CALIMS

Agencija za lijekove
i medicinska sredstva Crne Gore
Agency for Medicines and
Medical Devices of Montenegro

Veterinarski ljekovi – harmonizacija u procesu pristupanja Evropskoj uniji

Tatjana Babović

Zakonska regulativa u Crnoj Gori

- Harmonizovanje sa obimnom evropskom regulativom podrazumijeva česte promjene
- Regulativa iz oblasti ljekova
  - Zakon o lijekovima 2004 (“Sl.list CG” br. 80/04)
  - Izmjene i dopune Zakona 2008 (“Sl.list CG” br. 18/08)
  - Dopuna Zakona (“Sl.list RCG” br. 34/10)
- Nastavak procesa harmonizacije sa zakonodavstvom EU
  - Zakon o ljekovima ("Službeni list CG", br. 56/11)
  - Izmjene i dopune Zakona 2013 ("Službeni list CG" br. 06/13)
  - podzakonska akta

Zakonska regulativa u Crnoj Gori

- Donošenje novog Zakona o ljekovima korak ka potpunijoj harmonizaciji sa regulativom Evropske unije u oblasti ljekova za humanu upotrebu i upotrebu u veterinarstvu, u cilju uspostavljanja novih, viših standarda kako za pacijente, tako i za društvo u cjelini, odnosno farmaceutsku industriju, veledrogerije, uvoznike;
- Prvi uslov za zatvaranje Poglavlja 1. Sloboda kretanja robe

Nacrt novog Zakona o ljekovima

- Nacrt zakona pripremljen 2017

  Direktiva 2001/82/EC o kodeksu Zajednice koji se odnosi na veterinarske lijekove

  - 32004L0028
  - 32009L0009
  - 32009R0470

  Uredba (EZ) br. 726/2004 kojom se utvrđuju postupci Zajednice za odobravanje i nadzor ljekova za humanu i veterinarsku upotrebu i kojom se osniva Evropska agencija za ljekove

  - Usaglašavanje
  - Nacrt zakona zajedno sa tabelama usklađenosti upućen u EK 2018
  - EK dostavila prve komentare na nacrt u oktobru 2018.

Nacrt novog Zakona o ljekovima

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC:

Article 149

Repeal

Directive 2001/82/EC is repealed.

Article 160

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 28 January 2022.

Official Journal

L 4

of the European Union

English edition

Legislation

Volume 62
7 January 2019

Contents

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REGULATIONS

Nacrt novog Zakona o ljekovima

- Nakon komentara EK ponovna revizija teksta i unošenje izmjena/ dopuna (u odnosu na Direktivu 2001/82/EC)
- Dostavljanje EK revidiranog predloga zakona
- Odgovor EK u maju 2019.
- Ponovna revizija teksta i unošenje izmjena/ dopuna (u odnosu na Direktivu 2001/82/EC)
- Dalja komunikacija sa EK-septembar 2019.
- Procedura usvajanja – kraj 2019.
- Podzakonaska akta

Nacrt zakona

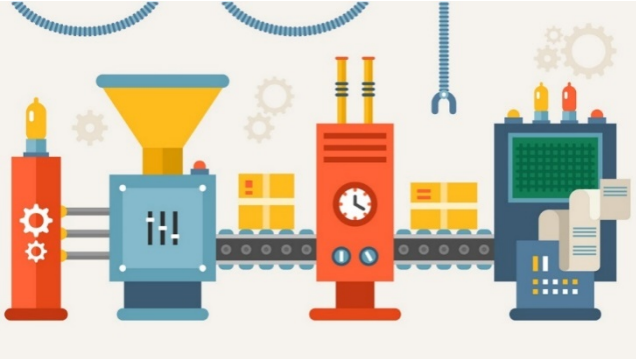
- Novi izrazi:
  - medicinirana hrana za životinje
  - neželjeno dejstvo veterinarskog lijeka
  - neželjeno dejstvo veterinarskog lijeka kod ljudi
  - ozbiljno neželjeno dejstvo veterinarskog lijeka
  - neodobrena upotreba veterinarskog lijeka (Off- lebel use)

Dozvola za lijek

- Precizno utvrđen sadržaj zahtjeva i neophodna dokumentacija za dobijanje dozvole za stavljanje u promet veterinarskog lijeka (čl. 12 Direktive 2001/82)
- Prenijete osnovne odredbe iz Poglavlja 4 Direktive koje se odnose na postupak međusobnog priznavanja i decentralizovani postupak (MRP ili DCP postupak) izdavanja dozvole za lijek
- Zahtjevi za imunološke veterinarske ljekove

Proizvodnja

- 2011 Obaveze proizvođača:
  - lice odgovorno za proizvodnju,
  - lice odgovorno za kontrolu kvaliteta i stavljanje svake serije lijeka u promet;
  - odgovarajući prostor, opremu i kadar.



- Nacrt zakona / Obaveze proizvođača
  - lice odgovorno za proizvodnju
  - lice odgovorno za stavljanje/puštanje svake serije lijeka u promet, stalno dostupno
  - kadar
  - prostor, oprema za proizvodnju, provjeru kvaliteta, skladištenje i distribuciju ljekova;
  - dostupnost
  - nezavisnost QP
  - API u skladu sa GMP/ Dobrom praksom u prometu na veliko aktivnih supstanci
  - kvalitet ekscipijenasa
  - prijavljivanje sumnje na falsifikat
  - provjera dobavljača
  - utvrdi autentičnost i kvalitet aktivnih i pomoćnih supstanci
  - odlaganje farmaceutskog otpada
  - evidencija

Promet

- 2011
  - lice odgovorno za skladištenje i distribuciju ljekova
  - drugi odgovarajući kadar
  - odgovarajući prostor i opremu za smještaj i čuvanje ljekova, vođenje evidencije, smještaj i čuvanje dokumentacije o kvalitetu ljekova, kao i prevozna sredstva za bezbjedan transport.
- Nacrt zakona
  - lice odgovorno za skladištenje i distribuciju
  - drugi odgovarajući kadar
  - odgovarajući prostor i opremu
  - dostupnost dokumentacije
  - plan hitnog povlačenja lijeka
  - vodi evidenciju o narudžbama, isporukama i posredovanju
  - prijava sumnje na falsifikovani lijek

Harmonizacija sa EU zahtjevima

- Izazovi u harmonizaciji (komunikacija sa EK)
  - coverage of all EU law requirements (definition or reference)
  - provisions incorrectly assumed to be non-transferable (MR, DCP)
  - future alignment (addoption of different instruments, alignment upon accession)
  - legal certainty and unconditionality (cross-references / dynamic cross-references)
  - narrower scope
  - translations

Poziv na druge EU propise

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Article 6

By way of derogation from paragraph 1, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, in accordance with Commission Decision 93/623/EEC of 20 October 1993 establishing the identification document (passport) accompanying registered equidae (1) and Commission Decision 2000/68/EC of 22 December 1999 amending Decision 93/623/EEC and establishing the identification of equidae for breeding and production (2), as not being intended for slaughter for human consumption.

Nacrt zakona

Izuzetno od stava 1 ovog člana, može se izdati dozvola za veterinarski lijek koji sadrži aktivne supstance koje nisu dozvoljene Listom iz stava 1 ovog člana, za liječenje životinja iz familije kopitara koje nisu namijenjene za ishranu ljudi u skladu sa posebnim propisom koji reguliše identifikaciju i registraciju kopitara.

Poziv na druge EU propise

Article 10

3. By way of derogation from Article 11, the Commission shall establish a list of substances:

— which are essential for the treatment of equidae, or

— which bring added clinical benefit compared to other treatment options available for equidae,

and for which the withdrawal period shall not be less than six months according to the control mechanisms laid down in Decisions 93/623/EEC and 2000/68/EC.

Nacrt zakona

Supstance iz stava 9 ovog člana nalaze se na Listi neophodnih supstanci za liječenje kopitara i supstanci koje donose dodatnu kliničku korist u odnosu na druge raspoložive mogućnosti za liječenje kopitara i za koje period karence nije manji od šest mjeseci.

Poziv na druge EU propise

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Article 11

Unless the medicinal product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than:

— 7 days for eggs,

— 7 days for milk,

— 28 days for meat from poultry and mammals including fat and offal,

— 500 degree-days for fish meat.

▼M3

The Commission may modify these withdrawal periods or establish other withdrawal periods.

Nacrt zakona

Period karence usklađuje se sa promjenama usvojenim od strane Evropske komisije.

Harmonizacija sa EU zahtjevima

Regulation (EU) 2019/6

'**veterinary medicinal product**' means any substance or combination of substances which fulfils at least one of the following conditions:

(a) it is presented as having properties for *treating or preventing disease in animals*;

(b) its purpose is to be used in, or administered to, animals with a view to *restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action*;

(c) its purpose is to be used in animals with a view to *making a medical diagnosis*;

(d) its purpose is to be used for euthanasia of animals;

Directive 2001/82 /EU

Veterinary medicinal product :

(a) any substance or combination of substances presented as having properties for *treating or preventing disease in animals*; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to *restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action*, or to *making a medical diagnosis*.

Harmonizacija sa EU zahtjevima

Regulation (EU) 2019/6

(33) 'veterinary prescription' means a document issued by a veterinarian for a *veterinary medicinal product* or a medicinal product for human use for its use in animals;

Directive 2001/82 /EU

21. Veterinary prescription: Any prescription for a *veterinary medicinal product* issued by a professional person qualified to do so in accordance with applicable national law.

Harmonizacija sa EU zahtjevima

- Regulation (EU) 2019/6

Definitions:

- antimicrobial resistance
- antimicrobial
- antiparasitic
- antibiotic
- metaphylaxis
- prophylaxis
- limited market
- pharmacovigilance
- control
- aquatic species
- food-producing animals
- variation
- advertising of veterinary medicinal products
- potential serious risk to human or animal health or to the environment
- novel therapy veterinary medicinal product
- epidemiological unit
- competent authority

Harmonizacija sa EU zahtjevima

- Directive 2001/82 /EU

Definitions:

- pre-mix for medicated feedingstuffs
- medicated feedingstuffs
- adverse reaction
- human adverse reaction
- serious adverse reaction
- unexpected adverse reaction
- periodic safety update reports
- post-marketing surveillance studies
- off-label use
- representative of the marketing authorisation holder
- Agency: The European Medicines Agency established by Regulation (EC) No 726/2004 (1).

Harmonizacija sa EU zahtjevima

Regulation (EU) 2019/6

Annex IV Corelation table

Directive 2001/82 /EU

Article 8 third sentence

If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, a Member State may permit the use, for the animal in question, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in the Member State in question but is authorised under the legislation of the third country. Member States shall take all appropriate measures concerning the supervision of the importation and the use of such immunological products.

Article 15

1. Applicants shall ensure that the detailed and critical summaries referred to in the second subparagraph of Article 12(3) are drafted and signed by persons with the requisite technical or professional qualifications, set out in a brief curriculum vitae, before being submitted to the competent authorities.
2. Persons with the technical or professional qualifications referred to in paragraph 1 shall justify any use made of the scientific literature referred to in Article 13a(1) in accordance with the conditions set out in Annex I.
3. A brief curriculum vitae of the persons referred to in paragraph 1 shall be appended to the detailed critical summaries.

Harmonizacija sa EU zahtjevima

- Regulation (EU) 2019/6 Annex IV Corelation table

Directive 2001/82/EC	This Regulation
Article 1	Article 4
Article 2(1)	Article 2(1)
Article 2(2)	Article 3
Article 2(3)	Article 2(2),(3) and (4)
Article 3	Article 2(4)
Article 4(2)	Article 5(6)
Article 5	Article 5
Article 5(1) second sentence	Article 38(3)
Article 5(2)	Article 58(1)
Article 6(1), (2)	Article 8(3)
Article 6(3)	Article 8(4)
Article 7	Article 116
Article 8	Article 116
Article 8 third sentence	
Article 9	Article 9
Article 14	Article 35
Article 16	Article 85
Article 17	Article 86
Article 18	Article 87
Article 19	Article 85
Article 20	Article 85
Article 21(1)	Article 47
Article 21(2)	Article 46
Article 22	Article 48
Article 23	Articles 28 and 29
Article 24	Article 30
Article 25	Article 33
Article 26(3)	Articles 25 and 26
Article 27	Article 58
Article 27a	Article 58(6)

Hvala na pažnji

http://calims.me