



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00982**

28 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 31 August. You wrote:

I am making this request under the Freedom of Information Act 2000. I am seeking recorded information about MHRA's duty, track record and statutory powers concerning counterfeit and unlicensed medicines generally, and the unlawful substitution of licensed prescription medicines with non-MA products.

1. MHRA's duty to protect patients from counterfeit and unlicensed medicines

The Novo Nordisk case shows a single manufacturer having to secure, through its own civil litigation, protection that patients might reasonably expect their medicines regulator to provide. Please provide recorded information setting out MHRA's statutory duty, objectives or public task in relation to protecting patients from counterfeit and unlicensed medicines generally — not limited to any single manufacturer's products — including the relevant legislative basis (e.g. under the Human Medicines Regulations 2012) and any published statement of MHRA's role in this area.

2. MHRA's own enforcement efforts and why they have had limited success

The judgment in Novo Nordisk A/S & Anor v British Telecommunications Plc & Ors [2026] EWHC 1094 (Ch) records that "the MHRA's own efforts at closing down infringing websites have met with limited success". Please provide any recorded information explaining what those efforts consisted of, why they have had limited success, and any internal review, assessment or lessons-learned exercise concerning this.

3. MHRA's response to the Novo Nordisk precedent for counterfeit medicines generally

Please provide any recorded information — including business cases, internal assessments, correspondence, minutes or strategy documents — concerning whether MHRA intends to pursue, seek or support a court-ordered website-blocking mechanism covering counterfeit and unlicensed medicines generally, rather than leaving this protection to depend on individual manufacturers bringing their own litigation product by product.

4. MHRA's statutory powers against counterfeits and unlawful substitution

The Novo Nordisk order demonstrates that website-blocking against counterfeit and unlicensed medicines is achievable through the courts. Please provide recorded information setting out what statutory powers MHRA itself holds — as opposed to relying on individual manufacturers' civil litigation — to prevent, disrupt or take enforcement action against: (a) the sale and supply of counterfeit or falsified medicines; and (b) the sale, supply, prescribing or dispensing of health/food supplements and other products without a UK marketing authorisation where they are used in place of, or presented as equivalent to, licensed prescription-only medicines.

5. Enforcement track record, 2021–2025

Against the background of the Novo Nordisk judgment's finding that "the MHRA's own efforts at closing down infringing websites have met with limited success", for each calendar year 2021–2025, where recorded, please provide the number of enforcement actions taken by MHRA against: (a) websites or sellers of counterfeit or falsified medicines; and (b) suppliers or sellers of non-MA products used as substitutes for licensed prescription medicines — together with the nature of the action taken (e.g. website takedown request, seizure, prosecution, warning) and the outcome, where recorded.

6. Cross-agency work and future plans

Following the Novo Nordisk judgment and the limitations of MHRA's own efforts that it identified, please provide any recorded information about work planned or under way, in conjunction with other bodies (e.g. GPhC, NHSBSA, police, Trading Standards, ISPs), to address counterfeit medicines and the unlawful substitution of licensed medicines with non-MA products during 2026–2030.

7. Chain of accountability — MHRA, ISPs and patient harm

Where a patient is harmed by a counterfeit or unlicensed medicine bought online, accountability arguably extends along a chain: MHRA's own statutory duty and powers to prevent access to the product; the ISP or hosting provider that supplies the platform enabling the sale, and which derives commercial benefit (e.g. hosting fees, advertising revenue) from doing so; and the counterfeiter itself. Please provide any recorded information setting out MHRA's own assessment or policy position on how responsibility is distributed across this chain, including whether MHRA considers ISPs and hosting providers to bear any statutory or regulatory responsibility for illegal medicine sales conducted through their platforms, and whether MHRA has ever sought — through litigation, regulatory referral or otherwise — to hold an ISP or hosting provider to account for hosting such sales.

I am seeking recorded information rather than asking MHRA to create new information or provide an opinion. Where the precise information requested is not held, please provide the closest equivalent information held. Where information is withheld, please identify the relevant FOIA exemption and provide the remainder where reasonably practicable. If any part of this request would exceed the appropriate cost limit, please identify the relevant part and provide the information that can be supplied within the limit so that I may refine the request.

MHRA Response

The MHRA has considered your request under the Freedom of Information Act 2000 (FOIA).

Your request comprises seven broad and interrelated questions concerning:

- the MHRA's statutory functions and enforcement powers;
- enforcement activity relating to counterfeit, falsified and unlicensed medicines;
- website disruption and blocking activity;
- internal assessments, reviews, business cases and policy development;
- cross-agency working;
- strategic and operational planning; and
- enforcement outcomes over multiple years.

To comply with the request, the MHRA would first need to establish whether information is held within the scope of each question. This would require searches across a number of business areas, likely including enforcement, intelligence, legal, policy, operational and corporate functions, together with searches of electronic records, correspondence, document repositories and case management systems.

The request also seeks a wide range of record types, including business cases, internal assessments, strategy documents, correspondence, meeting records, lessons-learned exercises, legal analyses, operational material and enforcement records.

The appropriate limit for central government bodies is £600, equivalent to 24 hours of work at the statutory rate of £25 per hour.

Having considered the breadth of the request, the number of subject areas covered, the range of information sought and the period to which the request relates, the MHRA estimates that the time required to establish what information is held and to locate and retrieve that information would substantially exceed the 24-hour appropriate limit before any consideration could be given to reviewing information for disclosure.

The MHRA therefore estimates that the cost of complying with the request would exceed the appropriate limit prescribed by the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004. The request is therefore refused under section 12(1) of FOIA.

The MHRA has considered whether advice and assistance could be provided, or whether any part of the request could reasonably be answered within the appropriate limit. Given the breadth of the request, the overlap between the questions, and the need to search multiple business areas to establish what information may be held, the MHRA's assessment is that complying with any substantive part of the request would still exceed the appropriate limit.

Section 16 Advice and Assistance

The MHRA recognises that you are seeking recorded information rather than requesting that new information be created.

In accordance with the duty to provide advice and assistance under section 16 FOIA, the MHRA has considered whether any meaningful information can be provided without undertaking the searches necessary to answer the request substantively.

The information set out below is therefore provided at a high level to assist you. It is intended to provide general contextual information relevant to the subject matter of the request and should not be interpreted as confirming whether specific information is or is not held.

The MHRA has not undertaken searches to determine whether additional information falling within the scope of the request is held. Determining whether such information is held, and if so locating, retrieving and reviewing it, would itself require searches that exceed the appropriate limit.

Question 1

The MHRA is the UK regulator for human medicines and is responsible for administering and enforcing the legislative framework governing human medicines. At a general level, this includes regulating the manufacture, importation, distribution and supply of medicines and taking compliance and enforcement action in respect of suspected breaches of medicines legislation. The principal legislative framework is the Human Medicines Regulations 2012.

Question 2

The MHRA undertakes compliance, intelligence, investigation and enforcement activity aimed at addressing the unlawful manufacture, distribution and supply of medicines, including activity relating to online supply routes and websites involved in suspected breaches of medicines legislation. Publicly available information demonstrates that the MHRA has taken enforcement action against the unlawful online sale and supply of medicines and has worked with partner organisations in support of those activities.

Question 3

The MHRA undertakes regulatory, compliance and enforcement activity aimed at addressing the unlawful manufacture, distribution and supply of medicines, including activity relating to websites involved in suspected breaches of medicines legislation. The Agency's role includes the investigation and enforcement of medicines legislation in support of its wider public health functions.

Question 4

The MHRA is responsible for administering and enforcing the UK regulatory framework for human medicines. At a general level, the statutory framework provides powers relating to the regulation of the manufacture, importation, distribution, sale and supply of medicines, together with investigatory and enforcement powers in respect of suspected breaches of medicines legislation. The medicines regulatory framework also contains provisions relating to unauthorised medicinal products, licensing requirements and offences connected with non-compliance.

Question 5

The MHRA undertakes compliance, intelligence, investigation and enforcement activity in relation to suspected breaches of medicines legislation, including activity concerning falsified and unauthorised medicinal products.

Publicly available MHRA material includes examples of seizures, investigations, arrests, prosecutions, warnings and other enforcement activity relating to suspected breaches of medicines legislation.

You may find it helpful to review publicly available MHRA enforcement announcements, operational updates and annual reporting material, which contain examples of enforcement activity undertaken during particular periods.

Question 6

The MHRA works with a range of domestic and international partners in support of its regulatory and enforcement functions. Publicly available information demonstrates that the MHRA participates in collaborative and multi-agency activity aimed at addressing the unlawful manufacture, importation, distribution and supply of medicines, including unlawful online sales and supply routes.

Question 7

The MHRA's role is to regulate medicines and enforce medicines legislation within the statutory framework governing human medicines. At a general level, the MHRA undertakes compliance, intelligence, investigation and enforcement activity relating to suspected breaches of medicines legislation, including activity concerning the unlawful online sale and supply of medicines. Publicly available information shows that the MHRA works with a range of organisations in carrying out these functions and takes action against those suspected of breaching medicines legislation.

Further Information

Beyond the high-level information provided above, the MHRA is unable to provide substantive responses to the specific matters raised in Questions 1 to 7. To do so would require searches across multiple business areas, record systems and document sets to establish whether information is held and, where information is held, to identify, retrieve and review that information for disclosure. Those activities fall within the scope of the section 12 refusal set out above.

For the avoidance of doubt, nothing in the information provided above should be interpreted as confirmation that specific assessments, business cases, strategies, correspondence, legal advice, operational plans, reviews, meeting records or other information falling within the scope of the request are held or are not held. Establishing whether any such information exists would itself require searches exceeding the appropriate limit prescribed by FOIA.

If you wish to refine your request, you may wish to focus on a specific topic, time period, enforcement activity or category of document. This may enable the MHRA to consider a narrower request within the statutory cost limit.

Sources of Public Information

As part of its duty under section 16 FOIA, the MHRA notes that information relevant to the general subject matter of this request may be available from the following publicly available sources:

- The Human Medicines Regulations 2012 (the principal legislative framework governing human medicines in the UK):
<https://www.legislation.gov.uk/ukxi/2012/1916/contents>
- Regulation 46 of the Human Medicines Regulations 2012, concerning the prohibition on the sale or supply of unauthorised medicinal products:
<https://www.legislation.gov.uk/ukxi/2012/1916/regulation/46/made>
- MHRA enforcement announcements, operational updates and news releases:
<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>
- MHRA annual reports, corporate publications and information about the Agency's functions:
<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about>

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 Contact Information](#) 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/>