Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00355**

23 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 30 March. You wrote:

Under the provisions of the Freedom of Information Act 2000, I am requesting the following information regarding the regulatory status, supply restrictions, and review process for subcutaneous hormone implants (specifically 25mg and 50mg Oestradiol and Testosterone pellets).

1. Regulatory Status and Patient Access
- Please provide the current official MHRA policy regarding the initiation of new patients on oestrogen implant therapy.

- Does the MHRA hold any recorded documentation or clinical guidance that mandates a "zero-initiation" policy for new patients in cases where all licensed alternatives have failed?

- Please provide the recorded criteria or conditions that must be met for the "existing patients only" restriction to be formally rescinded.

2. Alternative Manufacturers and cGMP Assessments
- Is the MHRA currently engaged in an active regulatory review of alternative manufacturers (e.g., manufacturers based in Australia or Europe) for the supply of oestradiol or testosterone implants to the UK market?

- Please provide the number of applications or "Special" clinical need requests received or reviewed by the MHRA for imported hormone implants from non-APT facilities between February 2025 and March 2026.

3. Review Status (APT Facility)
- Please confirm if the regulatory review regarding implants manufactured at the APT facility is officially concluded.

- If the review is ongoing, please provide the most recent recorded "estimated completion date" for this assessment.

4. Continuity of Supply (Stock Levels)

- Following the February 2025 update regarding an estimated 18-month supply of existing stock, does the MHRA hold a more recent stock audit or supply forecast for oestrogen implants as of March 2026?

- Has a new licensed source or Marketing Authorisation (MA) holder been identified or approved for these products since February 2025?

5. Testosterone Implants
- Please provide the current regulatory status of testosterone subcutaneous implants.

- Is this specific product subject to the same "existing patients only" supply restriction as oestrogen implants?

MHRA Response

We confirm that we hold the information you have requested.

We have repeated each of your questions below and provide our replies beneath each question:

1. Regulatory Status and Patient Access
- Please provide the current official MHRA policy regarding the initiation of new patients on oestrogen implant therapy.

Our reply: We hold no information to meet this request.

Please refer to advice and assistance section beneath the next reply below.

- Does the MHRA hold any recorded documentation or clinical guidance that mandates a "zero-initiation" policy for new patients in cases where all licensed alternatives have failed?

Our reply: We hold no information to meet this request. Please refer to advice and assistance section toward the end of this letter which relates to a suggestion to contact DHSC.

- Please provide the recorded criteria or conditions that must be met for the "existing patients only" restriction to be formally rescinded.

Our reply: We hold no information to meet this request.

Advice and assistance
Please see the below from update on the British Menopause Society, based on correspondence from the MHRA.

“The conclusion reached by the MHRA review is that the APT product may be currently the only suitable treatment option for some patients. In view of this we are allowing SmartWay to now supply the remaining imported stock of Estra 25mg and 50mg pellets in the UK to existing patients only, with discussion with their healthcare professional. Alternatives of the Testo product are available.

The MHRA has been informed existing stocks in the UK should be sufficient to meet patient needs for approximately 18 months, whilst alternate sources are sought. Therefore, we encourage patients who have these implants to speak to their healthcare professional and to discuss switching to licensed therapeutic options where possible”.

Update - Subcutaneous Hormone Implant Therapy - British Menopause Society

2. Alternative Manufacturers and cGMP Assessments
- Is the MHRA currently engaged in an active regulatory review of alternative manufacturers (e.g., manufacturers based in Australia or Europe) for the supply of oestradiol or testosterone implants to the UK market?

Our reply: We confirm that we hold information to confirm a positive reply, please also refer to advice and assistance below.

Advice and assistance
The MHRA and DHSC are continuing to proactively engage with manufacturers to explore the potential for UK licensing of these products, including companies that already market testosterone implants internationally, as well as UK suppliers with niche products within their portfolios. Manufacturers approached to date have not indicated plans to supply this product to the UK, which is ultimately their commercial decision to make, and we have not identified an alternative global source of estradiol implants to import into the UK. We approached a number of UK specials manufacturers who confirmed they are unable to manufacture these implants, and unfortunately an unlicensed testosterone 75 mg implant that had previously been imported from the USA is no longer available. However, we are engaging directly with the manufacturer of the USA product to better understand their position and future options.

Please also note, that we do not source medicines, nor do we find alternative sources of medicines, as this is not within our regulatory remit and is instead that of DHSC.

- Please provide the number of applications or "Special" clinical need requests received or reviewed by the MHRA for imported hormone implants from non-APT facilities between February 2025 and March 2026.

Our reply: We confirm we hold information related to this request. We had 90 notifications of 25 packs each of the intent to import testosterone implants by the importer Alium, in December 2025. These were packs of 10 pellets named: TESTOPEL PELLETS 75MG. These are licensed medicines in the USA.

3. Review Status (APT Facility)
- Please confirm if the regulatory review regarding implants manufactured at the APT facility is officially concluded.

Our reply: The status of this MHRA regulatory activity is currently concluded. However, there is no confirmed timescale for the restored supply of unlicensed estradiol and testosterone implants for UK patients. The MHRA and DHSC are continuing to proactively engage with manufacturers to explore the potential for UK licensing of these products, including companies that already market testosterone implants internationally, as well as UK suppliers with niche products within their portfolios. FDA activity which cross-relates to the supply issues remains open.

Advice and assistance
Please also refer to the weblink below (same as that provided above):
Update - Subcutaneous Hormone Implant Therapy - British Menopause Society

- If the review is ongoing, please provide the most recent recorded "estimated completion date" for this assessment.

Our reply: We do not hold this information, please refer to US FDA, see above.

4. Continuity of Supply (Stock Levels)
- Following the February 2025 update regarding an estimated 18-month supply of existing stock, does the MHRA hold a more recent stock audit or supply forecast for oestrogen implants as of March 2026?

Our reply: We hold information to meet this request, please refer to the below information which we received from DHSC.

“Given the above, there is no confirmed timescale for the restored supply of unlicensed estradiol and testosterone implants for UK patients. As of late March 2026, Smartway Pharma are holding approximately 15 months’ of unlicensed estradiol implant stock according to historic UK demand for existing patients. It is recognised that the reliability of supply through the unlicensed route can vary, particularly if there are changes or constraints in the source country; however, this remains an established mechanism for access where no licensed alternative is available, and the position continues to be kept under review”.

Advice and assistance
There is an option for you to contact DHSC to ask if that organisation holds further information, please refer to DHSC contact details at the end of this letter.

- Has a new licensed source or Marketing Authorisation (MA) holder been identified or approved for these products since February 2025?

Our reply: We confirm we do not hold information to meet this request.

5. Testosterone Implants
- Please provide the current regulatory status of testosterone subcutaneous implants.

Our reply: We can confirm that the Agency holds this information. However, the information is exempt under Section 21(1) of the Freedom of Information Act because the relevant legislation and guidelines are reasonably accessible to you, as these are already in the public domain. However, as the legislation is not presented in lay terminology, we have provided some advice and assistance which describes how an application for *testosterone subcutaneous implants would be* regulated. Please also refer to the advice and assistance given under our reply to question 2, where we confirm that there are currently no licensed testosterone subcutaneous implants supplied in the UK.

Advice and assistance
In essence a subcutaneous implant containing testosterone is treated as a medicine because this type of implant relies on passive diffusion of drug substance and the inactive components are treated as excipients and not device parts. However, if there was a clear plastic applicator, or metal part (e.g. an IUD) this could be a drug-device combination.

We would advise a potential applicant to submit an application for a subcutaneous implant containing testosterone as a marketing authorisation application to be regulated in line with the Human Medicines Regulations 2012 and other relevant guidelines the specific guideline/s can vary depending on the specific components and nature of the product.

- Is this specific product subject to the same "existing patients only" supply restriction as oestrogen implants?

Our reply: The same supply restriction applies to testosterone subcutaneous implants.

Advice and assistance
Please refer to the advice and assistance provided beneath the questions above, we also provide the contact details for DHSC below, please refer to the bottom part of the below webpage:

Department of Health and Social Care - GOV.UK

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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