Medicines – Publication of Regulation (EU) 2019/5 of 11 December 2018 amending Regulation (EC) No 726/2004 – Key Novelties

The *Official Journal of the European Union* of 7 January 2019 contains 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*" (the ***New Regulation***).

The New Regulation updates the EU regulatory framework governing medicinal products, in particular by amending Regulation 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*" (***Regulation 726/2004***). Regulation 726/2004 currently governs the centralised procedure for granting marketing authorisations for medicinal products for human and veterinary use as well as the functioning of the European Medicines Agency (***EMA***).

Here are the key novelties brought about by the New Regulation:

1. *Veterinary medicinal products* - The New Regulation restricts the scope of Regulation 726/2004 to medicinal products for human use. As from 28 January 2022, the authorisation and supervision of veterinary medicinal products will be governed exclusively by a new Regulation (EU) 2019/6 of 11 December 2018 "*on veterinary medicinal products and repealing Directive 2001/82/EC*". This Regulation was also published in the *Official Journal of the European Union* of 7 January 2019. Despite this change, the provisions of Regulation 726/2004 describing EMA's internal organisation and functioning when dealing with veterinary medicinal products will be maintained.

2. *Medicinal products for human use* - The New Regulation moves the core elements of the rules on the granting of a marketing authorisation (***MA***) subject to specific obligations to meet unmet medical needs[1] into Regulation

[1] *See*, current Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC)

726/2004. Likewise, the core elements of the rules on the examination of applications for variations to the terms of MAs[2] are moved into (i) Regulation 726/2004; and (ii) Directive 2001/83/EC of 6 November 2001 "*on the Community code relating to medicinal products for human use*" (***Directive 2001/83/EC***). In both cases, the New Regulation gives the European Commission (the ***Commission***) the power to adopt delegated acts which complement those core elements with further or updated provisions.

The changes which the New Regulation effects in this respect will apply from 28 January 2019.

3. *Penalties* - In the field of enforcement, and as from 28 January 2019, the New Regulation moves into Regulation 726/2004 the key rules on the financial penalties that can be imposed on MA holders (***MAHs***) for failure to comply with specific obligations in connection with their MA. The list specifying those obligations is also transferred.[3] In addition, the New Regulation empowers the Commission to adopt delegated acts laying down further procedures for imposing such financial penalties. Under a key novelty the Commission is given the power, if and when provided for in a delegated act, to impose financial penalties not only on the MAH but also on legal entities other than the MAH that form part of the same economic entity as the MAH and that (i) exerted a decisive influence over the MAH; or (ii) were involved in, or could have addressed, such failure to comply with the obligation by the MAH. Recital 8 to the New Regulation notes that, in the absence of such a rule, "*there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties*".

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[2] No 726/2004 of the European Parliament and of the Council. This Regulation will remain in force and continue to apply unless and until repealed (*See*, Article 4(1) of the New Regulation). *See*, current Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. This Regulation will remain in force and continue to apply unless and until repealed as regards medicinal products for human use that are covered by Regulation 726/2004 and Directive 2001/83/EC and that are not excluded from the scope of Regulation No 1234/2008 pursuant to Article 23b(4) and (5) of Directive 2001/83/EC (*See*, Article 4(2) of the New Regulation).

[3] *See*, current Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council. This Regulation will remain in force and continue to apply unless and until repealed (*See*, Article 4(1) of the New Regulation).

4. *Financing of EMA* - The New Regulation updates the provisions of Regulation 726/2004 on the financing of EMA and aligns these provisions with the various implementing Regulations in the field. These implementing Regulations detail, amongst others, the structure and level of fees payable to EMA for the services it provides to, for instance, MA applicants.

5. *Miscellaneous* - The New Regulation makes a number of technical amendments to Regulation 726/2004 so as to align the powers conferred on the Commission under that Regulation to the relevant procedural provisions of the Treaty on the Functioning of the European Union. Surprisingly, the current text of Regulation 726/2004 does not yet consider the impact of the 2007 Treaty of Lisbon on the decision-making procedures of the European Union.

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