



Medicines & Healthcare products Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00095**

4 March 2025

Dear [REDACTED],

Thank you for your Freedom of Information (Fol) request received on 4 February. You wrote:

This is a follow up request to my previous freedom of information request (ref: FOI2024/0008) concerning your review into the supply of Estra 25mg and 50mg pellets and testo-100 pellets in the UK.

In your response to my previous request you confirmed that:

"Considering this may be the only suitable treatment option for some patients and the absence of significant safety signals so far, the MHRA has decided to allow supply to resume following a preliminary analysis of available evidence, and while our more in-depth review continues". However, I am informed by the importer (Smartway Pharmaceuticals Ltd) that they have again been instructed to stop supplying these pellets.

Please could you provide the following information concerning this decision:

- 1. When was the current halt on supply of the implants instituted?*
- 2. Is this now a permanent cessation of supply?*
- 3. If the MHRA review of these pellets has now been concluded please confirm its conclusions and provide a copy of any written report outlining these.*
- 4. If the review is still undergoing:*
 - (i) why has the importer been instructed to halt supply now?*
 - (ii) are there any concerns for patient safety?*
 - (iii) when is it expected to conclude?*
- 5. What consultation has been undertaken with prescribers responsible for patients currently reliant on these implants both concerning the review generally, and more specifically concerning the current halt of supply.*
- 6. Please provide copies of any communications provided to, or received from, such prescribers by MHRA.*
- 7. Please provide copies of any communication with the US Food and Drug Administration with whom you were engaging concerning the manufacturer of the pellets.*

MHRA Response

The Agency has completed its search for the information you have requested, and we are able to confirm that we do hold the information you have requested.

Please note that some of the information cannot be disclosed and is being exempt from release for the reasons as outlined below.

1. When was the current halt on supply of the implants instituted?

Following an FDA inspection of the US manufacturer, Advanced Pharmaceutical Technology Inc., and report last year, SmartWay (the UK importer) placed a voluntary hold on the supply of these products.

2. Is this now a permanent cessation of supply?

MHRA is not objecting to SmartWay continuing to supply the remaining imported stock of Estra 25mg and 50mg pellets and Testo 100 in the UK to existing patients only, with discussion with their healthcare professional. The MHRA has been informed that existing stocks in the UK should be sufficient to meet patient needs for approximately 18 months.

3. If the MHRA review of these pellets has now been concluded please confirm its conclusions and provide a copy of any written report outlining these.

The conclusion reached by the MHRA review is that the APT product may be currently the only suitable and available treatment option for some patients.

4. If the review is still undergoing:

(i) why has the importer been instructed to halt supply now?

Following an FDA inspection of the US manufacturer, Advanced Pharmaceutical Technology Inc., and report last year, SmartWay (the UK importer) placed a voluntary hold on the supply of these products.

(ii) are there any concerns for patient safety?

We are not recommending that patients who have these implants have them removed. Patients taking these medicines are already monitored by their healthcare professional for any potential adverse reactions. Any suspected side effects can be reported to the MHRA using the [Yellow Card scheme website](#).

(iii) when is it expected to conclude?

The review is concluded to confirm that the manufacturing standards at the APT plant are not acceptable, and that alternative supplies are required.

5. What consultation has been undertaken with prescribers responsible for patients currently reliant on these implants both concerning the review generally, and more specifically concerning the current halt of supply.

We are not discontinuing supply at this stage and are actively working to maintain continued access to this medical product. We are in close communication with the Department of Health Medicines Supply team and the importer, SmartWay. We are also providing information regarding the results of the US FDA inspection of the facility. Our goal is to either support improvements in the manufacturing facility's standards to ensure patient safety or to source the product from an alternative GMP-accredited site.

6. Please provide copies of any communications provided to, or received from, such prescribers by MHRA.

7. Please provide copies of any communication with the US Food and Drug Administration with whom you were engaging concerning the manufacturer of the pellets.

The information you requested is being withheld as it falls under the exemption in Section 27(1) and Section 27(2) of the FoI Act.

Section 27(1) provides an exemption for information if its disclosure would, or would be likely to, harm UK interests which are set out in the exemption.

Section 27(2) provide an exemption for information obtained in confidence from another state, international organisation or international court.

As such, we are withholding the information due to a formal confidentiality agreement between the MHRA and the Food and Drug Administration (FDA). Disclosing this information would, or is likely to, harm the relationship between the MHRA and the FDA.

In applying this exemption, the agency has also balanced the public interest in withholding the information against the public interest in disclosing the information and on balance we find that withholding the information from release outweighs our obligation to release.

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.

Re-use of our information

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>