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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health Systems and products
**Medicinal products – authorisations, EMA**
Head of Unit

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# REVIEW OF THE VARIATIONS REGULATIONS: OUTCOME OF THE PUBLIC CONSULTATION

This document summarises the contributions made by stakeholders to DG Health and Consumers' public consultation on **the review of the legal framework for the handling of variations for medicinal products.**

## *Contributors*

The Commission received **43 contributions**. The respondents can be divided into 3 categories: national authorities, industry (associations and individual companies) and other stakeholders. A list detailing all contributors is provided in the Annex to this document.

All contributions and comments received provided valuable information for the Commission's further action in this field. This document summarises the stakeholders' points of view that are common to several contributors. Nevertheless, all contributions as they have been submitted are available in the Pharmaceuticals website.

## *Summary of contributions*

*Extension of the scope of the Variations Regulation to purely national marketing authorisations*

All stakeholders that have responded to the public consultation support the extension of the scope of the Variations Regulation to include changes to purely national marketing authorisations.

In general, stakeholders favour similar procedures to handle purely national variations as those already established in the Variations Regulation.

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As regards the specific questions on worksharing, a majority of the contributions indicated that where dossiers are not harmonized, difficulties could arise to accept assessments carried out by other Member States; however, this should not prevent applying worksharing for variations to purely national marketing authorisations. In most cases, it was widely supported by stakeholders that no pre-harmonization should be required to apply worksharing.

*Adaptation of procedures for centrally authorised products*

The competent authorities of Member States that have responded to the public consultation have generally show understanding about the workability concerns linked to the multiple changes of centralised marketing authorisations, but they noted that the situation is different for nationally authorised products.

Almost all other stakeholders contributing to the public consultation agreed with this approach, but some suggested that changes considered "critical" should be clearly defined; also the "Certificate of Pharmaceutical Product" should be issued by EMA prior to the Commission Decision.

*Mandatory date for implementation of changes in the product information*

This is an issue where views are divided; some stakeholders have shown clear support and others consider it is not necessary to act.

*Extension of the time limits for assessment of complex grouped applications*

In general, the extension of the deadline for assessment of complex applications was supported, provided that deadlines are fixed in advanced and are not extended for currently accepted groupings.

*Pandemic vaccines*

Only a limited number of stakeholders have given their views on whether changes in Article 21 of the variations Regulation are needed. The European Vaccines Manufacturers (EVM) considers the current legal framework flexible enough to allow prompt authorization of vaccines in an emergency situation. However, they suggest that some adaptation of EMA guidelines for the submission, assessment and authorization of vaccines may be necessary.

## Annex: list of contributors to the public consultation

**<u>Total:</u> 43 contributions**

### National authorities (14 contributions):

(1) Belgium FAGG-AFMPS Federal Agency for Medicines and Health Products

(2) Czech Republic Institute for State Control of Veterinary Biologicals and Medicaments

(3) Czech Republic State Institute for Drug Control and Ministry of Health

(4) Denmark Ministry of Health

(5) France Agence Nationale du Médicament Vétérinaire

(6) Germany BfArM PEI BVL

(7) Hungary Ministry of National Resources

(8) Italy Ministerio della Salute Dipartimento della Sanità Pubblica Veterinaria

(9) Lithuania States Medicines Control Agency

(10) Netherlands Ministry of Economic Affairs, Agriculture and Innovation

(11) Poland The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

(12) Spain AGEMED

(13) UK MHRA

(14) UK Veterinary Medicines Directorate (VMD)

### Industry (24 contributions):

*Associations (14 contributions)*

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

(16) APIC – Active Pharmaceutical Ingredients Committee

(17) APREFAR – Portuguese Regulatory Professionals Association

(18) BPI – German Pharmaceutical Industry Association

(19) EAEPC – European Association of Euro-Pharmaceutical Companies

(20) ECHAMP

(21) EFPIA – European Federation of Pharmaceutical Industries and Associations, including:

- EBE - European Biopharmaceutical Enterprises
- EVM - European Vaccines Manufacturers Association

(22) EGA – European Generic Medicines Association

(23) EGGVP – European Group for Generic Veterinary Products

(24) EUCOPE – European Confederation of Pharmaceutical Entrepreneurs

(25) EUROPABIO – European Association for Bioindustries

(26) EVM– European Vaccines Manufacturers Association

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

(28) IPFA – International Plasma Fractionation Association

*Individual companies (10 contributions)*

(29) Apotex Europe BV

(30) Bimeda

(31) ELC GROUP

(32) Laboratoire du Fractionnement et des Biotechnologies (LFB, S.A.).

(33) Laboratorios Maymó, S.A.

(34) MSD

(35) Mundipharma Research Ltd.

(36) Sanofi-Aventis GmbH Österreich

(37) Stallergenes

(38) Weleda AG

**Other stakeholders (5 contributions):**

(39) CMD(h) – Coordination Group for Mutual Recognition and Decentralised Procedures (human)

(40) CMD(v) – Coordination Group for Mutual Recognition and Decentralised Procedures (veterinary)

(41) EMA

(42) Nilesh Sheth

(43) Prescrire