Veterinary Medicines – Publication of Regulation (EU) 2019/6 of 11 December 2018 Modernising EU Regulatory Framework

After four years of negotiations, Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC[1] (the ***New Regulation***) was adopted on 11 December 2018 and published in the *Official Journal of the European Union* on 7 January 2019.[2] The New Regulation, which will apply as of 28 January 2022, aims to establish a modern regulatory framework for veterinary medicinal products (***VMPs***) and encompasses a broad range of concrete measures to achieve this goal.

Regulation (EC) 726/2004[3] currently governs the centralised procedure for granting marketing authorisations for medicinal products for both human and veterinary use and also regulates the European Medicines Agency (***EMA***). Regulation (EU) 2019/5[4], which was also published in the *Official Journal of the European Union* on 7 January 2019, repeals the provisions of Regulation (EU) 726/2004 relating to the authorisation and supervision of VMPs. However, specific provisions of Regulation (EC) 726/2004 relating to VMPs – especially those governing the internal organisation and functioning of EMA – are maintained. As of 28 January 2022, the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of VMPs will be exclusively governed by the New Regulation.

The New Regulation effects the following key changes:

1. *Antimicrobial resistance* - The New Regulation strengthens the existing EU framework in fighting antimicrobial resistance. To this end, the New Regulation:

   (i) bans the preventive use of antibiotics in groups of animals;

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1 Directive 2001/82/EC of 6 November 2001 on the Community Code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1-66).

2 OJ L 4, 7.1.2019, p. 43-167.

3 Regulation (EC) No 726/2004 of 31 March 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. 1-33).

4 Regulation (EU) 2019/5 of 11 December 2018 amending 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, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24-42).

(ii) extends the existing ban on the use of antimicrobials for promoting growth and increasing yield in veterinary feed to their use in VMPs;

(iii) restricts the metaphylactic use of antimicrobials;

(iv) permits EU Member States to reserve specific antimicrobials for humans only;

(v) obliges EU Member States to collect data on the sale and use of antimicrobials; and

(vi) prohibits, for imported animals and products from outside the EU, antimicrobials for promoting growth and places restrictions on antimicrobials reserved for human use.

2. *Availability and circulation of VMPs* - The New Regulation aims to increase the number and quality of VMPs and promote their availability and circulation across the EU. To this end, the New Regulation:

(i) harmonises the conditions for obtaining an authorisation for the wholesale distribution of VMPs;

(ii) mandates the establishment of a EU-wide database for wholesale distributors which have been found to comply with applicable legislation, following inspection by the competent authorities of the EU Member State in which such distributors are established;

(iii) authorises the sale at a distance of over-the-counter VMPs to buyers in other EU Member States. However, for those EU Member States where it is current practice to sell at a distance prescription VMPs (which to our understanding is the case in Sweden), such practice should be allowed to continue within the territory of these Member States only;

(iv) identifies the minimal elements of a veterinary prescription and allows for the cross-border recognition of such prescriptions. If a VMP has been prescribed in an EU Member State in which it is authorised, such prescription should be recognised and the VMP should be dispensed in other EU Member States; and

(v) sets out rules on advertising VMPs, which are to complement the general rules contained in Directive 2006/114/EC concerning misleading and comparative advertising.[5] In particular, the Regulation mandates the establishment of a common logo recognisable throughout the EU, which should assist consumers in identifying those websites which are legally empowered to offer VMPs for sale at a distance.

3. *Red tape cutting* - The New Regulation aims at reducing the administrative burden for pharmaceutical companies and strengthening the internal market. To this end, the New Regulation:

   (i) broadens the use of the centralised authorisation procedure. However, national authorisation procedures are concomitantly maintained due to the varying needs and business models existing in the different EU Member States.

   (ii) determines that, as a general rule and as opposed to the rules applying to medicinal products for human use, a marketing authorisation for a VMP should be granted for an unlimited period of time. The renewal of marketing authorisations for VMPs should be limited to exceptional cases; and

   (iii) presents simplified rules on packaging and labelling.

4. *Environmental protection* - The New Regulation imposes a mandatory environmental risk assessment for new VMP authorisations.

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[5] Directive 2006/114/EC of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21-27).