FOI 23/480 - Skyclarys progress

REQUEST
23 June 2023

I am writing to inquire about the availability of a new drug called Skyclarys (omaveloxolone), for the treatment of Friedreich's Ataxia in the United Kingdom. I am particularly interested in understanding when this medication will be made accessible.

I kindly request any information you can provide regarding its availability in the UK. I understand that the process of approving and launching new medications involves regulatory procedures, and I am interested to know if Skyclarys has been submitted for review to the relevant regulatory authorities in the UK.

If possible, could you please provide an update on the current status of the treatment in terms of regulatory approvals, clinical trials, or any other relevant information?

Additionally, it would be greatly appreciated if you could outline the estimated timeline for when patients with Friedreich's Ataxia in the UK can expect access to this medication.

MHRA RESPONSE
12 July 2023

Dear

Thank you for your email.

We are not in a position to advise when omaveloxolone is likely to authorised in the UK, please note that due to commercial reasons it is frequently the case that companies do not wish for details of their applications to be released. Therefore, we cannot confirm whether or not an application is held.

However, we can highlight a document which might be of interest, an agenda which is publicly available from the Committee for Medicinal Products for Human Use (CHMP, the committee responsible for preparing European Medicines Agency [EMA] opinions on human medicines). This agenda indicates that the medicine is currently under assessment with the EMA.

Draft CHMP Agenda 24-26 April 2023 (europa.eu) (page 13):
https://www.ema.europa.eu/en/documents/agenda/agenda-chmp-meeting-24-26-april-2023_en.pdf

We would suggest that you contact the company to ask about their plans for omaveloxolone regarding the UK market. With its role as the regulator in the UK, the MHRA does not solicit applications for new medicines, or the addition of indications to current authorised medicines, and we do not conduct our own product development.

You may also find the following of interest, whereby UK unlicensed medicines can be brought into the UK.

Unless exempt, a medicinal product must be the subject of a marketing authorisation (product licence) before being placed on the market. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product under certain circumstances. In the interest of public health the exemption is narrowly drawn because unlicensed medicines or "specials", unlike licensed medicinal products, may not have been assessed by the Licensing Authority against the criteria of safety, quality and efficacy. Further guidance is available on the MHRA website.

Each import request is assessed on a case-by-case basis, taking into account not only the product to be imported but also the special needs identified by the prescriber.

I hope this helps to provide some clarity on this situation.

Regarding whether any applications for omaveloxolone have been received by MHRA, we refuse to confirm or deny we hold any information relevant to your request under Section 41(2) and Section 43(3) of the FOI Act (FOIA).

Section 41(2) is an absolute exemption and no consideration of the public interest is required, except to state that we would consider confirmation of whether we hold this information to be an actionable breach of confidence. Section 43(3) is a conditional exemption and requires a consideration of the public interest. We have considered the public interest and cannot see any public interest argument that outweighs the commercial harm in confirming whether we hold this information, which could alert competitors to whether a company is close to obtaining a marketing authorisation or not.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

MHRA Customer Experience Centre
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