Attn.: To whom it may concern at agencies in

RMS: DK
CMS: BE, BG, CZ, DE, EE, ES, FR, LT, LU, LV, NL, PL, PT, RO, SI, SK

Athens, 29/9/2016

Subject: Submission of Application Dossier(s) for Marketing Authorisation of Vizibim Duo 0.3 mg/ml + 5 mg/ml, Preservative Free, eye drops solution, multidose container

DK/H/2711/001/DC

RMS: DK
CMS: BE, BG, CZ, DE, EE, ES, FR, LT, LU, LV, NL, PL, PT, RO, SI, SK

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): Vizibim Duo

Pharmaceutical form(s) and strength(s): eye drops solution, 0.3 mg/ml + 5 mg/ml

INN/active substance(s): Bimatoprost, Timolol Maleate

ATC Code(s):

Legal Basis of the Application(s):
When appropriate, please indicate:

- Use of European Reference Medicinal Product
- 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>

<1> media units per application and <1> copies 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 5.5 (5.5.0.005)**

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☒ 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: 12.1.5337.5000).**

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

- The application is submitted through CESP to the RMS and CMSs that are participating to the program.

The CESP-submission number is:

For DE:

☐ 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

Yours sincerely,

Regulatory Affairs Associate
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Greece
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For technical validation issues: