FW: Re: FOI 23/1007

[redacted]
Thu 25/01/2024 17:23
To [redacted]

1 attachments (140 KB)
FOI MHRA.pdf;

Sent this afternoon.

Thanks everyone for your help.

Best regards

[redacted]

From: FOILicensing
Sent: Thursday, January 25, 2024 5:21 PM
To: [redacted]
Subject: Re: FOI 23/1007
Importance: High

Dear [redacted]

Many thanks for your Freedom of Information (FOI) request sent to us on 27 December 2023. Please see below the responses to each of your questions:

1. Importation Process:

a. How is Droxidopa imported into the UK?

Currently there are no licensed medicines containing Droxidopa in the UK, as such its use and supply may take place in accordance with MHRA Guidance Note 14 for the manufacture and importation of unlicensed medicines.

b. Are there specific regulations or procedures governing the importation of Droxidopa?

These are publicly available in MHRA Guidance Note 14
https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

2. Licensing and Approval:

a. What is the current licensing status of Droxidopa in the UK?

Currently there are no licensed medicines containing Droxidopa in the UK.

b. Has Droxidopa been considered or evaluated for licensing in the UK?

Regarding whether we have received any applications for marketing authorisations for Droxidopa, we neither confirm nor deny we hold information relevant to your request. Section 41(2) and Section 43(3) of the Freedom of Information Act (FOIA) absolves us from the requirement to say whether or not we hold information:

***41.—(2)** The duty to confirm or deny does not arise if, or to the extent that, the confirmation or denial that would have to be given to comply with section 1(1)(a) would (apart from this Act) constitute an actionable breach of confidence.*

43.

(1)Information is exempt information if it constitutes a trade secret.

(2)Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

(3)The duty to confirm or deny does not arise if, or to the extent that, compliance with section 1(1)(a) would, or would be likely to, prejudice the interests mentioned in subsection (2).

Public interest test

Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering the neither confirm nor deny provision of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in neither confirming nor denying that the information is held outweighs the public interest in confirming or denying whether the MHRA holds the information you have requested. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in saying whether information is held or not. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of confirming whether or not we hold the information

To confirm or deny whether or not an application has been received by MHRA for Droxidopa would be of interest to patient groups and healthcare professionals in knowing and understanding whether a relevant treatment could soon be available to patients. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see what applications are currently being considered by MHRA.

Considerations in favour of neither confirming nor denying whether we hold the information

To confirm or deny whether we are currently considering an application for a particular medicine would be of great interest to rival companies who are marketing or looking to market their own products. Knowledge of whether an application is being considered by MHRA can be used as market intelligence in order to gauge when a new product is likely to come onto the market so strategies can be employed to prevent that product getting a foothold in the market. Further, to confirm or deny that we may hold any information on applications that are not yet authorised in the UK can create a chilling effect, with companies reluctant or unwilling to submit applications for their products to the UK. This would result in fewer medicines being available for patients.

c. If not licensed, under what scheme or regulations is it accessible within the country?

Currently there are no licensed medicines containing Droxidopa in the UK, as such its use and supply may take place in accordance with MHRA Guidance Note 14 for the manufacture and importation of unlicensed medicines.
https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

Information on clinical trials in the UK is already in the public domain, and can be found at https://www.clinicaltrialsregister.eu/ctr-search/search and https://classic.clinicaltrials.gov/ct2/home. Guidance on clinical trials performed in the UK can be found via the following link: https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk

3. Usage Information:

a. Which hospitals or healthcare facilities in the UK are known to import or use Droxidopa?

The requirements for importation of unlicensed medicines is described in MHRA Guidance Note 14 (https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials); Only licensed importers are allowed to import unlicensed medicines. The MHRA does not hold information on the use of unlicensed medicines in any healthcare setting. The use of unlicensed medicines is the responsibility of the prescribers responsible for the care of individual patients and the MHRA does not keep a record of these instances.

b. Are there any recorded instances or data available regarding the usage of Droxidopa in these healthcare settings?

Please see our response to question 3a, we hold no information on this.

4. Patient Eligibility Criteria:

a. What are the established criteria for determining patient eligibility to receive Droxidopa within the NHS?

Please see our response to question 3a, we hold no information on this.

b. Are these criteria standardized or subject to variations based on specific conditions or circumstances?

Please see our response to question 3a, we hold no information on this.

5. Patient Access in Life-Threatening Situations:

In cases where Droxidopa is deemed the only available treatment for a patient facing a life-threatening disorder or condition:

a. What provisions or rights exist for patients within the UK to access Droxidopa under such circumstances?

Please see our response to question 1 above.

b. Are there established pathways or considerations for expediting access to Droxidopa when it is identified as the sole viable treatment option for a life-threatening disorder?

Please see our response to question 1 above.

6. Guidelines and Protocols:

a. Are there official guidelines or protocols for the prescription and administration of Droxidopa within the NHS or specific healthcare settings?

Please see our response to question 1 above.

b. If available, could you provide details or documentation outlining these guidelines?

Please see our response to question 1 above.

7. Safety and Monitoring:

a. What safety protocols or monitoring mechanisms are in place for patients receiving Droxidopa in the UK?

The MHRA does not hold information on the use of unlicensed medicines in any healthcare setting.

b. Are there any reported adverse events or specific monitoring requirements associated with the use of Droxidopa?

The MHRA does not hold information on the use of unlicensed medicines in any healthcare setting.

8. Public Access to Information:

a. Is there publicly available information or documentation regarding Droxidopa's usage, importation, or guidelines within the UK? If so, where can this information be accessed?

The MHRA does not hold information on this.

9. Future Considerations:

a. Are there any ongoing assessments or considerations regarding the potential licensing or broader availability of Droxidopa within the UK's NHS?

Please see our response to question 2b above.

If you have a query about the information provided, please reply to this email

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

The FOILicensing Team

MHRA

From: [redacted]
Sent: Saturday, December 23, 2023 12:13 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 23/1007 - FOI

You don't often get email from [redacted] Learn why this is important

Dear Sir/Madam,

Please find attached with the present email a FOI request letter.

Regards

[redacted]

Department of Health's policy on the use of electronic communications. For more information on the Department of Health's email policy, click **DHTermsAndConditions**