EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – authorisations, EMA

Brussels, 2012

REVIEW OF THE VARIATIONS GUIDELINES: OUTCOME OF THE PUBLIC CONSULTATION

This document summarises the contributions made by stakeholders to DG Health and Consumers's public consultation on Regulation (EC) no 1234/2008 article 4: Review of the Variations Guidelines[1].

Contributors

The Commission received **40 contributions**. The participants can be divided into 3 categories: industry (associations and individual companies), national authorities, and other stakeholders. A list detailing all contributors is provided in the Annex to this document, with the exception of two contributors that requested to remain anonymous.

All contributions and comments received provided valuable information for the Commission services. However, in some cases, the contributions submitted went beyond the scope of the Variations Guideline and could not therefore be taken into account even if shared by several stakeholders.

As the contributions received have been extensive and detailed, this document only summarises comments related to new variations or new wording in the classification of variations that were common to a significant number of contributors. Nevertheless, all contributions received have been made available in the Pharmaceuticals website, with the exception of contributions from stakeholders that requested to remain anonymous.

Summary of contributions

Variation A.5

From the contributions received, it can be concluded that changes proposed to the description of this variations were not considered sufficiently clear and clarification has been requested.

1 http://ec.europa.eu/health/better-regulation-variations-regulations-developments_en.htm

Variation B.I.f.4 and B.II.h.4

The proposed distinction between variations to be submitted as Type IA immediate notification and as Type IA annual reporting under Variation B.I.f.4.a) and b) was not considered appropriate. The same comment was made in connection with Variation B.II.h.4.a) and b).

Variation B.II.b.2

Many contributors considered that classification of Variation B.II.b.2.c.2 should be Type IA immediate notification instead of Type II.

Variation B.II.d.1

A general comment in the contributions received in connection with this variation was that update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product is not a variation.

Variation C.I.3

The classification of Variation C.I.3.a) as Type IB was considered burdensome as it is related to the implementation of changes already agreed with the competent authorities.

Annex: list of contributors to the public consultation

Total: 40 contributions

Industry: 28 contributions:

Associations (14 contributions)

(1) AESGP – Association of the European Self-Medication Industry

(2) APIC – Active Pharmaceutical Ingredients Committee

(3) BPI – German Pharmaceutical Industry Association

(4) ECHAMP – European Coalition on Homeopathic and Antroposophic Medicinal Products

(5) EFPIA – European Federation of Pharmaceutical Industries and Associations; EBE – European biopharmaceutical enterprises; EVM – European Vaccine Manufacturers

(6) EGGVP – European Group for Generic Veterinary Products

(7) EUROPABIO – European Association for Bioindustries

(8) IFAH-Europe – International Federation for Animal Health – Europe

(9) I.P.F.A – International Plasma Fractionation association

(10) PHARMIG – Austrian Association of the Pharmaceutical Industry

(11) PPTA – Plasma Protein Therapeutics Association

(12) SFSTP - French Society of Pharmaceutical Science and Technology)

(13) VFA – Research-Based Pharmaceutical Companies, Germany

(14) EGA – European Generic Medicines Association

Individual companies (14 contributions)

(15) Alcon Laboratories

(16) Astron Research Limited, India

(17) Baush+Lomb – Healthcare US

(18) Biocon, India

(19) Ecupharma, Italy

(20) Focus Pharmaceuticals Ltd

(21) LEO Pharma, Denmark

(22) MedImmune

(23) Mithra pharmaceuticals

(24) Mundipharma Research

(25) Ranbaxy, India

(26) Regiomedica gmbh

(27) Shire, Switzerland

(28) Vetoquinol, UK

National authorities (5 contributions):

(29) Denmark – Danish Health and Medicines Authority

(30) BfArM– German Federal Institute for Drugs and Medical Devices

(31) France – French authorities

(32) Norway

(33) Spain – Spanish Agency for Medicines and Medical Devices

Other stakeholders (5 contributions):

(34) Nilesh Sheth - MRPharmS – Member of the Royal Pharmaceutical Society

(35) Leem

(36) Kinapse Ltd, UK – Life Sciences Consulting and Outsourcing

(37) Selvaraj.J. – Dr.Reddys laboratories Ltd, India

(38) Diamond BioPharm Limited

Not to be published (2 contributions)