EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Michael R. Cohen
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20 February 2012
EMA/86224/2012

Dear Mr Cohen

Subject: Letter regarding ambiguous labelling of eribulin in European countries

Thank you for your letter of 27 January 2012 expressing the concerns of the International Medication Safety Network (IMSN) with respect to the potential risk of dosing errors with Halaven (eribulin), due to the way that the strength is expressed in the product information.

The EU product information expresses the strength in terms of the base, as recommended by European guidelines – an approach which is supported by IMSN. At the time of approval of Halaven in the European Union, the CHMP considered that given that the medical community was used to the doses expressed in terms of eribulin mesylate (clinical trials, literature, approved USPI), it would be useful to include a reference to the dose of the salt in the product information. The current SmPC Guideline provides for two alternative wordings on how to express quantitatively an active substance which is present in the form of a salt or hydrate, e.g.:
- 60 mg toremifene (as citrate), or
- toremifene citrate equivalent to 60 mg toremifene.
So far the first option, which is also the one applied for Halaven, has been chosen in most centrally authorised products on the basis of the length of the statement and the subsequent space considerations in the labelling; this is especially important for multilingual labels where space is a crucial factor for the readability of the information.

In view of the comments received about a possible misunderstanding of the current wording and thus the potential risk of dosing errors, the CHMP has agreed that an update to the product information is necessary. The submission of this update will take place in March, following a consultation of the proposed wording with healthcare professionals, and is likely to be approved in April 2012. In the meantime, the CHMP is considering the need for a direct healthcare professional communication letter to clarify the expression of dose of Halaven in the current product information.

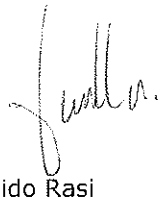
In addition, we have also conducted a search in the EudraVigilance database for eribulin and, up to a cut-off date of 24 January 2012, no spontaneous reports related to medication errors -or any other related terms that could suggest confusion between the dose of eribulin salt and base- have been received.

In line with our commitment to promote the safe use of medicines in the European Union, the Agency would like to establish a more general discussion with the IMSN and other stakeholders, in order to

define the wording more clearly in similar cases (e.g. expression of dose in terms of salt versus base). In addition, we would like to extend the contribution of the IMSN to the activities of the Quality Review of Documents (QRD) group on a more regular basis.

Please rest assured that the Agency always takes IMSN feedback very seriously and we are looking forward to developing a closer interaction with your network in the future.

Yours sincerely



Guido Rasi
Executive Director