

FOI 23/588

Dear

Thank you for your request of 02 August 2023 under the Freedom of Information Act, we apologise for the delay in our reply. You requested:

1. **Please provide a list of all notifications (specifying Wholesale Dealer’s Licence holder or Manufacturer’s “Specials” Licence holder, date of notification, product and quantity), received by MHRA in accordance with Schedule 4 of the Human Medicines Regulations 2012 for the import of Androfeme (which may also be described in the notification as testosterone cream or gel supplied by Lawley Pharmaceuticals or Perrigo) since 1 January 2020.**
2. **Please disclose the date of any meetings (whether in person or by telephone or video conference) since 1 January 2020 between MHRA and Lawley Pharmaceuticals (or representatives of the company) to discuss the potential licensing of Androfeme testosterone cream in the UK.**

Our responses are set out below.

1. Please find a table showing notifications to the MHRA of the licensed importer’s intent to import the specified unlicensed medicines between 01/01/2020 and 01/11/2023. Each notification usually has a quantity of 25 individual packs. We do not have a record of the supplier in our database so we are unable to identify which of the below may have been supplied by the entities you have asked about.

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Notification Month/Year	Proprietary Name	Importer Name	Number of Notifications
Feb/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	40
Mar/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	80

May/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	40
Jul/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	40
Aug/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	22
Sep/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	58
Oct/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	40
Nov/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	72
Dec/20	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	70
Jan/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	108
Mar/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	110
Apr/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	14
May/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	164
Jun/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	61
Jul/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	241
Aug/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	330
Sep/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	61

Oct/21	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	519
Jan/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	449
Feb/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	200
May/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	700
Jun/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	200
Jul/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	353
Jul/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	VERTICAL PHARMA RESOURCES LIMITED	26
Sep/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	599
Oct/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	399
Dec/22	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	399
Mar/23	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	399
May/23	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	200
Jul/23	ANDROFEME 1% W/V - CREAM - 1 X 50 ML	CLINIGEN HEALTHCARE LIMITED	403

2. Regarding this part of your request, this type of information would be commercially sensitive, and we cannot confirm or deny whether we have been involved in any such meetings. We consider this information to be exempt under Section 43(3) (Commercial interests) of the Freedom of Information (FOI) Act.

Section 43 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 company is meeting with us to discuss obtaining a marketing authorisation or not. Please note that in line with the guidance from the Information Commissioner's Office (ICO) we consider a response or disclosure under FOI to be made to the world at large, which in due course will be published (in a redacted form to remove personal information) on our website. So, whilst we are not referring to you as a competitor, any response or information we give to you or anyone else via FOI will become publicly available.

We apologise once again for the delay in this reply.

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

Or online via: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Yours sincerely

MHRA Customer Experience Centre

Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU