

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

<u>The Notice to Applicants - Volume 2B - Common Technical Document - Module1 - Administrative information</u>

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

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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

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

harmaceutical form	Solution for injection in pre-filled pen		(+) (-)
			(+)(-
			(+)(-)
Strength: 20/80	Un i µg/µ	T.	(A)
A(-4- w c			
Note: * for active substance se/active moiety	s presented in the form of salt or hydrate, the exp	oression of strength should	be based on
	s presented in the form of salt or hydrate, the exp		be based on
-			

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/ Hamburg Village 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

Signatory

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 **Address** Esplanade 39 Neustadt City/Locality/Town/ Hamburg Village Postcode 20354 Country Germany OrgID ORG-100001055 LocID LOC-100004659 Telephone +49 40 35908 243 E-mail dra@welding.eu **Date** 2019-02-01

* 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

	Note: The	following sections	should be complet	red where ap	opropriate.				
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	(acco	rding to Regulati	on (EC) No 726,	/2004)					
	1.1.2	2 A MUTUAL RE	COGNITION P	ROCEDUR	RE				
	(acco	rding to Article 2	28(2) of Directi	ve 2001/8	3/EC)				
	1.1.3	A DECENTRA	LISED PROCED	URE					
	(acco	rding to Article 2	8(3) of Directive	es 2001/83	3/EC)				
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	less tha	an 6/8/10 year	rs in the EEA:	been auti	iorised in ac	cordance v	vith Union pro	ovisions in fo	orce for not
								***************************************	7
	Product name	(invented)	Forsteo						
	Pharmace	eutical form(s)	Solution for in	njection				(6	

1.

TYPE OF APPLICATION

Strength (s)	Units	Marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisati on	+
250	µg/ml	Eli Lilly	EU/1/03/247/001-2		2003-06-09	
	uthorisati nion	on granted by				
		tate(EEA)				
I IM						

■ 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) Forsteo name Pharmaceutical form(s) Solution for injection Marketing Marketing Procedure number Strength Units authorisation authorisation for MRP/DCP (if (s) holder (note 1) number applicable) 250 µg/ml Eli Lilly EU/1/03/247/001-2 Marketing authorisation granted by ∪nion 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..



	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	O Marion 200 miles med 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	- The state of the
	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	$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $
	(Note: Also applies to Extension applications of PUMA)
1.6.5	HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION?

MARKETING AUTHORISATION APPLICATION PARTICULARS 2.

2.1 NAME(S) AND ATC CODE

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

please refer to annex 5.19

(Value populated from the "Declaration" section.)

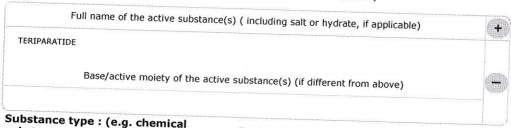
If different (invented) names in different Member States are proposed in a mutual recognition or decentralised procedure, these should be listed in (Annex 5.19)

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 molety 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.)



Substance type : (e.g. chemical substance, recombinant biological

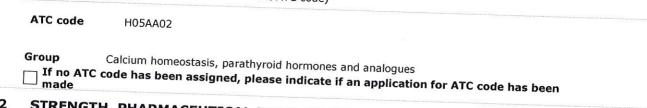
Peptide (chemically synthesised)

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

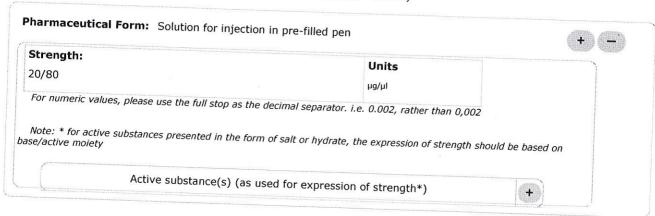
- please provide evidence and justification to support the claim of new active substance status in annex 5.23
- Known active substance
- 2.1.3 Pharmacotherapeutic group (Please use current ATC code)



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

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.)



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	OK Clear Cano	el
oute(s) of administrat	ion (use current list of standard terms - Europ	ean Pharmacopoeia)
Route of Administration	on Subcutaneous use	
ontainer, closure and a urrent list of standard (administration device(s), including description terms - European Pharmacopoeia)	of material from which it is constructed
For each type of pack	divo	
2.2.3.1 Package size		
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2.2.3.1 Package siz		
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For each container gi	ve:	_
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	☐ Attach a list of Mock-ups or Samples/specimens sent with the CMDh website) (Annex 5.17)	ne application, as appropriate (see EMA/
Does or m	Medical devices s this application include one or more medical devices within the meaning nore active implantable medical devices within the meaning of Article 1(2) inister a medicinal product?	of Article 1(2)(a) of Directive 93/42/EEC or one (c) of Directive 90/385/EEC intended to
	No Yes	
If yes use ii	s, does this medical device and the medicinal product form a single integr n the given combination and which is not reusable?	al product, which is intended exclusively for
	No 🔀 Yes	
Note: 2.2.4.	If no, CE marking of the device is mandatory. If yes, CE marking of the device is on 3 and 2.2.4.4	tional. Further details must be provided in sections
2.2.4.	.1 Device(s) identification	
	Name of the device (c) discountly	+ -
	Name of the device(s) disposable pen	
	Brief description of the device disposable pen consists of a front sub assem cartridge holder) as well as a rear sub assem meachmism)	bly (consisting of cap and bly (consisting of dose
2.2.4.	Serial numbers or other indications necessary to delimit precise not applicable 2 Manufacturer of the device(for manufacturers outside the EEA, please a	
		+ -
	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
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County Postcode Country Telephone E-mail

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Is th	e device(s) covered by cer	tificates issued by a Notifie	d Body?	
1 Not	fied Body			
II ye	s, please and the Manurac	turer's declaration of confo	rmity in module 3.2.R	of the EU-CTI
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	Not subject to me	dical prescription (Con	nplete 2.3.3 & 2.3.4)		/	
2.3.2	For products subject to	medicinal prescription				
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2.4	MARKETING AUT	HORISATION HOL	DER / CONTACT	PERSONS /	COMPANY	
2.4.1	Proposed marketing author European Union/each Mer	orisation holder/person l	egally responsible for p	placing the produc	t on the market in t	he
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		Neustadt			***************************************	
	City/Locality/Town/ Village	Hamburg				
1	Postcode	20354				
1000	Country	Germany				
	OrgID	ORG-100001055				
	LocID	LOC-100004659				
100	Telephone	+49 40 35908 243				
	E-mail	dra@welding.eu			The state of the s	

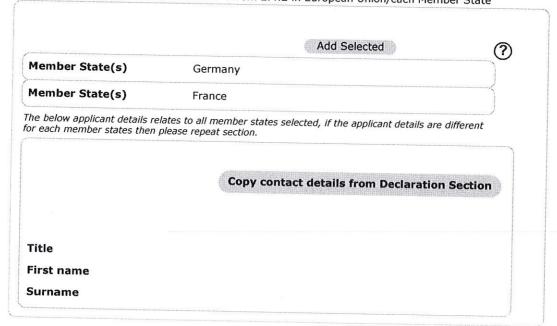
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2.4.2

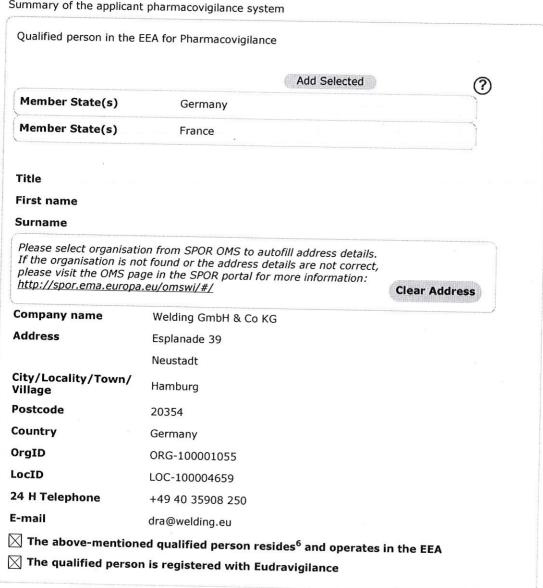
The below applicant details relates to all member states selected, if the applicant details are different for each member states then please repeat section. Copy contact details from Declaration Section Title Dr. First name Christian Surname Wilde Please select organisation from SPOR OMS to autofill 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/#/ Clear Address Company name Welding GmbH & Co KG Address Esplanade 39 Neustadt City/Locality/Town/ Hamburg Village **Postcode** 20354 Country Germany OrgID ORG-100001055 LocID LOC-100004659 **Telephone** +49 40 35908 243 E-mail dra@welding.eu If different to 2.4.1 above, attach letter of authorisation (Annex 5.4)

2.4.3 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



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/ Hamburg Village Postcode 20354 Country Germany OrgID ORG-100001055 LocID LOC-100004659 **Telephone** +49 40 35908 243 dra@welding.eu If different to 2.4.1 above, attach letter of (Annex 5.4) authorisation

2.4.4 Summary of the applicant pharmacovigilance system



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 Company name Welding GmbH & Co KG **Address** Esplanade 39 Neustadt City/Locality/Town/ Hamburg Village **Postcode** 20354 Country Germany OrgID ORG-100001055 LocID LOC-100004659 igwedge The Pharmacovigilance system master file location has been registered in Article 57 database

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

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

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

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.

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 Welding GmbH & Co KG Company name **Address** Esplanade 39 Neustadt City/Locality/Town/ Hamburg Village **Postcode** 20354 Country Germany 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 manufacture	r address? (Yes	No	
Please select organisation from SPOR OMS to at If the organisation is not found or the address of please visit the OMS page in the SPOR portal fo http://spor.ema.europa.eu/omswi/#/	letails are not correc	t,	Address	
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anufacturing Authorisation number				
Attach copy of manufacturing authorisation	m(a) (A			
	m(s) (Annex 5.6))		
	nber			

[Attach latest GMP certificate (Annex 5.9)	
(Or Control of the Con	
[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: 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

24 H Telephone:

+49 40 35908 151

E-mail

dra@welding.eu

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) \bowtie 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

2.5.1.2 Batch control Testing arrangements

	ol Testing - Microbiolo	uurai guideiine/2009/10/\	orisation): http://www.em WC500004706.pdf	
/		-		
Control of drug	product (endotoxins	and sterility)		₹
Attach cop	y of manufacturing	authorisation(s) or	other proof of GMP	/
∽ complianc o Or	,			(Annex 5.6)
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Address	-			
City/Locality/ Village	「own/			
Postcode				
Country				
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rief description	of control tests carrie	d out by the laboratory	(ies) concerned	
terpretation of the	Union Format for Manu	Procedures on Inspection	s and Exchange of Informa	ation' document, (see pages -
cument library/R	egulatory and procedur	al guideline/2009/10/WC	sation): <u>nttp://www.ema.e</u> 500004706.pdf	uropa.eu/docs/en_GB/
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Attach copy	of manufacturing a	uthorisation(s) or ot	her proof of CMD	
compliance	-		ner proof of GMP	(Annex 5.6)
Enter Eudra	DMP document refe	erence number		
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2.5.2

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2.5.3

Copy contact details from Declaration Section

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) Yes	○ No	
Name of	the ASMF holder	
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n EMA cert	rificate for a Vaccine Antigen Master File (VAMF) issued or sub /83/EC Annex I, Part III, being used for this MAA?	mitted in accordance with
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

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Qualitative and	
6.1	

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

1 +

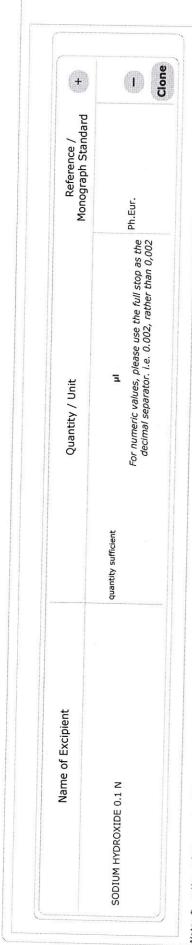
Pharmaceutical Form Solution for injection in pre-filled pen

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

Clone Clone + Reference / Monograph Standard 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 Quantity / Unit Units Іц/вц equal to List the active substance(s) separately from the excipient(s) For salts and hydrates only, corresponding to (indicate base/active moiety) Name of active substance TERIPARATIDE Strength 20/80

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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

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

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

age	
Overage	
Excipient	

2.6.2	List of materi	als of animal and/or human origin contained or used in the manufacturing process of the medicinal product
	NONE	product
	or specify bel	ow:
	* AS=active su culture medi ** as defined in	ubstance, EX=excipient (incl. starting materials used in the manufacture of the active substance/excipient), R=reagent/ ium (incl. those used in the preparation of master and working cell banks) section 2 (scope) of the CHMP Note for Guidance
	☐ If a Ph. E Council o	Eur. Certificate of suitability for TSE is available according to the Resolution AP/CSP(99)4 of the furope attach it in (Annex 5.12)
2.6.3	Is an EMA cert I, Part III, bei	tificate for a Plasma Master File (PMF) issued or submitted in accordance with Directive 2001/83/EC Annex
2.6.4	Does the medi 2001/18/EC?	icinal product contain or consist of Genetically Modified Organisms (GMOs) within the meaning of Directive
	○ Yes	● No

3. SCIENTIFIC ADVICE

○ Yes	No	c advice(s) given by EMA for this medicinal product?	
Was there s	cientific advice	(s) given by Member State(s) for this medicinal product?	
Member	State	Comme	
Member :	State	Germany 2015-08-12	

4.1		TIONAL/ ANCE W	MRP/DCP / ITH ARTIC	APPLICATION LE 8(j)-(l) OF	S, PLEASE COMP DIRECTIVE 2001	LETE THE FOLLO	WING IN
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4.1.2	! Is there anoth	ner Member	state(s) where	e an authorisation is	s granted for the same*	* product?	
	○Yes	No			granica for the same	product:	
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OTHER MARKETING AUTHORISATION APPLICATIONS

4.

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.