Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (Text with EEA relevance)

ANNEX I

Extensions of marketing authorisations

1. Changes to the active substance(s):

2. Changes to strength, pharmaceutical form and route of administration:

3. Other changes specific to veterinary medicinal products to be administered...

ANNEX II

Classification of variations

1. The following variations shall be classified as minor variations of...

2. The following variations shall be classified as major variations of...

ANNEX III

Cases for grouping variations referred to in Article 7(2)(b) and Article 13d(2)(b)

1. One of the variations in the group is an extension...
2. One of the variations in the group is a major...
3. One of the variations in the group is a minor...
4. All variations in the group relate solely to changes of...
5. All variations in the group are changes to an Active...
6. All variations in the group relate to a project intended...
7. All variations in the group are changes affecting the quality...
8. All variations in the group are changes to the pharmacovigilance...
9. All variations in the group are consequential to a given...
10. All variations in the group relate to the implementation of...
11. All variations in the group are consequential to the assessment...
12. All variations in the group are consequential to a given...
13. All variations in the group are consequential to a specific...
14. All variations in the group are consequential to a specific...

ANNEX IV

Elements to be submitted

1. A list of all the marketing authorisations affected by the...
2. A description of all the variations submitted, including:
3. All necessary documents as listed in the guidelines referred to...
4. Where a variation leads to or is the consequence of...
5. In the case of variations to centralised marketing authorisations, the...
6. In the case of variations to marketing authorisations granted by...

ANNEX V

PART 1

PART 2

1. Variations concerning a change to or addition of a non-food...
2. Variations concerning the replacement or addition of a serotype, strain,...
3. Variations concerning the replacement of a strain for a veterinary...

ANNEX VI

List of Member States referred in Article 24a

the Republic of Bulgaria, the Federal Republic of Germany.

(**1**) OJ L 311, 28.11.2001, p. 1.

(**2**) OJ L 311, 28.11.2001, p. 67.

(**3**) OJ L 136, 30.4.2004, p. 1.

(**4**) OJ L 159, 27.6.2003, p. 1.

(**5**) OJ L 159, 27.6.2003, p. 24.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 1234/2008. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked in part by S.I. 2019/775 Sch. 9 para. 1(p)