

FOI 23/659

Dear

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

A list of entities that have, in the past 3 years, notified the MHRA of intent to import the following medicinal products on an unlicensed basis:

- *Norma Testosterone Enanthate*
- *Rotexmedica Testosterone Enanthate*
- *Hikma Testosterone Cypionate*
- *Hospira Testosterone Cypionate*
- *Testex Prolongatum Testosterone Cypionate*
- *HCG Gonasi*
- *Pregnyl HCG*

We confirm that we hold some of the information you have requested.

The following license holders have notified the MHRA of their intent to import the unlicensed medicines on the list below, as per Regulation 167 of the Human Medicine Regulations 2012, since 01/01/2021. Please note that:

- Given these are active substance names the results include several different presentations.
- We do not hold information in our notifications database by brand for the testosterone products.

Based on your query the results retrievable are as below with the relevant search criteria:

“Testosterone Enanthate”

ALIUM MEDICAL LIMITED
CLINIGEN HEALTHCARE LIMITED
GALENIC LABORATORIES LIMITED
MAWDSLEY-BROOKS & COMPANY LIMITED
TARGET HEALTHCARE INTERNATIONAL LIMITED

“Testosterone Cypionate”

CLINIGEN HEALTHCARE LIMITED
GALENIC LABORATORIES LIMITED
MAWDSLEY-BROOKS & COMPANY LIMITED
SMARTWAY PHARMACEUTICALS LIMITED
TARGET HEALTHCARE LIMITED
WAYMADE PLC

“HCG”

No Results

“Gonasi”

ALIUM MEDICAL LIMITED
CLINIGEN HEALTHCARE LIMITED
IBSA PHARMA LIMITED
MAWDSLEY-BROOKS & COMPANY LIMITED
SMARTWAY PHARMACEUTICALS LIMITED
TARGET HEALTHCARE LIMITED
VERTICAL PHARMA RESOURCES LIMITED
WAYMADE PLC

“Pregnyl”

TARGET HEALTHCARE LIMITED
WAYMADE PLC

We hope you find this information helpful and we apologise once more 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

Yours sincerely

MHRA Customer Experience Centre

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