

Agence nationale de sécurité du médicament et des produits de santé (ANSM)  
143/147, boulevard Anatole France  
93285 SAINT-DENIS CEDEX  
France

September 28, 2015

**LETTER OF ACCESS TO OUR EUROPEAN DMF FOR TRAVOPROST  
(Internal DMF reference number )**

Number of Active Substance Master File: Travoprost  
Manufacturing site:

Active Substance Master File holder:

The aforementioned Active Substance Master File holder hereby authorizes the ANSM, to refer to and review the above mentioned Active Substance Master File in support of the following Marketing Authorization Application submitted by Pharmathen S.A. for:

**Traglafka 40 µg/ml, preservative free eye drops solution**

DC: DK/H/2599/001/DC  
MA number: -

Pharmathen S.A.  
6, Dervenakion str.,  
Pallini, Attiki

It is assumed that all and any information contained in this document is to be regarded as:

1. a trade secret as it contains unpublished details and results of private research proprietary to the DMF holder. the disclosure of which to its competitors could be disadvantageous; and
2. commercial or financial information that is privileged or confidential in that it contains data which is used in its business and is of a type customarily used in confidence, or regarded as privileged, and has not been disclosed to any member of the public by the DMF holder.

The DMF holder certifies that all operations, procedures, materials and specifications will be in conformance with said Master File.

The aforementioned Active Substance Master File holder commits to ensure batch to batch consistency and to inform Pharmathen S.A. and the ANSM, of any change in the Active Substance Master File.

For : S.A.

*Technical Director*