REGULATION (EC) No 540/95

Commission Regulation (EC) No 540/95 of 10 March 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93

(OJ No L 55 of 11. 3. 1995, p. 5)

THE COMMISSION OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([1]), and in particular Articles 22 (1) third paragraph and 44 (1) third paragraph thereof,

Whereas a number of adverse reactions not described in the summary of products characteristics of the medicinal product may occur and be identified at any time of marketing of a medicinal product;

Whereas Articles 22 (1) and 44 (1) have already provided for reporting of suspected serious adverse reactions to medicinal products for human use and to veterinary medicinal products respectively;

Whereas innovative medicinal products deserve a close pharmacovigilance supervision in the interest of human and animal health, inducing unexpected, non-serious, suspected adverse reactions, whether arising in the Community or in a third country and reported to the holders of marketing authorizations by health professionals and also, in the veterinary sector, by other appropriate persons;

Whereas holders of marketing authorizations should where necessary apply for a variation to the marketing authorization when it is confirmed that suspected unexpected adverse reactions not classified as serious are due to the medicinal product in question;

Whereas the European Agency for the Evaluation of Medicinal Products (hereinafter referred to as 'the Agency') should be responsible for coordinating the activities of the Member States in the field of monitoring of adverse reactions to medicinal products (pharmacovigilance);

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Standing Committees on Human and Veterinary Medicinal Products,

([1]) OJ No L 214 of 24. 8. 1993, p. 1.

HAS ADOPTED THIS REGULATION

Article 1

The person responsible for placing the medicinal product on the market shall ensure that suspected unexpected adverse reactions to a medicinal product authorized in accordance with the provisions of Regulation (EEC) No 2309/93, which are not classified serious, arising in the Community or in a third country, are reported to the competent authorities of all Member States and to the Agency.

Article 2

Unless other requirements have been laid down as a condition of granting the marketing authorization by the Community, suspected unexpected adverse reactions which are not serious shall be reported by the holder of the marketing authorization in a distinct and clearly identified section of the periodical reports referred to in Articles 22 (2) and 44 (2) of Regulation (EEC) No 2309/93 ('safety updates'). These safety updates shall consist of a line listing of individual case reports accompanied by an overall scientific evaluation including a narrative review of the nature and other relevant characteristics of reactions, with special attention to any change in frequency.

Article 3

Data should to be incorporated into the relevant safety update until the end of each period referred to in Articles 22 (2) and 44 (2) of Regulation (EEC) No 2309/93 ('data lock-point'). Safety updates shall be submitted to the competent authorities not later than 60 days after each data-lock point.

Article 4

Unexpected, non-serious, suspected adverse reactions which, according to the assessment carried out by the holder of the marketing authorization, can be attributed to the medicinal product and requiring a change to the summary of products characteristics referred to in Article 4 (9) second paragraph of Council Directive 65/65/EEC ([1]), as last amended by Directive 93/39/EEC ([2]), and in Article 5 (9) second paragraph of Council Directive 81/851/EEC ([3]), as last amended by Directive 93/40/EEC, shall be dealt with in accordance with Commission Regulation (EC) No 542/95 of 10 March 1995, as last amended by Directive 93/40/EEC ([4]), concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93 ([5]), and with Commission Regulation (EC) No 541/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization granted by a competent authorization of a Member State ([6]).

([1]) OJ No 22 of 9. 2. 1965, p. 369/65.
([2]) OJ No L 214 of 24. 8. 1993, p. 22.
([3]) OJ No L 317 of 6. 11. 1981, p. 1.
([4]) OJ No L 214 of 24. 8. 1993, p. 31.
([5]) OJ No L 55 of 11. 3. 1995, p. 15.
([6]) OJ No L 55 of 11. 3. 1995, p. 7.

Article 5

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Communities.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 March 1995.

For the Commission

Martin BANGEMANN

Member of the Commission