



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2024/00675**

29 November 2024

Dear [REDACTED],

Thank you for your Freedom of Information (FOI) request received on 3 November. You wrote:

Under FOI regs could you possibly supply me with the following:

- 1. Details of the informed consent process employed for medicinal products within Conditional Authorisation and/or Emergency Use Authorisation.*
- 2. Details of any directives to alter that process for any specific drugs under Conditional Authorisation and/or Emergency Use Authorisation, including the names of those CA/EUA drugs, dates and correspondence showing the directives given with regards to obtaining informed consent for these products.*

MHRA Response

We are unable to deal with your FOI request without clarification of the information you seek. We need clarification of the information you ask for to deal with your request. Please clarify what you are specifically referring to with the first point "*Details of the informed consent process ...*"

Are you requesting information about the informed consent application? Regulation 56 (previously Article 10c of Directive 2001/83/EC) refers to an application for marketing authorisation based on the full reference to the dossier of another product (the reference product), with the consent/authorisation of the authorisation holder of that reference product. Or are you seeking details on informed consent that must be obtained before starting any treatment or physical investigation or before providing personal care for a patient?

Under Section 16 of the FOI Act we should assist you in helping you focus your request. To help us do so, we would like to let you know that the topics you ask about are unclear; you should choose a more specific subject matter, for example, by clarifying whether your request concerns the authorisation of medicinal products under the informed consent process Regulation 56 (previously Article 10c of Directive 2001/83/EC) or whether it is about informed consent that recipients of medicinal products may be required to give.

Please be advised that any clarification we receive will be considered as a new request under the FOI Act.

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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