



## **EMEA PUBLIC STATEMENT ON ANTIMICROBIAL PRESERVATIVES IN OPHTHALMIC PREPARATIONS FOR HUMAN USE**

During the January 2009 CHMP meeting, the CHMP decided that a thorough scientific discussion was necessary in order to establish the value and safe use of antimicrobial preservatives in eye drops for human use. Thus, a CHMP ad-hoc group of experts was established. An outcome was reached in November 2009 and the following conclusions were agreed:

- Ophthalmic preparations without preservatives are needed for those patients who do not tolerate eye drops with preservatives. In addition, for long term treatment, formulations without preservatives are considered to be valuable alternatives. Ophthalmic preparations without preservatives are strongly recommended for use in paediatric patients, especially neonates. Therefore, pharmaceutical companies should develop preparations without preservatives wherever possible in order to cater for the diversity of patients' needs. Nevertheless, based on a review of available safety evidence, a general recommendation not to use preservatives in eye drops cannot be supported.
- When preservatives are required, the concentration should be at the minimum level consistent with satisfactory antimicrobial function in each individual preparation and a thorough justification for the choice of the preservative should be provided.
- Non-clinical and clinical studies of appropriate design and duration are needed to give reassurance that the proposed formulations are optimal in term of benefit/risk balance.
- When preservatives are required, the CHMP considers that it would be prudent to promote new ophthalmic preparations without any mercury-containing preservatives, e.g. thiomersal. This advice is also in line with the global goal of reducing environmental exposure to mercury.