Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2024/00647**

20 November 2024

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 23 October. You wrote:

> *'On 8 October 2024, the Medicines and Healthcare products Regulatory Agency (MHRA) published a press release confirming that MHRA has approved elafibranor (Iqirvo) to treat adult patients with primary biliary cholangitis.*
>
> *I write to request access to the following information under Section 1(1) of the Freedom of Information Act 2000 (FOIA):*
>
> *Please confirm whether elafibranor (Iqirvo) has been granted a conditional marketing authorisation (CMA) or a standard (full) marketing authorisation (MA).*
>
> * *In case it is a conditional approval, please provide the conditions associated with the MA.*
> * *In case it is full MA, please provide the scientific rationale, given that the EMA and US FDA has granted a CMA/ accelerated approval recently.*
> * *Please also provide details of any post-approval commitments that forms basis of the approval.*
>
> *Please provide (i) the original version (as submitted by the applicant);and (ii) the final version (at the time of approval), of the clinical overview (Module 2.5) of the marketing authorisation application of elafibranor (Iqirvo).*
>
> *Please provide correspondence (including questions and answers) exchanged between the applicant and MHRA including the final scientific assessment report related to the assessment of clinical benefit of elafibranor (Iqirvo).*
>
> *Please confirm the current status of orphan designation of elafibranor (Iqirvo) in UK following the issuance of PLGB license, and provide the supporting data submitted by the applicant to support the orphan designation.*
>
> *Please respond within 20 working days pursuant to Section 10(1) FOIA. If you have any queries regarding this request (or require payment for complying with this request), please contact us as soon as possible.'*

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we hold the information you have requested.

Some aspects of the information you have requested is being withheld as it falls under exemption of the Freedom of Information Act. These exemptions are discussed relating to each section of your request in turn below.

1) **Whether elafibranor (Iqirvo) has been granted a conditional marketing authorisation (CMA) or a standard (full) marketing authorisation (MA). In case it is a conditional approval, please provide the conditions associated with the MA. In case it is full MA, please provide the scientific rationale, given that the EMA and US FDA has granted a CMA/ accelerated approval recently. Please also provide details of any post-approval commitments that forms basis of the approval.**

   Iqirvo 80 mg film-coated tablets was granted as a full marketing authorisation. However, the medicine was authorised with conditions within the Risk Management Plan to perform additional pharmacovigilance activities.

   Regarding providing the scientific rational for this approval, this information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible as it is already in the public domain. The discussion of the scientific rationale and additional pharmacovigilance activities can be seen in the Public Assessment Report published on the MHRA products website under 'Iqirvo 80 mg film-coated tablets' here: https://mhraproducts4853.blob.core.windows.net/docs/868b19132b749500fa6cd20cd35401228c540a3a

2) **Please provide (i) the original version (as submitted by the applicant);and (ii) the final version (at the time of approval), of the clinical overview (Module 2.5) of the marketing authorisation application of elafibranor (Iqirvo).**

   We can confirm that the Agency holds this information. A single original version of Module 2.5 (Clinical Overview) was located and is provided in full with this response.

3) **Please provide correspondence (including questions and answers) exchanged between the applicant and MHRA including the final scientific assessment report related to the assessment of clinical benefit of elafibranor (Iqirvo).**

   We are able to confirm that the information you seek is held by the Agency. However, we are engaging exemption from disclosure under the following Sections of the FoI Act:
   - Section 21(1) of the Freedom of Information Act because sections of the information are reasonably accessible already in the public domain
   - Section 41(1) of the FoI Act, which protects information provided in confidence.
   - Section 43(1) and 43(2) of the FoI Act which protects commercial interests

   The reasons we are withholding correspondence (including questions and answers) exchanged between the applicant and MHRA including the final scientific assessment report are provided in more detail below.

- **Section 21(1) – already accessible in the public domain**
  The Public Assessment Reports published by the MHRA reflect the final scientific assessment reports with all confidential information removed. As such, the Public Assessment Report available on the MHRA products website is the final scientific report with the removal of all information that would be exempted by Section 41(1), Section 43(1) and Section 43(2). As such, the final scientific assessment report is exempt from disclosure under Section 21 of the FOI Act (information accessible by other means).

- **Section 41(1) - information provided in confidence**
  Correspondence throughout the application process includes information provided in confidence to the MHRA as the licensing authority. Section 41(1) is an absolute exemption and no consideration of the public interest is required. The withheld information was provided to the MHRA in confidence by a third-party for the purposes of assessment. This information has the necessary quality of confidence as it is more than trivial and not otherwise accessible; the preservation of confidences is recognised by the courts to be an important matter and one in which there is a strong public interest. In this case, the information was provided to the MHRA with explicit conditions on its use by the MHRA (including further disclosure) and an obligation of confidence therefore exists. For these reasons, disclosure would be likely to have a detrimental impact on the party who provided the information. In such circumstances, our view is that disclosure would be an actionable breach of that confidence, and this engages the Section 41(1) exemption**.**

- **Section 43(1) and Section 43(2) Commercial interests**
  Correspondence throughout the application process includes information deemed to impact the commercial interests of the applicant and release of the information would be likely to cause harm to the third party's commercial interests.

  We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information. As a qualified exemption, 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.

  In applying Section 43(1) and Section 43(2), the agency has balanced the public interest in withholding the information against the public interest in disclosing the information and on balance we find that withholding the information from release outweighs our obligation to release. In this case, we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity).

4) Please confirm the current status of orphan designation of elafibranor (Iqirvo) in UK following the issuance of PLGB license, and provide the supporting data submitted by the applicant to support the orphan designation.

During the assessment of the application, Iqirvo for the treatment of primary biliary cholangitis demonstrated fulfilment of the GB orphan designation criteria in line with the Human Medicines Regulations 2012 (as amended).

The Orphan Assessment report is provided with this response which contains the supporting data submitted by the applicant to support the orphan designation. Please note that very minor sections of the information has been redacted, and these sections are being exempt from release under Section 40 of the FoI Act. This exemption covers release of personal information.

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.

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/