Object: withdrawal of preservatives from ophthalmic preparations

Bois-Colombes, Feb the 13th, 2009

Dear Madam or Sir,
Keratos is a patient association focusing on ocular surface diseases and lachrymal dysfunctions (http://keratos.free.fr) particularly interested in the anterior ocular segment (notably the cornea) and the various serious consequences that ocular surface disorders induce.

As such, we would like to draw your attention to the problems inherent to the use of preservatives in ophthalmic preparations. It is commonly accepted, on the basis of INDEPENDENT medical literature and studies, that the systematic use of preservatives in eyedrops, such as benzalkonium chloride (although by far not the only culprit), is a serious deleterious factor for all chronic diseases that require the frequent instillation of eyedrops (even in originally healthy corneas).

Medical literature is very abundant on this matter, and ophthalmologists themselves are more and more aware of such – at first frequently insidious - dangers and advise their patients to avoid using preserved eyedrops and prefer non-preserved options. Unfortunately, these are not always available.

Therefore, we would like to raise your attention to the fact that preservatives have forced many of our members to suspend their many treatments due to severe allergic reactions or intolerances, the apparition of punctuate keratitis (a very frequent symptom of preservative use) or corneal erosions, irritations and other lachrymal disturbances.
Beyond these manifest intolerances, it is the medium-term cytotoxic effect that we fear the most, considering that it will leave most members with either an inadequate therapeutic option or a deteriorated cornea. Again, medical literature confirms the experience of our members.

Our treatments are directly impacted by the existence non-preserved options or lack thereof. This is clearly unacceptable considering that these risks may be totally avoided by the use of special containers (such as the ABAK or Comod system) or single use vials. Please consider reading more on what exactly is at stake on the following website: http://preservative.free.fr

EMEA and all other European regulating agencies have an important role to play concerning "sustainable" treatments options without risks. Thus, we would like to know what is your policy regarding the use of preservatives in ophthalmic preparations.

It is obvious that the first obligation of the pharmaceutical industry is to provide us with treatments that comply with the *primum non nocere* rule applicable (whenever feasible and it's clearly the case) to all those involved in medical treatments.

We have heard that a group of German citizens (Initiative Augentropfen) has recently sent a petition to the European authorities on this very matter (particularly for glaucoma patients but the stakes are the same for dry or allergic eyes and most ocular surface diseases), that will likely reach the EMEA itself. We hope that all regulating agencies, such as the AFSSAPS here in France, and moreover the EMEA, will finally adopt a policy in the best interest of all patients (and incidentally the laboratories that have made the appropriate efforts to respect our corneas).

We recently received from Alcon an indication that it will not adopt a more respectful attitude towards our corneas without being "encouraged" by the regulating agencies. Please ban preservatives in *medium to long-term* use ophthalmic preparations for the sake of our eyes.

Thank you very much for your time and interest regarding this issue,
Yours faithfully,

On behalf of Keratos,
Tiago Douwens Prats,
Président