

FOI 23/122

Dear

Thank you for your email.

"I am writing to you under the Freedom of Information Act 2000 to request the following information from the MHRA. Please may you provide me with:

The number of packs of AndroFeme® 1 (Cream containing 1% w/v (10mg/mL) Testosterone) imported into the UK in 2020, 2021 and 2022."

The MHRA does not hold a register of the number of packs of medicines imported into the United Kingdom. Please note that importers of unlicensed medicines are legally bound to notify the MHRA of their **intent** to import unlicensed medicines, they do not notify us of the physical importation. Once the **intent** to import unlicensed medicines is notified to the MHRA, we will assess the notifications and should we not object to the importation, a letter is issued to the potential importer. It is then a commercial decision of the potential importer to import or not the packs notified.

As a result, the MHRA is not able to provide you with the answer to your question of number of packs of AndroFeme® 1 (Cream containing 1% w/v (10mg/mL) Testosterone) imported into the UK in 2020, 2021 and 2022, since we do not hold that data.

However, MHRA can confirm that for the period 1/1/2020 to 31/12/2022 we received approximately 5000 notifications of **intent** to import AndroFeme cream; which total over 125,000 packs. Whether these packs were actually imported or not, we are not able to confirm.

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.

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
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
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