EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health Systems and products

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Brussels,
(2015)

Revision 12

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Module 1.2: Administrative information
Application form

September 2015

This application form will be included in:

The Rules governing Medicinal Products in the European Union
The Notice to Applicants - Volume 2B - Common Technical Document - Module1 - Administrative information

To be noted:
Mandatory use of electronic Application Forms for Centralised Procedure that explains parts in light grey. As from 01/01/2016, mandatory use of electronic application forms for all procedures

Revision 12
Update from September 2015 of section 1.4.1; taking into account the review of chapter 1 of July 2015.

[1] OJ L 299 of 27.10.2012, p. 1

TABLE OF CONTENTS

APPLICATION FORM

SUMMARY OF THE DOSSIER

APPLICATION FORM : ADMINISTRATIVE DATA

The application form is to be used for an application for a marketing authorisation of a medicinal product for human use submitted to (a) the European Medicines Agency under the centralised procedure or (b) a Member State (as well as Iceland, Liechtenstein and Norway) under either a national, mutual recognition procedure or decentralised procedure.

Usually a separate application form for each strength and pharmaceutical form is required.
For centralised procedures a combined application form is acceptable (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name Travoprost-Timolol Horus Pharma

Pharmaceutical Form: Eye drops, solution

Strength:	**Units**
40	µg/ml
Strength:	**Units**
5	mg/ml

Active Substance(s):
TRAVOPROST
TIMOLOL MALEATE

Add Active Substance (s)

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Applicant	Horus Pharma
Title	
First Name	
Surname	
Address 1	148 Avenue Georges Guynemer
Address 2	Cap Var D2, Saint Laurent du Var *(name of: city, town, village, etc)*
Postcode	06700
Country	France
Telephone	
Telefax	
E-mail	

Person authorised for communication*, on behalf of the Applicant:

Title

First name

Surname

It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate and that such data are not subject to regulatory data exclusivity in the Union.

It is hereby confirmed that fees will be paid/have been paid according to the national/European Union rules**.

On behalf of the applicant

Copy contact details from previous section

Titles

First name*

Surname

Function

Global Project Management Coordinator

Address 1 6, Dervenakion str.

Address 2 Pallini, Attiki
(name of: city, town, village, etc)

Postcode 153 51

Country Greece

Telephone

Telefax

E-mail

Date
2016-09-29

Signatory

* ☒ ***Note: please attach letter of authorisation for communication/signing on behalf of the applicant in (Annex 5.4)***

** ☒ ***Note: if fees have been paid, attach proof of payment in (Annex 5.1) - see information on fee payments on EMA/CMDh website.***

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

◯ **1.1.1 A CENTRALISED PROCEDURE**

(according to Regulation (EC) No 726/2004)

◯ **1.1.2 A MUTUAL RECOGNITION PROCEDURE**

(according to Article 28(2) of Directive 2001/83/EC)

◉ **1.1.3 A DECENTRALISED PROCEDURE**

(according to Article 28(3) of Directives 2001/83/EC)

Reference Member State	Denmark
Procedure number:	DK/H/2708/001/DC

Concerned Member State (specify)	France
Concerned Member State (specify)	Spain
Concerned Member State (specify)	Belgium
Concerned Member State (specify)	Luxembourg
Concerned Member State (specify)	Netherlands
Proposed/Agreed common renewal date	5 years from D210 of the DCP

◯ **1.1.4 A NATIONAL PROCEDURE**

1.2 ORPHAN MEDICINAL PRODUCT DESIGNATION

1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

◯ **Yes** ◉ **No**

1.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY
Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?

◯ **Yes** ◉ **No**

1.3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION , WHERE APPLICABLE?

◯ **Yes *(complete sections below and also complete 1.4 + 1.6)*** ◉ **No *(complete section 1.4 + 1.6)***

1.4 APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC[2]

Note: Section to be completed for any application, including applications referred to in section 1.3
For further details, refer to Notice of Applicants, Volume 2A, Chapter 1

1.4.1 ◯ **Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*)**

1.4.2 ☐ **Article 10(1) generic application**

1.4.3 ☒ **Article 10(3) hybrid application**

Note: Application for a medicinal product referring to a so-called reference medicinal product with a Marketing Authorisation in a Member State or in a Union (e.g. different pharmaceutical form, different therapeutic use .....)
Complete administrative and quality data, appropriate preclinical and clinical data.
Refer to Notice to Applicants, Volume 2A, Chapter 1.

Reference medicinal product:

Note: The chosen reference medicinal product must be a medicinal product authorised in the Union on the basis of a complete dossier in accordance with the provisions of the Article 8 of Directive 2001/83/EC.

■ **Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA:**

Note: This section defines the reference medicinal product chosen for the purposes of establishing the expiry of the data protection period.

Product (invented) name Duotrav

Pharmaceutical form(s) Eye drops, solution

Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation
40 µg/ml / 5 mg/ml	Alcon Laboratories (UK) Ltd	EU/1/06/338/001-003	2006-04-24

Marketing authorisation granted by

☒ **Union**

☐ **Member State(EEA)**

■ **Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product:**

Member State(s) Denmark

Member State(s) France

Member State(s) Spain

Member State(s) Belgium

Member State(s) Luxembourg

Member State(s) Netherlands

Product (invented) name Duotrav

Pharmaceutical form(s) Eye drops, solution

Strength(s)	Marketing authorisation holder (note 4)	Marketing authorisation number
40 µg/ml / 5 mg/ml	Alcon Laboratories (UK) Ltd	EU/1/06/338/001-006

Marketing authorisation granted by

☒ **Union**

☐ **Member State(EEA)**

■ Difference(s) compared to this reference medicinal product:

☐ **changes in the active substance(s)**

☐ **change in therapeutic indications**

☐ **change in pharmaceutical form**

☐ **change in strength(quantitative change to the active substance(s))**

☐ **change in route of administration**

☒ **bioequivalence cannot be demonstrated through bioavailability studies**

■ **Medicinal product which is or has been authorised in accordance with Union provisions in force used for the demonstration of bioequivalence (if applicable) and/or in other studies:**

Study reference number/EudraCT number

Product (invented) name

Pharmaceutical form(s) + −

Strength(s)	**Marketing authorisation holder (note 4)**	**Marketing authorisation number**	+ −

Marketing authorisation granted by

☐ **Union**

☐ **Member State(EEA)**

Member State of source

Note: Section to be duplicated for each product used for the demonstration of bioequivalence and/or in other studies.

1.4.4 ◯ **Article 10(4) similar biological application**

1.4.5 ◯ **Article 10a well-established use application**

Note: For further details, refer to Notice to Applicants, Volume 2A, Chapter 1.
For extensions of bibliographical applications, cross references can only be made to pre-clinical and clinical data

1.4.6 ◯ **Article 10b fixed combination application**

Note: Complete administrative and complete quality, pre-clinical and clinical data on the combination only; for further details refer to Notice of Applicants, Volume 2A, Chapter 1.
For extensions of fixed combination applications, cross references can only be made to pre-clinical and clinical data

1.4.7 ◯ **Article 10c informed consent application**

Note: - Application for a medicinal product possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of an authorised product where consent has been given by the existing marketing authorisation holder to use their data in support of this application
- Complete administrative data should be provided with consent to pharmaceutical, preclinical and clinical data
- The authorised product and the informed consent application can have the same or different MAH

1.4.8 ◯ **Article 16a Traditional use registration for herbal medicinal product**

Note: Complete application
Refer to Notice to Applicants, Volume 2A, Chapter 1

1.5 CONSIDERATION OF THIS APPLICATION REQUESTED UNDER THE FOLLOWING ARTICLE DIRECTIVE 2001/83/EC OR REGULATION (EC) NO 726/2004[3]

1.5.1 ◯ **Conditional Approval**

Note: centralised procedure only according to Article 14(7) of Regulation (EC) No 726/2004 and Commission Regulation (EC) No 507/2006

1.5.2 ◯ **Exceptional Circumstances**

Note: According to Article 22 of Directive 2001/83/EC and Article 14(8) of Regulation (EC) No 726/2004

1.5.3 ☐ **Accelerated Review**

Note: Centralised procedure only according to Article 14(9) of Regulation (EC) No 726/2004

1.5.4 ◯ **Article 10(1) of Directive 2001/83/EC / Article 14(11) of Regulation (EC) No 726/2004**

(one year of market protection for a new indication)

1.5.5 ◯ **Article 10(5) of Directive 2001/83/EC (one year of data exclusivity for a new indication)**

1.5.6 ◯ **Article 74(a) of Directive 2001/83/EC (one year of data exclusivity for a change in classification)**

1.6 REQUIREMENTS ACCORDING TO REGULATION (EC) No 1901/2006 ('PAEDIATRIC REGULATION')

☒ **Sections 1.6.1, 1.6.2 and 1.6.3 not applicable for well-established use, generic, hybrid and bio-similar applications and traditional herbal medicinal products**

1.6.4 ☐ **ARTICLE 30 (PUMA) OF THE PAEDIATRIC REGULATION APPLIES TO THIS APPLICATION:**

(Note: Also applies to Extension applications of PUMA)

1.6.5 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

◯ **Yes** ◉ **No** ◯ **Not Applicable**

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S) AND ATC CODE

2.1.1 Proposed (invented) name of the medicinal product in the European Union/Member State/ Iceland/ Liechtenstein/ Norway:

Travoprost-Timolol Horus Pharma

(Value populated from the "Declaration" section.)

☒ **If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in (Annex 5.19)**

2.1.2 Name of the active substance(s)

Note: Only one name should be given in the following order of priority: INN, Ph.Eur., National Pharmacopeia, common name, scientific name;*
** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

(The value of the active substances field has been populated from "Declaration" section.)

Active Substance	+
TIMOLOL MALEATE	−
TRAVOPROST	−

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code S01ED51

Group timolol, combinations

☐ **If no ATC code has been assigned, please indicate if an application for ATC code has been made**

2.2 STRENGTH, PHARMACEUTICAL FORM, ROUTE OF ADMINISTRATION, CONTAINER AND PACK SIZES

2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)

(The values of the following fields have been populated from "Declaration" section.)

Pharmaceutical Form: Eye drops, solution

Strength:	**Units**
40	µg/ml
Strength:	**Units**
5	mg/ml

Active Substance(s):
TRAVOPROST
TIMOLOL MALEATE

2.2.2 Route(s) of administration (use current list of standard terms - European Pharmacopoeia)

Route of Administration Ocular use

2.2.3 Container, closure and administration device(s), including description of material from which it is constructed. (use current list of standard terms - European Pharmacopoeia)

For each type of pack give:

2.2.3.1 Package Size 1 1 bottle of 2.5ml of the ophthalmic solution

2.2.3.1 Package Size 2 3 bottles of 2.5ml of the ophthalmic solution

Note: For mutual recognition and decentralised procedures, all package sizes authorised in the Reference Member State should be listed

Description
the preservative free eye drops, solution is packaged in a cardboard box marked with respective variable data (Lot, Exp) containing a white plastic bottle with ophthalmic dispenser.
The multi – dose container can be available in an overwrap, inside the carton box.
The primary packaging material is comprised by a 5ml PP bottle and a dispensing system which is prepared by Aeropump under the name 3K valve.
Each dispenser contains ≥2.5ml of solution and is tested on long term stability.
The primary packaging components are sterilized with ethylene oxide outsourced.

For each container give:

Container	Bottle
Material	PP bottle
Closure	Valve
Administration Device	

2.2.3.2 Proposed shelf life 36 Months

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

2.2.3.3 Proposed shelf life *(after first opening container)* 28 Days

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

2.2.3.4 Proposed shelf life *(after reconstitution or dilution)*

For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002

2.2.3.5 Proposed storage conditions
This medicinal product does not require any special temperature storage conditions

2.2.3.6 Proposed storage conditions after first opening
This medicinal product does not require any special storage conditions

☒ **Attach a list of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/ CMDh websites) (Annex 5.17)**

2.2.4 The medical product incorporates, as an integral part, one or more medical devices within the meaning of Article 1(2)(a) of Directive 93/42/EEC or one or more active implantable medical devices within the meaning of Article 1(2)(c) of Directive 90/385/EEC

☐ **Yes**

2.3 LEGAL STATUS

2.3.1 Proposed dispensing/classification

(Classification under Article 1(19) of Directive 2001/83/EC)

☒ **Subject to medical prescription *(Complete 2.3.2)***

all pack sizes

Add Selected

European Union/Member State	Denmark
European Union/Member State	France
European Union/Member State	Spain
European Union/Member State	Belgium
European Union/Member State	Luxembourg
European Union/Member State	Netherlands

☐ **Not subject to medical prescription** ***(Complete 2.3.3 & 2.3.4)***

2.3.2 For products subject to medicinal prescription

☒ **Product on prescription which may be renewed (if applicable)**

Add Selected

Member State	Denmark
Member State	France
Member State	Spain
Member State	Belgium
Member State	Luxembourg
Member State	Netherlands

☐ **Product on prescription which may not be renewed (if applicable)**

☐ **Product on special prescription***

☐ **Product on restricted prescription***

(Not all the listed options are available in each member state. Applicants are invited to indicate which categories they are requesting, however, the Member States reserve the right to apply only those categories provided for in their national legislation)
*Note: *For further information, please refer to Article 71 of Directive 2001/83/EC*

2.3.3 Supply for products not subject to medical prescription

☐ **Supply through pharmacies only**

☐ **Supply through non-pharmacy outlets and pharmacies (if applicable)**

2.3.4 Promotion for products not subject to medical prescription

☐ **Promotion to health care professionals only**

☐ **Promotion to general public and health care professionals**

2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS

◯ **Centralised procedure** ◉ **National procedure including mutual recognition/decentralised procedure**

Copy contact details from Declaration Section

Add Selected

Member State	Denmark

Member State	France
Member State	Spain
Member State	Belgium
Member State	Luxembourg

Company name HORUS PHARMA

Address 1 148 Avenue Georges Guynemer

Address 2 Cap Var D2, Saint Laurent du Var

(name of: city, town, village, etc)

Postcode 06700

Country France

Telephone

Telefax

E-mail

☒ **Attach proof of establishment of the applicant/MAH in the EEA (Annex 5.3)**

Has SME status been assigned by the EMA?

◉ **Yes** ○ **No**

EMA-SME Number

Date of expiry 2016-12-31

☒ **Attach copy of the "Qualification of SME Status" (Annex 5.7)**

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

○ **Yes (for fees paid, attach proof of payment in) (Annex 5.1)**

◉ **No**

Copy address from above address details

Add Selected ?

For Member State	Denmark
For Member State	Netherlands

Billing address (when relevant)

Company name HORUS PHARMA

VAT number FR17445317043

Address 1	148 Avenue Georges Guynemer
Address 2	Cap Var D2, Saint Laurent du Var *(name of: city, town, village, etc)*
Postcode	06700
Country	France
Telephone	
Telefax	
E-mail	vigilance@horus-pharma.fr
Purchase order(PO) number	n/a

◉ **Yes (for fees paid, attach proof of payment in) (Annex 5.1)**

○ **No**

For Member State	France
For Member State	Spain
For Member State	Belgium
For Member State	Luxembourg
For Member State	Netherlands

2.4.2 Person/company authorised for communication on behalf of the applicant during the procedure in the European Union/ each MS

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Add Selected

Member State(s)	Denmark
Member State(s)	France
Member State(s)	Spain
Member State(s)	Belgium
Member State(s)	Luxembourg
Member State(s)	Netherlands

The below applicant details relates to all member states selected, if the applicant details are different for each member states then please repeat section.

Title

First name

Surname

Company name Pharmathen S.A

Address 1	44 Kifissias Avenue
Address 2	Marousi, Attiki
	(name of: city, town, village, etc)
Postcode	151 25
Country	Greece
Telephone	
Telefax	
E-mail	

☒ **If different to 2.4.1 above, attach letter of authorisation** **(Annex 5.4)**

2.4.3 Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union/each MS

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Add Selected

Member State (s)	Denmark
Member State (s)	France
Member State (s)	Spain
Member State (s)	Belgium
Member State (s)	Luxembourg
Member State (s)	Netherlands

The below applicant details relates to all member states selected, if the applicant details are different for each member states then please repeat section.

Title	
First name	
Surname	
Company name	Pharmathen SA
Address 1	6, Dervenakion str.
Address 2	Pallini, Attiki
	(name of: city, town, village, etc)
Postcode	153 51
Country	Greece
Telephone	+30 210 66 04 300
Telefax	+30 210 66 04 749
E-mail	info@pharmathen.com

Title	
First name	
Surname	
Company name	Horus Pharma

Address 1	148 avenue Georges Guynemer
Address 2	Cap Var D2, Saint-Laurent du Var *(name of: city, town, village, etc)*
Postcode	06700
Country	France
Telephone	
Telefax	
E-mail	

☒ **If different to 2.4.1 above, attach letter of authorisation** **(Annex 5.4)**

2.4.4 Summary of the applicant pharmacovigilance system

Qualified person in the EEA for Pharmacovigilance

Copy contact details from 2.4.2 Section

Add Selected

Member State(s) Denmark

Member State(s) France

Member State(s) Spain

Member State(s) Belgium

Member State(s) Luxembourg

Member State(s) Netherlands

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

24 H Telephone

Telefax

E-mail

☒ **The above-mentioned qualified person resides[6] and operates in the EEA**

☒ **The qualified person is registered with Eudravigilance**

Copy contact details from 2.4.2 Section

Pharmacovigilance system master file

Number

Address 1

Address 2

Postcode

Country

Note: For Risk Management Plan, see module 1, 1.8.2

[6] For the purposes of this application form, a Qualified Person Responsible for Pharmacovigilance "resides" in the place where he/she makes his/her home, where he/she lives, can be traced, located, identified for all legal and contractual obligations, whether or not it is owned by him/her or he/she is permanently dwelling there.

2.4.5 Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)

Add Selected

European Union/Member State where application is made Denmark

European Union/Member State where application is made France

European Union/Member State where application is made Spain

European Union/Member State where application is made Belgium

European Union/Member State where application is made Luxembourg

European Union/Member State where application is made Netherlands

Name of the contact person

Title

First name

Surname

Company name Pharmathen SA

Address 1 6 Dervenakion str.

Address 2 Pallini, Attiki
(name of: city, town, village, etc)

Postcode 153 51

Country Greece

Telephone

Telefax

E-mail

Add Selected

European Union/Member State where application is made Denmark

European Union/Member State where application is made France

European Union/Member State where application is made Spain

European Union/Member State where application is made Belgium

European Union/Member State where application is made Luxembourg

European Union/Member State where application is made Netherlands

Name of the contact person

Title

First name

Surname

Company name Horus Pharma

Address 1 148 avenue Georges Guynemer

Address 2 Cap var D2, Saint-Laurent du Var
(name of: city, town, village, etc)

Postcode 06700

Country France

Telephone

Telefax

E-mail

2.5 MANUFACTURERS

Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

2.5.1 a Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):

all pack sizes

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Company name Pharmathen SA

Address 1 6 Dervenakion Str

Address 2 Pallini,
(name of: city, town, village, etc)

Postcode 153 51

Country Greece

Telephone + 30 210 66 04 300

Telefax +30 210 66 66 749

E-mail info@pharmathen.com

Manufacturing Authorisation number 0000006501/15/1

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

☐ **Enter EudraGMP manufacturing authorisation reference**

If available

☒ **Attach latest GMP certificate (Annex 5.9)**

Or

☐ **Enter EudraGMP certificate reference number**

all pack sizes

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Company name	JADRAN - GALENSKI LABORATORIJ d.d.
Address 1	Svilno 20,
Address 2	Rijeka *(name of: city, town, village, etc)*
Postcode	51000
Country	Croatia
Telephone	+385 51 660 700
Telefax	+385 51 546 024
E-mail	registracije@jgl.hr

Manufacturing Authorisation number UP/I-530-01/13-03/09

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

☐ **Enter EudraGMP manufacturing authorisation reference**

If available

☒ **Attach latest GMP certificate (Annex 5.9)**

Or

☐ **Enter EudraGMP certificate reference number**

2.5.1 b Official batch release for Blood products and Vaccines
Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)

Laboratory name

Address 1

Address 2

(name of: city, town, village, etc)

Postcode

Country

Telephone

Telefax

E-mail

2.5.1.1 Contact person in the EEA for product defects and recalls

Company name Pharmathen SA

Title

First name

Surname

Address 1	6 Dervenakion str.
Address 2	Pallini, Attiki *(name of: city, town, village, etc)*
Postcode	153 51
Country	Greece
24 H Telephone:	
Telefax	
E-mail	

2.5.1.2 Batch control Testing arrangements
Site(s) in the EEA or in countries where an MRA or other European Union arrangements apply, where batch control testing takes place as required by Article 51 of Directive 2001/83/EC:

Company name	JADRAN - GALENSKI LABORATORIJ d.d.
Address 1	Svilno 20,
Address 2	Rijeka *(name of: city, town, village, etc)*
Postcode	51000
Country	Croatia
Telephone	+385 51 660 700
Telefax	+385 51 546 024
E-mail	registracije@jgl.hr

Brief description of control tests carried out by the laboratory(ies) concerned
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

☒ **Attach copy of manufacturing authorisation(s) or other proof of GMP compliance** **(Annex 5.6)**

Or

☐ **Enter EudraGMP manufacturing authorisation reference**

Company name	Pharmathen S.A
Address 1	Dervenakion 6
Address 2	Pallini *(name of: city, town, village, etc)*
Postcode	153 51
Country	Greece
Telephone	+30 210 66 04 300
Telefax	+30 210 66 04 749
E-mail	info@pharmathen.com

Brief description of control tests carried out by the laboratory(ies) concerned
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

☒ **Attach copy of manufacturing authorisation(s) or other proof of GMP compliance** **(Annex 5.6)**

Or

☐ **Enter EudraGMP manufacturing authorisation reference**

2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture:
(Note: including manufacturing sites of any diluent/solvent presented in a separate container but forming part of the medicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). For each site provide the relevant information.)

Copy contact details from 2.5.1.a

bottle with solution

Do you have a separate admin and manufacturer address? ◯ **Yes** ◉ **No**

Company name	JADRAN - GALENSKI LABORATORIJ d.d.
Address 1	Svilno 20,
Address 2	Rijeka *(name of: city, town, village, etc)*
Postcode	51000
Country	Croatia
Telephone	+385 51 660 700
Telefax	+385 51 546 024
E-mail	registracije@jgl.hr

Brief description of functions performed:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Processing of sterile medicinal product - aseptically prepared

Quality Control Testing - Chemical/Physical

Primary packaging

Secondary packaging

Quality Control Testing - Microbiological - sterility

◉ **Site(s) is in the EEA:** ○ **Site(s) is outside the EEA:**

Manufacturing authorisation number 381-13-04/151-13-05

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

Enter EudraGMP Manufacturing Authorisation reference

Name of qualified person

(if not mentioned in manufacturing authorisation)

bottle with solution

Do you have a separate admin and manufacturer address? ○ **Yes** ◉ **No**

Company name	Pharmathen S.A
Address 1	Dervenakion 6
Address 2	Pallini *(name of: city, town, village, etc)*
Postcode	153 51
Country	Greece
Telephone	+30 210 66 04 300
Telefax	+30 210 66 04 749
E-mail	info@pharmathen.com

Brief description of functions performed:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

Secondary packaging

◉ **Site(s) is in the EEA:** ○ **Site(s) is outside the EEA:**

Manufacturing authorisation number 0000006501/15/1

☒ **Attach copy of manufacturing authorisation(s) (Annex 5.6)**

Or

Enter EudraGMP Manufacturing Authorisation reference

Name of qualified person Anastasios Eutaxiopoulos

(if not mentioned in manufacturing authorisation)

☒ **Attach flow chart indicating the sequence and activities of the different sites involved in the manufacturing process, including testing sites (Annex 5.8)**

2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture

Note: All manufacturing sites involved the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant.
For each site provide the relevant information.

Copy contact details from 2.5.1.a

Copy contact details from Declaration Section

(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

Active Substance	+
TRAVOPROST	−

Do you have a separate admin and manufacturer address? ◯ **Yes** ◯ **No**

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Manufacture of active substance by chemical synthesis

Manufacture of active substance intermediate by chemical synthesis

Quality Control Testing - Chemical/Physical

Primary Packaging of active substance

☒ **Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)**

☒ **For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the principles and guidelines on good manufacturing practice for starting materials (Annex 5.22)**

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?

◯ **Yes** ◉ **No**

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

○ Yes ○ No

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

○ Yes ◉ No

Is a Active Substance Master File to be used for the active substance(s)

◉ Yes ○ No

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

National ASMF reference number: (when applicable and only if EU ASMF reference number is not available)

Applicant part version number

Date of submission

Date of last update

☒ **Attach letter of access for European Union/Member State authorities where the application is made (see "European ASMF procedure for active ingredients")(Annex 5.10)**

☒ **Attach copy of confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC (Annex 5.11)**

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

◯ **Yes** ◉ **No**

(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

Active Substance	+
TRAVOPROST	−

Do you have a separate admin and manufacturer address? ◯ **Yes** ◯ **No**

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Microbiological - sterility

Quality Control Testing - Chemical/Physical

-Microbiology test
-IR Identification
-Optical Specific Rotation

-Water content (Karl Fisher)

☒ **Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch controls (Annex 5.8)**

☒ **For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the principles and guidelines on good manufacturing practice for starting materials (Annex 5.22)**

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?

◯ **Yes** ◉ **No**

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

◯ **Yes** ◉ **No**

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

◯ **Yes** ◉ **No**

Is a Active Substance Master File to be used for the active substance(s)

◯ **Yes** ◉ **No**

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

◯ **Yes** ◉ **No**

(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).

Active Substance	+
TIMOLOL MALEATE	−

Do you have a separate admin and manufacturer address? ◉ **Yes** ◯ **No**

Company name

Admin Office Address 1

Admin Office Address 2

Postcode

Admin Office Country

Admin Office Telephone

Admin Office Telefax n/a

Admin Office E-mail

Company name

Manufacturing Facility Address 1

Manufacturing Facility Address 2

Postcode

Manufacturing Facility Country

Manufacturing Facility Telephone

Manufacturing Facility Telefax

Manufacturing Facility E-mail

Brief description of manufacturing steps performed by manufacturing site:
(note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Manufacture of active substance by chemical synthesis

Quality Control Testing - Microbiological - non-sterility

☒ **Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites (Annex 5.8)**

☒ **For each active substance, attach a Qualified Person declaration that the active substance is manufactured in compliance with the principles and guidelines on good manufacturing practice for starting materials (Annex 5.22)**

Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement?

◯ **Yes** ◉ **No**

Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)?

◯ **Yes** ◉ **No**

Has a Ph.Eur. Certificate of suitability been issued for the active substance(s):

◉ **Yes** ◯ **No**

Name of the CEP holder

Name of the manufacturer if different from the above n/a

CEP number

Date of last update

☒ **Provide copy in (Annex 5.10)**

Is a Active Substance Master File to be used for the active substance(s)

◯ **Yes** ◉ **No**

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

◯ **Yes** ◉ **No**

2.5.4 Contract companies used for clinical trial(s) on bioavailability or bioequivalence or used for the validation of blood product manufacturing processes. For each contract company, state where analytical tests are performed and where clinical data are collected and give:

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)

A note should be given as to which quantity the composition refers (e.g. 1 capsule)

Pharmaceutical Form	Eye drops, solution	1.0	mg/ml

(The values of the pharmaceutical form, strength and active substances fields have been populated from "Declaration" section.)

Strength	**Units**
40	µg/ml

Strength	**Units**
5	mg/ml

List the active substance(s) separately from the excipient(s)

Name of active substance		Quantity / Unit		Reference / Monograph Standard
TRAVOPROST	equal to	40.0	µg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current USP
TIMOLOL	equal to	6.830	mg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

Solubilizing/stabilizing agent

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
MACROGOLGLYCEROL HYDROXYSTEARATE 40 PH. EUR.	equal to	mg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

Tonicity agent

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
SODIUM CHLORIDE	equal to	mg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

co-Solvent/ Tonicity agent

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
PROPYLENE GLYCOL	equal to	mg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

Buffering agent

Name of Excipient	Quantity / Unit	Reference / Monograph Standard

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
BORIC ACID PH. EUR.	equal to	mg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

Tonicity agent

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
MANNITOL	equal to	mg/ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

pH adjuster

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
SODIUM HYDROXIDE	quantity sufficient	pH *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

Vehicle

Name of Excipient	Quantity / Unit		Reference / Monograph Standard
PURIFIED WATER PH. EUR	quantity sufficient	ml *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Current Ph Eur

*Note: * Only one name of each substance should be given in the following order of priority: INN**, Ph.Eur., National Pharmacopoeia, common name, scientific name*
*** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

Details of any overages should not be included in the formulation columns but stated below:

Active Substance	Overage	+

Excipient	Overage	+

2.6.2 List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?

☒ **NONE**

or specify below:

* *AS=active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/ culture medium (incl. those used in the preparation of master and working cell banks)*
** *as defined in section 2 (scope) of the CHMP Note for Guidance*

☐ **If a Ph. Eur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the Council of Europe attach it in (Annex 5.12)**

2.6.3 Is an EMA certificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex I, Part III, being used for this MAA?

◯ **Yes** ◉ **No**

2.6.4 Does the medicinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive 2001/18/EC?

◯ **Yes** ◉ **No**

3. SCIENTIFIC ADVICE

3.1 Was there formal scientific advice(s) given by EMA for this medicinal product?

◯ **Yes** ◉ **No**

Was there scientific advice(s) given by Member State(s) for this medicinal product?

◯ **Yes** ◉ **No**

☐ **Attach copy of scientific advice(s)** **(Annex 5.14)**

4. OTHER MARKETING AUTHORISATION APPLICATIONS

4.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 8(j)-(l) OF DIRECTIVE 2001/83/EC

4.1.1 Is there another Member State(s) where an application for the same* product is pending**?

◯ **Yes** ◉ **No** ◯ **Not Applicable**

If yes, section 4.2 must be completed

4.1.2 Is there another Member state(s) where an authorisation is granted for the same* product?

◯ **Yes** ◉ **No**

4.1.3 Is there another Member State(s) where an authorisation was refused/suspended/revoked by competent authorities for the same* product?

◯ **Yes** ◉ **No**

If yes, section 4.2 must be completed

*Note: * "same product" means same qualitative and quantitative composition in active substance(s) and having the same pharmaceutical form from applicants belonging to the same mother company or group of companies OR which are "licensees".*
*** This is covering applications submitted at an earlier time or in parallel to this application if not already listed under 1.1.2 or 1.1.3*

4.2 MARKETING AUTHORISATION APPLICATIONS FOR THE SAME PRODUCT IN THE EEA (SAME QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM FROM APPLICANTS BELONGING TO THE SAME MOTHER COMPANY OR GROUP OF COMPANIES OR WHICH ARE "LICENSEES").

Note: refer to Commission Communications 98/C229/03

☐ **Authorised**

☐ **Submitted (which are not considered as a multiple/duplicate application - see Section 4.3)**

☐ **Refused**

☐ **Withdrawn (by applicant before authorisation)**

☐ **Withdrawn (by applicant after authorisation)**

☐ **Suspended/revoked (by competent authority)**

4.3 FOR MULTIPLE / DUPLICATE APPLICATIONS OF THE SAME MEDICINAL PRODUCT

Multiple/duplicate applications (submitted simultaneously or subsequently to the original product) for:

Name of other product	Travoprost/Timolol Pharmathen
Date of application (s)	2016-09-29
Applicant	Pharmathen S.A
Procedure number for MRP/DCP (if applicable)	DK/H/2707/001/DC

☐ **Attach copy of letter from Commission services, for centralised procedures only** **(Annex 5.16)**

Name of other product	Vizitrav Duo
Date of application (s)	2016-09-29
Applicant	PharmaSwiss Česká republika, s.r.o.
Procedure number for MRP/DCP (if applicable)	DK/H/2713/001/DC

☐ **Attach copy of letter from Commission services, for centralised procedures only** **(Annex 5.16)**

Name of other product	Galya
Date of application (s)	2016-09-29
Applicant	Pharmathen S.A.
Procedure number for MRP/DCP (if applicable)	DK/H/2714/001/DC

☐ **Attach copy of letter from Commission services, for centralised procedures only** **(Annex 5.16)**

4.4 MARKETING AUTHORISATION APPLICATIONS FOR THE SAME PRODUCT OUTSIDE THE EEA (I.E. FROM APPLICANTS BELONGING TO THE SAME MOTHER COMPANY OR GROUP OF COMPANIES OR WHICH ARE "LICENSEES". SAME QUALITATIVE AND QUANTITATIVE COMPOSITION IN THE ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM).

- ☐ **Authorised**
- ☐ **Pending**
- ☐ **Refused**
- ☐ **Withdrawn (by applicant before authorisation)**
- ☐ **Withdrawn (by applicant after authorisation)**
- ☐ **Suspended/revoked (by competent authority)**

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

☒ **5.1** **Proof of payment**

☐ **5.2** **Informed consent letter of marketing authorisation holder of authorised medicinal product.**

☒ **5.3** **Proof of establishment of the applicant in the EEA.**

☒ **5.4** **Letter of authorisation for communication on behalf of the applicant/MAH.**

☐ **5.5** (empty)

☒ **5.6** **Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply); any proof of authorisation in accordance with Article 8.3(k) of Directive 2001/83/EC.**

☒ **5.7** **Copy of the "Qualification of SME Status".**

☒ **5.8** **Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.**

☒ **5.9** **GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.**

☒ **5.10** **Letter(s) of access to Active Substance Master File(s) or copy of ph. Eur. Certificate(s) of Suitability.**

☒ **5.11** **Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.**

☐ **5.12** **Ph. Eur. Certificate(s) of suitability for TSE.**

☐ **5.13** **Written consent(s) of the competent authorities regarding GMO release in the environment.**

☐ **5.14** **Scientific Advice given by CHMP and/or by member state(s).**

☐ **5.15** **Copy of Marketing Authorization(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).**

☐ **5.16** **Letter by Commission services regarding multiple applications.**

☒ **5.17** **List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites).**

☐ **5.18** **Copy of the Orphan Designation Decision.**

☒ **5.19** **List of proposed (invented) names and marketing authorisation holders in the concerned member states.**

☐ **5.20** **Copy of EMA certificate for a Vaccine Antigen Master File(VAMF).**

☐ **5.21** **Copy of EMA certificate for a Plasma Master File (PMF).**

☒ **5.22** **For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holders (i.e located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the principles and guidelines of good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.**

☐ **5.23** **Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 8(3) of Directive 2001/83/EC.**

Note: To include attachments with this form, do not use the paper clip function. Attachments and annexes should be included in the same (eCTD) folder as the application form. For more detailed guidance see the eAF user guidance.