15 July 2012

Submission of comments on 'Guideline on the Details of the Various Categories of Variations' (Sanco.ddg1.d.5(2012)817838)

Comments from: MedImmune

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)	
	We support the EFPIA statement that biologics, in most cases, should not be treated differently than traditional pharmaceuticals. We also agree that Change Management Protocols, as suggested by EFPIA, should be a separate category. We support the EFPIA proposal for a fast track variation category to prevent drug shortages.	

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')***	
B.I.a.1 through B.I.d		Comment: Change Management Protocols may cover many different types of changes - addition of manufacturing sites, process changes, etc. Proposed change (if any): please consider adding "and no Post-Approval Change Management Protocol has been approved"	
B.I.a.2- conditions 8 and 9		Comment: It is unclear what is meant by "developed and optimised using an enhanced development approach" and "approved monitoring scheme" Proposed change (if any): please define "developed and optimised using an enhanced development approach" and "approved monitoring scheme"	
B.I.a.2 c)		Comment: It is unclear which protocol is being referenced. Rather than leave this to interpretation additional text is suggested. Proposed change (if any): please consider adding the following text "approved change management" prior to the final word "protocol" in the description	

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B.I.a.2.f)		Comment: Many older traditional biological products do not use enhanced development approach such as design space, yet with many years of production experience the process parameters are well-defined. Proposed change (if any): Propose adding another a new category g "Change to non critical process parameters where the process is well-defined for the particular manufacturing step(s)". Condition 9 could apply but condition 8 should not be required	
B.I.a.4 g)		Comment: It is unclear what is meant by "developed and optimised using an enhanced development approach" Proposed change (if any): please define "developed and optimised using an enhanced development approach" this is unclear	
B.I.b.2		Comment: The terms "biological/immunological/immunochemical method" may have different meanings and interpretations to industry Proposed change (if any): Please consider defining "biological/immunological/immunochemical method"	
B.I.f.4		Comment: A different wording choice other than "foreseen"	

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		would make the intent of the statement clearer. Proposed change (if any): Please consider revising to remove "foreseen" with "described" in the following, "Implementation of changes ***described*** in an approved change management protocol related to the active substance"	
B.I.f.4		Comment: Because B.I.f.3 requires an amendment to the protocol for minor changes B.I.f.4 "c)" is redundant. Based on EFPIA's general comment regarding biological medicinal products, B.I.f.4 "d)" is not required. Proposed change (if any): Please consider defining or providing examples of "minor changes" in a Q&A guidance or deleting "c)" and "d)".	
B.II.b.2		Comment: The current classification is confusing and the wording is not consistent with B.II.b.1. Proposed change (if any): Suggest aligning the classification to similar wording as B.II.b.1 to: "Replacement or addition of the batch release arrangements and quality control testing sites including importers of the finished product"	
B.II.b.3		Comment: Many older traditional biological products do not use enhanced development approach such as design space,	

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		yet with many years of production experience the process parameters are well-defined. Proposed change (if any): Propose adding another a new category g "Change to non critical process parameters where the process is well-defined for the particular manufacturing step(s)". Condition 9 could apply but condition 8 should not be required.	
B.II.i.1 (b)(1) and (2)		Comment: As currently written, the statement, "... with modification of the risk assessment." is unclear. Proposed change (if any): Please consider using the word "requires" rather than "with"	
B.II.i.1 (b)(2)		Comment: As currently written, the statement, "... without modification of the risk assessment" is unclear Proposed change (if any): Please consider using "does not require" rather than "without"	

Please add more rows if needed.