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Variation Ref	Variation Title	Current wording	Proposed Changes	Rationale
B.I.a.1.j	Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier	Changes to quality control testing arrangements for a biological active substance-replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical methods takes place	Reword the sentence as "Replacement or addition of a site for quality control arrangements for a biological active substance' The end of the sentence "site where batch control/testing including a biological / immunological / immunochemical methods takes place" should be moved into the Conditions column. Add a further condition "site where batch control/testing including only pharmacopoeial method"	Split in to several categories to facilitate risk based reporting based on significance of impact of the change to product quality: - changes of batch control testing site is performed only for pharmacopoeial (e.g.: microbiological) methods should be a type IA. - In other cases, it should be a type II.
B.I.b.2.a	Change in test procedure of active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance	Minor changes to an approved test procedure	Associated Condition to be fulfilled #4 "The test method is not a biological/immunological/immunochemical method, or a method using a biological reagent for a biological active substance (does not include standard pharmacopoeial microbiological methods)." should be reworded as "The modified method maintains or tightens precision, accuracy, specificity and sensitivity".	Certain changes to biological/immunological/immunochemical methods are performed to improve/maintain the assay performance (eg: modify sample and system suitability criterion) and these should be Type IA. This will harmonize reporting requirements in EU similar to US/Canada (do and tell approach)

B.I.d.1.a.4	Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier. a) Re-test period/storage period	Extension or introduction of a re-test period/storage period supported by real time data	It would be valuable to reconsider the current classification of Type IB and downgrade to Type IA.	The request to downgrade is because sponsor can make science based decisions to extend storage period under an approved protocol supported by real time data or introduce a retest period, and these will have no impact on quality, safety or efficacy of the product. This proposed change will also harmonize reporting requirements in EU similar to US/Canada (do and tell approach)
B.II.b.2.b	Change to importer, batch release arrangements and quality control testing of the finished product	Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and one of the test methods performed at that site is a biological / immunological / immunochemical method	The end of the sentence "and one of the methods performed at that site is biological / immunological / immunochemical methods" should be moved into the conditions column. Add a further condition "site where batch control/testing including only pharmacopoeial method"	Split in to several categories - changes of batch control testing site is performed only for pharmacopoeial (e.g.: microbiological) methods should be a type IA. - In other cases, it should be a type II.
B.I.a.2 B.II.b.3	Changes in the manufacturing process of active substance Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product	N/A	It would be valuable to reconsider the classification for a number of variation categories relating to biological/immunological products and substances (i.e. either by removing the current excluding condition(s), or by downgrading the classification from a Type II to a Type IB or IA).	In a number of instances there is strong scientific evidence that the changes have no impact on the Quality, Safety or Efficacy of the product, and therefore a comprehensive Type II assessment process (as currently foreseen) appears disproportionate to the potential risks (obvious examples include minor changes to manufacturing steps/equipment for drug substance/finished products). This will harmonize reporting requirements in EU similar to US/Canada

B.II.b.3.c	Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product	The product is a biological/immunological medicinal product and the change requires an assessment of comparability	Propose to change the wording to "The change refers to a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol	The proposed wording is to classify based on science based decision of significance of the change as opposed to subjective requirement of assessment of comparability. The proposed edit will also harmonize this language with the language in active substance section B.I.a.2.c.
B.II.f.1.b.5	Change in the shelf-life or storage conditions of the finished product b) Extension of the shelf life of the finished product	Extension of the shelf-life of a biological/immunological medicinal product in accordance with an approved stability protocol.	It would be valuable to reconsider the current classification of Type IB and downgrade to Type IA.	The request to downgrade is because sponsor can make science based decisions to extend shelf life under an approved protocol. This proposed change will also harmonize reporting requirements in EU similar to US/Canada (do and tell approach)