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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products ('VMP Regulation')

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1. INTRODUCTION

Regulation (EU) 2019/6 on veterinary medicinal products[1] was adopted on 11 December 2018 and entered into force on 27 January 2019. It has applied since 28 January 2022.

Regulation (EU) 2019/6 sets out a modern, innovative and fit-for-purpose legal framework on veterinary medicinal products ("VMPs"). It gives incentives to stimulate innovation for VMPs and increase their availability, whilst also strengthening the EU's actions to fight antimicrobial resistance. Regulation (EU) 2019/6 repealed and replaced Directive 2001/82/EC,[2] which needed to be adapted to scientific progress and to current market conditions and economic reality, while continuing to ensure a high level of protection of animal health and welfare, and safeguarding public health and protecting the environment.

Regulation (EU) 2019/6 contains a common framework for the authorisation of VMPs with a simplified assessment procedure and the possibility to extend the data protection period up to 18 years under certain conditions. It provides a clear definition and adequate rules for biological VMPs and novel therapy VMPs, which should incentivise the development of new VMPs in those areas. Opening up the centralised authorisation procedure to any VMP and allowing for marketing authorisations in exceptional circumstances is expected to positively broaden the spectrum of VMPs that may be brought to the market. Regulation (EU) 2019/6 brings autogeneous vaccines within its scope, sets up a Union Product Database, specifying clear and fully harmonised labelling requirements, adopting a simpler system for variation decisions and a risk-based approach for pharmacovigilance and controls. Finally, the Regulation provides for a wide range of concrete measures to fight antimicrobial resistance (AMR) and to promote a prudent and responsible use of antimicrobials in animals.

Regulation (EU) 2019/6 contains 18 empowerments for the Commission to adopt implementing acts and nine empowerments to adopt delegated acts.

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[1] 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 L4, 7.1.2019, p. 43).

[2] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Commmunity code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1). Directive 2001/82/EC applied to nationally authorised products. The previous rules for centrally authorised products were set out in Regulation (EC) No 726/2004 laying down Community 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), Regulation (EC) No 1901/2006 on medicinal products for paediatric use (OJ L 378, 27.12.2006, p. 1) and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 (OJ L4, 7.1.2019, p. 24) repealed the provisions of Regulation (EC) No 726/2004 concerning the authorisation of veterinary medicinal products, as Regulation (EU) 2019/6 brings together rules for both nationally and centrally authorised products.

2. LEGAL BASIS

Article 147(2) of Regulation (EU) 2019/6 on veterinary medicinal products confers the power on the Commission to adopt the delegated acts referred to in the provisions set out in that Article (see section 3, below). Pursuant to Article 147(2) of Regulation (EU) 2019/6, the power to adopt delegated acts concerning the matters listed therein is conferred on the Commission for a period of five years from 27 January 2019. The Commission is required to draw up a report to the European Parliament and the Council in respect of that delegation of power not later than nine months before the end of the five-year period. The delegation of power is to be tacitly extended for periods of identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. EXERCISE OF THE DELEGATION

According to Article 147(2) of Regulation (EU) 2019/6, the Commission is empowered to adopt the delegated acts referred to in Articles 37(4), 57(3), 106(6), 109(1), 115(3), 118(2), 136(7) and 146(1) and (2) of the Regulation.

3.1. EMPOWERMENTS USED DURING THE REPORTING PERIOD

During the reporting period[3], the Commission exercised its delegated powers, by adopting the following delegated acts[4]:

- Commission Delegated Regulation (EU) 2021/577 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the content and format of the information necessary to apply Articles 112(4) and 115(5) and to be contained in the single lifetime identification document referred to in Article 8(4) of that Regulation[5], as amended[6]. This act, adopted on the basis of Article 109(1) of Regulation (EU) 2019/6, entered into force on 29 April 2021 and entered into application on 28 January 2022.

- Commission Delegated Regulation (EU) 2021/578 of 29 January 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council with regard to requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals[7]. This act, adopted on the basis of Article 57(3) of Regulation (EU) 2019/6, entered into force on 29 April 2021 and entered into application on 28 January 2022.

- Commission Delegated Regulation (EU) 2021/805 of 8 March 2021 amending Annex II to Regulation (EU) 2019/6 of the European Parliament and of the Council[8]. This act, adopted on the basis of Article 146(2) of Regulation (EU) 2019/6, entered into force on 10 June 2021 and entered into application on 28 January 2022.

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3 The cut-off date for the inclusion in this section of delegated acts adopted during the reporting period is 28 April 2023.

4 The delegated acts are listed in the chronological order of their date of adoption.

5 OJ L 123 9.4.2021, p. 3.

6 Commission Delegated Regulation (EU) 2022/524 of 27 January 2022 correcting Delegated Regulation (EU) 2021/577 as regards certain references to veterinary medicinal products; OJ L 105, 4.4.2022, p. 1.

7 OJ L 123, 9.4.2021, p. 7.

8 OJ L 180, 21.5.2021, p. 3.

- Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans[9]. This act, adopted on the basis of Article 37(4) of Regulation (EU) 2019/6, entered into force on 26 October 2021 and entered into application on 28 January 2022.

- Commission Delegated Regulation (EU) 2023/183 of 23 November 2022 amending Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the requirements on compliance with good laboratory practice for veterinary medicinal products set out in Annex II to that Regulation[10]. This act, adopted on the basis of Article 146(1) of Regulation (EU) 2019/6, entered into force on 19 February 2023 and entered into application on 28 January 2022.

- Commission Delegated Regulation (EU) 2023/905 of 27 February 2023 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union[11]. This act was adopted on the basis of Article 118(2) of Regulation (EU) 2019/6.

The Commission notified each of the aforementioned delegated acts to the European Parliament and to the Council, in accordance with Article 147(6) of Regulation (EU) 2019/6. The European Parliament and the Council did not extend the objection period referred to in Article 147(7) of Regulation (EU) 2019/6 in relation to any of these acts, with the exception of Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans. The European Parliament extended the objection period by two months with respect to the latter act. Neither the European Parliament nor the Council objected to any of the above acts in accordance with Article 147(7) of Regulation (EU) 2019/6.

The Commission has so far used 6 out of the 9 empowerments in Article 147(2) of Regulation (EU) 2019/6 and which are therefore within the scope of this report.

3.2. EMPOWERMENTS NOT USED DURING THE REPORTING PERIOD

Certain empowerments of Regulation (EU) 2019/6 have not been used during the reporting period for the reasons explained below.

- Article 106(6)

The Commission is currently preparing a delegated act laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals, in accordance with Article 106(6) of Regulation (EU) 2019/6.

- Article 115(3)

[9] OJ L 353, 6.10.2021, p. 1.
[10] OJ L 26, 30.1.2023, p.7.
[11] OJ L 116, 04.05.2023, p.1.

There is currently no new scientific evidence reported regarding the areas covered by paragraphs 1 to 4 of Article 115 of Regulation (EU) 2019/6. However, future changes and developments may require proceeding with the preparation of a delegated act pursuant to Article 115(3).

- Article 136(7)

The Commission has not yet started preparing a delegated act under Article 136(7) of Regulation (EU) 2019/6, as the focus so far has been on empowerments with specific deadlines. However, it will proceed with preparation of a delegated act in due course.

CONCLUSION

The Commission sees the need for a tacit extension of the delegation of power provided for in Article 147(2) of Regulation (EU) 2019/6 for a period of five years, in accordance with that Article. This is due to the fact that the need to develop rules based on the empowerments granted by Article 147(2) of Regulation (EU) 2019/6 will remain in the future. This will be particularly important to provide the necessary flexibility in the new legal framework, to complement and adjust it regularly to the latest scientific standards and to allow the Commission to act in the areas where it did not act until now, but will need to do so in the future.

With this report, the Commission complies with the reporting requirements established in Article 147(2) of Regulation (EU) 2019/6.

The Commission invites the European Parliament and the Council to take note of this report.