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To whom it may concern in
the competent regulatory authorities in

RMS: DK
CMS: BG, CZ, EL, FR, HR, HU, NL, PL, SK

28/04/2017

Subject: Submission of Application Dossier(s) for Marketing Authorisation of Latanoprost 50 micrograms/mL PF eye drops solution

Procedure number: DK/H/2754/001/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):	**Vizilatan**
Pharmaceutical form(s) and strength(s):	**50 micrograms/ml eye drops, solution**
INN/active substance(s):	**Latanoprost**
ATC Code(s):	**S01EE01**

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

When appropriate, please indicate:

- Use of European Reference Medicinal Product	☐ Yes	☒ No
- 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 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 12.1.5

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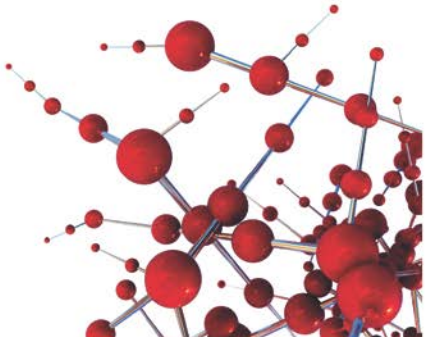

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☒ We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

☐ 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.)*

- Multiple/duplicate applications are submitted.
- The relevant fees have been paid.

☒ We, <Applicant>, 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 “ ”.

Yours sincerely,

Global Regulatory Submissions Manager
Pharmathen S.A.

For technical validation issues: at