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Committee for medicinal products for human use (CHMP)

ICH guideline S10 on photosafety evaluation of pharmaceuticals

Step 4

Transmission to CHMP	December 2012
Adoption by CHMP for release for consultation	December 2012
End of consultation (deadline for comments)	March 2013
Final adoption by CHMP	December 2013
Date for coming into effect	June 2014

Scope:

This guideline generally applies to new active pharmaceutical ingredients (APIs), new excipients clinical formulations for dermal application (including dermal patches), and photodynamic therapy products.

Specific guidance for pharmaceuticals given via ocular routes is not provided because the reliability of in vitro approaches in predicting ocular phototoxicity is unknown and there are no standardised in vivo approaches for assessing phototoxicity for products administered via the ocular routes (see note 1 of endnotes in the guideline).

Photodynamic therapy drugs are developed with photochemical reactivity as an inherent aspect of their intended pharmacology and additional assessment of their phototoxicity is not usually warranted. However, an evaluation of the toxicokinetics and tissue distribution of photodynamic therapy drugs is warranted to enable appropriate risk management in patients.

This guideline does not generally apply to peptides, proteins, antibody drug conjugates, or oligonucleotides. Further, this guideline does not apply to components of marketed products unless there is a new cause for concern for either the API or an excipient (e.g., a reformulation from a tablet to a topical cream).

Link to: Safety guidelines

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