

Shirley Ledlie

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**IN CONFIDENCE**

Dear Ms Ledlie,

Thank you for your enquiry requesting information relating to the incidence of Adverse Drug Reactions (ADRs).

In reference to your query, I can clarify that incidences of adverse reactions have been categorised in order to help determine the frequency with which they occur and to allow comparison between drugs with different adverse reactions. This work was conducted by the Council for International Organisations of Medical Sciences (CIOMS), an international, non-government, non-profit organisation, who facilitate and promote international activities in the field of biomedical sciences. In 1998 the CIOMS IV working group recommended strategies to facilitate and harmonise the sharing of action by regulators and manufacturers to enhance decision making with regards to safety action in the interest of public health. To permit comparison between drugs with different adverse reactions, the CIOMS working group proposed the following categories of incidence:

Very common:	>10% ( $\geq 1/10$ )
Common or frequent:	between 10% and 1% ( $\geq 1/100$ to $< 1/10$ )
Uncommon or infrequent	between 1% and 0.1% ( $\geq 1/1000$ to $< 1/100$ )
Rare	between 0.1% and 0.01% ( $\geq 1/10000$ to $< 1/1000$ )
Very rare	$< 0.01\%$ ( $< 1/10,000$ )

In certain cases, if a frequency cannot be estimated from the available data, an additional category frequency of 'not known' may be used.

For a side effect to be classed as 'very rare' the frequency with which it is seen must be less than 1 in 10,000 patients, anything greater than this would not fall under this category.

As mentioned in our previous correspondence, the frequency of a side effect, where it is known for example from clinical trials, is documented in the Summary of Product Characteristics. With regards to the reaction 'alopecia' in association with docetaxel, the SPC currently states 'alopecia' to be a 'very common' side effect – occurring with an incidence of  $\geq 1$  in 10.

I hope this information is of use to you.



Yours sincerely

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