



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2026/01059**

13 October 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 15 September 2026. You wrote:

'I would like to be sent all the information submitted by Astellas to support the licensing and wording of the SmPC for Fezolinetant in regards to breast cancer as per wording in section 4.4 (as below), as well as the documentation in relation to the MHRA in how it came to agree this wording.'

The SmPC contains the wording below in Regards to breast cancer:

4.4 Special warnings and precautions for use

Known or previous breast cancer or oestrogen-dependent malignancies

Women undergoing oncologic treatment (e.g., chemotherapy, radiation therapy, antihormone therapy) for breast cancer or other oestrogen-dependent malignancies have not been included in the clinical studies. Therefore, Veoza is not recommended for use in this population as the safety and efficacy are unknown.

Women with previous breast cancer or other oestrogen-dependent malignancies and no longer on any oncologic treatment have not been included in the clinical studies. A decision to treat these women with Veoza should be based on a benefit-risk consideration for the individual.

The SmPC contains no data to support the above and SKYLIGHY-1 and SKYLIGHT-2 excluded people with a history of breast cancer, and this is clearly stated in the wording above for both groups.

I therefore wish to understand what information was submitted to the MHRA by Astellas in regards to this and how the MHRA came to make this decision in relation to the wording related to breast cancer given the referenced data in the SmPC.'

MHRA Response

Your request has been interpreted as seeking more information on the background to the wording originating from the SmPC of Veoza (fezolinetant) 45 mg film-coated tablets (PLGB 00166/0437; ASTELLAS PHARMA LIMITED).

We note that a similar query was also submitted as a customer enquiry, and our response is included below as further context to this FOI request:

'The MHRA understands your question relates to the rationale for distinguishing between:

- women currently undergoing treatment for breast cancer or other oestrogen-dependent malignancies; and*
- women with a previous history of breast cancer or other oestrogen-dependent malignancies who are no longer receiving oncological treatment.*

As you note, these populations were not included in the pivotal clinical studies supporting the original authorisation of fezolinetant. The SmPC wording therefore reflects the limitations of the available evidence base and the degree of uncertainty applicable to each population, rather than evidence demonstrating established safety and efficacy in either group. The purpose of the wording is to provide prescribing guidance where direct clinical trial evidence is absent.

For women actively receiving treatment for breast cancer or another oestrogen-dependent malignancy, the SmPC states that use is not recommended because safety and efficacy have not been established in this population. This reflects the absence of clinical study data and the potential for additional clinical considerations in patients undergoing active oncological management.

For women with a previous history of breast cancer who are no longer receiving oncological treatment, the SmPC similarly acknowledges the absence of direct clinical study data. However, the wording permits consideration of treatment on an individual benefit-risk basis. This reflects a regulatory judgement that the risk-benefit balance may differ from that in patients receiving active cancer treatment, and that clinical decision-making should therefore be individualised.

The MHRA notes that the SmPC does not cite specific clinical study data demonstrating safety or efficacy in either population. Rather, the wording is intended to communicate the limitations of the available evidence and support appropriate clinical decision-making where evidence is incomplete.

The MHRA is unable to comment on decisions taken by NICE regarding eligibility for access to treatment, as these fall within NICE's remit.'

As stated in the response to the customer enquiry, the SmPC wording reflects data available for this medicine, and in this case highlights a patient population where safety and efficacy is unknown.

Individuals with previous or current history of malignant tumor (except for basal cell carcinoma) were excluded from the pivotal phase 3 studies conducted by the Marketing Authorisation Holder. Fezolinetant has also not been studied in individuals with vasomotor symptoms induced by pharmacologic treatment of malignancy (e.g., breast cancer).

This medicine was authorised via the European Commission Decision Reliance Procedure (ECDRP) route. In coming to its decision, MHRA relied on a European Commission decision (EMA/H/C/005851). For more information on how this medicine was authorised, please see the Public Assessment Report available on the MHRA website:

<https://products.mhra.gov.uk/search/?search=veoza&page=1>

The SmPC wording was requested by the EMA during their assessment, as reflected by wording on page 133 of the EMA Public Assessment Report:

'It is noted that patients with VMS with known or previous breast cancer or other oestrogen-dependent malignant tumours have not been included in the clinical trials and this information should be added to section 4.4 of the SmPC'

The EMA Public Assessment Report is available online here:

https://www.ema.europa.eu/en/documents/assessment-report/veoza-epar-public-assessment-report_en.pdf and they will be best placed to answer questions on the origin of this wording.

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

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Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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