

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)

CHAPTER I

GENERAL PROVISIONS

Article 1	Subject matter and scope
Article 2	Definitions
Article 3	Classification of variations
Article 4	Guidelines
Article 5	Recommendation on unforeseen variations
Article 6	Variations leading to the revision of product information
Article 7	Grouping of variations

CHAPTER II

VARIATIONS TO MARKETING AUTHORISATIONS GRANTED  
IN ACCORDANCE WITH DIRECTIVE 87/22/EEC, CHAPTER 4 OF  
DIRECTIVE 2001/82/EC OR CHAPTER 4 OF DIRECTIVE 2001/83/EC

Article 8	Notification procedure for minor variations of type IA
Article 9	Notification procedure for minor variations of type IB
Article 10	'Prior Approval' procedure for major variations of type II
Article 11	Measures to close the procedures of Articles 8 to 10
Article 12	Human influenza vaccines
Article 13	Coordination group and arbitration

CHAPTER IIa

VARIATIONS TO PURELY NATIONAL MARKETING AUTHORISATIONS

Article 13a	Notification procedure for minor variations of type IA
Article 13b	Notification procedure for minor variations of type IB
Article 13c	'Prior Approval' procedure for major variations of type II
Article 13d	Grouping of variations to purely national marketing authorisations
Article 13e	Measures to close the procedures of Articles 13a to 13c
Article 13f	Human influenza vaccines

CHAPTER III

VARIATIONS TO CENTRALISED MARKETING AUTHORISATIONS

Article 14	Notification procedure for minor variations of type IA
Article 15	Notification procedure for minor variations of type IB
Article 16	'Prior Approval' procedure for major variations of type II
Article 17	Measures to close the procedures of Articles 14 to 16

**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. (See end of Document for details) View outstanding changes

---

Article 18 Human influenza vaccines

## CHAPTER IV

### SECTION 1

#### Special procedures

Article 19 Extensions of marketing authorisations  
Article 20 Worksharing procedure  
Article 21 Pandemic situation with respect to human influenza  
Article 22 Urgent safety restrictions

### SECTION 2

Amendments to the decision granting the marketing authorisation and implementation

Article 23 Amendments to the decision granting the marketing authorisation  
Article 23a The statement indicating compliance with the agreed completed  
paediatric investigation...  
Article 24 Implementation of variations  
Article 24a Application of national provisions on variations to purely national  
marketing authorisations

## CHAPTER V

### FINAL PROVISIONS

Article 25 Continuous monitoring  
Article 26 Review  
Article 27 Repeal and transitional provision  
Article 28 Entry into force  
Signature

---

## 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...

**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. (See end of Document for details) [View outstanding changes](#)

---

## 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.

---

**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. (See end of Document for details) [View outstanding changes](#)

---

- (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\(p\)](#)