



Medicines & Healthcare products
Regulatory Agency

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

Our Ref: **FOI2024/00700**

10 December 2024

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 11 November. You wrote:

We wish to make a Freedom of Information ("FOI") request in connection with UK Marketing Authorisation ("MA") Nos. PLGB 00101/1150-1152, which authorise the sale of Tasigna (nilotinib) hard capsules at 50mg, 150mg and 200mg doses in the United Kingdom.

Specifically, we request copies of documents filed by the MA holder, relating to the recommendation in section 4.2 of the Summary of Product Characteristics ("SmPC") for the above-mentioned products that for patients unable to swallow capsules, the contents of those capsules may be dispersed in a teaspoon of apple sauce. Specifically, that recommendation reads:

"For patients who are unable to swallow hard capsules, the content of each hard capsule may be dispersed in one teaspoon of apple sauce (puréed apple) and should be taken immediately. Not more than one teaspoon of apple sauce and no food other than apple sauce must be used (see sections 4.4 and 5.2)."

The rationale for this recommendation is detailed in section 5.2 of the SmPC, which states, under the heading 'Bioavailability/bioequivalence studies' that:

"Single-dose administration of 400 mg nilotinib, using 2 hard capsules of 200 mg whereby the content of each hard capsule was dispersed in one teaspoon of apple sauce, was shown to be bioequivalent with a single-dose administration of 2 intact hard capsules of 200 mg."

Finally, while the assessment of the original MA applications for Tasigna was the responsibility of the EMA, rather than the UK MHRA, we would mention that when our firm, as a UK-registered business, has previously made documentary requests to the EMA, the EMA has refused to deal with these on the basis that we are not "citizens of the European Union and natural or legal persons residing or having their registered office in a EU Member State." Given that Tasigna is a product on the market in the UK which is being prescribed to and taken by UK citizens, we submit that the UK MHRA should provide the documents requested above if these are available.

MHRA Response

We can confirm that the Agency holds the information you are seeking. In response to your request, the data underpinning the advice in section 4.2 of the SPC comes from one specific study (Study CAMN107A2127). Please find attached the main body of the Clinical Study Report for this study (sections 1 – 14).

Please note that the documentation has been redacted under Section 40 (Personal information), Section 41 (Information given in confidence) and Section 43 (Commercial interests) of the Freedom of Information Act.

Disclosure of information subject to Section 40 (Personal information) would be an infringement of personal data. Section 40 (Personal information) is an absolute exemption, and no consideration of the public interest is required.

Section 41 (Information given in confidence) is an absolute exemption, and no consideration of the public interest is necessary, except to state that the release of this information withheld under this section of the FOI Act would be considered an actionable breach by the MHRA.

We have redacted some parts of the attached documentation under Section 43 (Commercial interests) of the FOI Act because the release of all, or part of, the information would, or would be likely to, cause harm to the third party's commercial interests. The exemption is to safeguard the commercially sensitive information/commercial enterprise. In this case, release of information would enable the competitors to overcome several regulatory hurdles in the research and development of their own products. This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. We have considered the balance of the public interest when applying this exemption. In this case, we have not identified any issues which would benefit the public, as a whole, by being brought to their attention.

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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