Commission Notice on marketing authorisations for veterinary medicinal products for which the expiry of the 5-year period of validity falls on or after the date of entry into application of Regulation (EU) 2019/6

(2021/C 274/02)

1. Introduction

The purpose of this Notice is to inform stakeholders on how the Commission intends to deal with centrally authorised veterinary medicinal products for which the expiry of the 5-year period of validity of the marketing authorisation falls on or after 28 January 2022. The Notice also addresses certain questions that may arise in relation to nationally authorised products.

This Notice should be read in conjunction with the relevant provisions of Directive 2001/82/EC ([1]) and Regulation (EU) 2019/6 on veterinary medicinal products ([2]). It clarifies the provisions already contained in the applicable legislation and does not extend in any way the obligations deriving from such legislation nor introduce any additional requirements on the concerned operators and competent authorities.

This Notice is merely intended to assist business operators and national competent authorities in the application of the relevant legislation. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law. The views expressed in this Notice cannot prejudge the position that the European Commission might take before the Union and national Courts.

2. Status of marketing authorisations for which the expiry of the 5-year period of validity falls on or after the date of entry into application of Regulation (EU) 2019/6

Regulation (EU) 2019/6 on veterinary medicinal products ('the VMP Regulation'), which repeals Directive 2001/82/EC, will enter into application on 28 January 2022.

Article 5(2) of the VMP Regulation provides that a marketing authorisation's validity is unlimited from the moment the authorisation is granted. Article 152(1) provides that marketing authorisations granted in accordance with both Directive 2001/82/EC and Regulation (EC) No 726/2004 ([3]) shall be deemed to have been issued in accordance with the VMP Regulation. However, Article 28(1) and (2) of Directive 2001/82/EC provides that marketing authorisations are initially valid for five years and become unlimited only after a renewal procedure. For centrally authorised products, Article 39 of Regulation (EC) No 726/2004 mirrors this provision.

Therefore, as of 28 January 2022, a new single-step system for acquiring a marketing authorisation for an unlimited duration will replace the previous two-step process of both Directive 2001/82/EC and Regulation (EC) No 726/2004.

The VMP Regulation does not foresee a situation that would require a renewal, as marketing authorisations granted under the Regulation are in principle valid for an unlimited period. Equally, it does not contain any provisions addressing the renewal of existing marketing authorisations granted under Directive 2001/82/EC or Regulation (EC) No 726/2004.

Furthermore, there is no legal basis in any of the relevant EU legislation to specifically anticipate that the marketing authorisations in question would automatically become valid for an unlimited period as of 28 January 2022. Consequently, regulatory action is required in order to give effect to Article 152(1) of the VMP Regulation, as explained below.

Marketing authorisations granted under Regulation (EC) No 726/2004 are in the form of a Commission Implementing Decision, which provides in its enacting terms that the period of validity of the marketing authorisation is five years from the date of notification of the Decision to the marketing authorisation holder. These individual decisions granting marketing authorisations will need to be amended to remove the provision with the expiry date. This applies in principle to both centrally authorised and nationally authorised products. For centrally authorised products, under EU law, it is only possible to do this by amending each decision individually.

([1]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([2]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([3]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

For nationally authorised products, Member States will need to take the necessary measures to ensure that the national decisions concerned are amended in due course in order to remove the 5-year time limit. The manner in which this is achieved will depend on national law.

3. **Applications for renewal submitted before entry into application of Regulation (EU) 2019/6**

Article 151 (1) and (2) of the VMP Regulation states that procedures concerning the applications for marketing authorisations for veterinary medicinal products or of variations that have been validated in accordance with either Regulation (EC) No 726/2004 or Directive 2001/82/EC before 28 January 2022 shall be completed in accordance with Regulation (EC) No 726/2004 and the Directive, respectively.

Consequently, applications for renewal of marketing authorisations granted under either Directive 2001/82/EC or Regulation (EC) No 726/2004 that are validated before entry into application of Regulation (EU) 2019/6 will be processed under Directive 2001/82/EC or Regulation (EC) No 726/2004, respectively. The relevant provisions require the submission of an application for a renewal at least six months before the expiry of the marketing authorisation.

Should they wish to (and in consultation with the relevant competent authority), marketing authorisation holders may apply for a renewal under Directive 2001/82/EC or Regulation (EC) No 726/2004 further in advance than the usual 6 months in cases where, in the absence of a request for renewal, the expiry of the marketing authorisation would fall upon or after entry into application of the VMP Regulation.

4. **Questions and Answers**

For both centrally and nationally authorised products

Question 1:

What do I need to do if the period of validity of the marketing authorisation for my veterinary medicinal product is due to expire upon or after the entry into application of the VMP Regulation?

Answer:

For centrally authorised veterinary medicinal products, the European Medicines Agency ('the Agency') will send a letter concerning the expiry of the validity of the marketing authorisation. You will need to reply to this letter to confirm whether or not you wish your marketing authorisation to be unlimited in duration upon expiry of its 5-year period of authorisation. If you reply in the affirmative, the Commission will then take the necessary steps to ensure that the marketing authorisation becomes unlimited in duration. If you reply in the negative or do not reply to the letter from the Agency, the marketing authorisation will automatically expire after the 5-year period of validity.

Alternatively, you could apply for a renewal, under existing legislation, before entry into application of the VMP Regulation ([4]) (see question 2 below).

For nationally authorised products, you should contact the national competent authority to ascertain what steps you must take.

Question 2:

In cases where the expiry of my marketing authorisation after the 5-year period would fall on or after entry into application of the VMP Regulation, can I choose to apply earlier than 6 months before expiry of the marketing authorisation for the renewal of the marketing authorisation for my veterinary medicinal product?

Answer:

Yes, in consultation with the relevant competent authority, it is possible to apply early for a renewal in these circumstances in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004, as applicable. Please note that the validation date of the renewal application should fall before 28 January 2022 and that in this case an assessment will be undertaken.

([4]) The validation date of the renewal application should be before 28 January 2022.

Question 3:

Would there be any assessment by the Commission or the national competent authority before the marketing authorisation decision is administratively amended to remove the 5-year time limit for the period of validity?

Answer:

No, there will be no assessment involved in an administrative removal of the 5-year limit for the period of validity, i.e. where no renewal application has been submitted.

Question 4:

What happens if, by 28 January 2022, a decision has not yet been taken on my ongoing application for renewal of a marketing authorisation submitted under Directive 2001/82/EC or Regulation (EC) No 726/2004, as applicable?

Answer:

In accordance with Article 151 of the VMP Regulation, the renewal request will be dealt with under Directive 2001/82/EC or Regulation (EC) No 726/2004, as applicable, and the marketing authorisation will remain valid until the end of its validity as stated in the decision granting the marketing authorisation.

Question 5:

What if the marketing authorisation for my veterinary medicinal product already has an unlimited duration?

Answer:

The status of your marketing authorisation will remain the same and no further action is required.

For centrally authorised products only

Question 6:

What if there is a gap in time between expiry of the 5-year time limit for the period of validity and the new decision making it unlimited?

Answer:

If you express your interest in obtaining an unlimited duration of the marketing authorisation for your veterinary medicinal product, the marketing authorisation will remain valid in practice until amendment of the marketing authorisation decision, which will 'regularise' the legal situation regarding unlimited duration of that marketing authorisation.

Question 7:

What if there are no upcoming procedures that would necessitate amendment of the decision for the veterinary medicinal product concerned before the expiry date of the marketing authorisation and following the entry into application of Regulation (EU) 2019/6?

Answer:

If there are no timely upcoming procedures, the Commission will issue a Decision amending the marketing authorisation at or around the marketing authorisation's expiry date. If such a Decision is not adopted before the expiry date of the marketing authorisation, the marketing authorisation will remain valid in practice until amendment of the marketing authorisation decision, which will 'regularise' the legal situation regarding unlimited duration of that marketing authorisation.

Question 8:

What will happen to my marketing authorisation if I do not submit a renewal application and I do not reply to the letter asking if I wish my marketing authorisation to become indefinite?

Answer:

The marketing authorisation would expire naturally at the current date of expiry of the period of validity.