EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation

eAF Version Number: 1.23.1.0

Revision 13

NOTICE TO APPLICANTS

Medicinal Products for Human Use

VOLUME 2B
Module 1.2: Administrative information
Application form

February 2018

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:
As from 01/01/2016, mandatory use of electronic application forms for all procedures. This document is for information purposes only. Not to be used for submissions.

Revision 13
Update from February 2018.

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

TABLE OF CONTENTS

APPLICATION FORM

SUMMARY OF THE DOSSIER

APPLICATION FORM : ADMINISTRATIVE DATA

For all applications 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 and for submissions to the European Medicines Agency under the centralised procedure use the electronic Application form available from http://esubmission.ema.europa.eu/eaf/index.html.

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

DECLARATION AND SIGNATURE

Product (invented) name please refer to annex 5.19

Pharmaceutical form (s): Solution for injection in pre-filled pen

Strength:	Units
20/80	µg/µl

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

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Full name of the active substance(s) (including salt or hydrate, if applicable):
TERIPARATIDE

OK Clear Cancel

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Applicant	Welding GmbH & Co KG
Address	Esplanade 39
	Neustadt
City/Locality/Town/ Village	Hamburg
Postcode	20354
Country	Germany
OrgID	ORG-100001055
LocID	LOC-100004659
Telephone	+49 40 35908 243
E-mail	dra@welding.eu

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	Dr.
First name*	Christian
Surname	Wilde
Function	Manager Regulatory Affairs

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Welding GmbH & Co KG
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Postcode	20354
Country	Germany
OrgID	ORG-100001055
LocID	LOC-100004659
Telephone	+49 40 35908 243
E-mail	dra@welding.eu

Date
2019-02-01

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	Germany
Procedure number:	DE/H/6160/001/DC
Concerned Member State (specify)	France
Proposed/Agreed common renewal date	5 years after end of DCP

◯ **1.1.4 A NATIONAL PROCEDURE**

1.2 ORPHAN MEDICINAL PRODUCT DESIGNATION

1.2.1 HAS ORPHAN DESIGNATION BEEN APPLIED FOR THIS MEDICINAL PRODUCT?

◯ **Yes** ◉ **No**

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

◯ **Yes** ◉ **No**

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

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

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

Note: Section to be completed for any application, including applications referred to in section 1.3
For further details, refer to Notice of Applicants, Volume 2A, Chapter 1
information on active substance status (new/known) should be provided in section 2.1.2

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**

Note: . application for a generic medicinal product as defined in Article 10(2)(b) referring to a so-called reference medicinal product with a marketing authorisation granted in a Member State or in the Community.
. complete administrative and quality data, appropriate pre-clinical and clinical data when applicable.
. 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 6/8/10 years in the EEA:**

Product (invented) name	Forsteo
Pharmaceutical form(s)	Solution for injection + −

Strength (s)	Units	Marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation
250	µg/ml	Eli Lilly	EU/1/03/247/001-2		2003-06-09

Marketing authorisation granted by

☒ **Union**

☐ **Member State(EEA)**

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

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

Member State(s) European Union

Product (invented) name Forsteo

Pharmaceutical form(s) Solution for injection

Strength (s)	Units	Marketing authorisation holder (note 1)	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)
250	µg/ml	Eli Lilly	EU/1/03/247/001-2	

Marketing authorisation granted by

☒ **Union**

☐ **Member State(EEA)**

Note 1: Should be considered the "same" as the one identified above, as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licencees")

■ **Medicinal product which is or has been authorised in accordance with Union provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:**

Note: Should be in accordance with the notion of global marketing authorisation, if different from the medicinal product identified above..

Product (invented) name

Pharmaceutical form(s)

Strength (s)	Units	Marketing authorisation holder (note 1)	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation

Member State of source

Bioavailabilty study(ies) reference number(s)/EudraCT numbers(s):

Marketing authorisation granted by

☐ **Union**

☐ **Member State(EEA)**

Note: Section to be duplicated for each product used for the demonstration of bioequivalence.

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

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

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

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

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

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

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

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

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

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

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

1.5.1 ◯ **Conditional Approval**

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

1.5.2 ◯ **Exceptional Circumstances**

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

1.5.3 ☐ **Accelerated Review**

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

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

(one year of market protection for a new indication)

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

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

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

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

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

(Note: Also applies to Extension applications of PUMA)

1.6.5 HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

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

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S) AND ATC CODE

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

please refer to annex 5.19

(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 Active substance(s)

*Note: * active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field:*

Name should be based on the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name.*

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

Full name of the active substance(s) (including salt or hydrate, if applicable)	+
TERIPARATIDE	
Base/active moiety of the active substance(s) (if different from above)	−

Substance type : (e.g. chemical substance, recombinant biological Peptide (chemically synthesised)

For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC :

◯ **Claim for new active substance(s)**

Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)

☐ ***please provide evidence and justification to support the claim of new active substance status in annex 5.23***

◉ **Known active substance**

2.1.3 Pharmacotherapeutic group (Please use current ATC code)

ATC code H05AA02

Group Calcium homeostasis, parathyroid hormones and 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.)

Pharmaceutical Form: Solution for injection in pre-filled pen + −

Strength:	**Units**
20/80	µg/µl

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

*Note: * for active substances presented in the form of salt or hydrate, the expression of strength should be based on base/active moiety*

Active substance(s) (as used for expression of strength*)	+

TERIPARATIDE

OK Clear Cancel

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

Route of Administration	Subcutaneous 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 pen

2.2.3.1 Package size 3 pens

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

Description
pre-filled cartridge in disposable pen device

For each container give:

Container	Cartridge
Material	siliconised Type I glass
Closure	plunger
Administration Device	Administration system

2.2.3.2 Proposed shelf life 36 Months

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

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

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

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

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

2.2.3.5 Proposed storage conditions
Store in a refrigerator (2°C – 8°C)

2.2.3.6 Proposed storage conditions after first opening
Store in a refrigerator (2°C – 8°C)

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

2.2.4 Medical devices

Does this application include 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 intended to administer a medicinal product?

☐ **No** ☒ **Yes**

If yes, does this medical device and the medicinal product form a single integral product, which is intended exclusively for use in the given combination and which is not reusable?

☐ **No** ☒ **Yes**

Note: If no, CE marking of the device is mandatory. If yes, CE marking of the device is optional. Further details must be provided in sections 2.2.4.3 and 2.2.4.4

2.2.4.1 Device(s) identification

Name of the device(s) disposable pen

Brief description of the device disposable pen consists of a front sub assembly (consisting of cap and cartridge holder) as well as a rear sub assembly (consisting of dose meachmism)

Serial numbers or other indications necessary to delimit precisely the device(s) incorporated

not applicable

2.2.4.2 Manufacturer of the device(for manufacturers outside the EEA, please add the authorised representative)

Name of contact person

Title

First name

Surname

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

State

County

Postcode

Country

Telephone

E-mail

2.2.4.3 CE mark

Does the device(s) have a CE mark?

◯ **Yes** ◉ **No**

If yes, please add the Manufacturer's declaration of conformity in module 3.2.R of the EU-CTD

2.2.4.4 Notified Body

Is the device(s) covered by certificates issued by a Notified Body?

◯ **Yes** ◉ **No**

If yes, please add the certificate(s) in module 3.2.R of the EU-CTD

Please indicate for each Notified Body involved:
(For combined ATMPs, identify a Notified Body in any case)

Name of the Notified Body

Notified Body number

Name of contact person

Title

First name

Surname

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

State

County

Postcode

Country

Telephone

E-mail

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)***

Add Selected

European Union/Member State Germany

European Union/Member State	France

☐ **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	Germany
Member State	France

☐ **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 Member State

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

Copy contact details from Declaration Section

Add Selected ?

Member State	Germany
Member State	France

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name	Welding GmbH & Co KG
Address	Esplanade 39
	Neustadt
City/Locality/Town/ Village	Hamburg
Postcode	20354
Country	Germany
OrgID	ORG-100001055
LocID	LOC-100004659
Telephone	+49 40 35908 243
E-mail	dra@welding.eu

☒ **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)

VAT number	DE118950828
Company name	Welding GmbH & Co. KG
Address	Esplanade 39
City/Locality/Town/ Village	Hamburg
State	
County	
Postcode	20354
Country	Germany
Telephone	+ 49 40 35908243
E-mail	dra@welding.eu
Purchase order(PO) number	

◉ **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 Member State

Add Selected ?

Member State(s)	Germany
Member State(s)	France

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

Copy contact details from Declaration Section

Title	Dr.
First name	Christian
Surname	Wilde

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

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E-mail	dra@welding.eu

☐ **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 Member State

Add Selected ?

Member State(s)	Germany
Member State(s)	France

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

Copy contact details from Declaration Section

Title	
First name	
Surname	

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

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Telephone	+49 40 35908 243
E-mail	dra@welding.eu

☐ **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

Add Selected

Member State(s)	Germany
Member State(s)	France

Title

First name

Surname

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

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Country	Germany
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LocID	LOC-100004659
24 H Telephone	+49 40 35908 250
E-mail	dra@welding.eu

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

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

Pharmacovigilance system master file

Number MFL3816

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

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Address	Esplanade 39
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City/Locality/Town/ Village	Hamburg
Postcode	20354
Country	Germany
OrgID	ORG-100001055
LocID	LOC-100004659

☒ **The Pharmacovigilance system master file location has been registered in Article 57 database**

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 Germany

European Union/Member State where application is made France

Name of the contact person

Title

First name

Surname

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

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OrgID	ORG-100001055
LocID	LOC-100004659
Telephone	+49 40 35908 151
E-mail	dra@welding.eu

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):

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

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/Village

County

Postcode

Country

OrgID

LocID

Telephone

E-mail

Manufacturing Authorisation number

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

Or

☐ **Enter EudraGDMP document reference number**

If available

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

Or

☐ **Enter EudraGDMP document 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

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

State

County

Postcode

Country

Telephone

E-mail

2.5.1.1 Contact person in the EEA for product defects and recalls

Title	Dr.
First name	Jens
Surname	Kemken

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
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24 H Telephone:	+49 40 35908 151
E-mail	dra@welding.eu

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:

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

Postcode

Country

OrgID

LocID

Telephone

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 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

Control of drug product (identification, assay, m-cresol content, related substances)

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

Or

☐ **Enter EudraGDMP document reference number**

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

State

County

Postcode

Country

Telephone

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 pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Quality Control Testing - Microbiological - sterility

Control of drug product (endotoxins and sterility)

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

Or

☐ **Enter EudraGDMP document reference number**

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

Postcode

Country

OrgID

LocID

Telephone

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 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

Control of drug product (appearance, clarity, coloration of solution, particulate matter, pH, extractable volume, integrity of cartridge, dose accuracy, sterility)

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

Or

☐ **Enter EudraGDMP document reference number**

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.)

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

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/Village

State

County

Postcode

Country

Telephone

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

Primary packaging

Processing of sterile medicinal product - aseptically prepared

Sterilisation - Filtration

Bulk product manufacturing and primary packaging (drug substance control [identity, appearance], compounding of product solution, sterile filtration and filling of cartridges)

◉ **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 EudraGDMP document reference number

Name of qualified person

(if not mentioned in manufacturing authorisation)

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

Please select organisation from SPOR OMS to autofill address details.
If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information:
http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/Village

County

Postcode

Country

OrgID

LocID

Telephone

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

Secondary packaging incl. assembly of pre-filled cartridges and pen parts

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

Manufacturing authorisation number MIA 1084

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

Or

Enter EudraGDMP document reference number

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.

(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	+
TERIPARATIDE	−

Copy contact details from Declaration Section

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

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/Village

Postcode

Country

OrgID

LocID

Telephone

E-mail

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

Manufacture of active substance by chemical synthesis

Quality Control Testing - Chemical/Physical

Manufacture and control 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**

Please

☒ **Attach latest GMP certificate or other proof of GMP compliance (Annex 5.9)**

Or

Enter EudraGMDP document reference number

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

◯ **Yes** ◉ **No**

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

◯ **Yes** ◉ **No**

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

◉ **Yes** ○ **No**

Name of the ASMF holder

Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: http://spor.ema.europa.eu/omswi/#/

Clear Address

Company name

Address

City/Locality/Town/ Village

Postcode

Country

OrgID

LocID

Telephone

E-mail

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 2001/83/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**

2.5.4 Contract companies used for all clinical trial(s) (including bioavailability and bioequivalence trials) included in the application 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)

Dosage form unit to which quantity the composition refers (e.g. 1 capsule)

Pharmaceutical Form Solution for injection in pre-filled pen

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

Strength	**Units**
20/80	µg/µl

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

Name of active substance		Quantity / Unit	Reference / Monograph Standard
TERIPARATIDE For salts and hydrates only, corresponding to (indicate base/active moiety)	equal to	**µg/ml** *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	
		For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002	

Clone

Clone

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
GLACIAL ACETIC ACID BP	equal to µg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph.Eur.	— Clone
SODIUM ACETATE ANHYDROUS	equal to µg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	USP NF	— Clone
MANNITOL	equal to mg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph.Eur.	— Clone
METACRESOL PH.EUR.	equal to µg *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph.Eur.	— Clone
WATER FOR INJECTION PH. EUR.	quantity sufficient µl *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph.Eur.	— Clone
HYDROCHLORIC ACID 0.1 N	quantity sufficient µl *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph.Eur.	— Clone

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
SODIUM HYDROXIDE 0.1 N	quantity sufficient µl *For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002*	Ph.Eur.	− Clone

*Note: * active substance should be indicated first as full substance. If the substance is included in the product as a salt or hydrate, this corresponding base/active moiety should be indicated in the additional field.*

*Name should be based on 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	+

Excipient	Overage	+

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

☒ **NONE**

or specify below:

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

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

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

○ **Yes** ◉ **No**

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

○ **Yes** ◉ **No**

3. SCIENTIFIC ADVICE

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

◯ **Yes** ◉ **No**

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

◉ **Yes** ◯ **No**

Member State	Germany
Date	2015-08-12
Reference(s) of the scientific advice(s)	BfArM_STN

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

4. OTHER MARKETING AUTHORISATION APPLICATIONS

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

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

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

If yes, section 4.2 must be completed

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

◯ **Yes** ◉ **No**

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

◯ **Yes** ◉ **No**

If yes, section 4.2 must be completed

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

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

Note: refer to Commission Communications 98/C229/03

☐ **Authorised**

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

☐ **Refused**

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

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

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

4.3 FOR MULTIPLE / DUPLICATE APPLICATIONS OF THE SAME MEDICINAL PRODUCT

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

Name of other product

Date of application (s)

Applicant

Procedure number for MRP/DCP (if applicable)

☐ **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 proof of GMP complaince; 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 Authorisation(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 authorisation number, the date of authorisation and the page which has been signed by the authorising 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.