Pharmathen

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

12/12/2016

**Subject: Submission of data requested during the validation phase 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 |

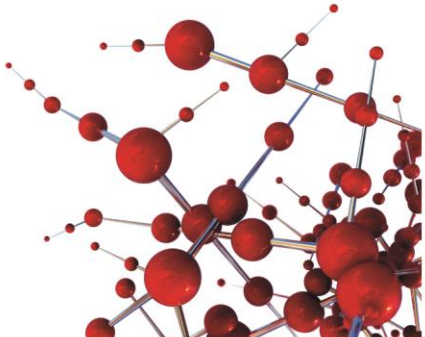
You will find enclosed the submission dossier as specified hereafter:

☒ eCTD format
Sequence number: 0001
☐ 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)*.

Pharmathen S.A.
6, Dervenakion Str.,
153 51 Pallini, Athens, Greece
Tel. : +30 210 66 04 300
Fax : +30 210 66 66 749
e-mail: info@pharmathen.com
www.pharmathen.com



☒ The eCTDhas 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 provide*

☐ 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

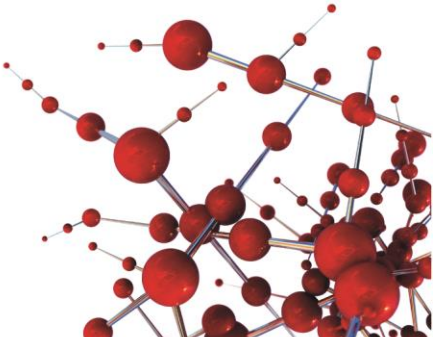
☒ There are, however, some different **national** documents (cover letter, application form. specific national requirements) that are submitted to the relevant RMS/CMS only, **within** the eCTD/NeeS dossier

The application is submitted through the CESP to the Member States that are participating to the program. The CESP-submission number is "CESP_Submission_ 431244".

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,



Pharmathen

Pharmathen S.A.
Monumental Plaza Building
A, 44 Kifisias Avenue,
151 25 Marousi, Attiki Greece