legal sale and supply in the UK (unless exempt).

- *Any internal MHRA documents assessing regulatory responsibility for these products.* No assessment was necessary; products containing chlorhexidine and/or cetrime intended for topical use for a medical purpose on humans are classified as medicinal products.

- *Any MHRA assessments of whether a regulatory gap existed between MHRA and OPSS.*

No regulatory gap existed so no assessment was necessary.

- *Any internal reviews, lessons-learned documents, or evaluations of how contaminated wipes reached the market and remained on sale.*

We hold no documents on this matter.

3. Investigation into manufacturer, supply chain, and production environment
OPSS states that MHRA was responsible for all investigations relating to the manufacturer and supply chain.

Please provide:

- *All MHRA investigation reports relating to the manufacturer, supply chain, or production environment.*
- *Any findings relating to systemic failures in manufacturing or quality control.*
- *Any enforcement notices, sanctions, compliance actions, or regulatory decisions issued by MHRA.*
- *Any correspondence with manufacturers or distributors relating to contamination.*

If MHRA took no enforcement action, please provide the reasoning and any internal decision records.

In July 2025, MHRA assessed the non-sterile alcohol-free wipes identified by the UK Health Security Agency (UKHSA) and, due to the presence of the ingredients cetrimide and chlorhexidine, determined them to be as medicinal products and subject to regulation under the Human Medicines Regulations 2012. These products do not hold relevant MHRA authorisations and we took compliance action. As a result, they were removed from sale but, as they were not in the UK legal medicines supply chain, the MHRA was unable to issue a recall.

4. Product recall decisions

OPSS states that manufacturers undertook voluntary recalls and that MHRA did not mandate a recall.

Please provide:

- *Any MHRA assessments of whether a mandatory recall was considered.*
- *Any risk assessments relating to the adequacy of voluntary recalls.*
- *Any MHRA verification that contaminated products were fully removed from the market.*
- *Any internal or external correspondence relating to recall decisions.*

Please see our response above, as they were not in the UK legal medicines supply chain, the MHRA was unable to issue a recall.

5. Coordination with UKHSA and OPSS

OPSS states that MHRA and UKHSA led the incident response.

Please provide:

- *MHRA's role in the UKHSA incident management team.*
- *Any MHRA instructions, guidance, or risk assessments issued to OPSS.*
- *Any MHRA evaluations of cross-regulator coordination.*
- *Any minutes, notes, or records of meetings involving MHRA, UKHSA, and OPSS.*

The investigation of these wipes was conducted by the UKHSA. MHRA took relevant compliance action to remove these products from sale.

6. Accountability for regulatory failure

OPSS has stated that accountability for regulatory failure is a matter for MHRA.

Please provide:

- *MHRA's formal position on whether contaminated consumer wipes reached the market under its regulatory oversight.*

- Any MHRA internal reviews, investigations, or lessons-learned documents relating to fatalities.
- Any planned or completed regulatory reforms arising from this incident.
- Any documents assessing MHRA's own performance or regulatory effectiveness.

Please see our response above. These products were brought to MHRA's attention by the UKHSA. We assessed these and due to the presence of cetrimide and chlorhexidine, they were determined to be as medicinal products and subject to regulation under the Human Medicines Regulations 2012. As they did not hold relevant MHRA authorisation, compliance action was taken and the products were removed from sale.

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/>