<Date of submission>

REGULATION (EC) No 1234/2008 ARTICLE 4:

REVIEW OF THE VARIATIONS GUIDELINES

Comments from:

Name of organisation or individual

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)*
	Any information which is needed for administrative reasons (e.g. address of MAH, address of QPPV etc) which is available from EVMPD should not trigger any variation in future unless the update in EVMPD is not done in the recommended timeframe. The classification of the specific change should remain (unless commented on later with respective arguments) but a footnote should be added similar to the one for C.I.8 b)	
	To avoid unnecessary variations a link to one or more CEPs should be possible in the database acc. Art. 57(2) (EVMPD) to any product. Updating or new CEP should trigger a variation only if specific condition(s) are not met e.g. no influence on the product quality or no change in content of the documentation is needed (e.g. additional particle size specification)	

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 excessive. It should be classified similar to 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): **IA_{IN}**	
B.II.e.5 a) 1.		Comment: Add line a) Proposed change (if any): IA Additional condition: Change documented in EVMPD in time	
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**	

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.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.