EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 July 2012

REGULATION (EC) No 1234/2008 ARTICLE 4:

REVIEW OF THE VARIATIONS GUIDELINES (Sanco.ddg1.d.5(2012)817838)

Comments from:

Name of organisation or individual
vfa.Research-Based Pharmaceutical Companies, Germany

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The revision of the variation regulation was triggered by the „better regulation" initiative. In consequence the adaptation of the classification guideline should follow the principle of a risk-based approach and take into consideration all legislative changes since its implementation. In particular the database according to Art. 57 (2), second subparagraph of Regulation (EC) 726/2004 (EVMPD) introduces a new concept of oversight. Marketing authorisation holders (MAH) are obliged to provide and update data that can be accessed by regulatory authorities at any time. This fundamental change of concept should be adequately reflected in the classification guideline: changes that have been updated in a timely manner in this mandatory database might be considered as introduced. Any further update via variations into MA-dossiers could be considered as merely administrative and be classified as type IA. The parallel consultation on fees for pharmacovigilance proposes an annual fee for all MA (also purely national authorisations). This has been justified by the maintenance of the database according to Art. 57 (2) amongst others. This database introduced a new administrative burden	

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	and - if adopted as proposed - in future additional fees for MAH. The European Commission might take this opportunity of the implementation of the pharmacovigilance legislation into the classification guideline to carefully weigh the impact of all those variations which could be considered „for information" because data have been submitted already for agreement in other procedures or have been submitted to the database. Duplicate submissions would not add to patients safety and should be avoided or be re-phrased in a way that creates the least burocratic burden to MAHs. vfa emphasises these points because they apply not only but in particular to nationally authorised products. The following changes are suggested in consideration of this proposed concept.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
new		Comment: Addition of a new side effect to section 4.8 which has no impact on the safety of the product. Proposed change (if any): **IA** Requested documentation: 1. Documentation why the ADR needs to be added 2. Expert statement why the ADR needs to be added and that there is no significant impact on the safety of the product 3. Revised product information	
A.1		Comment: Add line a) Proposed change (if any): **IA** Additional condition: Change documented in EVMPD in time	
A.2 a)		Comment: Add line aa) Proposed change (if any): **IA** Additional condition: Change documented in EVMPD in time	

Line number(s) of the relevant text ***(e.g. Lines 20-23)***	Stakeholder number ***(To be completed by the Agency)***	Comment and rationale; proposed changes ***(If changes to the wording are suggested, they should be highlighted using 'track changes')***	Outcome ***(To be completed by the Agency)***
A.3		Comment: Add line a) Proposed change (if any): **IA** Additional condition: Change documented in EVMPD in time	
B.II.b.2 c) 2.		Comment: Classification changed from IA_{IN} to II seems not to be adequate. It should be classified with the same principles as B.II.b.2 c) 1. With the same documentation requested there but the conditions proposed in B.II.b.2 c) 2. Proposed change (if any): **IB**	
B.II.e.5 a) 1.		Comment: Add line a) Proposed change (if any): IA Additional condition: Change documented in EVMPD in time	

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
C.I.3 a)		Comment: Classification is not adequate as no assessment should take place. If the applicant deviates from the agreed wording the requirements of this classification would not be met and the applicant is required to submit a type IB by default. Proposed change (if any): **IA**	
C.I.8 a)		Comment: Please add an additional case aa) Proposed change (if any): aa) Introduction of a summary of the pharmacovigilance system **IA** Additional condition: PSMF and QPPV are updated in EVMPD in time	

Please add more rows if needed.