



**ÚSKVBL**

Ústav pro státní kontrolu  
veterinárních  
biopreparátů a léčiv

**Information of Institute for State Control of Veterinary Biologicals and Medicines**

**Additional information to the guidance USKVBL/UST - 4/2008/Rev.5**

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## **Specification of the rules for administrative fees and reimbursement of costs of expert activities performed within the scope of the USKVBL after 28/01/2022**

The Institute for State Control of Veterinary Biologicals and Medicines informs applicants / marketing authorization holders about changes in the conditions for payment of administrative fees and reimbursement of costs of expert activities performed within the scope of USKVBL from 28 January 2022 in connection with the applicability of European Parliament and Council Regulation (EU) 2019/6 on veterinary medicinal products (hereinafter the NVR).

The NVR changes the existing rules for the marketing authorization of the veterinary medicinal products and their post-authorization management in the EU. This Regulation entered into force on the twentieth day following that of its publication in the Official Journal of the European Union on 7 January 2019, but applied from 28 January 2022.

The NVR is directly applicable, but in a number of respects it requires Member States to adopt implementing or adaptation rules and in a number of respects allows Member States to set their own regulatory conditions, as is the case for setting administrative fees and reimbursement of costs of expert activities in the area of the veterinary medicinal products regulation.

The national adaptation regulation will be the Act on Pharmaceuticals, whose adaptation amendment was approved at the government level and forwarded to the Chamber of Deputies of the Czech Republic. It can therefore be assumed that the amendment will be adopted at the turn of Q3 2022 and at the same time amendments to the relevant implementing legislation will be prepared (decrees).

It is clear that the period between the entry into force of the NVR and the adoption of the amendment to the Pharmaceuticals Act, or its implementing regulations, will need to be bridged accordingly.

The system of administrative fees and reimbursement of costs of expert activities must be resolved in this transitional period using the legislation in force so far, i.e.

- Act 634/2004 Coll., On administrative fees, as amended, and its tariff for administrative fees and further
- Decree No. 427/2008 Coll., On the determination of the amount of reimbursement of costs of expert activities performed within the competence of the State Institute for Drug Control and the Institute for State Control of Veterinary Biologicals and Medicines, as amended.

The fee amount for payments of expert activities, which in the new conditions retain the current scope and regulatory procedures in the main respects, are maintained for this period and an adjustment taking into account, for example, inflation or digitization issues will be proposed in preparation for the amendment of implementing legislation. This is also reflected in the fact that payments will

no longer be used in connection with the renewal of the authorization of veterinary medicinal products.

For the administration of individual expert activities, it will be necessary to make some adjustments of an administrative nature - for example, adjustment of the terminology used, subsequent adjustment of codes to identify the purpose of payments or modification of the relevant forms.

In addition to these administrative adjustments, it will be necessary to introduce some new activities in connection with the new conditions, especially in the area of variations to VMP marketing authorizations, which is an area that is undergoing fundamental eternal changes. In particular, the definition of new marketing authorisation variations for which no detailed expert evaluation is foreseen in their approval and where the administrative burden associated with identifying these variations, assessing them and approving them is de facto fully transferred to regulatory authorities, including the costs of digitizing of the whole process of administering these variations (working with the EU database on veterinary medicines and exchanging information between this database and the national database).

Regulation 2019/6 therefore introduces substantial changes to the rules laid down for variations to the marketing authorizations of the veterinary medicinal products and changes the way in which the variation types are divided and their classification. The classification of variations under Commission Regulation (EC) No 1234/2008 (and the guidelines for the different categories of amendments, for the implementation of the procedures set out in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008) will therefore no longer be used and according to Articles 61 and 62 of Regulation (EU) 2019/6 is replaced by two types of changes, namely those that do not require assessment (VNRA, classification codes start with the letters A, B, C or D) and by those which require assessment (classification codes start with the letters E, F, G, H or I). You can find more about the division of changes in the guideline - ÚSKVBL / REG-1/2022 Informace k novým pravidlům pro změny registrace veterinárních léčivých přípravků v souvislosti s nařízením 2019/6 (Information on the new rules for changes to the marketing authorization of the veterinary medicinal products in connection with Regulation 2019/6), which can be only found in Czech at <http://www.uskvbl.cz/cs/registrace-a-schvalovani/registrace-vlp/obecne-pokyny-a-informace/obecne-pokyny>. This is also related to changes applicable to the reimbursement of costs of expert activities in connection with variations to the marketing authorization of the veterinary medicinal products.

**The subject of reimbursement are both individual variation applications and grouped variation applications, and finally also variations for which a detailed expert evaluation is not expected within the framework of their approval pursuant to Article 61 of the NVR.**

**Another basic principle remains, i.e. the separate payment of the administrative fees, which remains in the current regime.**

**Annex: Specification of payments for variations according to the tariff in Annex No. 2 and No. 4 to Decree No. 427/2008 Coll.**

The information below complement the existing USKVBL/UST Guideline – 4/2008 Rev. 5 Administrative fees and reimbursement of costs of expert activities performed within the scope of the USKVBL until the entry into force of updated legislation in the Czech Republic, which will take into account the new rules set by Regulation 2019/6. All general rules and information regarding the method of payments remain unchanged and you will continue to find them in the current guideline.

**This approach shall apply to all marketing authorization applications submitted to the USKVBL or to variations recorded in the European Medicines Database (UPD) from 28/01/2022.**

**A. *Setting of payments for newly created categories of variations (variations not requiring assessment + variations with a reduced scope of assessment):***

| <b>NATIONAL MARKETING AUTHORISATIONS</b>                             |  |  |                                      |
|--|--|--|--------------------------------------|
| <b>Variation according to Regulation (EU) 2019/6</b>                 | <b>Code for generating the variable symbol</b> | <b>Definition of existing act (no longer valid) for the relevant code used</b>                   | <b>Amount of costs reimbursement</b> |
| VNRA, variations marked with classification codes A, B, C, D         | RN-11  | Application for variation – <b>type IA</b> (national procedure)                                  | 4 900,- CZK                          |
| Variations marked with classification codes E, F, G, H <b>R (30)</b> | RN-43  | Application for variation – <b>type IB</b> (national procedure)                                  | 6 860,- CZK                          |
| <b>CZ AS REFERENCE MEMBER STATE</b>                                  |  |  |                                      |
| VNRA, variations marked with classification codes A, B, C, D         | RRMS/ZIA-28                                    | Application for <b>type IA</b> variation within the Mutual Recognition Procedure with CZ as RMS. | 4 900,- CZK                          |
| Variations marked with classification codes E, F, G, H <b>R (30)</b> | RRMS/ZIB-27                                    | Application for <b>type IB</b> variation within the Mutual Recognition Procedure with CZ as RMS  | 7 350,- CZK                          |

|  | CZ AS CONCERNED MEMBER STATE |  |             |
|--|------------------------------|--|-------------|
| VNRA, variations marked with classification codes A, B, C, D         | RCMS/ZIA-37                  | Application for <b>type IA</b> variation within the Mutual Recognition Procedure with CZ as CMS.<br><br>Decision issued for veterinary medicinal product by the competent authority of another Member State. | 4 900,- CZK |
| Variations marked with classification codes E, F, G, H R <b>(30)</b> | RCMS/ZIB-36                  | Application for <b>type IB</b> variation within the Mutual Recognition Procedure with CZ as CMS.<br><br>Decision issued for veterinary medicinal product by the competent authority of another Member State. | 5 880,- CZK |

*B. Extrapolation of payments for the other variations to the marketing authorisations according to their difficulty in the following way:*

|  | NATIONAL MARKETING AUTHORISATIONS       |   |                               |
|--|---|---|-------------------------------|
| Variation according to Regulation (EU) 2019/6  | Code for generating the variable symbol | Definition of existing act (no longer valid) for the relevant code used   | Amount of costs reimbursement |
| Variations marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes which, by their nature, they establish a new VMP under Czech legislation, i.e. the addition of strength or pharmaceutical form of VMP - <b>E(90)</b> | RN-07                                   | Application for marketing authorisation of veterinary medicinal product – in defined cases.<br><br>With regard to a significant change in the nature, properties or method of use of the veterinary medicinal product, it is not possible to request a variation to the marketing authorisation of the relevant product – <b>Extension of MA by a maximum of one property</b> (e.g. strength, pharmaceutical form, addition of food-producing target animal). | 31 800,- CZK                  |



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|  | RN-D-57     | Other activities carried out only in cases where the applications do not contain requested data and documentation corresponding to the valid requirements and where the applicant is asked to complete the data or documentation.   | 4 900,- CZK  |
| Variations marked with classification codes E, F, G, H - S (60)  | RN-10       | Application for <b>type II</b> variation (national procedure)   | 24 000,- CZK |
|  | RN-D-60     | Other activities carried out only in cases where the applications do not contain requested data and documentation corresponding to the valid requirements and where the applicant is asked to complete the data or documentation.   | 4 900,- CZK  |
| <b>CZ AS REFERENCE MEMBER STATE</b>  |             |   |              |
| Variations marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes which, by their nature, they establish a new VMP under Czech legislation, i.e. the addition of strength or pharmaceutical form of VMP – E (90) | RRMS/EX-23a | Application for starting the mutual recognition procedure with CZ as RMS – in defined cases where with regard to a significant change in the nature, properties or method of use of the veterinary medicinal product, it is not possible to request a variation to the marketing authorisation of the relevant product - <b>Extension of MA</b> by a <b>maximum of one property</b> (e.g. strength, pharmaceutical form, addition of food-producing target animal), <b>maximum 5 CMS</b> are involved in the procedure. | 73 400,- CZK |



|   |             |   |               |
|---|-------------|---|---------------|
| Variations marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes which, by their nature, they establish a new VMP under Czech legislation, i.e. the addition of strength or pharmaceutical form of VMP – <b>E (90)</b> | RRMS/EX-23b | Application for starting the mutual recognition procedure with CZ as RMS – in defined cases where with regard to a significant change in the nature, properties or method of use of the veterinary medicinal product, it is not possible to request a variation to the marketing authorisation of the relevant product - <b>Extension of MA by a maximum of one property</b> (e.g. strength, pharmaceutical form, addition of food-producing target animal), <b>maximum 6-15 CMS</b> are involved in the procedure.       | 88 100,- CZK  |
| Variations marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes which, by their nature, they establish a new VMP under Czech legislation, i.e. the addition of strength or pharmaceutical form of VMP – <b>E (90)</b> | RRMS/EX-23c | Application for starting the mutual recognition procedure with CZ as RMS – in defined cases where with regard to a significant change in the nature, properties or method of use of the veterinary medicinal product, it is not possible to request a variation to the marketing authorisation of the relevant product - <b>Extension of MA by a maximum of one property</b> (e.g. strength, pharmaceutical form, addition of food-producing target animal), where more than <b>15 CMS</b> are involved in the procedure. | 102 800,- CZK |
|   | RRMS/EX-D73 | Other activities carried out only in cases where the applications do not contain requested data and documentation corresponding to the valid requirements and where the applicant is asked to complete the data or documentation.   | 7 300,- CZK   |

|   |              |  |              |
|---|--------------|--|--------------|
| Variations marked with classification codes E, F, G, H - <b>S (60)</b>  | RRMS/ZII-26a | Application for <b>type II</b> variation within the Mutual Recognition Procedure with CZ as RMS, <b>maximum 5 CMS</b> are involved in the procedure.   | 28 400,- CZK |
| Variations marked with classification codes E, F, G, H - <b>S (60)</b>  | RRMS/ZII-26b | Application for <b>type II</b> variation within the Mutual Recognition Procedure with CZ as RMS, <b>maximum 6-15 CMS</b> are involved in the procedure.  | 30 800,- CZK |
| Variations marked with classification codes E, F, G, H - <b>S (60)</b>  | RRMS/ZII-26c | Application for <b>type II</b> variation within the Mutual Recognition Procedure with CZ as RMS, <b>more than 15 CMS</b> are involved in the procedure.  | 33 300,- CZK |
| <b>CZ AS CONCERNED MEMBER STATE</b>   |              |  |              |
| Variations marked with classification codes G.I.7, G.I.9, G.I.10, G.I.13, G.I.14 and I, including those changes which, by their nature, they establish a new VMP under Czech legislation, i.e. the addition of strength or pharmaceutical form of VMP - <b>E (90)</b> | RCMS-33      | Application for recognition of a marketing authorisation decision issued for a veterinary medicinal product by the competent authority of another Member State – in defined cases where, with regard to a significant change in the nature, properties or use of the veterinary medicinal product, a variation to the marketing authorisation cannot be requested for the relevant product – <b>Extension of MA</b> of veterinary medicinal product. | 43 600,- CZK |
| Variations marked with classification codes E, F, G, H – <b>S (60)</b>  | RCMS/ZII-35  | Application for <b>type II</b> variation within the Mutual Recognition Procedure with CZ as CMS.<br><br>Decision issued for veterinary medicinal product by the competent authority of another Member State.   | 24 000,- CZK |

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