Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

20th December 2023

Dear [redacted]

FOI 23/907

Please accept our apologies for not meeting the requirements of your initial request. Thank you for your email dated 22nd November 2023, where you requested details on the following:

- The information I requested was specifically for 'persistent' alopecia. Not categorised as normal short-term alopecia expected with chemotherapy.
  So, please, how many reports have you had in total from oncologists/doctors/patients reporting 'persistent/permanent' alopecia from Docetaxel/Taxotere.

We can confirm up to and including 11/12/2023 we have received a total of 70 UK suspected spontaneous Adverse Drug Reaction (ADR) reports of docetaxel associated with alopecia and androgenic alopecia. Of these 70 ADR reports, 21 reports specifically stated that the alopecia was permanent, persistent, or irreversible. This is determined by the information we collect on the outcome of reactions submitted by the reporter, and there is also a free-text field for reporters to describe their events. We searched this field for the specific terms permanent, persistent, and irreversible. Please note this is based on the information provided by the reporter at the time the report was submitted to us.

When considering the above spontaneous ADR data, it is important to be aware of the following points:

- The inclusion of a particular reaction on our system does not necessarily mean that it has been caused by the suspect drug. Many factors must be considered in assessing causal relationships, including temporal association, the possible contribution of concomitant medication, and the underlying disease. We encourage reporters to report suspected ADRs i.e., the reporter does not have to be sure of a causal association between the drug and the reactions – a suspicion will suffice.
- It is important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions to drugs for several reasons. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.
- The number of reports received should not be used as a basis for determining the incidence of a reaction as neither the total number of reactions occurring, nor the number of patients using the drug is known.

We hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

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Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF