

# EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health Systems and products

eAF Version Number: 1.20.0.5

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:

#### 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.

<sup>&</sup>lt;sup>1</sup> OJ L 299 of 27.10.2012, p. 1

### **TABLE OF CONTENTS**

#### **DECLARATION AND SIGNATURE**

#### 1. TYPE OF APPLICATION

- 1.1 This application concerns
- 1.2 Orphan medicinal product information
- 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
- 1.4 This application submitted in accordance with the following Article in Directive 2001/83/EC
- 1.5 Consideration of this application also requested under the following article in Directive 2001/83/EC or Regulation (EC) N° 726/2004
- 1.6 Requirements according to Regulation (EC) No 1901/2006 ('Paediatric Regulation')

### 2. MARKETING AUTHORISATION APPLICATION PARTICULARS

- 2.1 Name(s) and ATC code
- 2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
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- 2.4 Marketing authorisation holder / Contact persons / Company
- 2.5 Manufacturers
- 2.6 Qualitative and quantitative composition

#### 3. SCIENTIFIC ADVICE

#### 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
- 4.2 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").
- 4.3 For multiple/duplicate applications of the same medicinal product
- 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 active substance(s) and having the same pharmaceutical form).
- **5.** ANNEXED DOCUMENTS (where appropriate)

#### FORM VALIDATION

#### **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 Vizilatan



#### Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Applicant	PharmaSwiss Česká republika s.r.o.
Title	
First Name	
Surname	
Address 1	Jankovcova 1569/2c
Address 2 (name of: city, town, village, etc)	Prague 7
Postcode	17000
Country	Czech Republic
Telephone	+420
Telefax	+420
E-mail	@valeant.com

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 **Title** First name\* **Surname Function** Global Submission Manager Address 1 44 Kifissias Avenue Address 2 (name of: city, town, village, Marousi, Attiki etc) 151 25 **Postcode** Greece Country **Telephone Telefax** E-mail **Date** 2017-04-28 Signatory

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

<sup>\*\*</sup> 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 fo	ollowing sections should be completed	where app	ropriate.
1.1	THIS A	APPLICATION CONCERN	IS	
	<b>1.1.1</b>	A CENTRALISED PROCEDURE		
	(accord	ling to Regulation (EC) No 726/2	004)	
	<b>1.1.2</b>	A MUTUAL RECOGNITION PRO	OCEDURE	<b>!</b>
	(accord	ling to Article 28(2) of Directive	2001/83	3/EC)
	<b>1.1.3</b>	A DECENTRALISED PROCEDU	RE	
	(accord	ling to Article 28(3) of Directives	2001/83/	EC)
		Reference Member State	Denmark	
		Procedure number:	DK/H/27	54/001/DC
		Concerned Member State (s	pecify)	Bulgaria
		Concerned Member State (s	pecify)	Croatia
		Concerned Member State (sp	pecify)	Czech Republic
		Concerned Member State (sp	pecify)	France
		Concerned Member State (s	pecify)	Greece
		Concerned Member State (s	pecify)	Hungary
		Concerned Member State (s	pecify)	Netherlands
		Concerned Member State (sp	pecify)	Poland
		Concerned Member State (s	pecify)	Slovakia
		Proposed/Agreed common redate	enewal	5 years from D210 of the DCP
	<b>1.1.4</b>	A NATIONAL PROCEDURE		
1.2	ORPH	AN MEDICINAL PRODUC	T DESI	GNATION
1.2.1	HAS ORPH	IAN DESIGNATION BEEN APPLIED	O FOR THI	S MEDICINAL PRODUCT?
	○ Yes	<ul><li>No</li></ul>		
1.2.2	Has any m	TION RELATING TO ORPHAN MAR nedicinal product been designated in this application?		USIVITY phan medicinal product for a condition relating to the indication
	○ Yes	<ul><li>No</li></ul>		
1.3	TO AN 1234/	<b>EXTENSION AS REFERE</b>	RED TO AL LEGI	ISTING MARKETING AUTHORISATION LEADING IN ANNEX I OF REGULATIONS (EC) NO ISLATION, WHERE APPLICABLE?  Olete 1.4 +  No (complete section 1.4 + 1.6)
1.4		CATION IS SUBMITTED TIVE 2001/83/EC <sup>2</sup>	IN ACC	CORDANCE WITH THE FOLLOWING ARTICLE IN
		n to be completed for any application orther details, refer to Notice of Applica		applications referred to in section 1.3 e 2A, Chapter 1
1.4.1	○ Article	e 8(3) application, (i.e dossie	r with ad	ministrative, quality, pre-clinical and clinical data*)
1.4.2	Articl	e 10(1) generic application		
1.4.3	X Article	e 10(3) hybrid application		

1.

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.

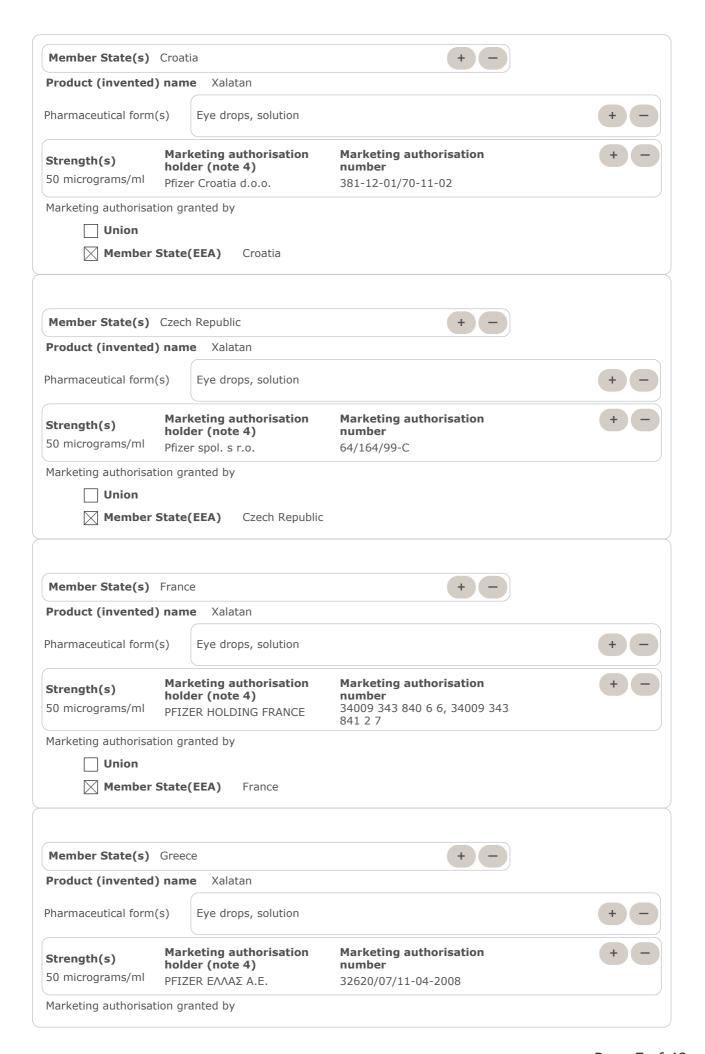
# ■ Medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA:

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

Product (invented	) name	Xalatan			
Pharmaceutical form	(s) (E	Eye drops, solution			+ -
Strength(s) 50 micrograms/ml	holde	eting authorisation r Limited	Marketing authorisation number PL 00057/1057	Date of authorisati	+ -
Marketing authorisa	tion gran	nted by			
Member	State(E	EA) United Kingdom	ı		

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

Member State(s)	Denmark	+ -	
Product (invented)	name Xalatan		
Pharmaceutical form(s	) Eye drops, solution		+ -
Strength(s)	Marketing authorisation holder (note 4)	Marketing authorisation number	+ -
50 micrograms/ml	Pfizer ApS	18752	
Marketing authorisation	on granted by		
Union			
Member S	tate(EEA) Denmark		
Member State(s)	Bulgaria	+ -	
Product (invented)	name Xalatan		
Product (invented) Pharmaceutical form(s			+ -
Pharmaceutical form(s  Strength(s)		Marketing authorisation number 9900241	+ -
Pharmaceutical form(s  Strength(s)  50 micrograms/ml	Eye drops, solution  Marketing authorisation holder (note 4)  Pfizer Enterprises SARL	number	+ -
Pharmaceutical form(s  Strength(s)	Eye drops, solution  Marketing authorisation holder (note 4)  Pfizer Enterprises SARL	number	+ -
Pharmaceutical form(s  Strength(s) 50 micrograms/ml  Marketing authorisation	Eye drops, solution  Marketing authorisation holder (note 4)  Pfizer Enterprises SARL  on granted by	number	+ -



☐ Union ☐ Member Stat	ce(EEA) Greece		
Marshau Chata (a) Albu			
Member State(s) Hur		+ -	
Product (invented) na	me Xalatan		
Pharmaceutical form(s)	Eye drops, solution		+ -
Strength(s) ho	arketing authorisation Ilder (note 4) zer Kft.	Marketing authorisation number OGYI-T-05637	+ -
Marketing authorisation	granted by		
Union	,		
Member Stat	ce(EEA) Hungary		
Member State(s) Net	herlands	+ -	
Product (invented) na	me Xalatan		
Pharmaceutical form(s)	Eye drops, solution		+ -
Strength(s) ho	arketing authorisation Ider (note 4) zer by	Marketing authorisation number RVG 21304	+ -
Marketing authorisation  Union  Member State			
Member State(s) Pola	and	+ -	
Product (invented) na	<b>me</b> Xalatan		
Pharmaceutical form(s)	Eye drops, solution		+ -
Strength(s) ho	arketing authorisation Ilder (note 4) zer Europe MA EEIG	Marketing authorisation number 04118	+ -
Marketing authorisation	granted by		
Union			
Member Stat	ce(EEA) Poland		
Member State(s) Slo		+ -	
Product (invented) na	me Xalatan		
Pharmaceutical form(s)	Eye drops, solution		+ -

Strength(s)	Marketing authorisation holder (note 4)	Marketing authorisation number	+ -
50 micrograms/ml	Pfizer Europe MA EEIG	64/0121/98-S	
Marketing authorisat	tion granted by		
Union			
Member	State(EEA) Slovakia		
■ Difference(s)	compared to this reference med	dicinal product:	
changes in	the active substance(s)		
change in	therapeutic indications		
change in	pharmaceutical form		
change in	strength(quantitative chang	e to the active substance(s))	
change in	route of administration		
bioequival	ence cannot be demonstrate	ed through bioavailability studies sed in accordance with Union provision ole) and/or in other studies:	ons in force used f
bioequival  dedicinal product vectors and the demonstration of the demon	ence cannot be demonstrate	sed in accordance with Union provisi	ons in force used f
bioequival  Medicinal product v e demonstration o  Study reference number/EudraCT	ence cannot be demonstrate	sed in accordance with Union provisi	ons in force used f
bioequival  Medicinal product v e demonstration o  Study reference number/EudraCT number	ence cannot be demonstrate which is or has been authori of bioequivalence (if applicab	sed in accordance with Union provisi	ons in force used f
bioequival	ence cannot be demonstrate which is or has been authori of bioequivalence (if applicab	sed in accordance with Union provisi	ons in force used f
bioequival  dedicinal product vectors  e demonstration of the control of the cont	ence cannot be demonstrate which is or has been authori of bioequivalence (if applicab	sed in accordance with Union provisi	ons in force used f
bioequivale dedicinal product to be demonstration of the demonstration o	which is or has been authorion bioequivalence (if applicable) name  (s)  Marketing authorisation holder (note 4)	sed in accordance with Union provision and/or in other studies:  Marketing authorisation	ons in force used f

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 <sup>3</sup>
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)
165	HAS THIS APPLICATION REEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

#### 2. MARKETING AUTHORISATION APPLICATION PARTICULARS

#### 2.1 NAME(S) AND ATC CODE

2 1 1	Proposed (invented)	name of the medicin	nal product in the	e European	Union/Member	State/ Id	celand/	Liechtenstein/
_,_,	Norway:							

Vizilatan

(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.)

Act	tive Substance	+
LATANOPROST		

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code S01EE01

Group Antiglaucoma preparations and miotics, prostaglandin analogues

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.)

Strength:	Units	
0	μg/ml	
ctive Substance(s): ATANOPROST		

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 2.5 ml solution

State	e should be listed	ion and decentralised procedures, all package sizes auti	horised in the Reference Member
Car	scription dboard box includi	ng a white plastic bottle with ophthalmic dispense	er containing 2.5ml of the
Fo	or each container g	ive:	
	Container	Bottle	
	Material	HDPE	
	Closure	Valve	
	Administration D	evice n/a	
	2.2.3.2 Propose	d shelf life 18	Months
		For numeric values, please use the full stop as the decir	mal separator. i.e. 0.002, rather than 0,002
	2.2.3.3 Propose (after first open)		Weeks
		For numeric values, please use the full stop as the decir	mal separator. i.e. 0.002, rather than 0,002
	2.2.3.4 Propose (after reconstitu dilution)		
		For numeric values, please use the full stop as the decir	mal separator. i.e. 0.002, rather than 0,002
	2 2 2 E Dramage	d storage conditions	ions
		duct does not require any special storage conditi	
	This medicinal pro	duct does not require any special storage conditions after first opening duct does not require any special storage conditions	ions
	This medicinal pro	d storage conditions after first opening	ions
	2.2.3.6 Propose This medicinal pro	d storage conditions after first opening duct does not require any special storage conditions ck-ups or Samples/specimens sent with the	
The m	2.2.3.6 Propose This medicinal pro ttach a list of Mo MDh websites) ( medical product increase of the	d storage conditions after first opening duct does not require any special storage conditions ck-ups or Samples/specimens sent with the	e application, as appropriate (see EMA,
The m of Direct	2.2.3.6 Propose This medicinal pro ttach a list of Mo MDh websites) ( medical product inc	d storage conditions after first opening duct does not require any special storage condition ck-ups or Samples/specimens sent with the Annex 5.17) orporates, as an integral part, one or more medic	e application, as appropriate (see EMA,
The mof Direct	This medicinal pro  2.2.3.6 Propose This medicinal pro  ttach a list of Mo MDh websites) (  nedical product incrective 93/42/EEC of the control of the contr	d storage conditions after first opening duct does not require any special storage condition ck-ups or Samples/specimens sent with the Annex 5.17) orporates, as an integral part, one or more medic	e application, as appropriate (see EMA,
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The m of Direct Direct You	2.2.3.6 Propose This medicinal pro ttach a list of Mo MDh websites) ( medical product incrective 93/42/EEC of tive 90/385/EEC es GAL STATUS used dispensing/cla	d storage conditions after first opening duct does not require any special storage condition  ck-ups or Samples/specimens sent with the Annex 5.17)  orporates, as an integral part, one or more medical or one or more active implantable medical devices	e application, as appropriate (see EMA)
The m of Direct Ye	This medicinal pro  2.2.3.6 Propose This medicinal pro  ttach a list of Mo MDh websites) (  medical product incrective 93/42/EEC of tive 90/385/EEC  es  GAL STATUS  psed dispensing/classification under Art	d storage conditions after first opening duct does not require any special storage conditions.  ck-ups or Samples/specimens sent with the Annex 5.17)  orporates, as an integral part, one or more medical or one or more active implantable medical devices assification	e application, as appropriate (see EMA)
The m of Direct Ye	This medicinal pro  2.2.3.6 Propose This medicinal pro  ttach a list of Mo MDh websites) (  medical product incrective 93/42/EEC of tive 90/385/EEC  es  GAL STATUS  psed dispensing/classification under Art	d storage conditions after first opening duct does not require any special storage conditions.  ck-ups or Samples/specimens sent with the Annex 5.17)  orporates, as an integral part, one or more medical one or more active implantable medical devices assisting the significant one or more active implantable medical devices.	e application, as appropriate (see EMA)
The m of Direct You LEC	This medicinal pro  2.2.3.6 Propose This medicinal pro  ttach a list of Mo MDh websites) (  medical product incrective 93/42/EEC of tive 90/385/EEC  es  GAL STATUS  psed dispensing/classification under Art	d storage conditions after first opening duct does not require any special storage conditions.  ck-ups or Samples/specimens sent with the Annex 5.17)  orporates, as an integral part, one or more medical one or more active implantable medical devices assisting the significant one or more active implantable medical devices.	e application, as appropriate (see EMA,

European Union	/Member State	Bulgaria	
European Union	/Member State	Croatia	
European Union	/Member State	Czech Republic	
European Union	/Member State	France	
European Union	/Member State	Greece	
European Union	/Member State	Hungary	
European Union	/Member State	Netherlands	
European Union	/Member State	Poland	
European Union	/Member State	Slovakia	
European Union	/Member State	Denmark	
Not subject to	medical prescript	tion (Complete 2.3.3 & 2.3.4	4)
For products subject	ct to medicinal presc	ription	
	·	nay be renewed (if applic	cable)
	Ad	ld Selected	?
Member State	Bulgaria		
Member State	Croatia		
Member State	Czech Republic		
Member State	France		
Member State	Greece		
Member State	Hungary		
Member State	Netherlands		
Member State	Poland		
Member State	Slovakia		
Member State	Denmark		
Product on pr	escription which m	nay not be renewed (if a	pplicable)
Product on sp	ecial prescription*	•	
Product on re	stricted prescription	on*	
however, the Member	States reserve the righ		re invited to indicate which categories they are reque is provided for in their national legislation) 33/EC
Supply for products	s not subject to med	ical prescription	
Supply throug	h pharmacies only	,	
Supply throug	h non-pharmacy o	utlets and pharmacies (i	f applicable)
Promotion for prod	ucts not subject to m	nedical prescription	
Promotion to	health care profess	sionals only	

2.3.2

2.3.3

2.3.4

## 2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

Promotion to general public and health care professionals

 $2.4.1 \quad \text{Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each MS}$ 

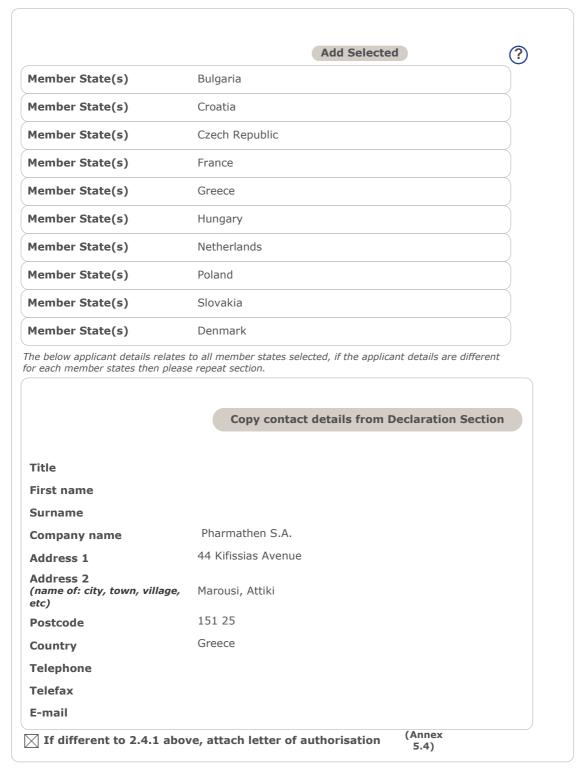
	Copy contact details from	<b>Declaration Section</b>
	Add Selected	?
mber State	Denmark	
nber State	Bulgaria	
mber State	Czech Republic	
nber State	Greece	
nber State	Croatia	
nber State	Hungary	
nber State	Poland	
mber State	Slovakia	
pany name	PharmaSwiss Česká republika s.r.o.	
ess 1	Jankovcova 1569/2c	
ress 2 ne of: city, town, villa	ge, Prague 7	
code	17000	
itry	Czech Republic	
phone	+420 234 719 601	
	+420 234 719 619	
efax ail	+420 234 719 619 czech.info@valeant.com tablishment of the applicant/MAH in the EEA (A	Annex 5.3)
Attach proof of essence of section of payment (where the all relevant fees before all relevant f	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Assigned by the EMA?	Annex 5.3)
fax ail  Attach proof of es s SME status been as Yes No of of payment (where we all relevant fees b  Yes (for fees paid)	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Assigned by the EMA?  relevant)  een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)	Annex 5.3)
Attach proof of es  SME status been as  Yes No  of of payment (where all relevant fees been as  Yes (for fees paid No  or Member State	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Assigned by the EMA?  relevant)  een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)  Bulgaria	Annex 5.3)
Attach proof of essence of some status been as Yes No of of payment (where we all relevant fees because of the year of the yea	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Assigned by the EMA?  relevant)  een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)	Annex 5.3)
Attach proof of essence of some status been as Yes No of of payment (where we all relevant fees because of the year of the yea	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Assigned by the EMA?  relevant)  een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)  Bulgaria	Annex 5.3)
Attach proof of essence of some status been as Yes No of of payment (where we all relevant fees because of Member State or Member State	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Assigned by the EMA?  relevant) een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)  Bulgaria  Czech Republic	Annex 5.3)
Attach proof of esses SME status been as Yes No of of payment (where we all relevant fees been as Yes (for fees paid) No or Member State or Member State or Member State	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Asigned by the EMA?  relevant) een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)  Bulgaria  Czech Republic  Greece	Annex 5.3)
Attach proof of essence of section of sectio	czech.info@valeant.com  tablishment of the applicant/MAH in the EEA (Asigned by the EMA?  relevant) een prepaid to competent authorities?  I, attach proof of payment in) (Annex 5.1)  Bulgaria  Czech Republic  Greece  Croatia	Annex 5.3)

No	
	Copy address from above address details
	Add Selected
For Member State	Denmark
Billing address (when relevan	t)
Company name	Valeant Pharma Poland sp. z o.o.
VAT number	8133676203
Address 1	Przemyslowa 2
Address 2 (name of: city, town, village, etc)	Rzeszow
Postcode	35-959
Country	Poland
Telephone	
Telefax	n/a
E-mail	
Purchase order(PO)	n/a

# **Copy contact details from Declaration Section Member State** France Laboratoire CHAUVIN **Company name** 416 rue Samuel Morse - CS99535 Address 1 Address 2 (name of: city, town, village, MONTPELLIER Cedex 2 etc) 34961 **Postcode** Country France +33 (0)4 67 12 33 47 Telephone **Telefax** + 33(0)4 67 12 30 91 E-mail RA\_France@bausch.com Has SME status been assigned by the EMA? 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) O No

**For Member State** France **Copy contact details from Declaration Section Member State** Netherlands **Company name** Bausch & Lomb Pharma Address 1 Bvd Lambermontlaan 430 Address 2 (name of: city, town, village, Brussel etc) **Postcode** B-1030 Country Belgium **Telephone** n/a **Telefax** regulatory.benelux@bausch.com E-mail Has SME status been assigned by the EMA? 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** Netherlands Billing address (when relevant) **Company name** Bausch & Lomb Pharma **VAT** number Address 1 Bvd Lambermontlaan 430 Address 2 Brussel (name of: city, town, village, etc) Postcode B-1030 Country Belgium **Telephone** Telefax regulatory.benelux@bausch.com E-mail Purchase order(PO) n/a number

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



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

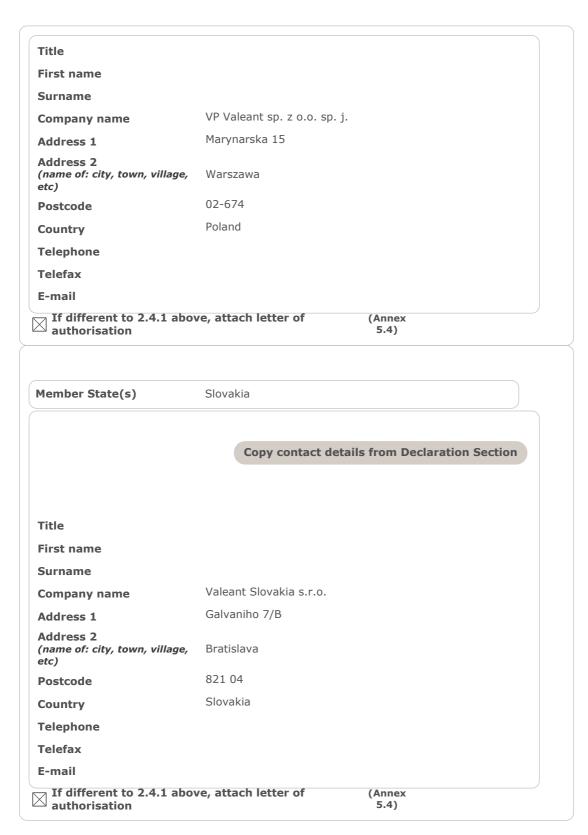


Title First name **Surname** PharmaSwiss Česká republika s.r.o. Company name Jankovcova 1569/2c Address 1 Address 2 (name of: city, town, village, Prague 7 etc) 17000 **Postcode** Czech Republic Country Telephone **Telefax** E-mail If different to 2.4.1 above, attach letter of authorisation (Annex 5.4) Member State(s) Bulgaria **Copy contact details from Declaration Section** Title First name **Surname** PharmaSwiss EOOD **Company name** 16, Troyanski prohod Str., fl.3, ap. 8&10, Lagera Address 1 Address 2 (name of: city, town, village, Sofia etc) 1612 Postcode Bulgaria Country Telephone **Telefax** E-mail If different to 2.4.1 above, attach letter of authorisation (Annex 5.4) Member State(s) Czech Republic **Copy contact details from Declaration Section** 

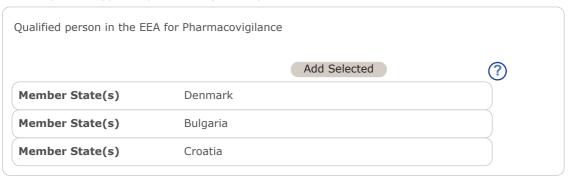
Title First name Surname PharmaSwiss Česká republika s.r.o. **Company name** Jankovcova 1569/2c Address 1 Address 2 (name of: city, town, village, Prague 7 etc) 17000 Postcode Czech Republic Country **Telephone** Telefax E-mail If different to 2.4.1 above, attach letter of authorisation (Annex 5.4) Member State(s) Greece **Copy contact details from Declaration Section** Title First name Surname Pharmaswiss Hellas A.E. **Company name** 53 Pentelis Ave. Address 1 Address 2 (name of: city, town, village, Vrilissia etc) 15235 Postcode Greece Country **Telephone** Telefax E-mail If different to 2.4.1 above, attach letter of authorisation (Annex 5.4) Member State(s) France **Copy contact details from Declaration Section** 

First name	
Surname	
Company name	Laboratoire CHAUVIN
Address 1	416 rue Samuel Morse - CS 99535
Address 2 (name of: city, town, village, etc)	Montpellier
Postcode	34961
Country	France
Telephone	
Telefax	
E-mail	
If different to 2.4.1 abov	ve, attach letter of (Annex 5.4)
Member State(s)	Croatia
First name	
First name Surname	
First name Surname Company name	PharmaSwiss d.o.o.
First name Surname Company name Address 1	PharmaSwiss d.o.o. Strojarska 20
First name Surname Company name Address 1 Address 2 (name of: city, town, village,	
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc)	Strojarska 20
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode	Strojarska 20 Zagreb
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country	Strojarska 20 Zagreb 10 000
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country Telephone	Strojarska 20 Zagreb 10 000
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country Telephone Telefax E-mail	Strojarska 20 Zagreb 10 000 Croatia
Address 2 (name of: city, town, village, etc) Postcode Country Telephone Telefax E-mail	Strojarska 20 Zagreb 10 000 Croatia
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country Telephone Telefax E-mail	Strojarska 20  Zagreb  10 000  Croatia  ve, attach letter of (Annex

irst name	
Surname	
Company name	Valeant Pharma Magyarország Kft.
Address 1	Csatárka út 82-84
Address 2 (name of: city, town, village, etc)	Budapest
Postcode	1025
Country	Hungary
Telephone	
Telefax	
E-mail	
If different to 2.4.1 above authorisation	ve, attach letter of (Annex 5.4)
Member State(s)	Netherlands
	Copy contact details from Declaration Section
	Copy contact details from Declaration Section
Title	Copy contact details from Declaration Section
	Copy contact details from Declaration Section
First name	
First name Surname	Copy contact details from Declaration Section  Bausch&Lomb Pharma
First name Surname Company name Address 1	
First name Surname Company name Address 1 Address 2 (name of: city, town, village,	Bausch&Lomb Pharma
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc)	Bausch&Lomb Pharma Bvd Lambermontlaan 430
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode	Bausch&Lomb Pharma Bvd Lambermontlaan 430 Bruxelles
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country	Bausch&Lomb Pharma Bvd Lambermontlaan 430 Bruxelles 1030
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country Telephone	Bausch&Lomb Pharma Bvd Lambermontlaan 430 Bruxelles 1030
etc) Postcode Country Telephone Telefax E-mail	Bausch&Lomb Pharma Bvd Lambermontlaan 430 Bruxelles 1030 Belgium
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country Telephone Telefax	Bausch&Lomb Pharma Bvd Lambermontlaan 430 Bruxelles 1030 Belgium
First name Surname Company name Address 1 Address 2 (name of: city, town, village, etc) Postcode Country Telephone Telefax E-mail	Bausch&Lomb Pharma Bvd Lambermontlaan 430 Bruxelles 1030 Belgium



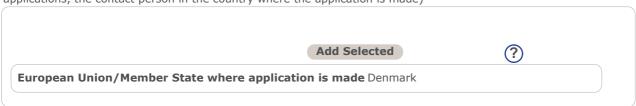
2.4.4 Summary of the applicant pharmacovigilance system



Member State(s)	Czech Republic
Member State(s)	Greece
Member State(s)	France
Member State(s)	Hungary
Member State(s)	Netherlands
Member State(s)	Poland
Member State(s)	Slovakia
Title	
First name	
Surname	
Company name	
Address 1	
Address 2 (name of: city, town, village, etc)	
Postcode	
Country	
24 H Telephone	
Telefax	
E-mail 	
	ualified person resides <sup>6</sup> and operates in the EEA
$igee$ The qualified person is $\mathfrak l$	registered with Eudravigilance
Pharmacovigilance system ma	chan file
	ster me
Number	ster me
	ster file
Number Address 1	ster me
Number  Address 1  Address 2 (name of: city, town, village,	ster file
Number Address 1 Address 2	ster file

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

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)



<sup>&</sup>lt;sup>6</sup> 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.

Name of the contact person

Title MD, PhD

First name Surname

**Company name** Valeant Pharma Poland sp. z o.o.

Address 1 Al. Szucha 13/15

Address 2

(name of: city, town, village, Warszawa

etc)

Postcode 00-580
Country Poland

Telephone
Telefax
E-mail

Add Selected



European Union/Member State where application is made Bulgaria

Name of the contact person

**Title** 

First name

Surname

Company name PharmaSwiss EOOD

Address 1 16, Troyanski prohod Str., fl.3, ap. 8&10, Lagera

Address 2

(name of: city, town, village, Sofia

etc)

Postcode 1612
Country Bulgaria

Telephone Telefax E-mail

Add Selected



**European Union/Member State where application is made** Czech Republic

Name of the contact person

Title

First name

Surname

**Company name** PharmaSwiss Česká republika s.r.o.

Address 1 Jankovcova 1569/2c

Address 2

(name of: city, town, village, Prague 7

etc)

Postcode 17000

**Country** Czech Republic

Telephone
Telefax
E-mail

Add Selected

(?)

**European Union/Member State where application is made** Greece

Name of the contact person

**Title** 

First name

Surname

**Company name** Pharmaswiss Hellas A.E.

**Address 1** 53 Pentelis Ave.

Address 2

(name of: city, town, village, Vrilissia

etc)

Postcode 15235 Country Greece

Telephone Telefax E-mail

Add Selected



European Union/Member State where application is made Croatia

Name of the contact person

Title

First name

**Surname** PharmaSwiss d.o.o.

**Company name** 

Address 1 Strojarska 20 Address 2 (name of: city, town, village, Zagreb etc) 10 000 Postcode Croatia Country **Telephone Telefax** E-mail (?) Add Selected European Union/Member State where application is made France Name of the contact person **Title** First name Surname Laboratoire Chauvin **Company name** 416 rue Samuel Morse - CS 99535 Address 1 Address 2 MONTPELLIER Cedex 2

(name of: city, town, village,

etc)

34961 **Postcode** 

France Country

**Telephone Telefax** E-mail

Add Selected



European Union/Member State where application is made Hungary

Name of the contact person

Title

First name

Surname

Valeant Pharma Magyarorszag Kft. **Company name** 

Address 1 Csatárka u. 82-84

Address 2

(name of: city, town, village, Budapest

etc)

Postcode 1025
Country Hungary

Telephone
Telefax
E-mail

Add Selected



European Union/Member State where application is made Netherlands

Name of the contact person

**Title** 

First name

Surname

Company name

Bausch&Lomb Pharma

Address 1

Bvd Lambermontlaan 430

Bruxelles

Address 2

(name of: city, town, village,

etc)

Postcode 1030
Country Belgium

Telephone Telefax E-mail

Add Selected



European Union/Member State where application is made Poland

Name of the contact person

Title

First name

**Surname** 

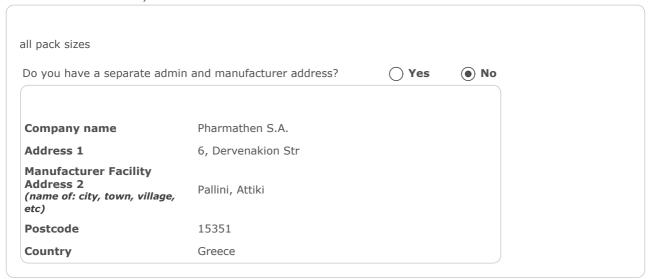
Company name Valeant Pharma Poland sp. z o.o.

Address 1 Al. Szucha 13/15 Str. Address 2 (name of: city, town, village, Warsaw etc) 00-580 **Postcode** Poland Country **Telephone Telefax** E-mail Add Selected (?) European Union/Member State where application is made Slovakia Name of the contact person **Title** First name Surname Valeant Slovakia s.r.o. **Company name** Galvaniho 7/B Address 1 Address 2 (name of: city, town, village, Bratislava etc) 821 04 **Postcode** Slovakia Country **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):



Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  Enter EudraGMP certificate reference number   Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility  Address 2 Emmerthal  (aname of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0  Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation(s) (Annex 5.6)		
E-mail info@pharmathen.com  Manufacturing Authorisation number 0000006501/15/1  Attach copy of manufacturing authorisation (s) (Annex 5.6)  The Enter EudraGMP manufacturing authorisation reference for available Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  Enter EudraGMP certificate reference number  Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility Address 2 Emmerthal (annew of city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0  Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisations (s) (Annex 5.6)  The Enter EudraGMP manufacturing authorisation reference for available  Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number	Telephone	+ 30 210 66 04 300
Manufacturing Authorisation number 0000006501/15/1  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Dr  Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Dr  Enter EudraGMP certificate reference number   Company name Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0  Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Dr  Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Dr  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines  tatals of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tatals of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tatals of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laborato	Telefax	+30 210 66 66 749
Attach copy of manufacturing authorisation(s) (Annex 5.6)  Tenter EudraGMP manufacturing authorisation reference f available Attach latest GMP certificate (Annex 5.9)  Tenter EudraGMP certificate reference number  Attach latest GMP certificate reference number  Enter EudraGMP certificate reference number  Lomapharm Rudolf Lohmann GmbH KG Address 1 Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc.)  Postcode 31860  Country Germany Telephone +49 5155 2791 219 E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Tenter EudraGMP manufacturing authorisation reference f available Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial or the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial service of the control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitial medicines Control Laboratory (OMCL) or laboratory designated for	E-mail	info@pharmathen.com
Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Tr  Enter EudraGMP certificate reference number   Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility  Address 2 Emmerthal  came of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0  Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Dr  Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of o	Manufacturing Authorisatio	n number 0000006501/15/1
Enter EudraGMP manufacturing authorisation reference f available  Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  Enter EudraGMP certificate reference number  Enter EudraGMP certificate reference number   Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility  Address 2 Emmerthal (rame of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0  Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation reference f available  Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitals.	X Attach copy of manufact	uring authorisation(s) (Annex 5.6)
f available Attach latest GMP certificate (Annex 5.9)  Enter EudraGMP certificate reference number  All pack sizes  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility  Address 2  (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Dr  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official manufacturing authorisation release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official manufacturing authorisation release for Blood products and Vaccines	Or	
Attach latest GMP certificate (Annex 5.9)  Dr  Enter EudraGMP certificate reference number  all pack sizes  Do you have a separate admin and manufacturer address?  Ves  No  Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility  Address 2  (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Dr  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offittal	Enter EudraGMP manufa	cturing authorisation reference
Enter EudraGMP certificate reference number  all pack sizes  Do you have a separate admin and manufacturer address? Yes No  Company name Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0  Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Dr  Enter EudraGMP manufacturing authorisation reference f available  Attach latest GMP certificate (Annex 5.9)  Dr  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines ttalls of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offittals	If available	
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Do you have a separate admin and manufacturer address? Yes No  Company name	Or	
Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Or  Enter EudraGMP products and Vaccines  titalis of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated for the purpose of official service (MCL) or laboratory designated	Enter EudraGMP certifica	ate reference number
Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Or  Enter EudraGMP products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official service of the control Laboratory (OMCL) or laboratory designated for the purpose of official service of the control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines cont	<u> </u>	
Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Or  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of offitials.		
Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation (s)  Or  Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Or  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines  tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official services of the control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of official medicines control Laboratory (OMCL) or laboratory designated for the purpose of off	all pack sizes	
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Address 1  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation (s) (Annex 5.6)  Or  Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Or  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of officials of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of officials.		
Address 1  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0  Telefax  +49 5155 2791 219  E-mail  service@lomapharm.de  Manufacturing Authorisation number  DE_NI_02_MIA_2015_0017/41401/H-36  Attach copy of manufacturing authorisation (s) (Annex 5.6)  Or  Enter EudraGMP manufacturing authorisation reference  f available  Attach latest GMP certificate (Annex 5.9)  Or  Enter EudraGMP certificate reference number  ficial batch release for Blood products and Vaccines tails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of officials of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of officials.	Company name	Lomanharm Pudolf Lohmann CmhH VC
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Telefax +49 5155 2791 219  E-mail service@lomapharm.de  Manufacturing Authorisation number DE_NI_02_MIA_2015_0017/41401/H-36  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  ficial batch release for Blood products and Vaccines stails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official medicines Control L	Country	Germany
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Attach copy of manufacturing authorisation(s) (Annex 5.6)  The Enter EudraGMP manufacturing authorisation reference for available  Attach latest GMP certificate (Annex 5.9)  The Enter EudraGMP certificate reference number  Actional batch release for Blood products and Vaccines stails of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official Medicines Control Laboratory (OMCL)	Manufacturing Authorisatio	n number DE NI 02 MIA 2015 0017/41401/H-36
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	tch release (in accordance wit	h Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as an
aboratory 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

PharmaSwiss Česká republika, s.r.o. **Company name** 

Title

First name

**Surname** 

Jankovcova 1569/2c Address 1

Address 2

(name of: city, town, village, Prague 7

etc)

17000 **Postcode** 

Czech Republic Country

24 H Telephone:

**Telefax** E-mail

Laboratoire Chauvin **Company name** 

**Title** 

First name

Surname

416 rue Samuel Morse CS 99535 Address 1

Address 2

(name of: city, town, village,

Montpellier Cedex 2

34961 **Postcode** France Country

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:

Pharmathen S.A. **Company name** 

Address 1	6, Dervenakion str.
Address 2 (name of: city, town, village, etc)	Pallini, Attiki
Postcode	15351
Country	Greece
Telephone	+ 30 210 66 04 300
Telefax	+ 30 210 66 66 749
E-mail	info@pharmathen.com
(note: please see the `Compilatio Interpretation of the Union Forma	sts carried out by the laboratory(ies) concerned nof Union Procedures on Inspections and Exchange of Information' document, (see pages - t for Manufacturer/Importer Authorisation): <a href="http://www.ema.europa.eu/docs/en_GB/">http://www.ema.europa.eu/docs/en_GB/</a> <a href="mailto:procedural_guideline/2009/10/WC500004706.pdf">procedural_guideline/2009/10/WC500004706.pdf</a>
Quality Control Testing - Che	emical/Physical
Quality Control Testing - Mic	robiological - sterility
Or	cturing authorisation(s) or other proof of GMP (Annex 5.6) acturing authorisation reference
Company name	Lomapharm Rudolf Lohmann GmbH KG
Address 1	Langes Feld 5
Address 2 (name of: city, town, village, etc)	Emmerthal
Postcode	31860
Country	Germany
Telephone	+49 5155 2791 0
Telefax	+49 5155 2791 219
E-mail	service@lomapharm.de
(note: please see the `Compilatio Interpretation of the Union Forma	sts carried out by the laboratory(ies) concerned nof Union Procedures on Inspections and Exchange of Information' document, (see pages - t for Manufacturer/Importer Authorisation): <a href="http://www.ema.europa.eu/docs/en_GB/procedural_guideline/2009/10/WC500004706.pdf">http://www.ema.europa.eu/docs/en_GB/procedural_guideline/2009/10/WC500004706.pdf</a>
Quality Control Testing - Che	emical/Physical
Attach copy of manufact compliance	cturing authorisation(s) or other proof of GMP (Annex 5.6)
Enter EndraGMD manuf	acturing authorisation reference

Postcode Country Telephone Telefax E-mail 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 page 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  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex 5.6)  Compliance  Or Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lote: including manufacturing sites of any diluent/solvent presented in a separate container but forming paredicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). Iter provide the relevant information.)	(name of: city, town, village, etc)  Postcode  Country  Telephone  Telefax  E-mail  Brief description of control tests of (note: please see the `Compilation of Interpretation of the Union Format for document_library/Regulatory_and_pro  Quality Control Testing - Microbio  Attach copy of manufacturic compliance  Or  Enter EudraGMP manufacturic danufacturer(s) of the medicinal pro-	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
Country Telephone Telefax E-mail 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 page Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulation_and_procedural_quideline/2009/10/WC500004706.pdf  Quality Control Testing - Microbiological - sterility  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex compliance or Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lote: including manufacturing sites of any diluent/solvent presented in a separate container but forming para edicinal product, quality control in-process testing sites, immediate and outer packaging and importer(s). It is provide the relevant information.)  bottle with solution  Do you have a separate admin and manufacturer address?  Yes No  Company name Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility  Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0	Country Telephone Telefax E-mail Brief description of control tests of (note: please see the `Compilation of Interpretation of the Union Format for document library/Regulatory and pro Quality Control Testing - Microbia  Attach copy of manufacturic compliance Or  Enter EudraGMP manufacturic danufacturer(s) of the medicinal pro	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
Telephone Telefax F-mail 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 page 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  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex compliance or com	Telephone Telefax E-mail Brief description of control tests of (note: please see the `Compilation of Interpretation of the Union Format for document_library/Regulatory_and_pro  Quality Control Testing - Microbio  Attach copy of manufacturic compliance Or  Enter EudraGMP manufacturic danufacturer(s) of the medicinal pro-	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
Telefax  E-mail  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 page interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/em GB/document_library/Regulatory_and_procedural_guideline/2009/10/MC500004706.pdf  Quality Control Testing - Microbiological - sterility  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex compliance or Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lote: including manufacturing sites of any diluent/solvent presented in a separate container but forming paradicinal product, quality control in-process testing sites, immediate and outer packaging and importer(s). It is provide the relevant information.)  bottle with solution  Do you have a separate admin and manufacturer address? Yes No  Company name Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0	Telefax  E-mail  Brief description of control tests of (note: please see the `Compilation of Interpretation of the Union Format for document library/Regulatory and pro  Quality Control Testing - Microbio  Attach copy of manufacturic compliance  Or  Enter EudraGMP manufacturic danufacturer(s) of the medicinal pro-	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
E-mail  Brief description of control tests carried out by the laboratory(les) concerned (note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see page interpretation of the Union Promat for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guldeline/2009/10/WC500004706.pdf  Quality Control Testing - Microbiological - sterility  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex compliance or Enter EudraGMP manufacturing authorisation reference  Brief EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lote: including manufacturing sites of any diluent/solvent presented in a separate container but forming paraedicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). It is provide the relevant information.)  bottle with solution  Do you have a separate admin and manufacturer address? Yes No  Company name Lomapharm Rudolf Lohmann GmbH KG  Address 1 Langes Feld 5  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0	E-mail  Brief description of control tests of (note: please see the `Compilation of Interpretation of the Union Format for document library/Regulatory and pro  Quality Control Testing - Microbia  Attach copy of manufacturic compliance  Or  Enter EudraGMP manufacturic Manufacturer(s) of the medicinal pro-	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
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 page Interpretation of the Union Format for Manufacturer/Imports Authorisation): http://www.ema.europa.eu/docs/en.GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf  Quality Control Testing - Microbiological - sterility  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex 5.6)  Or  Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lote: including manufacturing sites of any diluentysolvent presented in a separate container but forming par edicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). It is provide the relevant information.)  bottle with solution  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility Address 2  (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0	Brief description of control tests of (note: please see the `Compilation of Interpretation of the Union Format for document library/Regulatory and pro  Quality Control Testing - Microbio  Attach copy of manufacturic compliance  Or  Enter EudraGMP manufacturic Manufacturer(s) of the medicinal pro-	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
(note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see page Interpretation of the Union Format for Manufacture/Improrer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf  Quality Control Testing - Microbiological - sterility  Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex compliance)  Or  Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lotter including manufacturing sites of any diluent/solvent presented in a separate container but forming pare decicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). Iter provide the relevant information)  bottle with solution  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility Address 2  (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0	(note: please see the `Compilation of Interpretation of the Union Format for document_library/Regulatory_and_pro  Quality Control Testing - Microbio  Attach copy of manufacturic compliance  Or  Enter EudraGMP manufacturic Manufacturer(s) of the medicinal pro-	Union Procedures on Inspections a Manufacturer/Importer Authorisat cedural_guideline/2009/10/WC5000 plogical - sterility	nd Exchange of Inion): http://www.e	ema.europa.eu/do	cs/en_GB/
Attach copy of manufacturing authorisation(s) or other proof of GMP (Annex compliance or 5.6)  The Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lotte: including manufacturing sites of any diluent/solvent presented in a separate container but forming pare edicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). It is provide the relevant information.)  bottle with solution  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility  Address 2  (name of: city, town, village, etc.)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0	Attach copy of manufacturi compliance Or Enter EudraGMP manufacturi	ng authorisation(s) or othe			
compliance Or  Enter EudraGMP manufacturing authorisation reference  anufacturer(s) of the medicinal product and site(s) of manufacture: lotote: including manufacturing sites of any diluent/solvent presented in a separate container but forming pare decicinal product, quality control/ in-process testing sites, immediate and outer packaging and importer(s). It is provide the relevant information.)  bottle with solution  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Lomapharm Rudolf Lohmann GmbH KG  Address 1  Langes Feld 5  Manufacturer Facility  Address 2  (name of: city, town, village, etc)  Postcode  31860  Country  Germany  Telephone  +49 5155 2791 0	Or  Enter EudraGMP manufacturants  Annufacturer(s) of the medicinal pro-				
Address 1  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  Country  Telephone  Langes Feld 5  Emmerthal  Emmerthal  Fermany  +49 5155 2791 0	nedicinal product, quality control/ iite provide the relevant information  bottle with solution	s of any diluent/solvent presenn-process testing sites, immedia.)	nted in a separa diate and outer p	packaging and ii	
Address 1  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  Country  Telephone  Langes Feld 5  Emmerthal  Emmerthal  Fermany  +49 5155 2791 0					
Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany Telephone +49 5155 2791 0	Company name	Lomapharm Rudolf Lohmann (	GmbH KG		
Address 2 (name of: city, town, village, etc)  Postcode 31860  Country Germany  Telephone +49 5155 2791 0	Address 1	anges Feld 5			
Country Germany Telephone +49 5155 2791 0	Address 2 (name of: city, town, village,	Emmerthal			
<b>Telephone</b> +49 5155 2791 0	Postcode	31860			
	Country	Germany			
<b>Telefax</b> +49 5155 2791 219	Telephone	+49 5155 2791 0			
	Telefax	+49 5155 2791 219			
<b>E-mail</b> service@lomapharm.de	E-mail s	service@lomapharm.de			
Brief description of functions performed:	Brief description of functions performance: please see the `Compilation of I				

Primary packaging			
Secondary packaging			
Site(s) is in the EEA: (	Site(s) is outside the EEA:		
Manufacturing autho	risation number DE_N	II_02_MIA_2015_0017/	/41401/H-36
X Attach copy of ma	nufacturing authorisation(s)	(Annex 5.6)	
Or		(Junior Cio)	
Enter EudraGMP Man Authorisation refere			
Name of qualified pe			
	nufacturing authorisation)		
	n and manufacturer address?	○ Yes •	No
oo you have a separate admi		○ Yes ●	No
oo you have a separate admi	Pharmathen S.A.	○ Yes ④	No
Company name		○ Yes ④	No
Company name Address 1 Manufacturer Facility Address 2 Iname of: city, town, village,	Pharmathen S.A.	○ Yes ④	No
Company name Address 1 Manufacturer Facility Address 2 Viame of: city, town, village, etc)	Pharmathen S.A. 6, Dervenakion str.	○ Yes ⊚	No
Company name Address 1 Manufacturer Facility Address 2 Iname of: city, town, village, etc) Postcode	Pharmathen S.A. 6, Dervenakion str. Pallini, Attiki	Yes ●	No
Company name Address 1 Manufacturer Facility Address 2 name of: city, town, village, etc.) Postcode Country	Pharmathen S.A. 6, Dervenakion str. Pallini, Attiki 153 51	○ Yes ●	No
Company name Address 1 Manufacturer Facility Address 2 Manufacture, town, village, etc) Postcode Country Telephone	Pharmathen S.A. 6, Dervenakion str.  Pallini, Attiki  153 51  Greece	○ Yes ●	No
Company name Address 1 Manufacturer Facility Address 2 Iname of: city, town, village, etc) Postcode Country Telephone Telefax	Pharmathen S.A. 6, Dervenakion str.  Pallini, Attiki  153 51  Greece + 30 210 66 04 300	Yes ●	No
Company name Address 1 Manufacturer Facility Address 2 (name of: city, town, village, etc) Postcode Country Telephone Telefax E-mail rief description of functions pote: please see the `Compilation terpretation of the Union Format	Pharmathen S.A. 6, Dervenakion str.  Pallini, Attiki  153 51  Greece + 30 210 66 04 300 + 30 210 66 66 749 info@pharmathen.com	and Exchange of Informati	ion' document, (see pages -
Company name Address 1 Manufacturer Facility Address 2 (name of: city, town, village, etc.) Postcode Country Telephone Telefax E-mail rief description of functions pote: please see the `Compilation terpretation of the Union Format boument library/Regulatory and	Pharmathen S.A.  6, Dervenakion str.  Pallini, Attiki  153 51  Greece + 30 210 66 04 300 + 30 210 66 66 749  info@pharmathen.com  erformed: of Union Procedures on Inspections for Manufacturer/Importer Authorisa procedural_guideline/2009/10/WC50	and Exchange of Informati	ion' document, (see pages -
Company name  Address 1  Manufacturer Facility Address 2 (name of: city, town, village, etc)  Postcode  Country  Telephone  Telefax  E-mail  rief description of functions pote: please see the `Compilation iterpretation of the Union Format	Pharmathen S.A. 6, Dervenakion str.  Pallini, Attiki  153 51 Greece + 30 210 66 04 300 + 30 210 66 66 749 info@pharmathen.com  erformed: of Union Procedures on Inspections for Manufacturer/Importer Authorisa procedural_guideline/2009/10/WC50 mical/Physical	and Exchange of Informati	ion' document, (see pages -

110	nufacturing authorisation number
$\boxtimes$	Attach copy of manufacturing authorisation(s) (Annex 5.6)
Or	
	ter EudraGMP Manufacturing thorisation reference
Na	me of qualified person
(if ı	not mentioned in manufacturing authorisation)
ottle with	n solution
Do you ha	ave a separate admin and manufacturer address? Yes   No
Compan	y name
Address	1
	turer Facility
Address	
Postcode	e e
Country	
Telepho	ne
Telefax	
E-mail	
	ription of functions performed:
note: pleas nterpretation	ipcon of interiors performed:  e see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages on of the Union Format for Manufacturer/Importer Authorisation): <a href="http://www.ema.europa.eu/docs/en_GB/">http://www.ema.europa.eu/docs/en_GB/</a> ibrary/Regulatory and procedural guideline/2009/10/WC500004706.pdf
	ontrol Testing - Microbiological - sterility
Quality C	ontrol Testing - Microbiological - non-sterility

(if not mentioned in manufacturing authorisation)				
pttle				
Do you have a separate admin and manufacturer address?	Yes	<ul><li>No</li></ul>		
Company name				
Address 1				
Manufacturer Facility Address 2 (name of: city, town, village, etc)				
Postcode				
Country				
<b>Felephone</b>				
Гelefax				
E-mail				
erpretation of the Union Format for Manufacturer/Importer Authorisation	n): http://www.e	ema.europa.eu	i/docs/en_GB	oag <u>/</u>
terpretation of the Union Format for Manufacturer/Importer Authorisation of the Union Format for Manufacturer/Importer Authori	n): http://www.e	ema.europa.eu	ument, (see j //docs/en GB,	page L
ote: please see the `Compilation of Union Procedures on Inspections an terpretation of the Union Format for Manufacturer/Importer Authorisation outment_library/Regulatory_and_procedural_guideline/2009/10/WC500005terilisation - Gamma irradiation  Site(s) is in the EEA: Site(s) is outside the EEA:  Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (or  Enter EudraGMP Manufacturing Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)	n): http://www.e	ema.europa.eu	ument, (see j	pag //
terpretation of the Union Format for Manufacturer/Importer Authorisation bounent library/Regulatory_and_procedural_guideline/2009/10/WC5006  Sterilisation - Gamma irradiation  Site(s) is in the EEA: Site(s) is outside the EEA:  Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (core in the EudraGMP Manufacturing Authorisation reference  Name of qualified person  (if not mentioned in manufacturing authorisation)	n): http://www.e		ument, (see j	page
terpretation of the Union Format for Manufacturer/Importer Authorisation bounent library/Regulatory and procedural guideline/2009/10/WC5006  Sterilisation - Gamma irradiation  Site(s) is in the EEA: Site(s) is outside the EEA:  Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (some of qualified person (if not mentioned in manufacturing authorisation)	n): http://www.e	No	ument, (see j	page
terpretation of the Union Format for Manufacturer/Importer Authorisation bounent library/Regulatory_and_procedural_guideline/2009/10/WC5006  Sterilisation - Gamma irradiation  Site(s) is in the EEA: Site(s) is outside the EEA:  Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (core in the EudraGMP Manufacturing Authorisation reference  Name of qualified person  (if not mentioned in manufacturing authorisation)	n): http://www.e		ument, (see j //docs/en GB	page

Manufacturer Facility	
Address 2 (name of: city, town, village,	
etc)	
Postcode	
Country	
Telephone	
Telefax	
E-mail E-mail	
brief description of functions performed: note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' on the Union Format for Manufacturer/Importer Authorisation): <a href="http://www.ema.europa.cument_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf">http://www.ema.europa.cument_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf</a>	
Sterilisation - Chemical	
Site(s) is in the EEA: Site(s) is outside the EEA:	
Manufacturing authorisation number	
★ Attach copy of manufacturing authorisation(s) (Annex 5.6)	
Or	
Enter EudraGMP Manufacturing	
Enter EudraGMP Manufacturing Authorisation reference	
Authorisation reference	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  //alve  Do you have a separate admin and manufacturer address?  Yes  No	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Address 1	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Address 1  Manufacturer Facility  Address 2  (name of: city, town, village, etc)	
Authorisation reference Name of qualified person (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Address 1  Manufacturer Facility Address 2 (name of: city, town, village, etc.)  Postcode	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Address 1  Manufacturer Facility  Address 2  (name of: city, town, village, etc)  Postcode  Country	
Authorisation reference Name of qualified person  (if not mentioned in manufacturing authorisation)  /alve  Do you have a separate admin and manufacturer address?  Yes  No  Company name  Address 1  Manufacturer Facility  Address 2  (name of: city, town, village,	

Page 36 of 49

Site(s) is in the EEA:
Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Or  Enter EudraGMP Manufacturing Authorisation reference  Name of qualified person
Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Or  Enter EudraGMP Manufacturing Authorisation reference  Name of qualified person
Manufacturing authorisation number  Attach copy of manufacturing authorisation(s) (Annex 5.6)  Or  Enter EudraGMP Manufacturing Authorisation reference  Name of qualified person
Attach copy of manufacturing authorisation(s) (Annex 5.6)  Or  Enter EudraGMP Manufacturing Authorisation reference  Name of qualified person
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Name of qualified person
(if not mentioned in manufacturing authorisation)
Company name  Address 1  Manufacturer Facility  Address 2 (name of: city, town, village, etc)  Postcode  Country  Telephone
E-mail
rief description of functions performed: note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pagnerpretation of the Union Format for Manufacturer/Importer Authorisation): <a href="http://www.ema.europa.eu/docs/en_GB/ocument_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf">http://www.ema.europa.eu/docs/en_GB/ocument_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf</a>
Sterilisation - Chemical

Or
Enter EudraGMP Manufacturing
Authorisation reference
Name of qualified person
(if not mentioned in manufacturing authorisation)

- $\boxtimes$  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.

Active Substance		+
LATANOPROST		-
	Copy contact of	letails from Declaratio
you have a separate admin and manufacturer address	S? Yes	● No
mpany name		
dress 1		
nufacturer Facility dress 2		
me of: city, town, village, )		
stcode		
untry		
ephone		
efax		
nail		
f description of manufacturing steps performed by ma :: please see the `Compilation of Union Procedures on Inspect s - Interpretation of the Union Format for Manufacturer/Impo (en GB/document library/Regulatory and procedural guideli	tions and Exchange of I orter Authorisation): <u>ht</u>	p://www.ema.europa.eu/
nufacture of active substance by chemical synthesis		
nufacture of active substance intermediate by chemica	l synthesis	
lity Control Testing - Chemical/Physical		
ality Control Testing - Microbiological - non-sterility		
nary Packaging of active substance		
ondary 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
If yes, please provide summary information in(Annex 5.9) (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)
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
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

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 sul	omission	
Date of las	t update	
Name of th	ne ASMF holder	
Name of th	ne manufacturer if different from	
EU ASMF re	eference number if available	
applicable	SMF reference number: (when and only if EU ASMF reference not available)	
Applicant p	part version number	
Date of sul	omission	
Date of las	t update	
Name of th	ne ASMF holder	
Name of thabove	ne manufacturer if different from	
EU ASMF re	eference number if available	
applicable	SMF reference number: (when and only if EU ASMF reference not available)	
Applicant p	part version number	
Date of sul	omission	
Date of las	t update	
Name of th	ne ASMF holder	
Name of th	e manufacturer if different from	
EU ASMF re	eference number if available	
applicable	SMF reference number: (when and only if EU ASMF reference not available)	
Applicant p	part version number	
Date of sul	omission	
Date of las	t update	
Sapplication and EMA ceri	tter of access for European Union/Member State authorities where the on is made (see "European ASMF procedure for active ingredients")(Annex 5.10 tificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with L/83/EC Annex I, Part III, being used for this MAA?   No	0)

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)

te should be given as to which quantity the composition	n refers (e.g. 1 caps	sule)			
rmaceutical Form Eye drops, solution			1	ml	
e values of the pharmaceutical form, strength and active	e substances fields l	have been populated from	"Declaration" section.)		
Strength		Units	+ -		
50		μg/ml			
ist the active substance(s) separately from the excipien	t(s)				
					+ -
Name of active substance		Quantity / Ur	.i+	Reference /	+
Name of active substance		Quantity / Of	iii.	Monograph Standard	<b>T</b>
LATANOPROST	equal to	50	μg/ml	In house	
LATANOTROST		For numeric value decimal separa	es, please use the full stop as the tor. i.e. 0.002, rather than 0,002	III liouse	
		· · ·	·		
					+ -
				Reference /	
Name of Excipient		Quantity / L	Jnit	Monograph Standard	+
	equal to	m	g/ml		
MACROGOLGLYCEROL HYDROXYSTEARATE 40 PH. EUR.			ues, please use the full stop as the		
		decimal sepa	rator. i.e. 0.002, rather than 0,002		

Name of Excipient		Quantity / Unit		
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	
DISODIUM EDETATE	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	-
SODIUM DIHYDROGEN PHOSPHATE DIHYDRATE	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	-
DISODIUM PHOSPHATE, ANHYDROUS	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	
HYDROCHLORIC ACID 1N	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	-
SODIUM HYDROXIDE 1N	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	-
VATER FOR INJECTION	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

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

Active Substance	Overage +	+
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<sup>\*\*</sup> 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)

Excipient	Overage	+	

2.6.2	List of materia	s of animal and/or human origin contained or used in the manufacturing process of the medicinal product?
	<b>◯</b> NONE	
	or specify belo	w:
	culture mediu	ostance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/ m (incl. those used in the preparation of master and working cell banks) section 2 (scope) of the CHMP Note for Guidance
		ur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the Europe attach it in (Annex 5.12)
2.6.3		ificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex ag used for this MAA?
	Yes	No     No
2.6.4	Does the medi 2001/18/EC?	cinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive
	<b>○</b> Yes	<ul><li>No</li></ul>

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

**SCIENTIFIC ADVICE** 

3.

4.	OTHER MARKET	ING AUTHORISATION APPLICATION	ONS						
4.1		RP/DCP APPLICATIONS, PLEASE COMPLE H ARTICLE 8(j)-(l) OF DIRECTIVE 2001/		N					
4.1.1	Is there another Member Sta	ate(s) where an application for the same* product is per	nding**?						
	<b>○Yes ●No</b>	Not Applicable							
	If yes, section 4.2 must be o	completed							
4.1.2	Is there another Member sta	ite(s) where an authorisation is granted for the same* p	roduct?						
	<b>○Yes ● No</b>								
4.1.3	Is there another Member Stathe same* product?	ate(s) where an authorisation was refused/suspended/re	evoked by competent authoritie	s for					
	<b>○</b> Yes <b>●</b> No								
	If yes, section 4.2 must be o	completed							
	pharmaceutical form f	same qualitative and quantitative composition in active substan rom applicants belonging to the same mother company or group tions submitted at an earlier time or in parallel to this applicatio	of companies OR which are "license						
4.2	(SAME QUALITATIVAND HAVING THE SAME MOTHER "LICENSEES").	ORISATION APPLICATIONS FOR THE SAME AND QUANTITATIVE COMPOSITION IN SAME PHARMACEUTICAL FORM FROM AP COMPANY OR GROUP OF COMPANIES O	N ACTIVE SUBSTANCE( PLICANTS BELONGING	S)					
	Note: refer to Commission Comn	nunications 98/C229/03							
	Authorised								
	Submitted (which are 4.3)	not considered as a multiple/duplicate application	ı - see Section						
	Refused								
	Withdrawn (by application	Withdrawn (by applicant before authorisation)							
	Withdrawn (by applicant after authorisation)								
	Suspended/revoked (	by competent authority)							
4.3	FOR MILLTIPLE / D	UPLICATE APPLICATIONS OF THE SAME	MEDICINAL PRODUCT						
1.5	•	ns (submitted simultaneously or subsequently to the ori							
	Transper duplicate application	is (Submitted Simultaneously of Subsequently to the one	ginar producty for:						
	Name of other	Tanafra							
	Date of application	2017-04-28							
	(s) Applicant	Pharmathen S.A.							
	Procedure number								
	for MRP/DCP (if applicable)	DK/H/2755/001/DC							
		ter from Commission services, for centralised	(Annex 5.16)						
4.4	MARKETING AUTHOR EEA (I.E. FROM API GROUP OF COMPAN QUANTITATIVE CO SAME PHARMACEU	DRISATION APPLICATIONS FOR THE SAMPLICANTS BELONGING TO THE SAME MONIES OR WHICH ARE "LICENSEES". SAME MPOSITION IN THE ACTIVE SUBSTANCE	ME PRODUCT OUTSIDE THER COMPANY OR E QUALITATIVE AND	٦					
	Authorised								
	Pending								
	Refused								
	Withdrawn (by application	ant before authorisation)							

☐ Withdrawn (by applicant after authorisation)

	Suspended	/revoked	(by	competent	authority)	

## 5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

<b>5.1</b>	Proof of payment
5.2	Informed consent letter of marketing authorisation holder of authorised medicinal product.
<b>5.3</b>	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".
<b>5.8</b>	Flow-chart indicating all manufacturing and control sites involved in the manufacturing process o the medicinal product and the active substance.
<b>5.9</b>	GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.
<b>5.10</b>	Letter(s) of access to Active Substance Master File(s) or copy of ph. Eur. Certificate(s) of Suitability.
<b>∑</b> 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.
<b>5.17</b>	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.
<b>5.19</b>	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).
<b>∑</b> 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.