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, 21/11/2016

Subject: Submission of Validation Responses sequence 0001 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 the **Validation Responses sequence 0001** for the 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): S01ED51

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

When appropriate, please indicate:
- Use of European Reference Medicinal Product n/a
- 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>

<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)**

Pharmathen S.A.
Headquarters: 44, Kifissias Avenue
151 25 Marousi, Athens Greece
T: +30 210 6604 300, F: +30 210 6666 749
info@pharmathen.com

Registered Seat, manufacturing site: 6, Dervenakion str.
153 51 Pallini, Athens Greece
T: +30 210 6604 300, F: +30 210 6604 583
info@pharmathen.com
www.pharmathen.com

☒ 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:

Please note that the above mentioned procedure **DK/H/2711/001/DC** is a multiple application, submitted simultaneously and in parallel with three other procedures of the same medicinal product Bimatoprost-Timolol 0.3mg/mL + 5mg/mL, eye drops solution. The procedure numbers of the three other procedures are DK/H/2710/001/DC, DK/H/2712/001/DC and DK/H/2715/001/DC.
The applicant also confirms that the submitted documentation is identical for all four procedures, except for specific procedure-related documents in module 1.

The applicant would also like to make a note that it has been noticed that from section 3.3 literature reference of module 3 of the initial submission, one of the appendixes was inadvertently omitted. Since this document is considered important for the evaluation of the dossier, it has been agreed with the RMS that the appendix is provided with the validation sequence.

☐ 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,

Regulatory Affairs Associate
Pharmathen S.A.
44 Kifissias Ave., 15125 Marousi Attica, Greece
Tel: | F:
email: @pharmathen.com

Pharmathen

For technical validation issues: Mrs at @pharmathen.com