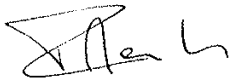
presence of a particular excipient. Therefore, when a preservative is included in the eye drops, the relevant warnings - if necessary – will also be included in the product information.

Furthermore, before applying for marketing authorisation, a pharmaceutical company is obliged to ensure that all excipients, including preservatives are used appropriately in the formulation of their medicinal products. The appropriateness of the pharmaceutical formulation is assessed by the regulatory authority in question, which needs to confirm that the formulation is suitable and complies with legislative requirements and the relevant scientific guidelines before a marketing authorisation can be granted.

Finally, we would like to inform you that the EMEA´s Committee for Medicinal Products for Human Use (CHMP) is considering further this issue in order to define clear criteria for the specific value and safe use of preservatives in eye drops.

We hope that you find this information useful.

Yours sincerely,



Dr Isabelle Moulon
Head of Medical Information Sector