Referral under Article 31 of Directive 2001/83/EC

Procedure No: EMEA/H/A-31/1361

Thiocolchicoside-containing medicinal products

Divergent statement

The undersigned members of CHMP did not agree with the CHMP's opinion recommending the variation to the terms of the Marketing Authorisations and conditions to be fulfilled by the MAHs for the medicinal products containing Thiocolchicoside. The reasons for divergent opinion were as follows:

Genotoxic effects (aneuploidy) have been shown. Whereas there may be a concentration threshold for these effects, there is no sufficient safety margin. Genotoxic effects were observed at concentrations that must be expected in humans treated with the proposed dose. A reduction of treatment time may reduce but cannot eliminate the risk of aneuploidy induction and possible consequences (e.g. carcinogenesis). As alternative therapeutic options without evidence for a cancer risk are available the continued use of thiocolchicoside seems not justified unless and until data are presented that confirms that there is a threshold for genotoxic effects of thiocolchicoside and that this threshold is not reached in patients.

CHMP members expressing a divergent opinion:

Pieter de Graeff	21 November 2013	Signature: ……...
Hubert Leufkens	21 November 2013	Signature: ……...
Harald Enzmann	21 November 2013	Signature: ……...
Jan Mueller-Berghaus	21 November 2013	Signature: ……...