



**EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL**

Health Systems and products

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Brussels,
(2015)

Revision 12

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B

Module 1.2: Administrative information
Application form

September 2015

This application form will be included in:

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

To be noted:

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

Revision 12

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

¹ OJ L 299 of 27.10.2012, p. 1

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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
- 2.3 Legal status
- 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 Vizibim Duo

Pharmaceutical Form: Eye drops, solution

Strength:	Units	<input type="button" value="+"/>	<input type="button" value="-"/>
0,3	mg/ml	<input type="button" value="+"/>	<input type="button" value="-"/>
5	mg/ml	<input type="button" value="+"/>	<input type="button" value="-"/>

Active Substance(s):
BIMATOPROST
TIMOLOL MALEATE

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Applicant PharmaSwiss Česká republika s.r.o.
Title Mrs
First Name
Surname
Address 1 Jankovcova 1569/2c
Address 2 Prague 7
(name of: city, town, village, etc)
Postcode 170 00
Country Czech Republic
Telephone +420 234
Telefax +420 234
E-mail @valeant.com

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

Title Mrs

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 Mrs

First name*

Surname

Function
Regulatory Affairs Associate

Address 1 Pharmathen S.A., 44 Kifissias Ave., Monumental Plaza Building A

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

Postcode 151 25

Country Greece

Telephone +30 210 66

Telefax +30 210 66

E-mail @pharmathen.com

Date
2016-09-29

Signatory

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

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

1. TYPE OF APPLICATION

Note: The following sections should be completed where appropriate.

1.1 THIS APPLICATION CONCERNS

1.1.1 A CENTRALISED PROCEDURE

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

1.1.2 A MUTUAL RECOGNITION PROCEDURE

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

1.1.3 A DECENTRALISED PROCEDURE

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

Reference Member State Denmark
Procedure number: DK/H/2711/001/DC

Concerned Member State (specify)	Belgium
Concerned Member State (specify)	Bulgaria
Concerned Member State (specify)	Czech Republic
Concerned Member State (specify)	Germany
Concerned Member State (specify)	Estonia
Concerned Member State (specify)	Spain
Concerned Member State (specify)	France
Concerned Member State (specify)	Lithuania
Concerned Member State (specify)	Luxembourg
Concerned Member State (specify)	Latvia
Concerned Member State (specify)	Netherlands
Concerned Member State (specify)	Poland
Concerned Member State (specify)	Portugal
Concerned Member State (specify)	Romania
Concerned Member State (specify)	Slovenia
Concerned Member State (specify)	Slovakia
Proposed/Agreed common renewal date	5 years from D210 of the DCP

1.1.4 A NATIONAL PROCEDURE

1.2 ORPHAN MEDICINAL PRODUCT DESIGNATION

1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

Yes No

1.2.2 INFORMATION RELATING TO ORPHAN MARKET EXCLUSIVITY

Has any medicinal product been designated as an Orphan medicinal product for a condition relating to the indication proposed in this application?

Yes No

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

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

1.4 APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/83/EC²

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

- 1.4.1 **Article 8(3) application, (i.e dossier with administrative, quality, pre-clinical and clinical data*)**
- 1.4.2 **Article 10(1) generic application**
- 1.4.3 **Article 10(3) hybrid application**

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

Reference medicinal product:

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

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

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

Product (invented) name Ganfort			
Pharmaceutical form(s) Eye drops, solution		+ -	
Strength(s) 0,3 mg/ml + 5 mg/ml	Marketing authorisation holder Allergan Pharmaceuticals Ireland	Marketing authorisation number EU/1/06/340/001-002	Date of authorisation 2006-05-19
Marketing authorisation granted by			
<input checked="" type="checkbox"/> Union			
<input type="checkbox"/> Member State(EEA)			

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

Member State(s) Belgium	+ -
Member State(s) Bulgaria	+ -
Member State(s) Czech Republic	+ -
Member State(s) Germany	+ -
Member State(s) Estonia	+ -
Member State(s) Spain	+ -
Member State(s) France	+ -
Member State(s) Lithuania	+ -
Member State(s) Luxembourg	+ -
Member State(s) Latvia	+ -
Member State(s) Netherlands	+ -
Member State(s) Poland	+ -

Member State(s)	Portugal	<input data-bbox="1007 152 1050 188" type="button" value="+"/>	<input data-bbox="1066 152 1109 188" type="button" value="-"/>
Member State(s)	Romania	<input data-bbox="1007 210 1050 246" type="button" value="+"/>	<input data-bbox="1066 210 1109 246" type="button" value="-"/>
Member State(s)	Slovenia	<input data-bbox="1007 268 1050 304" type="button" value="+"/>	<input data-bbox="1066 268 1109 304" type="button" value="-"/>
Member State(s)	Slovakia	<input data-bbox="1007 327 1050 362" type="button" value="+"/>	<input data-bbox="1066 327 1109 362" type="button" value="-"/>
Member State(s)	Denmark	<input data-bbox="1007 385 1050 421" type="button" value="+"/>	<input data-bbox="1066 385 1109 421" type="button" value="-"/>
Product (invented) name	Ganfort		
Pharmaceutical form(s)	Eye drops, solution		<input data-bbox="1310 495 1353 530" type="button" value="+"/> <input data-bbox="1369 495 1412 530" type="button" value="-"/>
Strength(s)	Marketing authorisation holder (note 4)	Marketing authorisation number	<input data-bbox="1310 573 1353 609" type="button" value="+"/> <input data-bbox="1369 573 1412 609" type="button" value="-"/>
0,3 mg/ml + 5 mg/ml	Allergan Pharmaceuticals Ireland	EU/1/06/340/001-005	
Marketing authorisation granted by			
<input checked="" type="checkbox"/> Union			
<input type="checkbox"/> Member State(EEA)			

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

- changes in the active substance(s)**
- change in therapeutic indications**
- change in pharmaceutical form**
- change in strength(quantitative change to the active substance(s))**
- change in route of administration**
- bioequivalence cannot be demonstrated through bioavailability studies**

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

Study reference number/EudraCT number			
Product (invented) name			
Pharmaceutical form(s)			<input data-bbox="1310 1563 1353 1599" type="button" value="+"/> <input data-bbox="1369 1563 1412 1599" type="button" value="-"/>
Strength(s)	Marketing authorisation holder (note 4)	Marketing authorisation number	<input data-bbox="1310 1641 1353 1677" type="button" value="+"/> <input data-bbox="1369 1641 1412 1677" type="button" value="-"/>
Marketing authorisation granted by			
<input type="checkbox"/> Union			
<input type="checkbox"/> Member State(EEA)			
Member State of source			

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

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

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

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

1.4.6 **Article 10b fixed combination application**

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

1.4.7 **Article 10c informed consent application**

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

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

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

1.5 CONSIDERATION OF THIS APPLICATION REQUESTED UNDER THE FOLLOWING ARTICLE DIRECTIVE 2001/83/EC OR REGULATION (EC) NO 726/2004³

1.5.1 **Conditional Approval**

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

1.5.2 **Exceptional Circumstances**

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

1.5.3 **Accelerated Review**

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

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

(one year of market protection for a new indication)

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

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

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

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

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

(Note: Also applies to Extension applications of PUMA)

1.6.5 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

Yes **No** **Not Applicable**

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S) AND ATC CODE

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

Vizibim Duo

(Value populated from the "Declaration" section.)

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

2.1.2 Name of the active substance(s)

Note: Only one name should be given in the following order of priority: INN*, Ph.Eur., National Pharmacopeia, common name, scientific name;

* The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)

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

Active Substance	
BIMATOPROST	+
TIMOLOL MALEATE	-

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code S01ED51

Group timolol, combinations

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

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

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

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

Pharmaceutical Form: Eye drops, solution

Strength:	Units
0,3	mg/ml
Strength:	Units
5	mg/ml

Active Substance(s):

BIMATOPROST
TIMOLOL MALEATE

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

Route of Administration Ocular use

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

For each type of pack give:

2.2.3.1 Package Size 1 1 bottle of 3 ml

2.2.3.1 Package Size 2 3 bottles of 3 ml

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

Description

The product is filled in White opaque 5 ml LDPE bottle and white Novelia nozzle (HDPE and silicone) with a blue tip and sealed with a white HDPE cap and packed in cardboard box.

For each container give:

Container	Bottle
Material	Low Density Polyethylene (LDPE)
Closure	Cap
Administration Device	N/A

2.2.3.2 Proposed shelf life 18 Months

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

2.2.3.3 Proposed shelf life (after first opening container) 4 Weeks

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

2.2.3.4 Proposed shelf life (after reconstitution or dilution) N/A

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

2.2.3.5 Proposed storage conditions

This medicinal product does not require any special storage conditions

2.2.3.6 Proposed storage conditions after first opening

This medicinal product does not require any special storage conditions

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

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

Yes

2.3 LEGAL STATUS

2.3.1 Proposed dispensing/classification

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

Subject to medical prescription (Complete 2.3.2)

all pack sizes

Add Selected



European Union/Member State	Belgium
European Union/Member State	Bulgaria
European Union/Member State	Czech Republic
European Union/Member State	Germany
European Union/Member State	Estonia
European Union/Member State	Spain
European Union/Member State	France
European Union/Member State	Lithuania
European Union/Member State	Luxembourg
European Union/Member State	Latvia
European Union/Member State	Netherlands
European Union/Member State	Poland
European Union/Member State	Portugal
European Union/Member State	Romania
European Union/Member State	Slovenia
European Union/Member State	Slovakia
European Union/Member State	Denmark

Not subject to medical prescription (Complete 2.3.3 & 2.3.4)

2.3.2 For products subject to medicinal prescription

Product on prescription which may be renewed (if applicable)

Add Selected



Member State	Belgium
Member State	Bulgaria
Member State	Czech Republic
Member State	Germany
Member State	Estonia
Member State	Spain
Member State	France
Member State	Lithuania
Member State	Luxembourg
Member State	Latvia
Member State	Netherlands
Member State	Poland
Member State	Portugal

Member State	Romania
Member State	Slovenia
Member State	Slovakia
Member State	Denmark

- Product on prescription which may not be renewed (if applicable)**
- Product on special prescription***
- Product on restricted prescription***

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

2.3.3 Supply for products not subject to medical prescription

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

2.3.4 Promotion for products not subject to medical prescription

- Promotion to health care professionals only**
- Promotion to general public and health care professionals**

2.4 MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY

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

- Centralised procedure**
- National procedure including mutual recognition/decentralised procedure**

Copy contact details from Declaration Section

Add Selected
?

Member State	Bulgaria
Member State	Czech Republic
Member State	Estonia
Member State	Spain
Member State	Lithuania
Member State	Latvia
Member State	Poland
Member State	Portugal
Member State	Romania
Member State	Slovenia
Member State	Slovakia
Member State	Denmark

Company name PharmaSwiss Česká republika s.r.o.

Address 1 Jankovcova 1569/2c
Address 2 Prague 7
(name of: city, town, village, etc)
Postcode 170 00
Country Czech Republic
Telephone +420 234 719
Telefax +420 234 719
E-mail czech.info@valeant.com

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

Has SME status been assigned by the EMA?

Yes **No**

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

For Member State Bulgaria

For Member State Czech Republic

For Member State Estonia

For Member State Spain

For Member State Lithuania

For Member State Latvia

For Member State Poland

For Member State Portugal

For Member State Romania

For Member State Slovakia

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

No

Copy address from above address details

Add Selected

For Member State Denmark

Billing address (when relevant)

Company name Valeant Sp. z o.o. sp. jawna

VAT number 8133676203

Address 1 Przemyslowa 2
Address 2 Rzeszow
(name of: city, town, village, etc)
Postcode 35-959
Country Poland
Telephone +48 17
Telefax -
E-mail @valeant.com
Purchase order(PO) number -

- Yes (for fees paid, attach proof of payment in) (Annex 5.1)**
 No

Copy address from above address details

Add Selected

For Member State Slovenia

Billing address (when relevant)

Company name -
VAT number -
Address 1 -
Address 2 -
(name of: city, town, village, etc)
Postcode -
Country -
Telephone -
Telefax -
E-mail slovenia.fees@valeant.com
Purchase order(PO) number -

Copy contact details from Declaration Section

Member State Belgium

Member State Luxembourg

Member State Netherlands

Company name Bausch & Lomb Pharma

Address 1 Bvd Lambermontlaan 430
Address 2 Brussel
(name of: city, town, village, etc)
Postcode B-1030
Country Belgium
Telephone 0032496
Telefax -
E-mail regulatory.benelux@bausch.com

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

Has SME status been assigned by the EMA?

Yes **No**

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

For Member State Belgium

For Member State Luxembourg

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 -

E-mail regulatory.benelux@bausch.com

Purchase order(PO) number -

Copy contact details from Declaration Section

Member State Germany

Company name Dr. Gerhard Mann chem.-pharm. Fabrik GmbH

Address 1 Brunsbütteler Damm 165-173

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

Postcode 13581

Country Germany

Telephone +49 (0)30

Telefax +49 (0)30

E-mail @bausch.com

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

Has SME status been assigned by the EMA?

Yes **No**

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 Germany

Billing address (when relevant)

Company name Valeant Sp. z o.o. sp. jawna

VAT number 8133676203

Address 1 Przemyslowa 2

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

Postcode 35-959

Country Poland

Telephone +48 17

Telefax -

E-mail @valeant.com

Purchase order(PO) number -

Copy contact details from Declaration Section

Member State France

Company name Laboratoire CHAUVIN

Address 1 416 rue Samuel Morse - CS99535
Address 2 MONTPELLIER Cedex 2
(name of: city, town, village, etc)
Postcode 34961
Country France
Telephone +33 (0)4 67 12
Telefax + 33(0)4 67 12
E-mail RA_France@bausch.com

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

Has SME status been assigned by the EMA?

Yes **No**

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

For Member State France

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Add Selected



Member State(s) Belgium

Member State(s) Bulgaria

Member State(s) Czech Republic

Member State(s) Germany

Member State(s) Estonia

Member State(s) Spain

Member State(s) France

Member State(s) Lithuania

Member State(s) Luxembourg

Member State(s) Latvia

Member State(s) Netherlands

Member State(s) Poland

Member State(s) Portugal

Member State(s) Romania

Member State(s) Slovenia

Member State(s) Slovakia

Member State(s) Denmark

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

Title Mrs
First name
Surname
Company name Pharmathen S.A.
Address 1 44 Kifissias Ave., Monumental Plaza Building A
Address 2 Marousi, Attiki
(name of: city, town, village, etc)
Postcode 151 25
Country Greece
Telephone +30 210 66
Telefax +30 210 66
E-mail @pharmathen.com

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

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Add Selected



Member State (s) Denmark

Title Ms.
First name
Surname
Company name PharmaSwiss Česká republika s.r.o.
Address 1 Jankovcova 1569/2c
Address 2 Prague 7
(name of: city, town, village, etc)
Postcode 170 00
Country Czech Republic
Telephone +420 234
Telefax +420 234
E-mail @valeant.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Bulgaria

Title Mrs.

First name

Surname

Company name PharmaSwiss EOOD

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

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

Postcode 1612

Country Bulgaria

Telephone + 359 2 895

Telefax +359 2 895

E-mail @valeant.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Czech Republic

Title Ms.

First name

Surname

Company name PharmaSwiss Česká republika s.r.o.

Address 1 Jankovcova 1569/2c

Address 2 Prague 7
(name of: city, town, village, etc)

Postcode 170 00

Country Czech Republic

Telephone +420 234

Telefax +420 234

E-mail @valeant.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Belgium

Member State (s) Luxembourg

Member State (s) Netherlands

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

Title Ms.

First name

Surname

Company name Bausch&Lomb Pharma

Address 1 Bvd Lambermontlaan 430

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

Postcode 1030

Country Belgium

Telephone

Telefax -

E-mail regulatory.benelux@bausch.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Germany

Title Mrs.

First name

Surname

Company name Dr. Gerhard Mann chem.-pharm. Fabrik GmbH

Address 1 Brunsbütteler Damm 165-173

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

Postcode 13581

Country Germany

Telephone +49 30

Telefax -

E-mail @bausch.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Estonia

Title Mr.

First name

Surname

Company name PharmaSwiss Eesti OÜ

Address 1 Tammsaare tee 47

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

Postcode 11316

Country Estonia

Telephone +372 68

Telefax -

E-mail @valeant.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Spain

Title Mrs.

First name

Surname

Company name Bausch & Lomb S.A.

Address 1 Avda. Valdelaparra 4.

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

Postcode 28108

Country Spain

Telephone +34 91

Telefax +34 91

E-mail @bausch.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) France

Title Ms.
First name
Surname
Company name Laboratoire CHAUVIN
Address 1 416 rue Samuel Morse - CS 99535
Address 2 Montpellier
(name of: city, town, village, etc)
Postcode 34961
Country France
Telephone + 33(0)4 67 12
Telefax + 33 (0)4 67 12
E-mail @bausch.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Lithuania

Title Mr.
First name
Surname
Company name UAB "PharmaSwiss"
Address 1 Šeimyniškių 21B
Address 2 Vilnius
(name of: city, town, village, etc)
Postcode LT - 09200
Country Lithuania
Telephone + 370
Telefax +370
E-mail @valeant.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Latvia

Title Mrs.
First name
Surname

Company name SIA PharmaSwiss Latvia

Address 1 Blaumaņa iela 5a-8

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

Postcode LV-1011

Country Latvia

Telephone + 371

Telefax + 371

E-mail @valeant.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Poland

Title Mrs.

First name

Surname

Company name VP Valeant Sp. z o.o. sp.j.

Address 1 Marynarska 15

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

Postcode 02-674

Country Poland

Telephone +48 22

Telefax + 48 22

E-mail @valeant.com

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

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Portugal

Title Mrs.

First name

Surname

Company name Bausch & Lomb S.A. – Suc. Portugal

Address 1 Av. da República, nº 25, 6-A.
Address 2 Lisboa
(name of: city, town, village, etc)
Postcode 1050-186
Country Portugal
Telephone + 351 21
Telefax + 351 21
E-mail @bausch.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Romania

Title Mrs.
First name
Surname
Company name Valeant Pharma SRL
Address 1 Maria Rosetti street, no 6, 7th floor, District 2
Address 2 Bucharest
(name of: city, town, village, etc)
Postcode 020485
Country Romania
Telephone
Telefax
E-mail @valeant.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Slovenia

Title Ms.
First name
Surname
Company name PharmaSwiss d.o.o.

Address 1 Brodišče 32
Address 2 Trzin
(name of: city, town, village, etc)
Postcode 1236
Country Slovenia
Telephone 00386 1
Telefax 00386 1
E-mail @valeant.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Member State (s) Slovakia

Title Mrs.
First name
Surname
Company name Valeant Slovakia s.r.o.
Address 1 Galvaniho 7/B
Address 2 Bratislava
(name of: city, town, village, etc)
Postcode 821 04
Country Slovakia
Telephone + 421 2 3233
Telefax -
E-mail @valeant.com

If different to 2.4.1 above, attach letter of authorisation

(Annex 5.4)

2.4.4 Summary of the applicant pharmacovigilance system

Qualified person in the EEA for Pharmacovigilance

Copy contact details from 2.4.2 Section

Add Selected



Member State(s) Belgium

Member State(s) Bulgaria

Member State(s) Czech Republic

Member State(s) Germany

Member State(s) Estonia

Member State(s) Spain

Member State(s) France

Member State(s) Lithuania

Member State(s) Luxembourg

Member State(s) Latvia

Member State(s) Netherlands

Member State(s) Poland

Member State(s) Portugal

Member State(s) Romania

Member State(s) Slovenia

Member State(s) Slovakia

Member State(s) Denmark

Title MD,PhD,MBA

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

24 H Telephone

Telefax

E-mail

The above-mentioned qualified person resides⁶ and operates in the EEA

The qualified person is registered with Eudravigilance

Copy contact details from 2.4.2 Section

Pharmacovigilance system master file

Number

Address 1

Address 2

Postcode

Country

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

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

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

Add Selected



European Union/Member State where application is made Denmark

Name of the contact person

Title MD, PhD

First name

Surname

Company name Valeant sp. z o.o. sp. j.

Address 1 Al. Szucha 13/15

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

Postcode 00-580

Country Poland

Telephone +48 22203

Telefax +48 22203

E-mail @valeant.com

Add Selected



European Union/Member State where application is made Bulgaria

Name of the contact person

Title Ms.

First name

Surname

Company name PharmaSwiss EOOD

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

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

Postcode 1612

Country Bulgaria

Telephone

Telefax

E-mail @valeant.com

Add Selected



European Union/Member State where application is made Czech Republic

Name of the contact person

Title Ms.

First name

Surname

Company name PharmaSwiss Česká republika s.r.o.

Address 1 Jankovcova 1569/2c
Address 2 Prague 7
(name of: city, town, village, etc)
Postcode 170 00
Country Czech Republic
Telephone
Telefax
E-mail @valeant.com

Add Selected



European Union/Member State where application is made Belgium

European Union/Member State where application is made Luxembourg

European Union/Member State where application is made Netherlands

Name of the contact person

Title Ms.

First name

Surname

Company name Bausch&Lomb Pharma

Address 1 Bvd Lambermontlaan 430

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

Postcode 1030

Country Belgium

Telephone 00 32496

Telefax -

E-mail regulatory.benelux@bausch.com

Add Selected



European Union/Member State where application is made Germany

Name of the contact person

Title Mr.

First name

Surname

Company name Dr. Gerhard Mann chem.-pharm. Fabrik GmbH

Address 1 Brunsbütteler Damm 165-173

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

Postcode 13581

Country Germany

Telephone +49 30 330

Telefax -

E-mail @bausch.com

Add Selected



European Union/Member State where application is made Estonia

Name of the contact person

Title Mr.

First name

Surname

Company name PharmaSwiss Eesti OÜ

Address 1 Tammsaare tee 47

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

Postcode 11316

Country Estonia

Telephone +372

Telefax -

E-mail @valeant.com

Add Selected



European Union/Member State where application is made Spain

Name of the contact person

Title Mrs.

First name

Surname

Company name Bausch & Lomb S.A.

Address 1 Avda. Valdelaparra 4.

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

Postcode 28108

Country Spain

Telephone (+34) 91 657

Telefax -

E-mail @bausch.com

Add Selected



European Union/Member State where application is made France

Name of the contact person

Title Mrs.

First name

Surname

Company name Laboratoire Chauvin

Address 1 416 rue Samuel Morse - CS 99535
Address 2 Montpellier Cedex 2
(name of: city, town, village, etc)
Postcode 34961
Country France
Telephone + 33(0)4 67
Telefax + 33 (0)4 67
E-mail @bausch.com

Add Selected



European Union/Member State where application is made Lithuania

Name of the contact person

Title Mr.

First name

Surname

Company name UAB "PharmaSwiss"

Address 1 Šeimyniškių 21B

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

Postcode LT - 09200

Country Lithuania

Telephone

Telefax

E-mail @valeant.com

Add Selected



European Union/Member State where application is made Latvia

Name of the contact person

Title Ms.

First name

Surname

Company name SIA PharmaSwiss Latvia

Address 1 Blaumaņa iela 5a-8

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

Postcode LV-1011

Country Latvia

Telephone + 371 254

Telefax + 371 675

E-mail @valeant.com

Add Selected



European Union/Member State where application is made Poland

Name of the contact person

Title Mr.

First name

Surname

Company name Al. Szucha 13/15 Str.

Address 1 Marynarska 15

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

Postcode 00-580

Country Poland

Telephone +48 22

Telefax +48 22

E-mail @valeant.com

Add Selected



European Union/Member State where application is made Portugal

Name of the contact person

Title Mrs.

First name

Surname

Company name Bausch & Lomb S.A.

Address 1 Avda. Valdelaparra 4.

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

Postcode 28108

Country Spain

Telephone (+34) 91

Telefax -

E-mail @bausch.com

Add Selected



European Union/Member State where application is made Romania

Name of the contact person

Title Mrs.

First name

Surname

Company name Valeant Pharma SRL

Address 1	Maria Rosetti street, no 6, 7th floor, District 2
Address 2	Bucharest <i>(name of: city, town, village, etc)</i>
Postcode	020485
Country	Romania
Telephone	
Telefax	
E-mail	@valeant.com

Add Selected ?

European Union/Member State where application is made Slovenia

Name of the contact person

Title	Mrs.
First name	
Surname	
Company name	PharmaSwiss d.o.o.
Address 1	Brodišče 32
Address 2	Trzin <i>(name of: city, town, village, etc)</i>
Postcode	1236
Country	Slovenia
Telephone	00386
Telefax	00386
E-mail	@valeant.com

Add Selected ?

European Union/Member State where application is made Slovakia

Name of the contact person

Title	Mrs.
First name	
Surname	
Company name	Valeant Slovakia s.r.o.
Address 1	Galvaniho 7/B
Address 2	Bratislava <i>(name of: city, town, village, etc)</i>
Postcode	821 04
Country	Slovakia
Telephone	+ 421 2 3233
Telefax	-
E-mail	@valeant.com

2.5 MANUFACTURERS

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

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

all pack sizes

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

Company name	EXCELVISION
Address 1	27 rue de la Lombardière
Address 2	ZI La Lombardière, ANNONAY <i>(name of: city, town, village, etc)</i>
Postcode	07100
Country	France
Telephone	04.75.32.
Telefax	04.75.32.
E-mail	@fareva.com

Manufacturing Authorisation number M 16/014

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

Or

Enter EudraGMP manufacturing authorisation reference

If available

Attach latest GMP certificate (Annex 5.9)

Or

Enter EudraGMP certificate reference number

all pack sizes

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

Company name	Pharmathen S.A.
Address 1	6, Dervenakion str.
Address 2	Pallini, Attiki <i>(name of: city, town, village, etc)</i>
Postcode	153 51
Country	Greece
Telephone	+30 210
Telefax	+30 210
E-mail	info@pharmathen.com

Manufacturing Authorisation number 0000006501/15/1

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

Or

Enter EudraGMP manufacturing authorisation reference

If available

Attach latest GMP certificate (Annex 5.9)

Or

Enter EudraGMP certificate reference number

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

Laboratory name

Address 1

Address 2

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

Postcode

Country

Telephone

Telefax

E-mail

- 2.5.1.1 Contact person in the EEA for product defects and recalls

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

Title -

First name

Surname

Address 1 Jankovcova 1569/2c

Address 2 Prague 7

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

Postcode 170 00

Country Czech Republic

24 H Telephone: +420 702

Telefax -

E-mail @valeant.com

Company name Laboratoire Chauvin

Title -

First name

Surname

Address 1 416 rue Samuel Morse CS 99535

Address 2 Montpellier Cedex 2

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

Postcode 34961

Country France

24 H Telephone: +33 601

Telefax -

E-mail @bausch.com

2.5.1.2 Batch control Testing arrangements

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

Company name EXCELVISION

Address 1 27 rue de la Lombardière

Address 2 ZI La Lombardière, ANNONAY
(name of: city, town, village, etc)

Postcode 07100

Country France

Telephone 04.75.32.

Telefax 04.75.32.

E-mail @fareva.com

Brief description of control tests carried out by the laboratory(ies) concerned

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

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

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

Or

Enter EudraGMP manufacturing authorisation reference

Company name Pharmathen S.A.

Address 1 6, Dervenakion str.

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

Postcode 153 51

Country Greece

Telephone +30 210 6665

Telefax +30 210 6666

E-mail info@pharmathen.com

Brief description of control tests carried out by the laboratory(ies) concerned

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

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

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

Or

Enter EudraGMP manufacturing authorisation reference

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

Copy contact details from 2.5.1.a

bottle with solution

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

Company name	EXCELVISION
Address 1	27 rue de la Lombardière
Address 2	ZI La Lombardière, ANNONAY <i>(name of: city, town, village, etc)</i>
Postcode	07100
Country	France
Telephone	04.75.32.
Telefax	04.75.32.
E-mail	@fareva.com

Brief description of functions performed:

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

Processing of sterile medicinal product - aseptically prepared

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

Primary packaging

Secondary packaging

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

Manufacturing authorisation number M 16/014

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

Or

Enter EudraGMP Manufacturing Authorisation reference

Name of qualified person

(if not mentioned in manufacturing authorisation)

bottle with solution

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

Company name	Pharmathen S.A.
Address 1	6, Dervenakion str.
Address 2	Pallini, Attiki <i>(name of: city, town, village, etc)</i>
Postcode	153 51
Country	Greece
Telephone	+30 210 6665
Telefax	+30 210 6666
E-mail	info@pharmathen.com

Brief description of functions performed:

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

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - sterility

Secondary packaging

Site(s) is in the EEA: Site(s) is outside the EEA:

Manufacturing authorisation number 0000006501/15/1

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

Or

**Enter EudraGMP Manufacturing
Authorisation reference**

Name of qualified person

(if not mentioned in manufacturing authorisation)

bottle with solution

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

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Brief description of functions performed:

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

Secondary packaging

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
Authorisation reference**

Name of qualified person

(if not mentioned in manufacturing authorisation)

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

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

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

Copy contact details from 2.5.1.a

Copy contact details from Declaration Section

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

Active Substance	+
BIMATOPROST	-

Do you have a separate admin and manufacturer address?

Yes

No

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

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

Active substance intermediate physical processing

Active substance physical processing

Manufacture of active substance intermediate by chemical synthesis

Manufacture of active substance by chemical synthesis

Quality Control Testing - Chemical/Physical

Quality Control Testing - Microbiological - non-sterility

Primary Packaging of active substance

Secondary Packaging of active substance

Storage and/or distribution of active substance

All manufacturing and testing steps of the active substance.

Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control sites

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

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

Yes No

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

Yes No

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 No

Name of the ASMF holder

Name of the manufacturer if different from above

EU ASMF reference number if available

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

Applicant part version number

Date of submission

Date of last update

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

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

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

Yes **No**

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

Active Substance	
TIMOLOL MALEATE	<input type="button" value="+"/> <input type="button" value="-"/>

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

Company name

Admin Office Address

1

Admin Office Address

2

Postcode

Admin Office Country

Admin Office Telephone

Admin Office Telefax n/a

Admin Office E-mail

Company name
Manufacturing Facility Address 1
Manufacturing Facility Address 2

Postcode
Manufacturing Facility Country
Manufacturing Facility Telephone
Manufacturing Facility Telefax
Manufacturing Facility E-mail

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

- Active substance intermediate physical processing
- Active substance physical processing
- Manufacture of active substance intermediate by chemical synthesis
- Manufacture of active substance by chemical synthesis
- Quality Control Testing - Chemical/Physical
- Quality Control Testing - Microbiological - non-sterility
- Primary Packaging of active substance
- Secondary Packaging of active substance
- Storage and/or distribution of active substance

- Attach flow-chart indicating the sequence and activities of the different sites involved in the manufacturing process, including batch control** (Annex 5.9)
- 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 5.9.1)

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

Yes No

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

Yes No

- 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

Name of the CEP holder

Name of the manufacturer if different from the above

CEP number

Date of last update

Provide copy in (Annex 5.10)

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

Yes **No**

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

Yes **No**

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

2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

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

Pharmaceutical Form Eye drops, solution

1

mg/ml

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

Strength

0,3

Units

mg/ml

+ -

Strength

5

Units

mg/ml

+ -

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

Name of active substance

Quantity / Unit

Reference /
Monograph Standard

BIMATOPROST

equal to

mg/ml

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

In house

TIMOLOL MALEATE

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.

TIMOLOL

equivalent to

mg/ml

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

Current Ph. Eur.

+ -

Tonicity agent

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

+ -

Buffering agent-tonicity agent

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+ -
SODIUM PHOSPHATE DIBASIC HEPTAHYDRATE	equal to mg/ml <i>For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002</i>	Current USP	-

+ -

Buffering agent-tonicity agent

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

+ -

Adjust pH

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+ -
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Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
SODIUM HYDROXIDE (1N) AND/OR HYDROCHLORIC ACID (1N)	quantity sufficient pH	Current Ph. Eur.	-

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

			+	-
Diluent				
Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+	
WATER FOR INJECTION	quantity sufficient ml	Current Ph. Eur.	-	

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

Note: * Only one name of each substance should be given in the following order of priority: INN**, Ph.Eur., National Pharmacopoeia, common name, scientific name

** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)

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

Active Substance	Overage	+	Excipient	Overage	+
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2.6.2 List of materials of animal and/or human origin contained or used in the manufacturing process of the medicinal product?

NONE

or specify below:

* *AS=active substance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/culture medium (incl. those used in the preparation of master and working cell banks)*

** *as defined in section 2 (scope) of the CHMP Note for Guidance*

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

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

Yes **No**

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

Yes **No**

3. SCIENTIFIC ADVICE

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

Yes No

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

Yes No

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

4. OTHER MARKETING AUTHORISATION APPLICATIONS

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

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

Yes No Not Applicable

If yes, section 4.2 must be completed

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

Yes No

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

Yes No

If yes, section 4.2 must be completed

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

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

Note: refer to Commission Communications 98/C229/03

- Authorised
- Submitted (which are not considered as a multiple/duplicate application - see Section 4.3)
- Refused
- Withdrawn (by applicant before authorisation)
- Withdrawn (by applicant after authorisation)
- Suspended/revoked (by competent authority)

4.3 FOR MULTIPLE / DUPLICATE APPLICATIONS OF THE SAME MEDICINAL PRODUCT

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

Name of other product Bimatoprost/Timolol Pharmathen
Date of application (s) 2016-09-30
Applicant Pharmathen S.A. (MAH Pharmathen S.A.)
Procedure number for MRP/DCP (if applicable) DK/H/2710/001/DC

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

Name of other product Bimatoprost - Timolol Horus Pharma
Date of application (s) 2016-09-30
Applicant HORUS PHARMA
Procedure number for MRP/DCP (if applicable) DK/H/2712/001/DC

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

Name of other product LENIGRON
Date of application (s) 2016-09-30
Applicant Pharmathen S.A.
Procedure number for MRP/DCP (if applicable) DK/H/2715/001/DC

Attach copy of letter from Commission services, for centralised procedures only

(Annex 5.16)

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

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

5. ANNEXED DOCUMENTS (WHERE APPROPRIATE)

- 5.1 Proof of payment
- 5.2 Informed consent letter of marketing authorisation holder of authorised medicinal product.
- 5.3 Proof of establishment of the applicant in the EEA.
- 5.4 Letter of authorisation for communication on behalf of the applicant/MAH.
- 5.5 (empty)
- 5.6 Manufacturing Authorisation required under Article 40 of Directive 2001/83/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply); any proof of authorisation in accordance with Article 8.3(k) of Directive 2001/83/EC.
- 5.7 Copy of the "Qualification of SME Status".
- 5.8 Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance.
- 5.9 GMP certificate(s) or other GMP statement(s); Where applicable a summary of other GMP inspections performed.
- 5.10 Letter(s) of access to Active Substance Master File(s) or copy of ph. Eur. Certificate(s) of Suitability.
- 5.11 Copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex I of Directive 2001/83/EC.
- 5.12 Ph. Eur. Certificate(s) of suitability for TSE.
- 5.13 Written consent(s) of the competent authorities regarding GMO release in the environment.
- 5.14 Scientific Advice given by CHMP and/or by member state(s).
- 5.15 Copy of Marketing Authorization(s) required under Article 8(j)-(L) of Directive 2001/83/EC in the EEA and the equivalent in third countries on request (a photocopy of the pages which give the marketing authorization number, the date of authorisation and the page which has been signed by the authorizing competent authority will suffice).
- 5.16 Letter by Commission services regarding multiple applications.
- 5.17 List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDh websites).
- 5.18 Copy of the Orphan Designation Decision.
- 5.19 List of proposed (invented) names and marketing authorisation holders in the concerned member states.
- 5.20 Copy of EMA certificate for a Vaccine Antigen Master File(VAMF).
- 5.21 Copy of EMA certificate for a Plasma Master File (PMF).
- 5.22 For each active substance, attach a declaration(s) from the Qualified Person of the manufacturing authorisation holder in Section 2.5.1 and from the Qualified Person of the manufacturing authorisation holders (i.e located in EEA) listed in Section 2.5.2 where the active substance is used as a starting material that the active substance is manufactured in compliance with the principles and guidelines of good manufacturing practice for starting materials. Alternatively, such declaration may be signed by one Qualified Person on behalf of all QPs involved (provided this is clearly indicated). The declaration should refer to an audit and the date of the audit.
- 5.23 Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 8(3) of Directive 2001/83/EC.

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