



CMDv Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation (EC) No 1234/2008

Section of the Classification Guideline	Date issued	Summary of the proposed change	Proposed classification	Proposed conditions, where relevant
C.II.6.z	11.12.2009	Inclusion of traceability stickers in product carton	Type IA	
B.II.d.2.e	22.09.2010	Replacement of a biological or immunological reference preparation (e.g. reference vaccine batch, reference serum batch) in an immunological/immunochemical test method, which may have a potential significant impact on the quality of the product (e.g. estimate of potency).	Type II	N/A
C.I	11.11.2010	Harmonisation of the SPC between original and new concerned Member States after a repeat use MRP	Type II	N/A
N/A Annex I of (variation) Regulation (EC) 1234/2008	31.10.2011	Decrease in vial size for a multi-dose vaccine + consequential changes: reduction in diluent volume, reduction in dose volume, increasing antigen & excipient concentration per 1 ml, change in specification of in-process and final control (different no. CFU/ml).	Line extension: Annex I, 2.c) change or addition of a new strength/potency	Decrease in vial size and consequential changes to be included in the scope of the line extension