Pharmathen

Attn.: To whom it may concern at agencies in

RMS: DK
CMS: DE, EL, ES, FR, UK

Athens, 02/10/2015

Subject: Submission of a parallel Application Dossier(s) for Marketing Authorisation of Travoprost 40 micrograms/ml preservative free eye drops, solution in multi dose container with procedure number DK/H/2599/001/DC
RMS: DK CMSs: DE, EL, ES, FR, UK

Dear Sirs,

We are pleased to submit our Application Dossier(s) for a parallel Decentralised Procedure to DK/H/2475/001/DC which details are as follows:

Name of the medicinal product(s) (in the RMS): Traglafka
Pharmaceutical form(s) and strength(s): 40 micrograms/ml preservative free eye drops, solution
INN/active substance(s): Travoprost **ATC Code(s):** S01EE04

Legal Basis of the Application(s): Article 10(3) hybrid application

When appropriate, please indicate:
- Use of European Reference Medicinal Product **TRAVATAN 40 micrograms/ml eye drops, solution, Alcon Laboratories (UK) Ltd**
- If the strength(s) of the Reference MP differs between RMS/CMS ☐
  Yes ☒
  No
- If the pharmaceutical form(s) of the Reference MP differs between RMS/CMS ☐
  Yes ☒
  No
- If the indication(s) of the Reference MP differs between RMS/CMS ☐
  Yes ☒
  No

We are applying for a parallel procedure according to the Doc.Ref.: CMDh/271/2012, Rev0 October 2012. Submission of multiple applications during ongoing decentralised procedures is allowed and we have also the confirmation of RMS DK and all CMSs involved.

Modules 2, 3, 4 &5 of this application are identical to those of procedure DK/H/2475/001/DC

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The product information texts (1.3.1) in Module 1 are identical to the PI texts from the procdure DK/H/2475/001/DC

The differences between the new application-DK/H/2599/001/DC and the procedure DK/H/2475/001/DC lie in Module 1 and are listed below:

1.2- Application form
1.2-Annex 5.4 updated
1.2-Annex 5.6-Pharmathen S.A.
1.2-Annex 5.19
1.8- Pharmathen's Summary of PhV system and RMP

You will find enclosed the submission dossier as specified hereafter:

☒ eCTD format
Sequence number: 0000

<1> media unit per application and <1> copy are provided.

☒ We confirm that all future submissions for this specific product will be submitted in this same format *(NeeS format may be upgraded to eCTD later)*.

☒ The eCTD has passed the applicant's internal technical validation (all P/F criteria passed and all BP criteria have been fulfilled up to our best knowledge) using **EURS validator - Version 4 (4.0.0.009)**

☒ We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker. **(Symantec Endpoint Protection version: 12.1.4013.4013).**

- The relevant fees will be/have been paid according to national rules.

- The application is submitted through CESP to the RMS and the CMSs DE, UK, ES, FR since they are participating to the program. The submission in EL will be made via CD. The CESP-submission number is: CESP_Submission_239333

☐ The dispatch list is appended (to RMS only).
☒ The dispatch list will be forwarded to the RMS as soon as the application has been submitted to all CMS.

☒ We, Pharmathen S.A. hereby certify that the dossier submitted to the RMS and CMS(s) are fully identical.

☒ There are, however, some different **national** documents <cover letter><application form><specific national requirements> that are submitted to the relevant RMS/CMS only, **within** the eCTD/NeeS dossier

We, Pharmathen SA, also hereby certify that the content of the electronic submission is identical to the paper version.

Yours sincerely,

Pharmathen

Regulatory Affairs Associate

| web:www.pharmathen.com

For technical validation issues: at