1.5. SPECIFIC REQUIREMENTS FOR DIFFERENT TYPES OF APPLICATIONS

1.5.2. Information for generic, "hybrid" or bio-similar applications

The present application of Travoprost/ Pharmathen 40 micrograms/mL preservative free eye drops, solution in multi dose container complies with the definition of a "hybrid" medicinal product as stated in Article 10(3) of Directive 2001/83/EC as amended, as it has:

- the same qualitative and quantitative composition in active substances as the reference medicinal product,
- the same pharmaceutical form as the reference medicinal product (eye drops solution)
- the bioavailability studies cannot be used to demonstrate bioequivalence

The reference medicinal product is TRAVATAN 40 micrograms/ml eye drops, solution, which has been authorized in the European community for more than ten years (first approved on 29-11-2001) by means of a centralized procedure.

The application is a "hybrid application", since bioequivalence cannot be demonstrated through bioavailability studies. Thus, the application complies with Article 10(3) of Directive 2001/83/EC as amended.