

Postupak prijave za dobivanje / produženje / izmjenu odobrenja za stavljanje VMP-a u promet u RH

Ksenija Šandor

**Hrvatski veterinarski institut
Odjel za veterinarsko javno zdravstvo
Laboratorij za analizu veterinarsko-medicinskih pripravaka**

Zagreb, 18.03.2016.

UVOD





Informacije i upute

Ministarstvo poljoprivrede, Uprava za veterinarstvo i sigurnost hrane

<http://www.veterinarstvo.hr/default.aspx?id=13>

Hrvatski veterinarski institut

<http://www.veinst.hr/laboratorij-za-analizu-veterinarsko-medicinskih-pripravaka>

Heads of Medicines Agencies

<http://www.hma.eu/160.html>

EudraLex

http://ec.europa.eu/health/documents/eudralex/index_en.htm

Volume 5 Pharmaceutical legislation Medicinal Products for veterinary use

- ❑ Direktive (engl. *Directive*), Uredbe (engl. *Regulation*) i razni drugi propisi poput Smjernica (engl. *Guideline*), Odluka (engl. *Decision*) i sl.

http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm

Volume 6 Notice to Applicants and Regulatory Guidelines for Medicinal products for Veterinary use

- ❑ Volume 6A Procedures for marketing authorisation
- ❑ Volume 6B Presentation and content of the dossier - Notice to Applicants
- ❑ Volume 6C Regulatory Guidelines

http://ec.europa.eu/health/documents/eudralex/vol-6/index_en.htm

VNeeS = Veterinary non-eCTD (hrv. ne-eZTD)

Dokumentacija o VMP-u

- Papirnata kopija
- Tvrdi optički medij (CD ili DVD)
- Eudralink (eudralink@ema.europa.eu)
- Portali: CESP, eSubmission Gateway / Web Client

Uzorci VMP-a

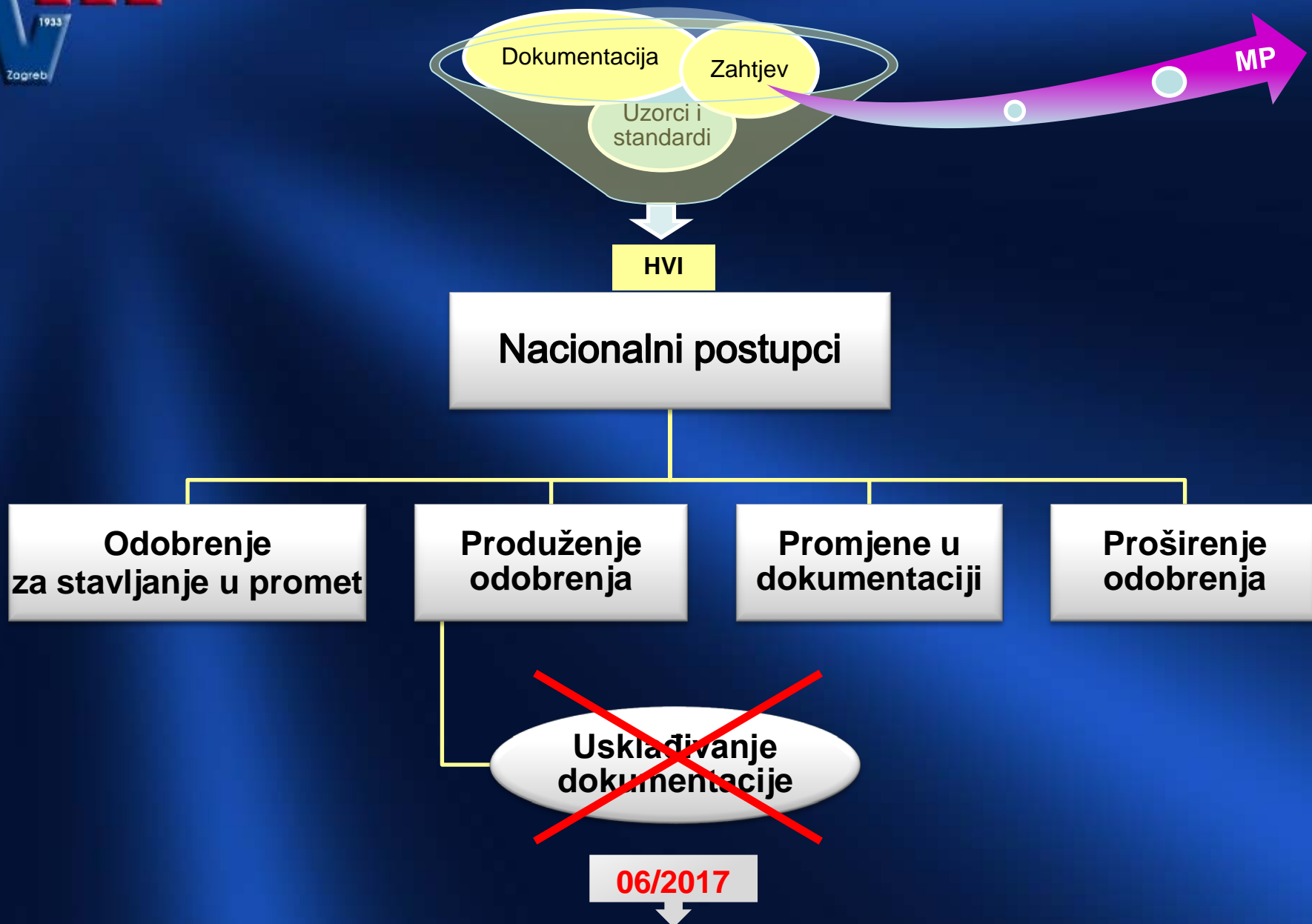
- Najmanje 3 uzorka
- Certifikat analize

Standardi

- Djelatne tvari
- Srodne tvari djelatne tvari
- Nečistoće djelatne tvari
- Pomoćne tvari

```

gtoc.pdf
├── add-info
│   └── cc
├── p1
│   ├── p1-toc.pdf
│   ├── 1a-admin-info
│   ├── 1b-spc-pl
│   ├── 1c-dacs
│   │   ├── 1c1-qual
│   │   ├── 1c2-saf-resid
│   │   └── 1c3-effic
│   └── 1-responses
├── p2
│   ├── p2-toc.pdf
│   ├── 2a-qual-quant-partic
│   ├── 2b-manuf
│   ├── 2c-contr-start-mat
│   │   ├── 2c1-act-sub
│   │   ├── 2c2-excip
│   │   ├── 2c3-cont-clos-sys
│   │   └── 2c4-bio-origin
│   ├── 2d-contr-intermed
│   ├── 2e-tests-fin-prod
│   ├── 2f-stab
│   │   ├── 2f1-act-sub
│   │   └── 2f2-fin-prod
│   └── 2g-other-info
├── p3
│   ├── p3-toc.pdf
│   ├── 3a-saf
│   │   ├── 3a1-ident
│   │   ├── 3a2-pharmacol
│   │   ├── 3a3-tox
│   │   ├── 3a4-other
│   │   ├── 3a5-ura
│   │   └── 3a6-era
│   ├── 3b-resid
│   │   └── 3b1-ident
│   ├── 3b2-metab-resid
│   └── 3b3-resid-analyt-met
└── p4
    ├── p4-toc.pdf
    ├── 4a-preclin
    │   ├── 4a1-pharmacol
    │   ├── 4a2-resist
    │   └── 4a3-tas
    └── 4b-clin
    
```



Europski postupci

Centralizirani postupak
(engl. *Centralised Procedure, CP*)

Decentralizirani postupak
(engl. *Decentralised Procedure, DCP*)

Postupak međusobnog priznavanja
(engl. *Mutual Recognition Procedure, MRP*)

Ponovljeni postupak
(engl. *Repeat Use Procedure, RUP*)

Produženje odobrenja u EU postupku
(engl. *Renewals in EU Procedures*)

Postupak odobravanja promjena
(engl. *Variations, VAR*)

Zajednički postupak odobravanja izmjena
(engl. *Worksharing Procedure, WS*)

Postupak proširenja odobrenja
(engl. *Extension*)

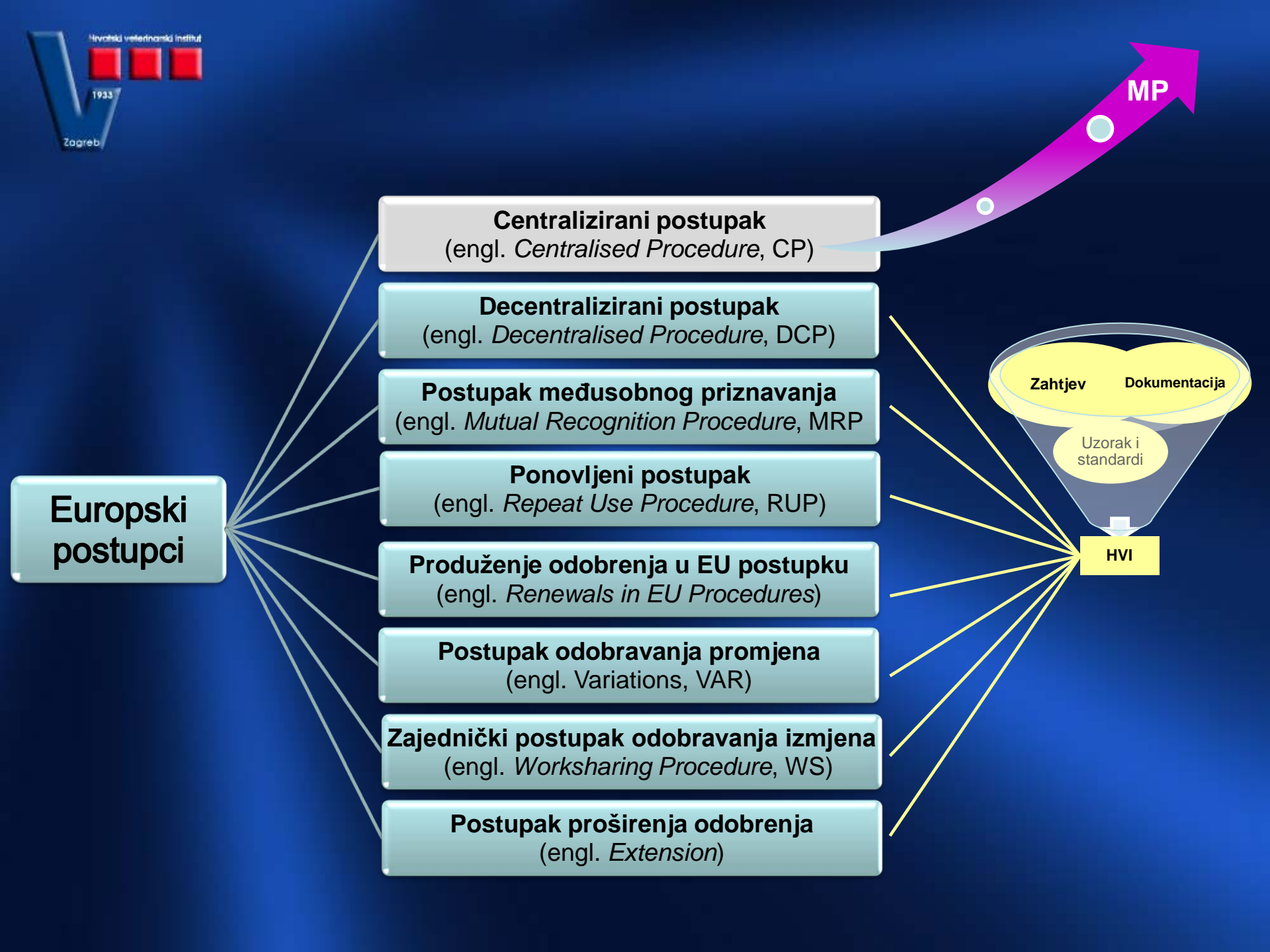
Zahtjev

Dokumentacija

Uzorak i
standardi

HVI

MP



ISPUNJAVANJE PRIJAVE ZA PROCJENU DOKUMENTACIJE

**Obrasci za prijavu
u word dokumentu**
(engl. *Word Application
Forms, wAF*)

**Elektronički
obraci za prijavu**
(engl. *Electronic
Application Forms, eAF*)

**Portal za podnošenje
zahtjeva i dokumentacije**
(engl. *Single Submission
Portal*)

2013 - 2015

2016

2018

- ❑ **eAF obrazac obvezan za sve NP i EU postupke od 01.01.2016.**
- ❑ eAF je dinamičan PDF dokument u formatu obrasca s XML arhitekturom (XFA).
- ❑ XFA-format omogućava provjeru digitalnog potpisa (zaključanog dokumenta) s dva stanja valjanosti podataka, „valjano” i „nevaljano”.
- ❑ eAF osigurava cjelovitost, autentičnost i sprječava zlouporabu dokumenta.
- ❑ Prednosti eAF-a:
 - jednostavno kretanje kroz obrazac i pretraživanje teksta,
 - olakšan unos, izvoz i ekstrahiranje podataka,
 - on-line pristup standardnim izrazima,
 - mogućnost provjere valjanosti podataka,
 - približavanje postupku jedinstvene prijave.

❑ Pregled dokumenata, obrazaca, vodiča i uputa:

<http://esubmission.ema.europa.eu/eaf/index.html>

- ✓ **Harmonised Technical Guidance for Using of Electronic Application Forms (eAF) for human and veterinary medicinal products in the EU**
- ✓ **User Guide For The Electronic Application Form For A Marketing Authorisation (Veterinary)**
- ✓ **eAF – Questions & Answers**

Form	Notice to Applicant Revision	Electronic Forms version 1.19 (effective from the 30th November 2015, Replaces v.1.18 on 11 Jan 2016)	Release Notes version 1.19 (effective from the 30th November 2015)
MAA-Human	Revision 12	MAA-Human Form 23/02/2016 New	MAA-H Release Notes 23/02/2016 New
Variation	Revision June 2015	Variation Form 23/02/2016 New	Variation Release Notes 23/02/2016 New
Renewal	Revision June 2012	Renewal Form 23/02/2016 New	Renewal Release Notes 23/02/2016 New
MAA-Vet	Revision 7.4	MAA-Vet Form 23/02/2016 New	MAA-Vet Release Notes 23/02/2016 New

❑ Tehnički zahtjevi:

- ✓ Adobe Reader / Acrobat program (verzija 10 ili viša)
- ✓ Internetski preglednici: **Internet Explorer**, Mozilla Firefox

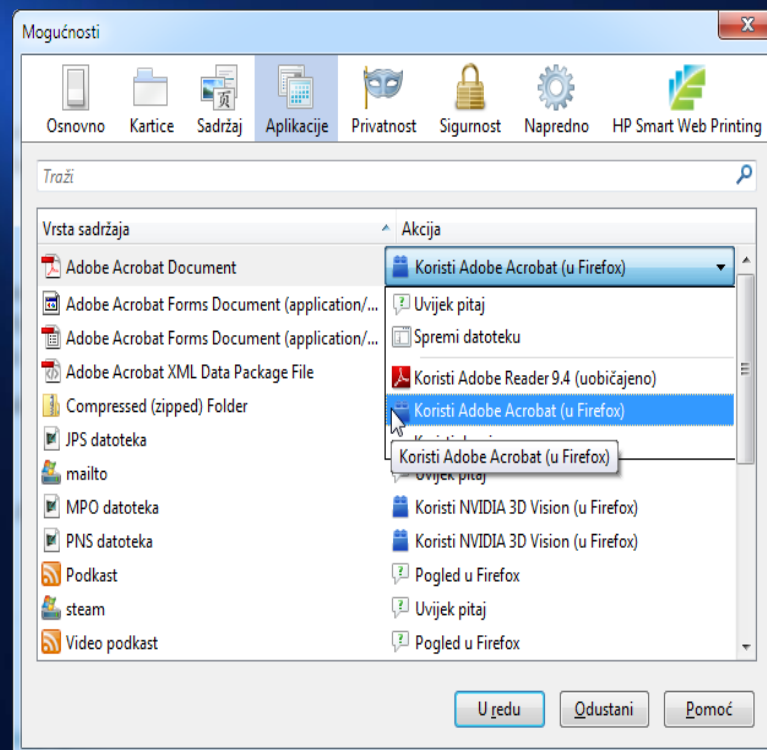
<http://helpx.adobe.com/lifecycle/kb/xf-forms-firefox-chrome.html>

<http://esubmission.ema.europa.eu/eaf/docs/Technical%20User%20Guide%20for%20eAF.pdf>



Mozilla Firefox postavke:

1. Na vrhu Firefox prozora, kliknite na **Alati** **Firefox** izbornik (**Alati** izbornik u Windows XP), i nakon toga kliknite na **Opcije Opcije...**
2. Izaberite panel **Aplikacije** .
3. Nađite Adobe Acrobat Document na listi i kliknite na njega da ga označite.
4. Kliknite na strelicu za otvaranje padajućeg izbornika u stupcu **Akcija** za stavku Adobe Acrobat Document i izaberite **Koristi Adobe Acrobat (u Firefox)**.



- ☐ **Popunjavanje eAF obrasca nije moguće bez internetskog pristupa.**
- ☐ **Otvaranje eAF je sporo zbog očitavanja lista s EUTCT web-servisa.**
- ☐ **Postupak otvaranja eAF-a:**
 - **preuzeti i spremiti eAF u određenu datoteku na računalu**
 - **kod prvog otvaranja eAF-a pojavljuje se upozorenje o sigurnosnom riziku**
 - **odabrati opciju „Trust this document always”.**
- ☐ **Prije zaključavanja obrasca spremiti obrazac i u nezaključanoj formi zbog mogućih intervencija poput prijave promjene istog proizvoda i sl.**

Zahtjev za prijavu dobivanja odobrenja za stavljanje VMP-a u promet

Form	Notice to Applicant Revision	Electronic Forms version 1.19 (effective from the 30th November 2015, Replaces v.1.18 on 11 Jan 2016)	Release Notes version 1.19 (effective from the 30th November 2015)
MAA-Vet	Revision 7.4	MAA-Vet Form 23/02/2016 New	MAA-Vet Release Notes 23/02/2016 New





**EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL**

Consumer goods
Pharmaceuticals

eAF Version Number: 1.19.0.2

Brussels, 01.06.2015

Revision 7.4

NOTICE TO APPLICANTS

Medicinal Products for Veterinary Use

VOLUME 6B

Presentation and content of the dossier-Part 1
Summary of the dossier Part 1A
Application form

June 2015

This application form will be included in:

The Rules governing Veterinary medicinal products in the European Union

The Notice to Applicants - Volume 6B Administrative information

Revision 7.4

Mandatory use of electronic Application Forms for Centralised Procedure

TABLE OF CONTENTS

DECLARATION AND SIGNATURE

otključani obrazac

1. TYPE OF APPLICATION

- 1.1 This application concerns**
- 1.2 Application for a change to your existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) no 1234/2008, or any national legislation**
- 1.3 According to Directive 2001/82/EC¹ or Regulation 726/2004**
- 1.4 Maximum Residue Limit (MRL) status**
- 1.5 Consideration of this application under Article 26(3) of Directive 2001/82/EC, Article 39(7) or Article 39(8) of Regulation 726/2004**

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

- 2.1 Name(s) and ATC vet 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 applications only, please complete the following in accordance with Article 12 of Directive 2001/82/EC**
- 4.2 Marketing authorisation applications for the same product in the EEA**
- 4.3 For multiple/duplicate applications of the same veterinary medicinal product**
- 4.4 Marketing authorisation applications for the same product outside the EEA**

5. ANNEXED Documents (where appropriate)

NOTES

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 veterinary 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 required (information on each pharmaceutical form and strength should be provided successively, where appropriate).

DECLARATION AND SIGNATURE

Product (invented) name

Pharmaceutical Form:

Strength: Units

Active Substance

A/SOLOMON ISLANDS/3/2006 (H1H1) - LIKE STRAIN (A/SOLOMON ISLANDS/3/2006 REASS. IVR-14
ACESULFAME
ACESULFAME POTASSIUM
ALOGUTAMOL
ALPRAZOLAM
AMFEPRAMONE
AMFEPRAMONE HYDROCHLORIDE
AMFEPRAMONE RESINATE
AMMONIA SOLUTION
AMMONIUM CHLORIDE

Populate data in sections 2.1.2, 2.2.1 and 2.6.1

Applicant

Title

First Name

Surname

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

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

Title

First name

Surname

It is hereby confirmed that all existing data which are relevant to the quality, safety and clinical part of the medicinal product have been supplied in the dossier, as appropriate.

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

On behalf of the applicant

Copy contact details from previous section

Title

First name

Surname

Function

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Date

Signatory

Prilog 5.4.
Pismo ovlaštenja za komunikaciju u ime
podnositelja/nositelja odobrenja

* ☐ 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 in the Notice to Applicants, Volume 6A, Chapter 7.

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 32(2) of Directives 2001/82/EC)
- ☒ 1.1.3 A DECENTRALISED PROCEDURE (according to Article 32(3) of Directive 2001/82/EC)
- ☒ 1.1.4 A NATIONAL PROCEDURE

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

- ☒ Yes (complete sections below and also complete 1.4) ☐ No (complete section 1.3 and 1.4.)

1.3 THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC

Note: - section to be completed for any application, including applications referred to in section 1.2
- for further details, consult the Notice of Applicants, Volume 6A, Chapter 1

1.4 MRL STATUS (ONLY FOR FOOD-PRODUCING SPECIES)

When the veterinary medical product is intended for use in food-producing animals, please provide the following information as available at the time of submission of the application¹

Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010

substance(s)		+	-
		+	-
		+	-
Marker residue			
Other Provisions			
Therapeutic classification			
Animal species		+	-
MRL	Target Tissues		

Application for a Maximum Residue Limit has been made to the EMA ☐ Yes ☐ Not applicable

¹All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given.

1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004

- 1.5.1 ☐ Exceptional Circumstances
Note: according to Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) No 726/2004

- 1.5.2 ☐ Accelerated Review
Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)

- 1.5.3 ☐ Article 13(5) of Directive 2001/82/EC (one year of data exclusivity for each extension to another food-producing species within five years of the initial authorisation)

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 32(2) of Directives 2001/82/EC)
- ☐ 1.1.3 A DECENTRALISED PROCEDURE (according to Article 32(3) of Directive 2001/82/EC)
- ☒ 1.1.4 A NATIONAL PROCEDURE

Member state	<input type="text"/>
Application number	<input type="text"/>

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

- ☐ Yes (complete sections below and also complete 1.4) ☒ No (complete section 1.3 and 1.4.)

1.3 THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC

Note: - section to be completed for any application, including applications referred to in section 1.2
- for further details, consult the Notice of Applicants, Volume 6A, Chapter 1

- 1.3.1 ☐ Article 12(3) application, (i.e. dossier with administrative, quality, safety and clinical data*)

*for extensions of complete applications, cross references can only be made to safety and clinical data.

- 1.3.2 ☒ Article 13(1) Generic application

Note: - application for a generic veterinary medicinal product as defined in Article 13(2)(b) referring to a so-called reference veterinary medicinal product with a Marketing authorisation granted in a Member State or in the European Union.
- complete administrative and quality data, appropriate safety and clinical data when applicable see Chapter 1 of Notice to Applicants, Volume 6A

Reference Veterinary 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 Article 12 of Directive 2001/82/EC.

Veterinary 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:

Product (invented) name				<input type="text"/>
Pharmaceutical form(s)				<input type="text"/>
Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Marketing authorisation granted by				
<input type="checkbox"/> Union				
<input type="checkbox"/> Member State(EEA)				

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

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

Product (invented) name				<input type="text"/>
Pharmaceutical form(s)				<input type="text"/>
Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Marketing authorisation granted by				
<input type="checkbox"/> Union				
<input type="checkbox"/> Member State(EEA)				

Veterinary medicinal product which is or has been authorised in accordance with Union provision 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				<input type="text"/>
Pharmaceutical form(s)				<input type="text"/>
Strength(s)	Marketing authorisation holder	Marketing authorisation number	Date of authorisation	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Marketing authorisation granted by				
<input type="checkbox"/> Union				
<input type="checkbox"/> Member State(EEA)				
Member State of source				<input type="text"/>
Bioavailability study(ies) reference number(s)				<input type="text"/>

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

- 1.3.3 ☐ Article 13(3) hybrid application
- 1.3.4 ☐ Article 13(4) Similar biological application
- 1.3.5 ☐ Article 13a - Well established Veterinary use
- 1.3.6 ☐ Article 13b - Fixed combination
- 1.3.7 ☐ Article 13c - Informed consent application
- 1.3.8 ☐ Article 13d - Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted

1.4 MRL STATUS (ONLY FOR FOOD-PRODUCING SPECIES)

When the veterinary medicinal product is intended for use in food-producing animals, please provide the following information as available at the time of submission of the application¹

Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010

substance(s)	<input type="text"/>
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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 32(2) of Directives 2001/82/EC)
- ☐ 1.1.3 A DECENTRALISED PROCEDURE (according to Article 32(3) of Directive 2001/82/EC)
- ☒ 1.1.4 A NATIONAL PROCEDURE

Member state	<input type="text"/>
Application number	<input type="text"/>

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

- ☒ Yes (complete sections below and also complete 1.4) ☐ No (complete section 1.3 and 1.4.)

- ☐ Qualitative change in declared active substance not defined as a new active substance
- ☐ Change of bioavailability
- ☐ Change of pharmacokinetics
- ☐ Change or addition of a new strength/potency
- ☐ Change or addition of a new pharmaceutical form
- ☐ Change or addition of a new route of administration
- ☐ Change or addition of a food-producing target animal species

Note:

. the applicant of the present application must be the same as the marketing authorisation holder of the existing marketing authorisation
. section 1.3.1 (extension) or section 1.3.2 (not extension) should be completed without prejudice to the provisions of Articles 12, 13, 14 and 25 of Directive 2001/82/EC

For an existing marketing authorisation in the European Union/ Member State where the application is made

Product (invented) name	<input type="text"/>		
Pharmaceutical form(s)	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Strength(s)	Marketing authorisation holder	Marketing authorisation number	<input type="button" value="+"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="-"/>

1.3 THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC

Note: - section to be completed for any application, including applications referred to in section 1.2
- for further details, consult the Notice of Applicants, Volume 6A, Chapter 1

1.4 MRL STATUS (ONLY FOR FOOD-PRODUCING SPECIES)

When the veterinary medical product is intended for use in food-producing animals, please provide the following information as available at the time of submission of the application¹

Maximum Residue Limits (MRL) according to Commission Regulation (EU) No 37/2010

substance(s)	<input type="button" value="+"/>	<input type="button" value="-"/>
<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>

Marker residue	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Other Provisions	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Therapeutic classification	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Animal species	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
MRL	<input type="text"/>	Target Tissues	<input type="button" value="+"/>

Application for a Maximum Residue Limit has been made to the EMA ☒ Yes ☐ Not applicable

substance(s)	<input type="button" value="+"/>	<input type="button" value="-"/>
Date of Submission	<input type="text"/>	<input type="button" value="+"/>
Species	<input type="text"/>	<input type="button" value="+"/>
Remarks	<input type="text"/>	

¹All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given.

1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) NO 726/2004

- 1.5.1 ☐ Exceptional Circumstances
Note: according to Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) No 726/2004
- 1.5.2 ☐ Accelerated Review
Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)
- 1.5.3 ☐ Article 13(5) of Directive 2001/82/EC (one year of data exclusivity for each extension to another food-producing species within five years of the initial authorisation)

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

2.1 NAME(S), ATC VET CODE AND TARGET SPECIES

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

(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 5.18)

- 2.1.2 Name of the active substance(s)

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

Active Substance	+	-

Note: only one name 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)

- 2.1.3 Pharmacotherapeutic group (Please use current ATC vet code) & 2.1.4 Target Species

Target species	+	-

ATC code

Group

☐ If no ATC vet code has been assigned, please indicate if an application for the ATC vet 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:

Strength:	Units

Active Substance	+	-

OK Clear Cancel

- 2.2.2 Route(s) of administration (click 'find' to use the current list of standard terms - European Pharmacopoeia)

Route of Administration	+	-

Target species

- 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

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

Description:

--

For each container give:

	+	-
Container		
Material		
Closure		
Administration Device		

2.2.3.2 Proposed shelf life

2.2.3.3 Proposed shelf life (after first opening container)

2.2.3.4 Proposed shelf life (after reconstitution or dilution)

2.2.3.5 Proposed storage conditions

2.2.3.6 Proposed storage conditions after first opening

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

2.3 LEGAL STATUS

- 2.3.1 Proposed administration

- ☒ Only by a veterinary surgeon
☒ By a veterinary surgeon or under their direct responsibility
☒ Other

- 2.3.2 Proposed dispensing/classification

- ☐ Subject to medical prescription (Complete 2.3.3)
☐ Not subject to medical prescription (Complete 2.3.4 & 2.3.5)
☐ Subject to other controls

- 2.3.3 For veterinary products subject to medical prescriptions

- ☐ Veterinary product on prescription which **may** be renewed (if applicable)

Prilog 5.17.
Nacrt vanjskog / unutarnjeg pakovanja

- ☐ Veterinary product on prescription which **may not** be renewed (if applicable)
- ☐ Veterinary product on **special** prescription
- ☐ Veterinary product on **restricted** prescription

(Not all the listed options are applicable 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)

2.3.4 Supply for products not subject to medical prescription

- ☐ Supply through pharmacies only
- ☐ Supply through non-pharmacy outlets and pharmacies (if applicable)
- ☐ Supply/administration by veterinary surgeons only
- ☐ Supply by pharmacies and/or veterinary surgeons for animals under their care
- ☐ Supply through authorised distributor
- ☐ General sale

2.3.5 Promotion for product not subject to medical prescription

- ☐ Promotion to veterinary professionals only
- ☐ Promotion to the general public and veterinary 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

Member State(s) + -
 Company Name
 Address 1
 Address 2
 Postcode
 Country
 Telephone
 Telefax
 E-mail

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

Has SME status been assigned by the EMA?

☐ Yes ☐ No

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

+ -

For Member State(s) + -

Billing address (when relevant)

Company name
 VAT number
 Address 1
 Address 2
 Postcode
 Country
 Telephone
 Telefax
 E-mail
 Purchase order(PO) number

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

Title
 First name
 Surname
 Company name
 Address 1
 Address 2
 Postcode
 Country
 Telephone
 Telefax
 E-mail

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

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

+ -

Copy contact details from 2.4.1 Section

Copy contact details from Declaration Section

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

☐ If different to 2.4.1 above, attach letter of authorisation ([Annex 5.4](#))

2.4.4 Qualified person in the EEA for Pharmacovigilance

Copy contact details from 2.4.2 Section

Title

First name

Surname

Company name

Address 1

Address 2

Postcode

Country

24 H Telephone

Telefax

E-mail

☐ The above-mentioned qualified person resides³ and operates in the EEA

☐ The qualified person is registered with Eudravigilance

☐ Attach detailed description of the pharmacovigilance system See Also ([Annex - 5.20](#)).

Prilog 5.20.
Detaljan opis sustava farmakovigilancije i po mogućnosti prikaz sustava upravljanja rizicima

³For 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.

2.5 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) responsible for batch release in the EEA in accordance with Article 55 and Article 53 of Directive 2001/82/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

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Manufacturing Authorisation number

☐ 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

Prilog 5.6.
Proizvodna dozvola (mjesto otpuštanja serije VMP-a u promet)

Prilog 5.9.
Izjava Nadležnog tijela koje je provelo inspekciju ili GMP-certifikat (mjesto otpuštanja serije VMP-a u promet)

- 2.5.1 b) Official batch release for Vaccines:
Details of the Official Medicines Control Laboratory (OMCL) or laboratory designed for the purpose of Official batch release (in accordance with Articles 81 and 82 of Directive 2001/82/EC as amended)

Laboratory Name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

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

Company name

Title

First name

Surname

Address 1

Address 2

Postcode

Country

24H Telephone

Telefax

E-mail

2.5.1.2 Batch control/Testing arrangements

Sites in EEA or in countries where an MRA or other European union arrangements apply where batch control/testing takes place as required by Article 55 of Directive 2001/82/EC

Company Name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Brief description of control tests carried out by the laboratory(ies) concerned:
(note: please see the "Compilation of Union Procedures on Inspections and Exchange of Information" document, (see 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)

Prilog 5.6.
Proizvodna dozvola i GMP certifikat
(mjesto kontrole serije VMP-a)

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

Or

☐ Enter EudraGMP manufacturing authorisation reference

2.5.2

Manufacturer(s) of the veterinary 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 veterinary medicinal product, quality control sites, in-process testing sites, immediate and outer packaging and importer(s)). For each site provide the following information

Copy contact details from 2.5.1.a

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)

Prilog 5.8.
Dijagram faza i aktivnosti svih mjesta proizvodnje
VMP-a uključujući i mjesta kontrole kvalitete

☐ Site is in the EEA

☐ Site is outside the EEA

☐ 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 in the manufacturing process of each source of active substance should be listed. Brokers 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 information below.

(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).

Copy contact details from 2.5.1.a

Copy contact details from Declaration Section

Active Substance

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)

☐ 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 detailed guidelines on good manufacturing practice for starting materials (Annex 5.19)

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

Is a Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/ original?

☐ Yes ☐ No

Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/82/EC (Annex I), being used for this MAA?

☐ Yes ☐ No

2.5.4 Contract companies used for clinical trial(s), bioavailability or bioequivalence trials
For each contract company, state where analytical tests are performed and where clinical data are collected and give:

Add Study

Prilog 5.8.
Dijagram faza i aktivnosti svih mjesta proizvodnje
djelatne tvari uključujući i mjesta kontrole kvalitete

Prilog 5.19.
Izjava odgovorne osobe o GMP
sukladnosti proizvođača djelatne
tvari
OBRAZAC: EMA/334808/2014

Prilog 5.10.
- Pismo o dopuštenju pristupa
HR- procjenitelja ASMF-u
- Kopija CEP-a

Certificate of suitability
No. R1-CEP 2003-172-Rev 00

1 *Name of the substance:*
2 **GELATIN**
3 Alkaline Hide Gelatin Lots: LFN8904 08 LFN8905 08
4 *Name of holder:* LFN8906 08 LFN8907 08
5 **GELITA GROUP**
6 Uferstrasse 7
7 Germany-69412 Eberbach
8 *Site(s) of production:*
9 **GELITA DO BRASIL — MARINGA PLANT**
10 Rod. Maringa — Iguaraçu-Pr 317
11 Km 09 Gleba Ribeirão
12 Brazil-87001-970 Maringa, PR
13 **GELITA DO BRASIL — ESTANCIA VELHA PLANT**
14 2070, R. Campo Grande
15 Brazil-93600-000 Estancia Velha, RS
16 **GELITA DO BRASIL - MOCOCA PLANT**
17 Av. Tiradentes s/no.
18 Brazil-13733-400 Mococa, SP
19 **GELITA DO BRASIL-COTIA PLANT**
20 Rua Phillip Leiner 200
21 Km 28.3 Rodovia Raposo Tavares
22 Brazil-06714-285 Cotia, SP

23 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
24 **R0-CEP 2003-172-REV 03**

25 After examination of the information provided on the origin of raw material(s) and type of
26 tissue(s) used and on the manufacturing process for this substance on the site(s) of
27 production mentioned above, we certify that the substance **GELATIN** meets the criteria
28 described in the current version of the monograph Products with risk of transmitting
29 agents of animal spongiform encephalopathies no. 1483 of the European
30 Pharmacopoeia, current edition including supplements.

31 - countries of origin of source materials: Argentina, Brazil and Uruguay
32 - nature of animal tissues used in manufacture: Bovine hides
33 - manufacturing process: Alkaline process

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : http://www.edqm.eu

34 The submitted dossier must be updated after any significant change that may alter the
35 quality, safety or efficacy of the substance, or that may alter the risk of transmitting
36 animal spongiform encephalopathy agents.

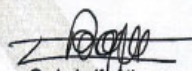
37 Manufacture of the substance shall take place in accordance with a suitable quality
38 assurance system such as ISO 9001 and HACCP, and in accordance with the dossier
39 submitted.

40 Failure to comply with these provisions will render this certificate void.

41 The certificate is valid provided there has been no deterioration in the TSE status of the
42 country(ies) of origin of the source material.

43 This certificate is renewed from **25 July 2008** according to the provisions of Resolution
44 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC
45 and any subsequent amendment, and the related guidelines.

46 This certificate has:
47 lines.


On behalf of the
Director of EDQM & HealthCare



Strasbourg, 15 July 2008

DECLARATION OF ACCESS (to be filled in by the certificate holder under their own responsibility)

GELITA Group, as holder of the certificate of suitability
R1-CEP 2003-172-Rev 00 for GELATIN

hereby authorises
(name of the pharmaceutical company)

to use the above-mentioned certificate of suitability in support of their application(s) for the following
Marketing Authorisation(s): (name of product(s) and marketing number(s), if known)

The holder also certifies that no significant changes to the operations as described in the CEP dossier
have been made since the granting of this version of the certificate.

Date and Signature (of the CEP holder):
May 29th, 2008

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : http://www.edqm.eu

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

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

StrengthUnits

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

Name of active substance	Quantity / Unit	Reference / Monograph Standard
<div></div>	<div></div>	<div></div>

Name of Excipient	Quantity / Unit	Reference / Monograph Standard
<div></div>	<div></div>	<div></div>

Page 15 of 23

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	<div></div>	Excipient	Overage	<div></div>
------------------	---------	-------------	-----------	---------	-------------

Page 16 of 22

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

☐ NONE

or specify below:

Name

Function* ☒ AS ☐ EX ☐ R

☐ Animal Origin susceptible to TSE**

☐ Other Animal Origin

☐ Human Origin

☐ Certificate of suitability for TSE

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

** as defined in section 2 (scope) of the Note for Guidance on minimising the risk of transmitting animal spongiform encephalopath agents via human and veterinary medicinal products

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

☒ Yes ☐ No

If yes, does the product comply with Directive 2001/18/EC?

☒ Yes ☐ No

☐ Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive (Annex 5.13)

Prilog 5.13.
Kopija odobrenja Nadležnih tijela za uvođenje
GMO-a u okoliš

3. SCIENTIFIC ADVICE

3.1 Was there formal scientific advice given by the CVMP for this veterinary medicinal product?

☐ Yes ☐ No

Was a scientific recommendation(s) given by a Member State(s) for this veterinary medicinal product?

☐ Yes ☐ No

☐ Attach a copy of the scientific advice letter (Annex 5.14)

Prilog 5.14.
Stručni savjet CVMP-a ili zemlje članice EU

Prilog 5.12.
Ph. Eur. certifikat o
sigurnosti primjene tvari s
obzirom na prijenos TSE-a

4. OTHER MARKETING AUTHORISATION APPLICATIONS

4.1 FOR NATIONAL APPLICATIONS ONLY, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(N) OF DIRECTIVE 2001/82/EC

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



If yes, section 4.2 must be completed

☒ Yes ☐ No ☐ Not Applicable

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?



If yes, section 4.2 must be completed

☐ Yes ☐ No

*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)

Country	<input type="text"/>	+ -
Date of submission	<input type="text"/>	
Procedure number for MRP/DCP (if applicable)	<input type="text"/>	

☐ Refused

☐ Withdrawn (by applicant before authorisation)

☐ Withdrawn (by applicant after authorisation)

☐ Suspended/revoked (by competent authority)

4.3 FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT

Multiple applications (submitted simultaneously or subsequent to the original product) for:

Name of other product	<input type="text"/>	+ -
Date of application	<input type="text"/>	
Applicant	<input type="text"/>	

Procedure number for MRP/DCP (if applicable)

☐ Attach copy of letter from the 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

Country	<input type="text"/>	+ -
Date of authorisation	<input type="text"/>	
Invented name	<input type="text"/>	

☐ 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 veterinary 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) or Curriculum Vitae of the Qualified Person for Pharmacovigilance
- ☐ 5.6 Manufacturing Authorisation required under Article 44 of Directive 2001/82/EC (or equivalent, outside of the EEA where MRA or other European Union arrangements apply). A reference to EudraGMP will suffice when available.
- ☐ 5.7 (empty) or Justification for more than one manufacturer responsible for batch release in the EEA
- ☐ 5.8 Flow-chart indicating all sites involved in the manufacturing process of the veterinary medicinal product or active substance (including sites involved in sampling and testing for batch release of products manufactured in third countries). Note: ALL manufacturing and control sites mentioned throughout the dossier MUST be consistent regarding their names, detailed addresses and activities
- ☐ 5.9 Statement (or GMP Certificate issued by an EEA inspectorate, when available) from the competent authority which carried out the inspection of the manufacturing site(s) (not older than 3 years). References to Eudra GMP will suffice when available. Where applicable a summary of the other GMP inspections performed in the last 2 years.
- ☐ 5.10 Letter(s) of access to Active Substance Master File(s) (Drug 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 2001/82/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 CVMP or Member State.
- ☐ 5.15 Copy of Marketing Authorization(s) required under Article 12(3)n of Directive 2001/82/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 from Commission services regarding multiple applications.
- ☐ 5.17 List of Mock-ups or Samples/specimens sent with the application, as appropriate (see EMA/CMDv website).
- ☐ 5.18 List of proposed (invented) names and marketing authorisation holders in the concerned member states.
- ☐ 5.19 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 each 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 detailed guidelines on 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).
- ☐ 5.20 Detailed description of the Pharmacovigilance system and, where appropriate, the risk management system that the Applicant will put in place.
- ☐ 5.21 Copy of the 'Qualification of SME Status'.
- ☐ 5.22 Evidence and justification to support the claim of new active substance status in the Union for applications based on Article 12(3) of Directive 2001/82/EC.
- ☐ 5.23 Copy of EMA certificate for a Vaccine Antigen Master File.

NOTES

¹ As Amended by Directive 2004/28/EC

² According to Article 50a of Directive 2001/82/EC, manufacture includes complete or partial manufacture, import, dividing up, packaging or presentation prior to its incorporation into a veterinary medicinal product, including re-packaging or re-labelling as carried out by a distributor.

³ All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in any of the Annexes of Commission Regulation (EU) no. 37/2010 should also be listed and an appropriate justification given.

⁴ "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".

FORM VALIDATION

Validation Errors: 0



Validate Form

Error Color Scheme ☒ Yellow ☐ Red

Save Form

Print Form

Export XML

Import XML

Update lists

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

Title	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>

It is hereby confirmed that all existing data which are relevant to the quality, safety and clinical part of the medicinal product have been supplied in the dossier, as appropriate.
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	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>
Function	<input type="text"/>
Address 1	<input type="text"/>
Address 2	<input type="text"/>
Postcode	<input type="text"/>
Country	<input type="text"/>
Telephone	<input type="text"/>
Telefax	<input type="text"/>
E-mail	<input type="text"/>
Date	<input type="text"/>
Signatory	<input type="text"/>

* ☐ 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 in the Notice to Applicants, Volume 6A, Chapter 7.

It is hereby confirmed that all existing data which are relevant to the quality, safety and clinical part of the medicinal product have been supplied in the dossier, as appropriate.
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	ivan
Surname	horvat
Function	
Address 1	savska
Address 2	
Postcode	10000
Country	Croatia
Telephone	555555555
Telefax	
E-mail	ivan@zg.hr
Date	2016-03-09
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 in the Notice to Applicants, Volume 6A, Chapter 7.

zaključani obrazac

TABLE OF CONTENTS

DECLARATION AND SIGNATURE

1. TYPE OF APPLICATION

- 1.1 This application concerns
- 1.2 Application for a change to your existing marketing authorisation leading to an extension as referred to in Annex I of Regulation (EC) no 1234/2008, or any national legislation
- 1.3 According to Directive 2001/82/EC¹ or Regulation 726/2004
- 1.4 Maximum Residue Limit (MRL) status
- 1.5 Consideration of this application under Article 26(3) of Directive 2001/82/EC, Article 39(7) or Article 39(8) of Regulation 726/2004

2. MARKETING AUTHORISATION APPLICATION PARTICULARS

- 2.1 Name(s) and ATC vet 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

Zahtjev za prijavu produženja odobrenja za stavljanje VMP-a u promet

Form	Notice to Applicant Revision	Electronic Forms version 1.19 (effective from the 30th November 2015, Replaces v.1.18 on 11 Jan 2016)	Release Notes version 1.19 (effective from the 30th November 2015)
Renewal	Revision June2012	Renewal Form 23/02/2016 New	Renewal Release Notes 23/02/2016 New





**EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL**

Consumer goods
Pharmaceuticals

eAF Version Number: 1.19.0.2

June 2015

NOTICE TO APPLICANTS

APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION

TABLE OF CONTENTS

- 1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION**
- 2. APPROVED MANUFACTURERS**
- 3. QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE
SUBSTANCE(S) AND THE EXCIPIENT(S)**

DECLARATION AND SIGNATURE

NOTES

FORM VALIDATION

otključani obrazac

1. APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION

- ☐ HUMAN ☒ VETERINARY
- ☐ National authorisation in MRP/DCP
- ☐ EU authorisation
- ☒ National authorisation only

Is the product currently marketed? ☒ Yes ☐ No



In which Member States? 

Member state  

Invented Name

Pharmaceutical form(s)   

Strength(s) Units   

Active Substance  

[Click here to populate data in section 3](#)

Target Species   

ATC code

Group



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

Route of Administration   

Member state  

MA Number  

Name and address of MA holder

Member state  

Company Name

Address 1

Address 2


Postcode

Country

Telephone

Telefax

E-mail

Name and address of Contact 

Title

First name

Surname

Company Name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Applicant's reference

2. APPROVED MANUFACTURERS

Authorised manufacturer(s) (or importer) responsible for **batch release** in the EEA (in accordance with Articles 40 and 51 of Directive 2001/83/EC, as amended, or Articles 44 and 55 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Decision))

+ -

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

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

For blood products and vaccines:

State laboratory or laboratory designated for official **batch release**, as accordance with Articles 111(1), 113, 114 (1)-(2) and 115 of Directive 2001/83/EC as amended.

Copy address details from 'batch release'

+ -

Laboratory Name

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

+ -

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where **batch control/testing** takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above

Copy address details from 'batch release'

+ -

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

+ -

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

Manufacturer(s) of the **medicinal product** and site(s) of manufacture (including diluent and solvent manufacturing sites)

Copy address details from 'batch release'

+ -

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 by manufacturer of dosage form/assembly, etc (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/WC50004706.pdf)

+ -

Manufacturer(s) of the **active substance(s)**

Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not sufficient

(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.)

Copy address details from 'batch release'

+ -

Active Substance

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

+ -

Company name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

3. QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)

(For centrally authorised products the composition should be provided separately in tabular format as part of the Quality Expert Statement.)

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

Pharmaceutical Form

(The values of the pharmaceutical form, strength and active substances fields have been populated from "section 1".)

Strength		Units		
<input type="text"/>		<input type="text"/>		

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

Name of active substance		Quantity / Unit		Reference / Monograph Standard	
<input type="text"/>		<input type="text"/>		<input type="text"/>	
<input type="text"/>		<input type="text"/>		<input type="text"/>	

Name of Excipient		Quantity / Unit		Reference / Monograph Standard
<input type="text"/>		<input type="text"/>		<input type="text"/>

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

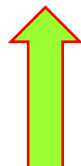
** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)

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

Active Substance	Overage	+	Excipient	Overage	+
------------------	---------	---	-----------	---------	---


(If revised product information (SmPC, Labelling and/or Package Leaflet) is proposed to take account of issues raised by the expert, specify the precise present and proposed wording, underlining or highlighting the changed words. Alternatively, such listing may be provided as a separate document attached to the application form).

PRESENT PRODUCT INFORMATION TEXT	PROPOSED PRODUCT INFORMATION TEXT	
		+
		-



4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR VETERINARY MEDICINAL PRODUCTS ONLY



- ☒ 1 Cover Letter
- ☐ 1.1 Comprehensive table of content
- ☒ 2 Renewal Application Form with the following annexes:
 - ☒ 2.1 List of all authorised product presentations for which renewal is sought in tabular format
 - ☒ 2.2 Details on contact persons:
 - ☒ 2.4 Chronological list of all post authorisation submissions (variations, extensions etc.), conditions and, any Specific Obligations (for centrally authorised products) submitted since grant of marketing authorisation or last renewal indicating scope, status, date of submission and date when issue has been resolved
 - ☐ 2.5 Revised list of all remaining conditions and, any Specific Obligations (for centrally authorised products) (where applicable)
 - ☐ 2.6 Proof of payment of fee, where relevant
 - ☒ 2.7 A statement, or when available, a certificate of GMP compliance, not more than three years old, for the manufacturer(s) of the medicinal product listed in the application issued by an EEA competent authority or MRA partner authority.
 - ☒ 2.8 In addition, for manufacturing sites of the medicinal product not located in the EEA or in the territory of an MRA partner, a list of the most recent GMP inspections carried out by other authorities indicating the date, inspection team and outcome.
 - ☒ 2.9 A declaration by the Qualified Person (QP) of each of the manufacturing authorisation holders (i.e. located in the EEA) listed in the application form where the active substance(s) is used as a starting material, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU ⁴ 
 - ☒ 2.10 Where different, a declaration by the Qualified Person (QP) of the manufacturing authorisation holder(s) listed in the application form as responsible for batch release, that the active substance(s) is manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU ⁵ 
- ☒ 3 SPC, Labelling and Package Leaflet
- ☒ 4 Quality expert statement (incl. Signature + CV), including:
 - ☒ 4.1 Currently authorised specifications for the active substance and the finished product
 - ☒ 4.2 Qualitative and quantitative composition in terms of the active substance(s) and the excipient(s)
- ☒ 5 Clinical expert statement (incl. Signature + CV)
- ☒ 6 Safety expert statement (incl. Signature + CV)
- ☒ 7 Periodic Safety Update Report and Summary Bridging Report if applicable
- ☒ 8 Declaration of current TSE status

DECLARATION AND SIGNATURE

I hereby make application for the above Marketing Authorisation to be renewed. I declare that the quality of the product, in respect of the methods of preparation and control, has been regularly updated by variation procedure to take account of technical and scientific progress in accordance with Article 23 of Directive 2001/83/EC or Article 27 (1) of Directive 2001/82/EC or Article 16 or Article 41(1) of Regulation (EC) No 726/2004. The product conforms with current CHMP/CVMP quality guidelines where relevant. I confirm that no changes have been made to the product particulars other than those approved by the Competent Authority.

☐ Proof of payment (when relevant)

Title	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>
Status (Job Title)	<input type="text"/>
Date	<input type="text"/>

Signatory

Additional Signatory

Page 12 of 14

NOTES

¹ Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential MRP/DCP Number according to Volume 2A, Chapter 2, 7. Numbering System for the Procedures for Mutual Recognition and Decentralised Procedure as published on the Website of the European Commission (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)

Veterinary Medicinal Products: Renewal number to be issued by the Reference Member State before submission of the application according to the corresponding CMD(v) Best Practice Guide (<http://www.hma.eu>)

² For centrally authorised products a list of EU Member States / Norway / Iceland where the product is on the market should be provided in a separate appendix

³ For centrally authorised products this information, including packaging and pack size(s), should be provided in tabular format in a separate appendix (cf. Annex A to CHMP/CVMP Opinion)

⁴ As specified in section 2.4.3 in Part 1A. If different, attach letter of authorisation

^{5&6} Where more than one Qualified Person (QP) is involved, a single declaration by one of the QPs that the active substance(s) used as a starting material are manufactured in accordance with the guidelines on good manufacturing practice for starting materials as adopted by the EU, may be submitted provided that:

- The declaration makes it clear that it is signed on behalf of all the involved QPs.
- The arrangements are underpinned by a technical agreement as described in Chapter 7 of the GMP Guide and the QP providing the declaration is the one identified in the agreement as taking specific responsibility for the GMP compliance of the active substance manufacturer(s).

Page 13 of 14

FORM VALIDATION

Validation Errors: 0

Validate Form

Error Color Scheme ☒ Yellow ☐ Red

Save Form

Print Form

Export XML

Import XML

Update lists

Page 13 of 13

Zahtjev za prijavu odobrenja izmjena u dokumentaciji VMP-a

Form	Notice to Applicant Revision	Electronic Forms version 1.19 (effective from the 30th November 2015, Replaces v.1.18 on 11 Jan 2016)	Release Notes version 1.19 (effective from the 30th November 2015)
Variation	Revision June 2015	Variation Form 23/02/2016 New	Variation Release Notes 23/02/2016 New

Pojedinačna promjena:

- IA
- IB → pr. B.II.b.3.f.
- II
- proširenje

Grupna promjena:

- IA
- IB → pr. B.II.b.3.f.
- II
- proširenje

Worksharing postupak:

- IA
- IB → pr. B.II.b.3.f.
- II
- proširenje

☐ Commission Regulation (EC) No 1234/2008 od 24.11.2008.

☐ Commission Regulation (EU) 712/2012 od 03.08.2012.

☐ **Smjernica / Vodič za klasifikaciju promjena**

http://ec.europa.eu/health/files/eudralex/vol1/c_2013_223/c_2013_2804_en.pdf



June 2015

NOTICE TO APPLICANTS

APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION

TABLE OF CONTENTS

- 1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION**
- 2. PRODUCTS CONCERNED BY THIS APPLICATION⁷**
- 3. TYPES OF CHANGE(S)**

ANNEXED DOCUMENTS (WHERE APPROPRIATE)

DECLARATION OF THE APPLICANT

SIGNATURE

NOTES

FORM VALIDATION

otključani obrazac

1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION




- ☐ Human ☒ Veterinary
- ☐ National Authorisation in MRP/DCP
- ☐ EU Authorisation
- ☒ National Authorisation

Variation procedure number(s)¹ 

[Click here to populate variation number in section 2](#)

+ -

Type of Application (tick all applicable options)

- ☐ Single variation ☐ Type IA_{MH}
- ☒ Grouping of variations ☐ Type IA
- ☐ Including a line extension³  ☐ Type IB unforeseen² 
- ☐ Worksharing ☒ Type IB
- ☐ Type II ☐ Type II Art. 29⁴ 

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

- ☐ Indication
- ☐ Paediatric requirements
- ☐ Safety
- ☒ Quality
- ☐ Annual variation for human influenza vaccines
- ☐ Non-food producing target species
- ☐ Other

Name and address of the Applicant/MA Holder⁵ 


Company Name

Address 1

Address 2

Postcode

Country

Name and address of contact person⁶ 

[Copy contact details from previous Section](#)

+ -

Member State(s) + -

Title

First name

Surname

Company Name

Address 1

Address 2

Postcode

Country

Telephone

Telefax

E-mail

NAPOMENA:

promjene koje se prijavljuju istovremeno s proširenjem
Zahtjev za prijavu promjena je **PRILOG**
Zahtjevu za dobivanje odobrenja proširenja

2. PRODUCTS CONCERNED BY THIS APPLICATION⁷

(Invented) Name

Pharmaceutical Form:

Strength: Units

Active Substance

OK

Clear

Cancel

MA Holder Name

MA Number⁸

see Annex A

see Annex B

3. TYPES OF CHANGE(S)

☐ Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked.

Variations included in this application: Please follow instructions below to add variation

To add a variation Item, Click Show All Types and select check boxes for the required variation items. When all items have been selected click Show only Selected.

Show Only Selected / Collapse All

Variation	Selected
B.II.b.3 f)	1

A. Administrative change		Procedure type	
<input type="checkbox"/> z)	Other variation	<input type="checkbox"/> IA <input type="checkbox"/> IB <input type="checkbox"/> II	<div>Art. 5 Implement. Date: <input type="text"/></div>

Page 6 of 57

Page 50 of 57

3. TYPES OF CHANGE(S)

☐ Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked.

Variations included in this application: Please follow instructions below to add variation

To add a variation Item, Click Show All Types and select check boxes for the required variation items. When all items have been selected click Show only Selected.

Show All Types Refresh Selected

Variation	Selected
B.II.b.3 f)	1

B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product		Procedure type	
<input checked="" type="checkbox"/> f)	Minor change in the manufacturing process of an aqueous oral suspension	IB	<div></div>

⁸If one of the conditions is not met and the change is not specifically listed as Type II.

PRECISE SCOPE AND BACKGROUND FOR CHANGE, AND JUSTIFICATION FOR GROUPING, WORKSHARING AND CLASSIFICATION OF UNFORESEEN CHANGES (if applicable)
(include a description and background of all the proposed changes. In case of grouping and worksharing a justification should be provided in a separate paragraph. If a variation concerns an unforeseen change, include a justification for its proposed classification).




B.II.b.3 f) + -			
PRESENT ^{9,10}		PROPOSED ^{9,10} i	
Text	Sterilisation process is performed by filtration.	Sterilisation process is performed by heat (121-134°C under pressure).	+ -
Image			+ -

D-U-N-S number ¹¹	D-U-N-S number ¹¹	i
EU or National ASMF reference number ¹²	EU or National ASMF reference number ¹²	i

OTHER APPLICATIONS¹³ i

ANNEXED DOCUMENTS (WHERE APPROPRIATE)


The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:

- ☐ Summary of product characteristics
- ☐ Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation¹⁷ 
- ☐ Labelling
- ☐ Package leaflet
- ☐ Mock-ups¹⁸ 
- ☐ Specimens¹⁸ 

DECLARATION OF THE APPLICANT

I hereby submit a notification/application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that *(Please tick appropriate declarations)*:

- ☒ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);
- ☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;
- ☐ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
- ☐ Where applicable, national fees have been prepaid or will be paid in accordance with national requirements;
- ☐ This notification/application has been submitted simultaneously in RMS and all CMSs *(for products within the Mutual Recognition Procedure and worksharing)* or both to EMA and (Co-)Rapporteur *(for products within the Centralised Procedure)* or, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/ CMS *(as applicable)* and the EMA;
- ☐ For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.

Change(s) will be implemented from¹⁹:  ☐ Next production run/next printing

☐ Date


SIGNATURE

☐ Proof of payment (when relevant)

Title	<input type="text"/>
First name	<input type="text"/>
Surname	<input type="text"/>
Status (Job title)	<input type="text"/>

☐ For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the MAs concerned.

Date

Main Signatory²¹ 

Additional Signatory

NOTES

¹ Human Medicinal Products: Number to be completed by the Marketing Authorisation Holder, reflecting the correct sequential Mutual Recognition Procedure Number according to Chapter 1 of the 'Best Practice Guides for the submission and processing of variations in the Mutual Recognition Procedure' (<http://www.hma.eu>).
Veterinary Medicinal Products: Variation number to be issued by the Reference Member State before submission of the application according to the corresponding VMRF-G Best Practice Guide (<http://www.hma.eu>).
Centralised procedure: The sequential EMA procedure number (not the MAH's internal number) should be provided here, when known to the Marketing Authorisation Holder. For worksharing procedures with EMA as reference authority, the 'high-level' EMA worksharing procedure number needs to be provided.
Purely nationally authorised products: Number to be completed according to requirements of the relevant National Competent Authority

² A variation is considered 'unforeseen' when the proposed variation is not considered a minor variation of Type IB following the Commission Guideline, or has not been classified as a Type IB variation in an Article 5 recommendation. When one or more of the conditions established in the guideline for a Type IA variation are not met, the concerned change may be submitted as a Type IB variation unless the change is specifically classified as a major variation of Type II.

³ If the variations are part of a grouped submission including a line-extension, this application form should be considered an annex to the application form for the extension application.

⁴ Type II variation submitted under Article 29 of Regulation (EC) No 1901/2006.

⁵ For worksharing or grouped variations affecting more than one MA, indicate the MA holder to be used as reference MA holder for the handling of the procedure.

⁶ As specified in section 2.4.3 in Part IA/Module 1 Application Form. If different, attach letter of authorisation. For worksharing or grouped variations affecting more than one MA, a single contact should be designated for the application (see also Signatory box below). In case of national marketing authorisations, several contact points in different Member States can be introduced for type II variations and worksharing.

⁷ If this list is very extensive (more than 20 products) it may be added as annex to the application form. For products authorised via the Centralised Procedure, the Annex A of the product(s) concerned should be provided as an Annex to the application form. For worksharing procedures submitted to the EMA, which include nationally authorised products, relevant product and Member State details should be provided as an Annex B to the application form (Using the *template on the EMA website*). For MRP/DCP procedures, "list of concerned products" can be provided as Annex to the application form.

⁸ Indicate the MA numbers affected. For the MRP variation number, which is a product specific number, see the Best Practice Guide on Variations, Chapter 1, example: NL/H/0123/001-004/IB/033/G. For purely nationally authorised products: number to be completed according to requirements of the relevant National Competent Authority.

⁹ Specify the precise present and proposed wording or specification, including dossier section number(s) at the lowest possible level.

¹⁰ For SPC, labelling and package leaflet changes, underline or highlight the changed words presented in the table above or provide as a separate Annex. To underline, set italic or set bold, select the words and use following key combinations: CTRL+U, CTRL+I, CTRL+B on Windows and CMD+U, CMD+I, CMD+B on Mac.

¹¹ If applicable, include D-U-N-S number. The Data Universal Numbering System (D-U-N-S) is a system developed by DUN & Bradstreet (D&B) which assigns a unique digit numeric identifier to a single business entity. It is used in this case to facilitate the identification of manufacturing sites outside of EEA.

¹² If applicable, include EU or National ASMF reference number (only if EU ASMF reference number is not available)

¹³ Due to complexity it is not necessary to complete this section for worksharing or grouped variations affecting more than one MA.

¹⁴ Same applicant/marketing authorisation holder: as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licensees").

¹⁵ To be ticked when the PIP Opinion includes a waiver

¹⁶ To be ticked only if there is a product-specific waiver opinion covering all the subsets of the paediatric population.

¹⁷ Only for centrally authorised products (Annex II of the EU MA).

¹⁸ See Chapter 7 of Volume 6A of the Notice to Applicants or Transfer of information contained in Notice to Applicants, Volume 2A, Chapter 7 (<http://www.hma.eu>) or Dossier requirements for Centrally Authorised Products (<http://www.ema.europa.eu>).

Page 10 of 12

¹⁹ Only to be completed for Type IB and Type II variations.

²⁰ (empty)

²¹ The main signatory is mandatory.

Page 11 of 12

FORM VALIDATION

Validation Errors: 0



Validate Form

Error Color Scheme ☒ Yellow ☐ Red

Save Form

Print Form

Export XML

Import XML

Update lists

Page 11 of 11

Hvala na pažnji

