

To whom it may concern in
the competent regulatory authorities in
RMS: DK
CMS: FR, BE, NL, LU, DE, ES, PL, BG, SK, HU, EL, RO, LT, EE, PT

29/09/2016

Subject: Submission of Application Dossier(s) for Marketing Authorisation of Travoprost / Timolol 40 micrograms/ml + 5mg/ml preservative free eye drops, solution in multi dose container

Procedure number: DK/H/2713/001/DC

Dear Sirs,

We are pleased to submit our Application Dossier(s) for a Decentralised Procedure which details are as follows:

Name of the medicinal product(s) (in the RMS): Vizitrav Duo 40 micrograms/mL + 5 mg/mL eye drops, solution

Pharmaceutical form(s) and strength(s): 40 micrograms/ml + 5mg/ml preservative free eye drops, solution

INN/active substance(s): Travoprost/ Timolol Maleate ATC Code(s): S01ED51

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

When appropriate, please indicate:

Use of European Reference Medicinal Product: **DuoTrav 40 µg/ml / 5 mg/ml eye drops, solution**

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

You will find enclosed the submission dossier as specified hereafter:

eCTD format

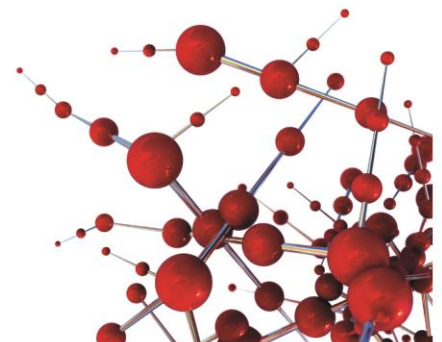
Sequence number: 0000

NeeS format

Sequence number (if used): <Four digit number>

Appropriate number of media units and paper copies are provided according to national requirements. The paper copies are printed from the published e-CTD and thus identical to the e-CTD. Additional paper copies are available upon request.

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 Symantec Endpoint Protection version 12.1.1101.401
- We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

The dossier is submitted in paper format (*Note: Full paper dossiers can only be submitted to NCAs still accepting paper submissions and should only be used exceptionally when a valid electronic format dossier really could not be provided*)

An identical electronic copy of the paper dossier is also provided

Number of paper binders provided:

- Module 1: <xx> enclosures
- Module 2: <xx> enclosures
- Module 3: <xx> enclosures
- Module 4: <xx> enclosures
- Module 5: <xx> enclosures

Different formats (eCTD, NeeS, other electronic or paper) are submitted to different RMS/CMS (specify differences to different NSAs in text below): (*This is not recommended and do require an explanation if needed.*)

- The relevant fees have been paid, where appropriate.

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, **outside** the eCTD/NeeS dossier

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

The application is submitted through the CESP to the Member States that are participating to the program. The CESP-submission number is "CESP_Submission_394671".

We would also like to clarify that following confirmation by the EMA (workaround EMA Ticket: 500755), the different PSMFs of this procedure have been added into a separate Annex and is provided in the same folder of Module 1.2. The Annex is called the same as the section - i.e. PSMF.

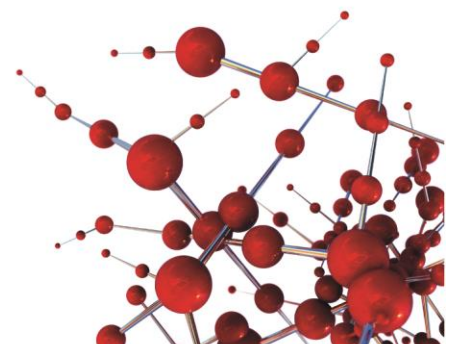
The same dossier was submitted in all of the below parallel DCP procedures:

DK/H/2707/001/DC Pharmathen SA

DK/H/2708/001/DC Horus Pharma

DK/H/2714/001/DC Pharmathen SA

Yours sincerely,





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