ACT ON AMENDMENTS TO THE VETERINARY MEDICINAL PRODUCTS ACT

Article 1

In the Veterinary Medicinal Products Act (Official Gazette, No. 84/08, 56/13, 94/13 and 15/15), in Article 1, Paragraph 2, Item d), after the word: "material", the comma and words: "chemicals for reducing micro-organisms for use in veterinary medicine" are deleted.

Article 2

In Article 2, in front of the words: "Particular Terms", a paragraph designation is inserted which reads: "(1)".

In Paragraph 1, Item 52 the word: "registered" is replaced with the words: "which has authorisation".

After Item 63 at the end of the sentence, instead of a period, a semicolon is inserted and Items 64, 65 and 66 are added which read:

"64. *The exit of VMP* is the wholesale of VMP from the Republic of Croatia to member states:

65. *The VMP marketing authorisation holder* is a natural or legal person with headquarters in the European Union and which has approval from a relevant body or European Commission for the marketing of VMP;

66. *The entry of VMP* is the wholesale of VMP from member states into the Republic of Croatia.".

Inserted after Paragraph 1 is Paragraph 2 which reads:

"(2) By way of derogation from Paragraph 1, Item 20 of this Article, the relevant body for issuing VMP manufacturing authorisation, good manufacturing practice inspection, the issuing of authorisations for the wholesale distribution of VMP and supervision of wholesale distribution of VMP is the Agency for Medicinal Products and Medical Devices of Croatia (hereinafter: HALMED).".

Article 3

In Article 23.a, Paragraph 2 is deleted.

In the current Paragraph 3, which now becomes Paragraph 2, the words: "referred to in Paragraph 2 of this Article" are deleted.

Article 4

In Article 25, Paragraph 1, after the words: "relevant body", the comma are words: "subject to the opinion of the Committee for VMP referred to in Article 34 of this Act" are deleted.

Article 5

In Article 33, Paragraph 2, the following is amended and now reads:

"(2) The report on VMP evaluation referred to in Paragraph 1 of this Article contains comments on the documentation which in turn refers to results from pharmacological testing, testing for safety and for residues as well as preclinical and clinical testing of VMP is

regularly updated with all new available data important for evaluating quality, safety or efficacy of the respective VMP.”.

Article 6

Article 34 is deleted.

Article 7

In Article 37, Item 9, the word: “compound” is replaced with the word: “substance”.

Article 8

In Article 39, Paragraph 1, the words: “from the issuing of marketing authorisation it has not been marketed” is replaced with the words: “was not marketed in the Republic of Croatia”.

Article 9

In Article 41, Paragraph 1, the word: “updated” is added after the words: “request and”.

After Paragraph 4, a new Paragraph 5 is added which reads:

“(5) The prolongation of VMP marketing authorisation for the respective refers to provisions of Article 22.a Paragraphs 2, 3 and 8 to 12 of this Act.”.

The current Paragraphs 5 to 8 now become Paragraphs 6 to 9.

Article 10

In Article 43, Item 3, the words: “three months” are replaced with the words: “12 months”.

Article 11

Article 44 is altered and now reads:

“(1) After expiration of the period for which the authorisation referred to in Article 22, Paragraph 3 of this Act is issued, the series of VMP, if its validity period does not expire beforehand, may be retailed at most for another 12 months, if:

- a request for removing the VMP from the register referred to in Article 43, Item 1 of this Act is filed.

- the period for which the authorisation has been issued has expired.

(2) Upon termination of the authorisation referred to in Article 43, Item 2 of this Act, the VMP is immediately withdrawn from the market.

(3) It is prohibited to market a VMP with an expired validity period or if improper quality, harmfulness or inefficacy has been proven.”.

Article 12

In Article 48, placed before the current Paragraph 1 is the new Paragraph 1 which now reads:

"(1) Legal and natural persons in the Republic of Croatia may undertake activities for complete or partial manufacturing of VMP only on the basis and in compliance with the manufacturing authorisation.".

In the current Paragraph 1, which now becomes Paragraph 2, the words: "relevant body" are replaced with the word: "HALMED".

The current Paragraph 2 becomes Paragraph 3.

In the current Paragraph 3, which now becomes Paragraph 4, the words: "Relevant body" are replaced with the word: "HALMED".

The current Paragraph 4 becomes Paragraph 5.

The current Paragraph 5, which becomes Paragraph 6, is altered and now reads:

"(6) In the Ordinance, the Minister will specify the content of the documentation which is submitted for the purpose of obtaining authorisation.".

Article 13

Article 49 is altered and now reads:

"(1) If the applicant fulfils all conditions stipulated in the provisions of this Act, HALMED will provide VMP manufacturing authorisation in accordance with Article 48 of this Act.

(2) The approval referred to in Paragraph 1 of this Article is issued on the basis of opinion given by HALMED's inspector, on the fulfilment of good manufacturing practice requisites, and upon the performed inspection at the production site.

(3) HALMED issues the authorisation referred to in Paragraph 1 of this Article within a period of 90 days from the date of the proper submission of the application.

(4) If the applicant fails to fulfil all conditions as stipulated in the provisions of this Act, HALMED may issue a VMP manufacturing authorisation with a period of time for rectification of identified insufficiencies.

(5) VMP manufacturing authorisation referred to in Paragraph 4 of this Article ceases to be valid upon expiration of the period determined for rectification of identified insufficiencies.

(6) The authorisation referred to in Paragraph 1 of this Article, is also necessary for:

a) VMP intended for export or clinical testing,

b) various procedures for distributing, packaging or equipping VMP,

c) import of VMP from third countries.

(7) By way of derogation from Paragraphs 1 and 6 of this Article, VMP manufacturing authorisation is not necessary for preparation, distribution, changing the packaging or equipping smaller packaging of finished products if the procedure is performed by expert employees in veterinary pharmacies, solely for retail supply.

(8) HALMED maintains the register of legal and natural persons to whom VMP manufacturing authorisation has been issued.

(9) In the Ordinance, the Minister will specify the content of the documentation submitted for the purpose of obtaining VMP manufacturing authorisation, as well as the content of documentation necessary for entry into the register referred to in Paragraph 8 of this Article.".

Article 14

In Article 50, Paragraph 1, the paragraph designation which reads: “(1)” in front of the word: “Authorisation” is deleted.

Paragraph 2 is deleted.

Article 15

In Article 51, a new Paragraph 3 and Paragraph 4 are added after Paragraph 2 and which now read:

“(3) HALMED issues a confirmation on fulfilling the principles of good manufacturing practice for VMP.

(4) The authorised legal persons referred to in Article 22.a, Paragraph 1 and Article 63, Paragraph 2 of this Act are obliged to provide HALMED for temporary use, all requested documentation on VMP and manufacturers of VMP, for the purpose of inspecting as to whether the principles of good manufacturing practice have been met.”.

The current Paragraph 3 now becomes Paragraph 5.

Article 16

In Article 52, Paragraph 1, the words: “relevant body” is replaced with the words: “HALMED and submit the documentation”.

In Paragraph 2, the words: “Relevant body” is replaced with the word: “HALMED”.

Paragraph 5 is deleted.

Article 17

In Article 53, Paragraph 1, the paragraph designation is deleted and the words: “Relevant body” is replaced with the word: “HALMED”.

Paragraph 2 is deleted.

Article 18

In Article 56, Paragraph 2, the words: “Relevant body” is replaced with the word: “HALMED, if wholesale distributor meets the requirements as stipulated in the provisions of this Act”.

In Paragraph 3, the words: “Relevant body” is replaced with the word: “HALMED”, and the word: “complete” is replaced with the word: “proper”.

In Paragraph 5, the words: “Relevant body” is replaced with the word: “HALMED”.

In Paragraph 7, the words: “Relevant body” is replaced with the word: “HALMED”.

In Paragraph 8, the words: “Relevant body” is replaced with the word: “HALMED”.

Paragraph 9 is altered and now reads:

“(9) The content, form and manner of maintaining the register referred to in Paragraph 7 of this Article is stipulated by the minister as defined in the ordinance.”.

Article 19

In Article 57, Paragraph 1, the words: “Relevant body” is replaced with the word: “HALMED”.

Article 20

In Article 58, Paragraph 3, after the words: “veterinary activity”, a comma is inserted and the words added: “scientific-research institutions which have approval for conducting experiments on animals”.

Article 21

Article 60 is altered and now reads:

“(1) At the suggestion of HALMED’s inspector, HALMED may temporarily prohibit the wholesale distributor from conducting wholesale distribution of VMP, or terminate the authorisation for wholesale distribution of VMP if it is ascertained that the marketing authorisation holder fails to fulfil stipulated conditions or undertakes VMP wholesale activities contrary to the provisions of this Act.

(2) The wholesale distributor referred to in Article 56, Paragraph 1 of this Act is removed from HALMED’s register in the following cases:

1. submission of a request for removal,
2. termination of the authorisation,
3. when it is ascertained that activities have not been conducted for a period of time exceeding one year,
4. termination of the legal person.”.

Article 22

Article 61 is altered and now reads:

“(1) The exit of VMP, parallel import, parallel distribution and entry of VMP may be undertaken by wholesale distributor.

(2) VMP import may be undertaken only by a legal or physical person who has a manufacturing authorisation for VMP.

(3) Entry of VMP into the territory of the Republic of Croatia from a third country, which is intended for marketing in a member state, must be accompanied by a copy of the VMP manufacturing authorisation.

(4) Entry of VMP which does not have marketing authorisation as referred to in Article 9, Paragraph 1 of this Act or VMP which is being tested, may be conducted by wholesale distributor as referred to in Paragraph 1 of this Article, only on the basis of approval from the relevant body.

(5) Import of VMP which does not have marketing authorisation as referred to in Article 9, Paragraph 1 of this Act or VMP which is being tested, may be conducted by a legal or physical person as referred to in Paragraph 2 of this Article, only on the basis of approval from the relevant body.

(6) Approval for import or entry is not necessary for:

- VMP which has marketing authorisation from the relevant body of the European Commission or which has approval for parallel import or parallel distribution.
- Active substances and excipients, intermediate products or VMP for which the VMP manufacturer carries out some production processes in the Republic of Croatia.

(7) In the Ordinance, the Minister will specify the content of the documentation which is submitted for the purpose of obtaining approval for import and export.”.

(8) The entry, import, parallel distribution, export or exit of VMP which contains drugs or psychotropic substances and substances from which drugs can be obtained, is subjected to the provisions of a special act on the suppression of drug abuse.”.

Article 23

Article 62 is altered and now reads:

"(1) The retail sale of VMP is carried out in veterinary pharmacies based on and in compliance with authorisation for retail sale of VMP.

(2) Prior to commencing activities, the veterinary pharmacy must submit for each location an application for the issuing of authorisation for retail sale of VMP to the relevant body.

(3) Documentation is to accompany the application referred to in Paragraph 2 of this Article.

(4) The documentation referred to in Paragraph 3 of this Article must cite the responsible person, employed at the veterinary pharmacy for jobs in implementing the quality assurance system.

(5) Approval referred to in Paragraph 1 of this Article is issued by the relevant body if the veterinary pharmacy meets conditions as stipulated in the provisions of this Act.

(6) Homeopathic VMP may be retailed only by veterinary pharmacies.

(7) The holder of authorisation for the retail sale of VMP is obliged to maintain stipulated records on the retail of VMP, which must be accessible to the relevant body for a period of at least five years.

(8) The register of the holders of authorisation for the retail sale of VMP is maintained by the relevant body.

(9) VMP which is dispensed on a veterinary prescription may be sold only to adults.

(10) The veterinary pharmacy is obliged to submit to the relevant body, data on any changes for authorisation for the retail sale of VMP, within a period of 15 days from the actual changes.

(11) The content, form and manner of maintaining the register referred to in Paragraph 7 and 8 of this Article as well as the form, content of the application and documentation referred to in Paragraph 3 of this Article is stipulated by the minister as defined in the ordinance.".

Article 24

After Article 62.a, a new title above the Article is added and Article 62.b now reads:

"*Removing a veterinary pharmacy from the register*

Article 62.b

(1) The relevant body may at the request of the veterinary inspector, temporarily prohibit the undertaking of activities in the retail sale of VMP or terminate the authorisation for the retail sale of VMP if it is ascertained that the authorisation holder fails to fulfil stipulated conditions or undertakes activities in the retail sale of VMP contrary to the provisions of this Act.

(2) The veterinary pharmacy referred to in Article 62, Paragraph 1 of this Act is deleted from HALMED's registered in the following cases:

1. submission of a request for deletion,
2. termination of authorisation,
3. when it is ascertained that no activity has been undertaken for a period exceeding one year,
4. termination of the legal person.".

Article 25

In Article 64, Paragraph 2, the words: “with permanent residency on the territory of the Republic of Croatia” is deleted.

Article 26

In Article 79, Paragraph 1, after the words: “marketing of VMP”, the comma and words “manufacturing of VMP” and the words: “wholesale and” are deleted.

In Paragraph 2, Paragraph 3 is added which reads:

“(3) The expenses in the procedures for granting, refusing, amending and repealing authorisation for the wholesale distribution of VMP and the wholesale distribution of VMP supervision, as well as the costs for granting, refusing, amending and repealing VMP manufacturing authorisation, VMP manufacturing supervision and issuing of confirmation on complying with the principles of good manufacturing practice for VMP, which is carried out by HALMED in accordance with the provisions of this Act, is determined by the minister, and borne by the applicant or holder of VMP manufacturing authorisation or authorisation for the wholesale distribution of VMP.”.

Article 27

In Article 80, Paragraph 1, the paragraph designation and the words: “and chemicals for reduction of micro-organisms for use in veterinary medicine” is deleted.

Paragraph 2 is deleted.

Article 28

In Article 82, Paragraph 2, the words: “and official veterinarians” is replaced with the words: “State Inspectorate”.

After Paragraph 2, a new Paragraph 3 is added and now reads:

By way of derogation from Paragraph 2 of this Article, inspections in implementation of this Act and laws passed on the basis of this Act relating to the issuing of VMP manufacturing authorisation, supervision of good manufacturing practice for VMP, the issuing of authorisation for the wholesale distribution of VMP and supervision of the wholesale distribution of VMP is performed by HALMED’s inspectors.”.

In the current Paragraph 3 which now becomes Paragraph 4, after the words “veterinary medicine” a comma is inserted, and the following words added: “special laws on the State Inspectorate”.

The current Paragraph 4 now becomes Paragraph 5.

Article 29

In Article 83, Paragraph 1, Items 6 and 7 are altered and now read:

“6. places the VMP in retail sale, more than 12 months after expiry of the period for which the VMP authorisation was issued or for VMP the validity period of which has expired contrary to Article 44, Paragraph 1 of this Act, or the VMP has shown to have insufficiencies in terms of quality, harmfulness or inefficacy, contrary to Article 44, Paragraph 3 of this Act.

7. manufactures the VMP without VMP manufacturing authorisation or the VMP is not manufactured in compliance with issued manufacturing authorisation, contrary to Article 48, Paragraph 1 of this Act,".

Items 11 and 12 are altered and now read:

"11. undertakes activity of VMP retail sale without authorisation for retail sale of VMP, contrary to the provisions of Article 62, Paragraph 1 of this Act,

12. undertakes activity of VMP exit, parallel import, parallel distribution or entry of VMP without authorisation for wholesale distribution of VMP, contrary to Article 61, Paragraph 1 of this Act, or the importing of VMP without approval for production, contrary to Article 61, Paragraph 2 of this Act.

Item 15 is altered and now reads:

"15. Prevents veterinary inspectors or HALMED's inspectors from conducting supervision or does not act according to the final legally binding decision of the veterinary inspector or HALMED's inspector, contrary to the provisions of Article 82, Paragraphs 2 and 3 of this Act.".

Article 30

In Article 85, Paragraph 1, Items 4 and 5 are altered and now read:

"4. VMP which is dispensed on a veterinary prescription is sold to a minor, contrary to the provisions of Article 62, Paragraph 9 of this Act,

5. the veterinary pharmacy does not have employed a responsible person for implementing the quality assurance system or does not maintain stipulated records on the retail sale of VMP, contrary to Article 62, Paragraphs 4 and 7 of the Act,".

After Item 10 at the end of the sentence, instead of a period, a comma is placed and Items 11 and 12 are added which read:

"11. The veterinary pharmacy does not submit to the competent authority information on changes to the authorisation for the wholesale distribution of VMP within a period of 15 days of the actual change, contrary to Article 62, Paragraph 10 of this Act,

12. without approval from the competent authority, the wholesale conducts entry of VMP or the manufacturer imports VMP into the Republic of Croatia, which does not have a marketing authorisation, contrary to Article 61, Paragraphs 4 and 5 of this Act.".

Article 31

In the entire text of the Veterinary Medicinal Products Act (Official Gazette, No. 84/08, 56/13, 94/13 and 15/15), the words: "Report on VMP evaluation" in the specific declination is replaced by the words: "Report on VMP assessment" in the appropriate declination.

TRANSITIONAL AND FINAL PROVISIONS

Article 32

Procedures for issuing VMP manufacturing authorisation and authorisation for wholesale distribution of VMP that have commenced prior to this Act coming into force will be completed in accordance with the provisions of the Veterinary Medicinal Products Act (Official Gazette, No. 84/08, 56/13, 94/13 and 15/15).

The procedures for extension of VMP marketing authorisation referred to in Article 41, Paragraph 5 of this Act that have commenced prior to this Act coming into force will be completed in accordance with the provisions of the Veterinary Medicinal Products Act (Official Gazette, No. 84/08, 56/13, 94/13 and 15/15).

Article 33

This Act will be published in the Official Gazette and comes into force on 1 April 2019.