

NATIONAL SANITARY VETERINARY AND FOOD SAFETY AUTHORITY

ORDER

amending and supplementing

the Sanitary Veterinary Rule on the procedure for placing on the market and use of reagents and diagnostic kits for veterinary use, approved by Order No 81/2008 of the President of the National Sanitary Veterinary and Food Safety Authority

Having regard to the Approval No 576/12.05.2025, drawn up by the Directorate for Coordination of Laboratories and Veterinary Medicinal Products of the National Sanitary Veterinary and Food Safety Authority;

Having regard to the provisions of Article 10(b) of Government Order No 42/2004 on the organization of the sanitary-veterinary and food safety activity, approved with amendments and completions by Law No 215/2004, as subsequently amended and supplemented;

Pursuant to Article 3(1) and (3), as well as Article 4(3) of Government Decision No 1415/2009 on the organisation and functioning of the National Sanitary Veterinary and Food Safety Authority and its subordination units, as subsequently amended and supplemented;

the President of the National Sanitary Veterinary and Food Safety Authority hereby issues the following order:

Article 1. - The Sanitary Veterinary Rule on the procedure for placing on the market and use of reagents and diagnostic kits for veterinary use, approved by Order No 81/2008 of the President of the National Sanitary Veterinary and Food Safety Authority, published in the Official Gazette of Romania, Part I, No 726 of 27 October 2008, as amended, shall be amended and supplemented as follows:

1. Article 2 shall be amended to read as follows:

"Article 2- This sanitary veterinary rule shall not apply to rapid veterinary diagnostic tests nor to tests carried out by European reference laboratories in accordance with the provisions of the European regulations in force."

2. In Article 3, points d), e), k) and n) shall be amended to read as follows:

"d) manufacturing authorisation - an act issued by a competent authority in the European Union, permitting the production of reagents and diagnostic kits for veterinary use, in accordance with the model set out in Annex No 2;

e) provisional authorisation for use - the document issued by the Specialised Directorate of the National Sanitary Veterinary and Food Safety Authority, in accordance with the model set out in Annex 3, where there are no authorised reagents and diagnostic kits for veterinary use or where authorised reagents and diagnostic kits are not available in Romania;

k) competent national reference laboratory - the laboratory designated in accordance with the provisions of the Order No 205/2007 of the President of the National Sanitary Veterinary and Food Safety Authority approving national reference laboratories and their tasks, as subsequently amended and supplemented;

n) diagnostic kit for veterinary use - the totality of reagents and required materials, included in a secondary package, used to determine the health or disease status of animals, to detect etiological agents, or to perform qualitative and/or quantitative determination of specific parameters (immunological, biophysical, biochemical, and haematological), for the purpose of establishing the animal's health status."

3. In article 4, letters b) and c) shall be repealed.

4. In article 4 paragraphs 4 and 6 shall be amended to read as follows:

"4. The fee for the evaluation of documentation for issuing the authorisation to manufacture reagents is laid down in Order No 96/2014 of the President of the National Sanitary Veterinary and Food Safety Authority on the approval of applicable fees in the sanitary veterinary and food safety field, as amended and supplemented, and shall be paid into the account of the Institute for Control of Biological Products and Veterinary Medicines.

(6) Any changes to the documentation on the basis of which the manufacturing authorisation was issued must be notified within 30 calendar days to the Institute for Control of Biological Products and Veterinary Medicines in order to update the manufacturing authorisation. The fee provided for in Order of the President of the National Sanitary Veterinary and Food Safety Authority No 96/2014, as subsequently amended and supplemented, shall no longer be charged for updating the manufacturing data and issuing the amended manufacturing authorisation. The updating of the data in the manufacturing authorisation shall be carried out without prejudice to the period of validity referred to in paragraph 5."

5. In article 6 paragraphs 3 and 5 shall be amended to read as follows:

"3. The marketing authorisation for the products referred to in this sanitary veterinary rule shall be issued within maximum 90 days from the date of submission of the technical documentation provided for at Article 8. and of the proof of payment of the fee provided for in Order of the President of the National Sanitary Veterinary and Food Safety Authority No 96/2014, as subsequently amended and supplemented.

5. If, during the course of the procedure, the Institute for Control of Biological Products and Veterinary Medicines requests clarification or completion of the technical documentation submitted in support of the application for marketing authorisation, the reply must be sent in full within a maximum of 30 working days from receipt of the request; in that case, the procedure shall be suspended until the submission of the additional information requested by the Institute for Control of Biological Products and Veterinary Medicines."

6. In Article 6, a new paragraph 6 is inserted after paragraph 5, reading as follows:

"6. If the marketing authorisation holder fails to respond to the request for completion of the technical documentation within the established deadline, the authorization request shall be cancelled, and the applicant shall be informed in writing. The cancellation of the application for authorisation shall not prevent the marketing authorisation holder from submitting a new application when the technical documentation is complete".

7. Article 8(3) shall be amended to read as follows:

"3. The application must be accompanied both by the technical documentation of the product and by a copy of the manufacturing authorisation or an equivalent document authorising the manufacturing process."

8. In Article 8, a new paragraph 4 is inserted after paragraph 3, reading as follows:

"4. In the case of indigenous products, the manufacturing authorisation shall be verified in the records of the Institute for Control of Biological Products and Veterinary Medicines."

9. In Article 11, after paragraph 1, a new paragraph 1¹ is inserted, reading as follows:

"1¹. Any form of advertising for reagents and diagnostic kits must be approved by the Institute for Control of Biological Products and Veterinary Medicines. Advertising for reagents and diagnostic kits shall be only permitted when addressed exclusively to the following persons:

- a) veterinarians,
- b) persons who are authorised to supply veterinary medicinal products in accordance with the legislation in force."

10. Article 11(2) shall be amended to read as follows:

"2. The fees for the preparation of the assessment report with a view to the authorisation and reauthorisation of the marketing of veterinary ingredients and diagnostic kits, as well as for changing the conditions under which the marketing authorisation was issued shall be laid down in the Order of the President of the National Sanitary Veterinary and Food Safety Authority No 96/2014, as subsequently amended and supplemented, and shall be paid to the account of the Institute for Control of Biological Products and Veterinary Medicines."

11. In Article 11, two new paragraphs, 2¹ and 2², are inserted after paragraph 2, with the following content:

"2¹. Proof of payment of these fees shall be submitted with the application for authorisation/reauthorisation/modification of the conditions on which the marketing authorisation was issued or within the first 14 days from the date of receipt of the payment documents from the Institute for Control of Biological Products and Veterinary Medicines.

(2²) The evaluation procedure shall start on the date of submission of the proof of payment of the evaluation fee. If the fee is not paid within the established deadline, the procedure shall be cancelled, and the applicant shall be informed in writing."

12. Article 11(3) shall be amended to read as follows:

"(3) The fees for carrying out laboratory analyses, approving advertising material and issuing the duplicate marketing authorisation and testing of reagents and diagnostic kits for veterinary use in order to verify the diagnostic value are laid down in Order No 96/2014 of the President of the National Sanitary Veterinary and Food Safety Authority, as subsequently amended and supplemented."

13. In Article 11, paragraph 4 shall be repealed.

14. After Article 21, paragraph 6, five new paragraphs, 7-11, shall be introduced, with the following content:

"7. By way of derogation from the provisions of paragraph 2(c), if the epidemiological situation so requires, the National Sanitary Veterinary and Food Safety Authority may issue the provisional authorisation for use at the request of the laboratories within the county sanitary veterinary and food safety directorates, respectively of Bucharest Municipality, only to the reagents and diagnostic sets for veterinary use necessary in the diagnosis of the emerging/List A diseases.

(8) In the case of the products referred to in paragraph 2(a) and (c) and paragraph 7, the provisional authorisation for use shall be granted only once.

(9) The National Sanitary Veterinary and Food Safety Authority may extend the period of validity of the provisional authorisation for use issued for the products referred to in

paragraph 2(a) and (c) and paragraph 7 only if proof is provided that the technical documentation for the product authorisation has been submitted, in accordance with the provisions of Chapter IV.

(10) For the products referred to in paragraph 7, the Institute for Diagnosis and Animal Health shall determine the quantity of product for which the extension of the period of validity of the provisional authorisation for use is granted.

(11) The deadline for extending the validity of the temporary use authorization shall be established following consultation with the Institute for Control of Biological Products and Veterinary Medicines."

15. In Article 19, a new paragraph 4 is inserted after paragraph 3, reading as follows:

"(4) The implementation period for the modifications referred to in paragraph 1 is a maximum of 10 days for type I changes referred to in paragraph 1 letter a), and a maximum of 60 days for type II changes referred to in paragraph (1) letter b)."

16. Article 22(2) shall be amended to read as follows:

"2. The data referred to in paragraph 1 must be written in Romanian; multilingual labels are also accepted."

17. Article 23(2) shall be amended to read as follows:

"2. The inclusion of the instructions for use on the product packaging is mandatory, unless all the information required in accordance with the provisions of this Article is mentioned on the secondary packaging; the instructions for use must refer only to the product in question and must be written in Romanian."

18. Article 24(2) shall be amended to read as follows:

"2. For the reauthorization of the marketing of reagents and veterinary diagnostic kits that have not been subject to laboratory control because they were not marketed during the validity period of the marketing authorization, the procedure provided in Chapter IV shall apply."

19. In article 25 paragraphs 1 and 2 shall be amended to read as follows:

"1. Any operation involving the trade in veterinary reagents and diagnostic kits shall be notified in writing to the Institute for Control of Biological Products and Veterinary Medicines.

(2) The notification of the trade of reagents and veterinary diagnostic kits shall be made by the economic operator within maximum 5 days from the receipt of the products in a veterinary pharmaceutical warehouse authorized for the distribution of veterinary medicinal products, reagents, and veterinary diagnostic kits, in accordance with the provisions of the Order of the President of the National Sanitary Veterinary and Food Safety Authority No 83/2014 approving the Veterinary Health Rule on the conditions of organisation and operation of veterinary pharmaceutical establishments and the procedure for sanitary veterinary registration/sanitary veterinary authorisation of establishments and activities in the veterinary pharmaceutical field, as subsequently amended and supplemented."

20. Article 25(3)-(5) shall be amended to read as follows:

"(3) The notification template for trade operations with reagents and diagnostic kits for veterinary use is set out in Annex No 4."

(4) The Institute for Control of Biological Products and Veterinary Medicines shall draw up a register, in accordance with the model set out in Annex No 5, and record therein all trade operations with notified veterinary reagents and diagnostic kits."

(5) "The Institute for Control of Biological Products and Veterinary Medicines shall keep a record of notifications for kit trade operations and shall make this information available to the National Sanitary Veterinary and Food Safety Authority on request."

21. Article 27 paragraph 1 letter b) shall be amended to read as follows:

"b) reagents/diagnostic kits for veterinary use used to carry out the Strategic Programme of Actions for the prevention and control of diseases in animals, those transmissible from animals to humans, animal protection and environmental protection shall be marketed without an analysis report attesting their conformity with the data contained in the technical documentation."

22. In Article 27, paragraph 3 shall be repealed.

23. Throughout Annexes 4 and 5, the words "import/export operations and intra-Community trade" shall be replaced by the words "trade operations".

24. Annex 9 shall be amended to read as follows:

"Annex No 9

<i>Phase 1 - Evaluation of the technical documentation (TD) and test samples</i>	
Maximum 20 days after submission of the application	<ul style="list-style-type: none"> • receipt of the application for authorisation, DT to the ICBMV and proof of payment of the authorisation fee; • TD evaluation; • if applicable, the ICBMV sends a request for clarifications/additional information to the applicant; • the applicant shall send the answers to the address for clarification/additional information requests within maximum 30 days after receipt of the notification (this time limit shall be stated in the notification); • the ICBMV issues the TD evaluation report; • taking samples from the applicant's warehouse.
<i>Phase 2 - Laboratory testing</i>	
Day 0 - day 21	ICBMV laboratory testing.
Day 22	If the results of the laboratory tests are appropriate, the ICBMV sends a request to the NRL or other authorised veterinary laboratory for the evaluation of the diagnostic value and samples for testing.
<i>Phase 3 - Diagnostic value control</i>	
Day 23 - Day 60	<ul style="list-style-type: none"> • the preparation of payment documents by the National Reference Laboratory (NRL); • The NRL or other authorised veterinary laboratory sends the Diagnostic Value Verification Report

	(DVVR) to the ICVMB.
Phase 4 - Issuance of marketing authorisation documents	
Day 61 - Day 70	<ul style="list-style-type: none"> • ICBMV issues the analysis bulletin (AB); • preparation of payment documents; • The ICBMV shall notify the applicant of the fees to be paid by the applicant within 5 days; • The ICBMV shall draw up the final authorisation report proposing, on the basis of reasons, whether or not the marketing authorisation should be granted."

Article II. This Order was adopted in accordance with the notification procedure laid down in Directive (EU) 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Article III. This order shall be published in the Official Gazette of Romania, Part I.

President
of the National Sanitary Veterinary and Food Safety Authority,