FOI 23/592

Dear

Thank you for your email.

> *Re: Elacestrant (Orserdu)*
>
> *Do you have any indication of the possible time frame when UK licence approval might be granted please? It was approved by the US FDA at the end of January 2023.*

We confirm that there is no marketing authorisation currently granted for Elacestrant (Orserdu), and regarding whether any application has been received by MHRA, we refuse to confirm or deny we hold any information under Section 41 (S41) and Section 43 (S43) of the FOI Act (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 alerting competitors to whether a competitor is close to obtaining a marketing authorisation or not. You may wish to contact the company directly, as they may be willing to provide an update on their regulatory position.

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

MHRA Customer Experience Centre