2.7 Clinical Summary

This generic formulation refers to the drug product Travoprost/Timolol preservative free eye drops solution, available in the 0.004%/0.5% and is indicated in adults for the decrease of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

The present marketing authorisation application is related to a generic medicinal product claiming essential similarity to Duotrav® eye drops, solution preserved with polyquaternium-1 (Alcon Laboratories (UK) Ltd) and authorised pursuant to Article 10 (3) of Directive 2001/83/EC.

The majority of the clinical data appearing in the current overview are based solely on bibliographical research. The cited articles refer to reviews and/or clinical studies performed in humans.

Travoprost and Timolol are not new chemical entities, and this application is for a hybrid product claiming essential similarity to DuoTrav® (Alcon Laboratories UK Ltd).
As no new additional studies have been provided within the documentation, a full Clinical Summary is not included.

Except for the exclusion of the preservative in the applicant's formulation, its product is essentially similar to the originator product in formulation and dosage form. The physicochemical properties and the ingredients of both products (both active and non-active) are essentially similar (see *Section 32p22*). Specifically:

1. Surface tension is known to play an important role in the bioavailability of the drug substance in eye drops. To ensure pharmaceutical equivalence between the test and reference products, comparative surface tension data are provided. The method used to measure surface tension and the results of the tests are described in *dossier section 32p22.* The data demonstrates that all three pilot batches have similar surface tension values to those of the originator's products available on the European market. Therefore, surface tension issues are considered resolved from a physicochemical point of view.
2. An extensive *in vitro* investigation of the product was performed and compared to DuoTrav® from several different European markets. Analysis of surface tension, average deliverable volume/variation and total number of drops per container results are presented, as well as appearance, Assay and Related substances for both Travoprost and Timolol, pH, Timolol Enantiomeric purity determination and osmolality results. These comparative *in vitro* data are presented in *dossier section 32p22.* On reviewing all results of the generic product batches versus the originators, it can be concluded that physicochemical characteristics are similar.

In conclusion, the quality data demonstrates that the proposed product is essentially similar to the originator product in formulation and dosage form. Significantly, the physicochemical properties of both products are essentially similar. Therefore, Travoprost-Timolol/Pharmathen (40 µg/mL + 5 mg/ml) preservative free eye drops, solution in multi dose container poses no potential risk to public health and safety.