Regulation (EC) No 726/2004 of the European Parliament and of the Council 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 (Text with EEA relevance)

TITLE II

AUTHORISATION AND SUPERVISION OF MEDICINAL PRODUCTS FOR HUMAN USE

Chapter 3

Pharmacovigilance

Article 21

For the purposes of this Chapter, Article 106(2) of Directive 2001/83/EC shall apply.

Article 22

The Agency, acting in close cooperation with the national pharmacovigilance systems established in accordance with Article 102 of Directive 2001/83/EC, shall receive all relevant information concerning suspected adverse reactions to medicinal products for human use which have been authorised by the Community in accordance with this Regulation. Where appropriate, the Committee for Medicinal Products for Human Use shall, in accordance with Article 5 of this Regulation, draw up opinions on the measures necessary. These opinions shall be made publicly accessible.

The measures referred to in the first paragraph may include amendments to the marketing authorisation granted in accordance with Article 10. They shall be adopted in accordance with the procedure referred to in Article 87(3).

The holder of the marketing authorisation and the competent authorities of Member States shall ensure that all relevant information concerning suspected adverse reactions to the medicinal products authorised under this Regulation are brought to the attention of the Agency in accordance with the provisions of this Regulation. Patients shall be encouraged to communicate any adverse reaction to health-care professionals.

Article 23

The holder of an authorisation for a medicinal product for human use granted in accordance with the provisions of this Regulation shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

That qualified person shall reside in the Community and shall be responsible for the following:

(a) establishing and managing a system which ensures that information concerning all suspected adverse reactions which are reported to the personnel of the company and to medical representatives is collected, evaluated and collated so that it may be accessed at a single point within the Community;

(b) preparing the reports referred to in Article 24(3) for the competent authorities of the Member States and the Agency in accordance with the requirements of this Regulation;

(c) ensuring that any request from the competent authorities for the provision of additional information necessary for the evaluation of the risks and benefits of a medicinal product is answered fully and promptly, including the provision of information regarding the volume of sales or prescriptions for the medicinal product concerned;

(d) providing the competent authorities with any other information relevant to the evaluation of the risks and benefits of a medicinal product, particularly information concerning post-authorisation safety studies.

Article 24

1 The holder of the marketing authorisation for a medicinal product for human use shall ensure that all suspected serious adverse reactions to a medicinal product authorised in accordance with this Regulation occurring within the Community which a health-care professional brings to his attention are recorded and reported promptly to Member States within the territory of which the incident occurred, and no later than 15 days following the receipt of the information.

The holder of the marketing authorisation shall record any other suspected serious adverse reactions occurring within the Community, in accordance with the guide referred to in Article 26, of which he may reasonably be expected to be aware, and promptly notify the competent authority of Member States in the territory of which the incident occurred and the Agency, and no later than 15 days following receipt of the information.

2 **[**[F1]The holder of the marketing authorisation for a medicinal product for human use shall ensure that all suspected serious unexpected adverse reactions and any suspected transmission via a medicinal product of any infectious agent occurring in the territory of a third country are reported promptly to Member States and the Agency, and no later than 15 days following receipt of the information. The Commission shall adopt provisions for the reporting of suspected unexpected adverse reactions which are not serious, whether occurring in the Community or in a third country. Those measures, designed to amend non-essential elements of this regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 87(2a).**]**

Save in exceptional circumstances, these reactions shall be transmitted electronically in the form of a report and in accordance with the guide referred to in Article 26.

3 The holder of the marketing authorisation for a medicinal product for human use shall maintain detailed records of all suspected adverse reactions within or outside the Community which are reported to him by a health-care professional.

Unless other requirements have been laid down as a condition for the granting of the marketing authorisation by the Community, these records shall be submitted, in the form of a periodic safety update report, to the Agency and Member States immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the Community market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

These reports shall be accompanied by a scientific evaluation, particularly of the risk-benefit balance of the medicinal product.

[[F1]4 The Commission may lay down provisions to amend paragraph 3 in view of experience gained with its operation. 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).**]**

5 The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised medicinal product without giving prior or simultaneous notification to the Agency.

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these obligations is subject to effective, proportionate and dissuasive penalties.

Textual Amendments

F1 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 25

Each Member State shall ensure that all suspected serious adverse reactions occurring within their territory to a medicinal product for human use authorised in accordance with this Regulation which are brought to their attention are recorded and reported promptly to the Agency and the marketing authorisation holder, and no later than 15 days following receipt of the information.

The Agency shall forward the information to the national pharmacovigilance systems set up in accordance with Article 102 of Directive 2001/83/EC.

Article 26

The Commission, in consultation with the Agency, Member States and interested parties, shall draw up a guide on the collection, verification and presentation of adverse-reaction reports. This guide shall contain, in particular, for the benefit of health-care professionals, recommendations concerning the communication of information on adverse reactions.

In accordance with this guide, holders of marketing authorisations shall use the medical terminology accepted at international level for the transmission of adverse-reaction reports.

The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC. Such data shall be made publicly accessible, if relevant, after evaluation.

For a period of five years following the initial placing on the market in the Community, the Agency may request that the marketing authorisation holder arrange for specific pharmacovigilance data to be collected from targeted groups of patients. The Agency shall state the reasons for the request. The marketing authorisation holder shall collate and assess the data collected and submit it to the Agency for evaluation.

Article 27

The Agency shall collaborate with the World Health Organisation in matters of international pharmacovigilance and shall take the necessary steps to submit to it, promptly, appropriate and adequate information regarding the measures taken in the Community which may have a bearing on public health protection in third countries; it shall send a copy thereof to the Commission and the Member States.

Article 28

The Agency and Member States' competent authorities shall cooperate to continuously develop pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of routes of authorisation, including the use of collaborative approaches, to maximise use of resources available within the Community.

[F1*Article 29*

The Commission may adopt any amendment which may be necessary to update the provisions of this Chapter in order to take account of scientific and technical progress. 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 (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.

Status:
Point in time view as at 20/04/2009.

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, Chapter 3.