COMMISSION DIRECTIVE 2000/38/EC

of 5 June 2000

amending Chapter Va (Pharmacovigilance) of Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1], as last amended by Directive 93/39/EEC [2], and in particular Article 29i thereof,

Whereas:

(1) In order to ensure the continued safety of medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Community are continually adapted to take account of scientific and technical progress.

(2) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.

(3) The increasing use of the mutual recognition procedure established by Directive 75/319/EEC requires that current procedures for reporting and dissemination of suspected adverse drug reactions be amended to ensure better coordination between Member States.

(4) The increasing use of electronic networks for communication of information on adverse drug reactions to medicinal products marketed in the Community is intended to allow competent authorities to share the information at the same time.

(5) It is necessary to further define terms currently used within the pharmacovigilance systems.

(6) It is the interst of the Community to ensure that the pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.

(7) Holders of marketing authorisations should additionally be proactively responsible for on-going pharmacovigilance of the medicinal products they place on the market.

(8) The measures provided for in this Directive are in conformity with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 147, 9.6.1975, p. 13.
[2] OJ L 214, 24.8.1993, p. 22.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Chapter Va (Pharmacovigilance) of Directive 75/319/EEC is hereby amended as follows:

1. In Article 29a, the third paragraph is hereby replaced by the following text:

   'This system shall also take into account any available information on misuse and abuse of medicinal products which may have an impact on the evaluation of their benefits and risks.'

2. Article 29b is hereby replaced by the following text:

   '*Article 29b*

   For the purpose of this Directive, the following definitions shall apply:

   (a) *adverse reaction* means a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function;

   (b) *serious adverse* action means an adverse action which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congential anomaly/birth defect;

   (c) *unexpected adverse reaction* means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;

   (d) *periodic safety update reports* means the periodical reports containing the records referred to in Article 29d;

   (e) *post-authorisation safety study* means a pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product;

   (f) *abuse* of medicinal products means persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.