Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

19 April 2024

MHRA reference: FOI 24/329

Dear [redacted]

Thank you for your information request, which we received on 5 April 2024. You asked:

> *"I wish to make an application under the Freedom of Information Act regarding the recent embargo on imports of hormone implants into the UK*
>
> *I have recently been informed (as a patient in Wales) that the Medicines and Healthcare products Regulatory Agency (MHRA) has informed all menopause clinics in the UK that the implants have been placed on hold for import into the UK due to quality assurance issues.*
>
> *I request the specific list of reasons for this please, all information held on the subject of subcutaneous oestrogen and testosterone hormonal implants.*
>
> *What are the quality issues that have been raised?*
> *What is the nature of the original complaint?*
> *Are there any particular batches or serial numbers affected?*
> *What is the nature of the complaints procedure as a result of identifying QA concerns?*
> *What is the response time for closing the original complaint?*
>
> *Please supply all details and advise when you expect the original complaint to close."*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

Regarding your questions concerning the recent pause on imports of unlicensed hormone implants into the UK, the regulation of medicines on the UK market is undertaken by MHRA in accordance with the Human Medicines Regulations 2012 (SI 2012/1916). There are two routes possible with licensed and unlicensed medicines potentially being supplied. We encourage licensed supply as this means

medicines are required to be authorised before being placed on the market. This means the licensing authority has reviewed the quality, safety and efficacy of authorised medicines.

Nevertheless, there are legal provisions allowing for unlicensed medicines to be prescribed and supplied to patients, when there are no licensed medicines that are available and capable of meeting the special clinical needs of individual patients. Their use is the responsibility of the prescriber responsible for the care of individual patients.

Estra 25mg and 50mg pellets are unlicensed medicines in the UK and in the USA. This means these medicines are not overseen by a regulatory authority and there are no guarantees to their composition, safety or efficacy. Unlicensed medicines are not authorised by the MHRA and as such have not been assessed for their quality, safety or efficacy. However, unlicensed medicines are generally expected to meet certain UK manufacturing standards in the interest of safeguarding patients' health.

When the MHRA became aware of concerns over manufacturing standards at the implant manufacturing site in the USA, the MHRA decided to implement a precautionary pause on the importation of these implants while an initial review of all the available information was conducted.

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.

We recognise that temporarily pausing the imports of Estra 25mg and 50mg pellets into the United Kingdom has caused concerns among the group of patients who rely on these medicines. We unreservedly apologise for the concerns caused. Your safety is our top priority and as a result we initially decided to pause imports as a precautionary step given the potential for the implants to cause harm to patients.

We have engaged with the US competent authority, the Food and Drug Administration (FDA), to better understand their findings on this manufacturing site. Once we understand this, we will share our findings with the importer and consult with prescribers responsible for patients currently receiving these implants so they can make appropriate decisions in their patients' best interests.

Regarding your specific questions (in bold and italics):

What are the quality issues that have been raised?
What is the nature of the original complaint?
Are there any particular batches or serial numbers affected?

We have stated above that a precautionary pause was implemented because MHRA became aware of concerns over manufacturing standards at the implant

manufacturing site in the USA. MHRA has decided to allow supply to resume following a preliminary analysis of available evidence, and while our more in-depth review continues.

As a more in-depth review is ongoing, we exempt releasing any further information under Section 35 (formulation of government policy) of the Freedom of Information Act (FOIA):

> ***35 Formulation of government policy, etc.***
> *(1) Information held by a government department or by the Welsh Assembly Government] is exempt information if it relates to—*
> *(a)the formulation or development of government policy,*

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when considering this class-based exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in providing this information outweighs the public interest in withholding the information you have requested. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in providing this information. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public.

Considerations in favour of providing information requested
To provide the information requested would be of interest to patients who want to understand the investigation into an imported medicine that they are currently prescribed. It would also be of benefit in general to show transparency in MHRA's day-to-day work for the public to see progress with the current investigation.

Considerations in favour of withholding the information
The review is still ongoing and has not yet concluded. This means that Section 35(1)(a) is engaged and will remain engaged until our review has concluded. To provide information at this point could prejudice this review, by releasing information into the public domain that could be used for persons to try to reach their own conclusions before we have concluded our review. As we have stated, 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.

After considering these circumstances, the public interest favours withholding this information while the review is ongoing. Please also be aware that even after our review has concluded, other exemptions may apply to some information relevant to your request, such as Section 41 (information provided in confidence), Section 43 (commercial interests), Section 21 (information accessible by other means) and Section 22 (information intended for future publication).

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What is the nature of the complaints procedure as a result of identifying QA concerns?
What is the response time for closing the original complaint?

The processes followed by the MHRA when making decisions that impact the availability of medical treatments, including hormone implants, are detailed in the Human Medicines Regulation 2012. We have engaged with the US competent authority, the Food and Drug Administration (FDA), to better understand their findings on this manufacturing site. Once we understand this, we will share our findings with the importer and consult with prescribers responsible for patients currently receiving these implants so they can make appropriate decisions in their patients' best interests. We currently have no date for concluding our review, but we are treating this with the highest priority.

If you have a query about the information provided, please reply to this email

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

This concludes our response to your request.

If you have a query about this response, please contact us at

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Medicines & Healthcare products Regulatory Agency

MHRA Customer Experience Centre
Communications and Engagement Team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Appeal rights

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The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

Re-use of our information