European Medicines Agency
*Pre-Authorisation Evaluation of Medicines for Human Use*

London, 25 September 2008
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**SUMMARY OF POSITIVE OPINION***
**for**
**AZARGA**

International Nonproprietary Name (INN): ***brinzolamide / timolol***

On 25 September 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Azarga 10 mg/ml / 5 mg/ml Eye drops, suspension intended the treatment of elevated intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.

The applicant for this medicinal product is Alcon Laboratories (UK) Ltd.

The active substances of Azarga are two well known ophthalmic drugs, Timolol (5 mg/mL) and Brinzolamide (10 mg/mL), in a fixed combination.

Brinzolamide is a carbonic anhydrase II (CA-II) inhibitor. These compounds decrease the aqueous humor production by means of inhibiting the conversion of carbon dioxide to bicarbonate in the ciliary body of the eye, thus decreasing intraocular pressure (IOP).
Timolol is a non-selective $\beta_1$ and $\beta_2$ adrenoceptor antagonist that lowers IOP by suppressing aqueous humor formation in humans.

The benefits with Azarga are its ability to decrease intraocular pressure without having to administer separately brinzolamide and timolol eye drops. The most common side effects are blurred vision, eye irritation, eye pain, and foreign body sensation.

A pharmacovigilance plan for Azarga, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication for AZARGA is: Decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Azarga and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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