



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00909**

14 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 14th August 2026. You wrote:

"I am requesting recorded information under the Freedom of Information Act 2000.

I note that in FOI2024/00264 the MHRA confirmed that Manufacturer's "Specials" Licences are not published online, and disclosed a copy of an MS licence redacted for personal data under section 40(2) and limited commercially sensitive material under section 43(2). This request follows the approach taken in that response.

1. Please provide a copy of the current Manufacturer's "Specials" Licence (all sections, including Section 1, the Section 2 variation history, and Section 3/Annex 1 site information including the authorised-operations and dosage-form schedules and any Part 2 importation authorisations) held by Rokshaw Limited of Sunderland, redacted as necessary in line with the approach taken in FOI2024/00264.

2. Please confirm the date on which the licence, or any predecessor licence subsequently subject to a change of ownership, was first granted. We are not requesting personal data, batch or product-specific information, customer information, or any commercial terms. The dosage-form authorisation schedule of an MS licence is structural information of the same character already disclosed in FOI2024/00264, in which the MHRA identified no commercial harm arising from its release."

MHRA Response

The first part of our response relates to question 1, where we attach a copy of the current manufacturer's specials licence held by Rokshaw Limited. Redactions have been made as detailed below.

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that "Personal data shall be processed lawfully, fairly and in a transparent manner...".

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the FoI Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018

MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised must be able to demonstrate that at least one of the above criteria apply.

Other information you have requested is commercially sensitive and is therefore exempt from release under Section 43(2) of the FoI Act.

Section 43(2) exempts information which, if disclosed, would be likely to prejudice the commercial interests of any person including a public authority. It protects not only the commercial interests of third parties but also the commercial interests of the Agency. It is intended to protect the ability of a public authority like MHRA to obtain goods or services on the best possible commercial terms and to protect the legitimate commercial interests of its suppliers. The information you seek falls into this category.

In this instance we feel that the release of this information could present a risk to third parties' commercial operations, as well as extending to a government department. To better define the information exempted and the justifications underpinning this please see below where there is also a consideration of the public interest:

- Other companies and/or organisations listed in the licence, such forms of commercial relationships are considered to be commercially sensitive, and this is in line with the [HMA/EMA guideline](#), which, while chiefly applicable to marketing authorisations the same principle applies. We perceive there to be a low public interest in this type of information, as it mainly relates to the operations of the importer. We have also not identified an underpinning public health concern, or matter of importance which for example would further public debate.

Part two of our response

This part of our response addresses your second question. We confirm this information is held in our records; the licence was first approved on 12 March 2015.

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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