FOI 23/287 – reports on LUNSUMIO (mosunetuzumab) and the new active substance status of mosunetuzumab

MHRA RESPONSE
17 May 2023

Dear

Thank you for your email of 14 April where you have asked "**RE: LUNSUMIO (mosunetuzumab): PLGB 00031/0933-0934**

Please provide copies of the following documents concerning the above product:

1. Report on similarity of Lunsumio with Gazyvaro
2. Report on new active substance status of mosunetuzumab
We understand both documents are dated 21 April 2022"

Please find below a link to our website page available to view for a Public Assessment Report for this product.
https://mhraproducts4853.blob.core.windows.net/docs/c61808cd8b4e8622c09b7f626dd9ce0b3f42db54

There is also an assessment performed by the European Medicines Agency (EMA), as this was a reliance route and MHRA accepted the EC decision and their assessment of this product it is also useful, linked below:
https://www.ema.europa.eu/en/medicines/human/EPAR/lunsumio

The documents you have requested are based on the below from page 10 of the EMA EPAR:
Q1 - The CHMP adopted a report on similarity of Lunsumio with Gazyvaro on 22 April 2022
Q2 - Furthermore, the CHMP adopted a report on New Active Substance (NAS) status of the active substance contained in the medicinal product 22 April 2022

The similarity report asked for in Q1 was part of the Orphan Drug assessment for Lunsumio, which is published by the EMA and MHRA (see links above). As any non-confidential information is already published (and so exempt under S21 of the FOIA), the remaining information in that report is commercially sensitive and so would be exempt under S41/43 of the FOIA.

The new active substance status referred to in Q2 concerns an assessment of the quality aspects of the active substance mosunetuzumab to ascertain whether this can be considered a new active substance. This would also be exempt under S41/43 of the FOIA.

S41 is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence. S43 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 divulging trade secrets that explain how the active substance is manufactured.

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

If you remain dissatisfied following any internal review, you may ask the Information Commissioner (ICO) to decide on whether or not we have interpreted the FOIA correctly in dealing with the request and subsequent internal review. 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 ICO's address is:

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

Yours sincerely

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000