



**HRVATSKI VETERINARSKI INSTITUT**  
**10000 ZAGREB, Savska cesta 143, P.P. 883**  
**Telefon 01/6123-666, Telefax 01/6190-841**  
**[www.veinst.hr](http://www.veinst.hr)**

**Odjel za veterinarsko javno zdravstvo**  
*Laboratorij za analizu*  
*veterinarsko-medicinskih pripravaka*

**Doc. dr. sc. Svjetlana Terzić**

# Svrha radionice

- ☐ Dokumentacija o VMP
- ☐ Najčešća pitanja, komentari i nedostatci u zahtjevu za procjenu i dokumentaciji HVI-a
- ☐ Najčešća pitanja podnositelja zahtjeva

- ☐ Uvod
  - ☐ osnovne informacije
- ☐ Sadržaj dokumentacije o VMP-u
  - ☐ opći dio
  - ☐ analitički dio
  - ☐ neškodljivost/sigurnost
  - ☐ klinički dio
- ☐ Zahtjev za procjenu dokumentacije
  - ☐ odobrenje, produženje odobrenja
- ☐ EU postupci (CP, DCP, MRP, RUP, WS)
- ☐ Promjene
- ☐ Diskusija



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**<http://www.veinst.hr/organizacija/60>**

Radno vrijeme Laboratorija

**7.30 do 15.00 sati radnim danima**

**8.00 do 12.00 sati subotom**

Radno vrijeme prijamnog ureda

**8.00 do 18.00 sati radnim danom**

**8.00 do 12.00 sati subotom**

# Zakoni i pravilnici

## Nacionalni propisi

## Europski propisi

### **Uredbe Komisije**

2001/82/EC  
2004/28/EC  
2004/726/EC  
2008/1234/EC  
2009/9/EC  
2009/470/EC

### **Zakon o VMP**

N.N. 84/2008  
N.N.56/2013  
N.N. 15/2015

### **Pravilnik o VMP**

N.N. 30/2009  
N.N. 73/2009  
N.N. 146/2010  
N.N. 32/2011  
N.N. 67/2013

**Pravilnik o farmakološki djelatnim tvarima i njihovoj klasifikaciji u odnosu na NDK rezidua u hrani životinjskog podrijetla**

N.N. 21/2011



# Farmakopeja

...nekad



...sada

<https://farmakopeja.halmed.hr/>  
<http://online.edqm.eu/EN/entry.htm>



# Eudralex

[Volume 1 - EU pharmaceutical legislation for medicinal products for human use](#)

[Volume 5 - EU pharmaceutical legislation for medicinal products for veterinary use](#)

[Volume 2 - Notice to applicants and regulatory guidelines for medicinal products for human use](#)

[Volume 3 - Scientific guidelines for medicinal products for human use](#)

[Volume 4 - Guidelines for good manufacturing practices for medicinal products for human and veterinary use](#)

[Volume 6 - Notice to applicants and regulatory guidelines for medicinal products for veterinary use](#)

[Volume 7 - Scientific guidelines for medicinal products for veterinary use](#)

[Volume 8 - Maximum residue limits](#)

[Volume 9 - Guidelines for pharmacovigilance for medicinal products for human and veterinary use](#)

[Volume 10 - Guidelines for clinical trial](#)

European Medicines Agency (EMA)

<http://www.ema.europa.eu/ema/>

International Cooperation on Harmonisation of Technical Requirements  
for Registration of Veterinary Medicinal Products (VICH)

<http://www.vichsec.org/>

World Organisation for Animal Health (OIE)

<http://www.oie.int/>

International Federation for Animal Health Europe (IFAHE)

<http://www.ifaheurope.org/>

European Directorate for the Quality of Medicines & Health Care (EDQM)

<https://www.edqm.eu/en/edqm-homepage-628.html>

Heads of Medicines Agency (HMA)

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

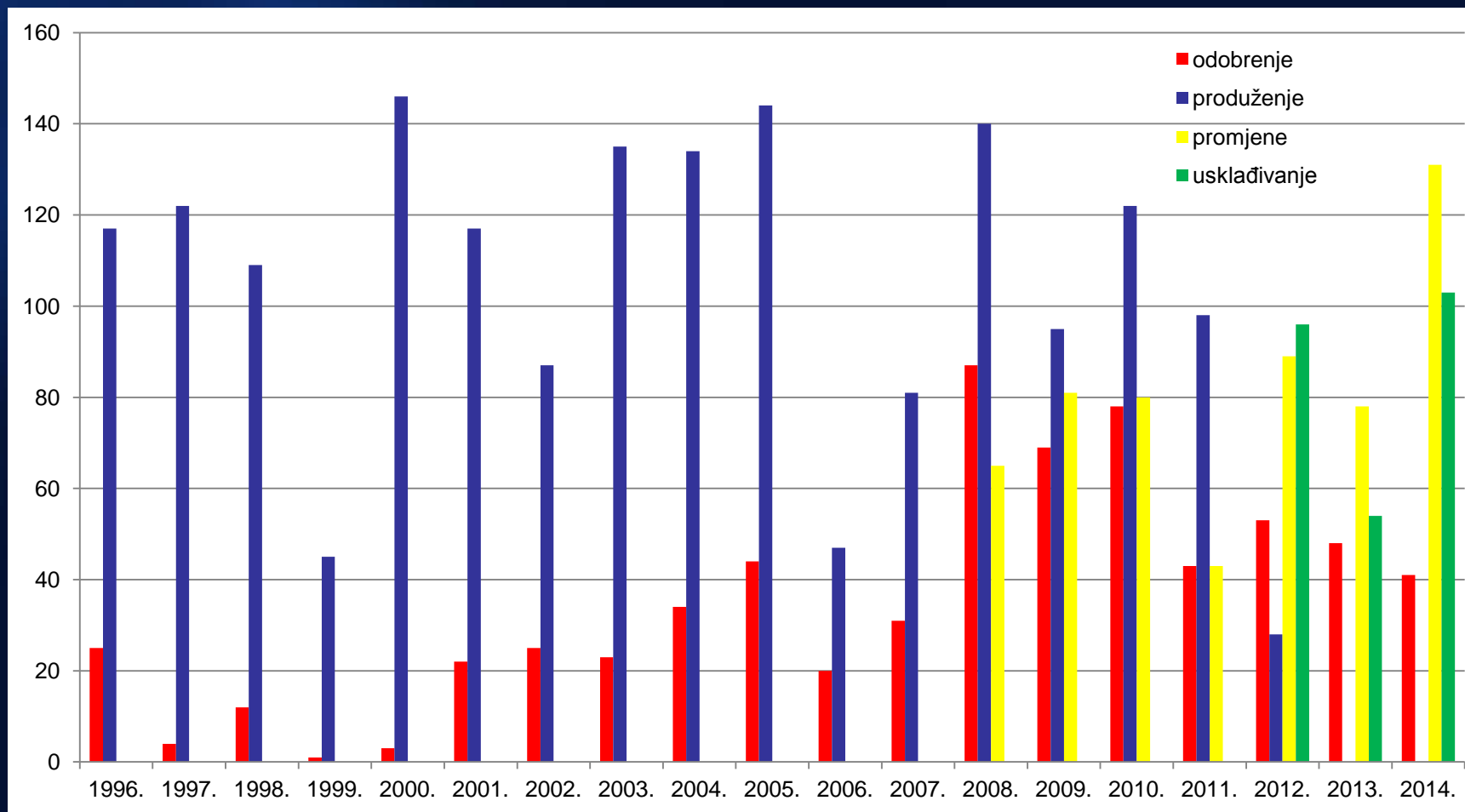
# Vrste zahtjeva za procjenu dokumentacije (nacionalni postupak)

- ☐ Zahtjev za odobrenje za stavljanje VMP-a u promet
- ☐ Zahtjev za produženje odobrenja za stavljanje VMP-a u promet (usklađivanje)
- ☐ Zahtjev za promjene u tijeku važećeg odobrenja

# Odobreni VMP-i na dan 1. 09. 2015.

- 587 nacionalnih odobrenja (uključujući DCP, MRP, RUP)
- 184 centralizirano odobrena VMP-a

# Nacionalni postupci od 1996.do 2014.



# Veterinarsko-medicinski proizvodi (1)

Veterinarsko-medicinski proizvod (VMP) je:

- a) svaka tvar ili mješavina tvari koja ima svojstvo liječenja ili sprječavanja bolesti životinja; ili
- b) svaka tvar ili mješavina tvari koje se mogu primijeniti na životinjama u svrhu obnavljanja, ispravljanja ili prilagodbe fizioloških funkcija farmakološkim, imunološkim ili metaboličkim djelovanjem ili postavljanjem medicinske dijagnoze, te sredstva za redukciju mikroorganizama za primjenu u veterini;



VMP biljnog podrijetla (u daljnjem tekstu: biljni VMP) je svaki biljni VMP čiju je neškodljivost i djelotvornost moguće prepoznati na temelju njegove dugotrajne primjene u Republici Hrvatskoj ili Europskoj uniji i koji udovoljava zahtjevima propisanim odredbama ovoga Zakona.

Homeopatski VMP je svaki VMP izrađen iz homeopatske »izvorne tinkture« u skladu s homeopatskim postupcima proizvodnje opisanim u Europskoj farmakopeji ili, u njenom nedostatku, u važećoj Hrvatskoj farmakopeji i važećim farmakopejama država članica. Homeopatski VMP može sadržavati nekoliko aktivnih principa



## Veterinarsko-medicinski proizvodi (2)

Imunološki VMP je VMP koji sadržava cjepiva, toksine, serume ili alergene, a primjenjuje se kod životinja radi postizanja aktivne ili pasivne imunosti te dijagnosticiranja imunosnog stanja.

Galenski pripravak je pripravak provjerene kvalitete izrađen u galenskom laboratoriju na temelju veterinarskog recepta u skladu s važećom farmakopejom, poznatom i prihvaćenom recepturom te normama dobre prakse za galenske laboratorije.

Magistralni pripravak je pripravak izrađen u ljekarni na temelju pojedinačnoga veterinarskog recepta za jednu životinju ili skupinu životinja iste vrste.

Referentni VMP je VMP odobren za stavljanje u promet u Republici Hrvatskoj ili Europskoj uniji na temelju dokumentacije o kvaliteti, neškodljivosti i djelotvornosti.

**Directive 2004/28/EC Article 12**

## **Pravilnik o VMP (N.N.32/2011)**

### **GLAVA III. UVJETI ZA POSEBNE ZAHTJEVE ZA IZDAVANJE ODOBRENJA ZA STAVLJANJE VMP U PROMET**

Generički VMP je VMP koji ima isti kvalitativni i kvantitativni sastav djelatnih tvari i isti farmaceutski oblik kao i referentni VMP i čija je bioekvivalencija s referentnim VMP dokazana odgovarajućim ispitivanjima bioraspoloživosti. Različite soli, esteri, eteri, izomeri, mješavine izomera, kompleksi i derivati neke djelatne tvari smatrat će se istom djelatnom tvari, osim ako se znatno ne razlikuju u svojstvima glede neškodljivosti i/ili djelotvornosti.

**Directive 2004/28/EC Article 12(3) - application, (i.e. dossier with administrative, quality, safety and clinical data\*)**

In cases where the veterinary medicinal product does not fall under the definition of a generic medicinal product set out in paragraph 2(b) or where bio-equivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

**Directive 2004/28/EC Article 13 (3)- hybrid application**

Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided

**Directive 2004/28/EC Article 13(4)- Similar biological application**



By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law on the protection of industrial and commercial property, the applicant shall not be required to provide the results of safety and residue tests or of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex I. In that event, the applicant shall provide appropriate scientific literature.

**2004/28/EC Article 13a – Well established veterinary**

In the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with point (j) of the first subparagraph of Article 12(3), but it shall not be necessary to provide scientific references relating to each individual active substance.

**Directive 2004/28/EC Article 13b - Fixed combination**



After the marketing authorization has been granted, the marketing authorization holder may allow use to be made of the pharmaceutical, safety and residues, pre-clinical and clinical documentation contained in the file for the veterinary medicinal product with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

**Directive 2004/28/EC Article 13c - Informed consent application**

By way of derogation from point (j) of the first subparagraph of Article 12(3), and in exceptional circumstances with respect to immunological veterinary medicinal products, the applicant shall not be required to provide the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons, in particular on account of other Community provisions.'

**Directive 2004/28/EC Article 13d – Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted**

# Minor use-minor species (MUMS)

## Minor species

There is no legislative definition in the EU for major or minor species. However, major species were defined by the CVMP.

All animal species which are not considered major, are as a consequence, classed as minor species.

Major species have been defined for the purposes of this policy as follows:

### Major food producing animal species:

cattle (dairy and meat animals), sheep (meat animals), pigs, chickens (including laying hens), salmon.

### Major companion animal species:

cats, dogs.

All other animal species, which are not considered major, are as a consequence, classed as minor species.

# MUMS

## Minor use

Minor use in a major species is generally considered as the use of veterinary medicinal products for the treatment of diseases that occur infrequently or occur in limited geographical areas and thus are indicated for a smaller market sector.

Experience has shown that there is insufficient data in the veterinary domain with respect to the incidence and prevalence of diseases to enable objective cut off values to be established below which a disease is considered minor. Therefore a case by case approach will continued to be used in classifying a product as MUMS/limited market.

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general\\_content\\_000499.jsp&mid=WC0b01ac05803ddc15](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000499.jsp&mid=WC0b01ac05803ddc15)

# Limited market

## Limited market

A market for a veterinary medicinal product that is **limited in size** due to the product being indicated for a **disease or condition that represents a minor use in a major species or that occurs in a minor species**; this term is retained as it is the term used in Article 79 of Regulation (EC) No 726/2004 but is interchangeable with the term MUMS in the context of this document.

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Regulatory\\_and\\_procedural\\_guideline/2014/09/WC500172928.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/09/WC500172928.pdf)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2014/12/WC500179577.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/12/WC500179577.pdf)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/10/WC500004277.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004277.pdf)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/10/WC500004581.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004581.pdf)

[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/10/WC500004678.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004678.pdf)





# Ustanove u sustavu nacionalnog postupka odobravanja VMP-a u RH

Ministarstvo poljoprivrede  
(nadležno tijelo)

Hrvatski veterinarski institut  
(Veterinarski fakultet)

# Vrste zahtjeva za procjenu dokumentacije (nacionalni postupak)

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<http://www.veinst.hr/organizacija/60>



# Nacionalni postupak odobravanja VMP-a

## Podnositelj zahtjeva

proizvođač/nositelj odobrenja/predstavnik nositelja odobrenja ili ?



Zahtjev, dokumentacija i prilozi



Hrvatski veterinarski institut/Veterinarski fakultet

Validacija zahtjeva (60 dana)



Obavijest o valjanosti zahtjeva podnosiocu



Zahtjev za izdavanje odobrenja Ministarstvu poljoprivrede

**Pitanja MAH-u  
do 150. dana**

**Pregled dokumentacije  
(0 dan)**

**Analiza**

**Odgovori**

**(180 dana)**

**Pregled SPC**

**Izvješća o dokumentaciji**

**Povjerenstvo za VMP-e (mišljenje)**

**Ministarstvo poljoprivrede  
Rješenje o odobrenju za stavljanje u promet  
(60 dana)**

# Lista pitanja HVI-a

Nakon procjene dokumentacije nositelju odobrenja upućuje se lista pitanja i komentara na hrvatskom jeziku.

## Primjedbe na odgovore

- ☐ Pitanja ponekad nisu dobro prevedena te su odgovori nepotpuni.
- ☐ Na poslana pitanja nekada HVI dugo čeka odgovore.
- ☐ Odgovori često nisu potpuni, uopće nisu dostavljeni ili se dostavljaju u više navrata.
- ☐ Pregled prijedloga teksta SPC-a, označavanja i upute nekada traje nepotrebno dugo.

# Komentari i pitanja podnositelja zahtjeva

- ☐ Upućena pitanja nisu jasna podnositeljima zahtjeva.
- ☐ Prigovor podnositelja zahtjeva na listu pitanja ili na broj pitanja.
- ☐ Zašto se pitanja šalju podnositelju zahtjeva, a ne proizvođaču?
- ☐ Zašto se plaćaju usluge procjene dokumentacije prije izdavanja odobrenja?