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 (Text with EEA relevance)

TITLE I

DEFINITIONS AND SCOPE

Article 1

The purpose of this Regulation is to lay down **[**[F1]Union**]** procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human and veterinary use, and to establish a European Medicines Agency (hereinafter referred to as 'the Agency').

The provisions of this Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions. In particular, Member States shall be free to choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/5 of the European Parliament and of the Council 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 (Text with EEA relevance).

Article 2

The definitions laid down in Article 1 of Directive 2001/83/EC and those laid down in Article 1 of Directive 2001/82/EC shall apply for the purposes of this Regulation.

The holder of a marketing authorisation for medicinal products covered by this Regulation must be established in the **[**[F1]Union**]**. The holder shall be responsible for the placing on the market of those medicinal products, whether he does it himself or via one or more persons designated to that effect.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/5 of the European Parliament and of the Council 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 (Text with EEA relevance).

Article 3

1 No medicinal product appearing in the Annex may be placed on the market within the **[**F1Union unless a marketing authorisation has been granted by the Union**]** in accordance with the provisions of this Regulation.

2 Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the **[**F1Union**]** in accordance with the provisions of this Regulation, if:

a the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorised in the **[**F1Union**]**; or

b the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interests of patients or animal health at **[**F1Union**]** level.

Immunological veterinary medicinal products for the treatment of animal diseases that are subject to **[**F1Union**]** prophylactic measures may also be granted such authorisation.

3 A generic medicinal product of a reference medicinal product authorised by the **[**F1Union**]** may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC and Directive 2001/82/EC under the following conditions:

a the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC or Article 13 of Directive 2001/82/EC;

b the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the **[**F1Union**]** except for those parts of the summary of product characteristics referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed; and

c the generic medicinal product is authorised under the same name in all the Member States where the application has been made. For the purposes of this provision, all the linguistic versions of the INN (international non-proprietary name) shall be considered to be the same name.

[F24 After the competent committee of the Agency has been consulted, the Commission may adapt the Annex to technical and scientific progress and may adopt any necessary amendments without extending the scope of the centralised procedure.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 87(2a).**]**

Textual Amendments

F1 Substituted by Regulation (EU) 2019/5 of the European Parliament and of the Council 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 (Text with EEA relevance).

F2 Substituted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

Article 4

1 Applications for the marketing authorisations referred to in Article 3 shall be submitted to the Agency.

2 The **[**F1Union**]** shall grant and supervise marketing authorisations for medicinal products for human use in accordance with Title II.

3 The **[**F1Union**]** shall grant and supervise marketing authorisations for veterinary medicinal products in accordance with Title III.

Textual Amendments

F1 Substituted by Regulation (EU) 2019/5 of the European Parliament and of the Council 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 (Text with EEA relevance).

Status:
Point in time view as at 28/01/2019.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 726/2004 of the European Parliament and of the Council, TITLE I.