ANNEX III

Cases for grouping variations referred to in Article 7(2)(b)

1. One of the variations in the group is an extension of the marketing authorisation.

2. One of the variations in the group is a major variation of type II; all other variations in the group are variations which are consequential to this major variation of type II.

3. One of the variations in the group is a minor variation of type IB; all other variations in the group are minor variations which are consequential to this minor variation of type IB.

4. All variations in the group relate solely to changes of administrative nature to the summary of product characteristics, labelling and package leaflet or insert.

5. All variations in the group are changes to an Active Substance Master File, Vaccine Antigen Master File or Plasma Master File.

6. All variations in the group relate to a project intended to improve the manufacturing process and the quality of the medicinal product concerned or its active substance(s).

7. All variations in the group are changes affecting the quality of a human pandemic influenza vaccine.

8. All variations in the group are changes to the pharmacovigilance system referred to in points (ia) and (n) of Article 8(3) of Directive 2001/83/EC or points (k) and (o) of Article 12(3) of Directive 2001/82/EC.

9. All variations in the group are consequential to a given urgent safety restriction and submitted in accordance with Article 22.

10. All variations in the group relate to the implementation of a given class labelling.

11. All variations in the group are consequential to the assessment of a given periodic safety update report.

12. All variations in the group are consequential to a given post-authorisation study conducted under the supervision of the holder.

13. All variations in the group are consequential to a specific obligation carried out pursuant to Article 14(7) of Regulation (EC) No 726/2004.

14. All variations in the group are consequential to a specific procedure or condition carried out pursuant to Articles 14(8) or 39(7) of Regulation (EC) No 726/2004, Article 22 of Directive 2001/83/EC or Article 26(3) of Directive 2001/82/EC.