



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2026/00978**

25 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 1 September 2026.
You wrote:

We would like to request information regarding the British Pharmacopoeia monograph for Ramipril tablets (strengths 1.25 mg, 2.5 mg, 5 mg and 10 mg).

Specifically, we seek clarification on the scientific and regulatory basis used by the British Pharmacopoeia Commission to establish the impurity limits for Ramipril Impurity D + Impurity E (per strength), any other impurity, and total impurities (per strength) in the monograph.

In this context, we would appreciate confirmation as to whether relevant international guidelines (e.g. ICH Q3A(R2), ICH Q3B(R2), ICH M7, EMA impurity guidance, including EMA/CHMP/4299/2026) were considered in setting these limits, and whether any toxicological evaluation formed part of the assessment.

Furthermore, a summary of the approach used in establishing these limits, including any non-confidential information on the supporting data, scientific justification, or expert advisory group considerations involved in the decision-making process, would be highly appreciated.

We understand that commercially confidential or proprietary data may be redacted and confirm that we are not requesting access to such information.

MHRA Response

The related substances limits in the BP monograph for Ramipril Tablets were based on registered limits approved by MHRA assessors, and taking into account the Ph Eur monograph for Ramipril. Supporting stability data, a toxicological report on impurity E, information on routes of impurity formation and comments on the draft monograph provided by manufacturers during the monograph development process were also considered by the BP Expert Advisory Group. The BP monograph for Ramipril Tablets was first published in BP 2007.

Please see attached minutes of discussions by our Expert Advisory Group, between 2003 and 2007, concerning Ramipril Tablets related substances test and limits, with personal names and company names redacted under Section 40 (personal information) and Section 41 (information provided in confidence).

Section 40

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.

Section 41

Section 41 is an absolute exemption, and no consideration of the public interest is required, except to state that we consider disclosure of the information to constitute an actionable breach of confidence.

Please also see attached the draft British Pharmacopoeia (BP) monograph for Ramipril Tablets.

We would also like to inform you that we have a dedicated mailbox specifically for enquiries to the BP, which should be used as a first point of call for any further enquiries. This is provided below.

bpcom@mhra.gov.uk

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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