Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

02 October 2023

Dear [redacted]

Thank you for your request for information dated 11 September 2023, we have provided our answers beneath each of your questions, as listed below.

1. "Are Estariadol, Testosterone and GNrH Antagonists licensed for use on transgender and non-binary patients to aid in their medical transition and if not, why? It is often the claim of general practitioners and NHS administrators that the drugs aren't licensed for this purpose, but I am unable to find any corroborating sources to this effect.

Our response: *These products are not currently licensed specifically for transgender and non-binary patients; this however, does not preclude their use in this group should the clinician consider it in the best interest of the patient. This is a clinical decision, which the doctor and patient will make together in the clinic.*

Each marketing authorisation (MA) is issued with product information, including a summary of product characteristics. Section 4.1 of the SmPC will list the indications (uses) for which the product is authorised. These documents are available on the following websites, eMC or MHRA Products | Home. Please note, there is a typo in your request, Estariadol, is likely to be Estradiol.

A medicine is approved for use in a particular indication(s) based on the (clinical) evidence provided in support of its use by demonstrating efficacy and safety of the medicine in that indication. In the absence of submission of said evidence as part of a new MA or extension of a current MA, the MHRA is unable to approve the use in that indication.

2. One of your collegues notified me that drugs are licensed for use based on two key factors. The first is efficacy, and the second is safety. For this, clinical trials need to be conducted to objectively determine whether these medicines are licensed for use. Have such trials been conducted and what were the results?

Our response: *Where the benefit-risk in relation to the quality, safety and efficacy of a product in relation to the indication sought is found to be positive, a marketing authorisation (MA) can be issued. In relation to your enquiry which has a focus on already authorised products but for a new use, in this scenario it would be unlikely that additional quality data would be necessary, however for approval of the medicines in any specific population, data demonstrating clinical efficacy and safety- usually generated through clinical trials—would be required.*

3. If you didn't conduct clinical trials, do you plan to do so in the future?

Our response: *The MHRA does not conduct clinical trials and has no current plans to do so. Rather the MHRA reviews the results of clinical trials conducted by other stakeholders such as academic institutions, pharmaceutical companies etc. This may relate to new safety information or as part of applications for new uses or new medicines. Further details of ongoing clinical trials are listed publicly on the following databases:*

https://www.clinicaltrials.gov/
This is a database of federally and privately supported clinical trials conducted in the United States and around the world. The database is managed by the National Institutes of Health in the United States.

https://www.clinicaltrialsregister.eu/ctr-search/search
A database of interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA) and clinical trials conducted outside the EU/EEA that are linked to European paediatric-medicine development.

https://scanmedicine.com/
ScanMedicine is a comprehensive database of clinical trials, developed by the National Institute for Health and Care Research Innovation Observatory (NIHRIO), The University of Newcastle upon Tyne

4. What would be needed to license Estariadol, Testosterone and GNrH antagonists for this particular use?

Our response: *The requirements in relation to Marketing Authorisations and extension of indications (adding a new use or new patient population) would be evidence that the medicine is safe and efficacious in the proposed indication or population and which demonstrates the benefits outweigh the*

risks. For more information, please refer to public assessment reports on MHRA Products | Home (the menu on the left of this page can be used to filter for public assessment reports, and these documents can act as a helpful example of the types of information and data that are required).

One option would be to encourage pharmaceutical companies that hold Marketing Authorisations (MAs) for relevant products to apply for use in gender dysphoria or gender reassignment. Alternatively, there is provision under UK medicines regulation for prescribers to request use of unlicensed products by named patients where there is a special clinical need (see https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials).

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 online via an electronic form:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or

by writing to:
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Yours sincerely
MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

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Yours sincerely,

FOI Team