London, 12 March 2009
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Président de Keratos
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Re: Withdrawal of preservatives from ophthalmic preparations

Dear Mr

Thank you very much for your letter of 12 February 2009, in which you express some concerns over the use of preservatives in eye drops. The European Medicines Agency (EMEA) has already been made aware of these concerns, which were expressed to the European Parliament by a German patients' organisation.

The standards for eye drops are set out in the monographs of the European Pharmacopoeia. For safety reasons, guidelines and pharmacopoeial monographs establish strict requirements on the sterility of ophthalmologic preparations. It is of utmost importance that microbial contamination be avoided, since ocular infections can threaten the sight.

Eye drops can be packaged in single or multi-dose containers. When multidose containers are used, preservatives may be necessary to prevent microbial contamination of the eye drop solution during use. Preservatives may also be used to increase the solubility or the penetration of the active substance.

The preserved eye drops currently in use fulfil an important medical need, especially for the elderly and for patients with impaired vision, who may find small, single dose containers difficult to use because of problems with manual dexterity. In addition, preservatives are well tolerated in the majority of patients, even when used in the long term.

It should be pointed out that in line with the European legislation into force, a list of all excipients in ophthalmic medicinal products must appear on the products' external labelling. All reported adverse reactions must also be described in the product information.

In addition, according to the official guidance (Excipients in the label and package leaflet of medicinal products for human use - Notice to Applicants, Volume 3B), when a warning or