
STATUTORY INSTRUMENTS

2009 No. 3222

**MEDICINES
FEES AND CHARGES
CONSUMER PROTECTION**

**The Medicines (Products for Human Use)
(Amendments to Fees for Variations) Regulations 2009**

Made - - - - *7th December 2009*
Laid before Parliament *10th December 2009*
Coming into force - - *1st January 2010*

The Secretary of State for Health and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Regulations in exercise of the powers conferred on them by section 1(1) and (2) of the Medicines Act 1971(1) or, in the case of the Minister, the powers conferred by those provisions and now vested in him(2).

In so far as these Regulations are not made under section 1(1) and (2) of the Medicines Act 1971, the Secretary of State makes these Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(3) and section 56(1) and (2) of the Finance Act 1973(4). The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products(5).

The Treasury has consented to the making of these Regulations as required by section 1(1) of the Medicines Act 1971 and section 56(1) of the Finance Act 1973.

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- (1) 1971 c.69; relevant amendments were made by regulation 45(2) of S.I. 2008/2297 and section 21 of the Health and Medicines Act 1988 (c.49). By virtue of section 1(3) of the Medicines Act 1971, expressions used in that section as amended have the same meaning as in the Medicines Act 1968 (c.67) as amended. *See* therefore section 1(1) of the 1968 Act, as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, by article 5 of, and the Schedule to, S.I. 1993/3142, by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794 and by regulation 44 of, and Schedule 8 to, S.I. 2006/2407. Section 1(1) of the 1968 Act contains a definition of the expression “the Ministers”, which is relevant to the powers being exercised in the making of these Regulations. *See also* regulation 9(12) of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144), by virtue of which the references in section 1(1) and (2)(b) of the 1971 Act to an application for a licence or for the variation or renewal of such a licence under Part II of the 1968 Act include reference to an application for a marketing authorization under the Regulations or for the variation or renewal of such an authorization.
- (2) In the case of the Secretary of State by virtue of article 2(1) of S.I. 1999/3142. In the case of the Minister for Health, Social Services and Public Safety by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Department for which the Minister is responsible was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).
- (3) 1972 c.68; as amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51).
- (4) 1973 c.51.
- (5) S.I. 1972/1811.

In accordance with section 129(6) of the Medicines Act 1968⁽⁶⁾, the Secretary of State for Health and the Department of Health, Social Services and Public Safety have consulted with such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

PART 1

GENERAL

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Products for Human Use) (Amendments to Fees for Variations) Regulations 2009 and shall come into force on 1st January 2010.

(2) In these Regulations—

“Fees Regulations 2009” means the Medicines (Products for Human Use) (Fees) Regulations 2009⁽⁷⁾; and

“Marketing Authorisations Regulations 1994” means the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994⁽⁸⁾.

PART 2

AMENDMENTS TO THE FEES REGULATIONS 2009 IN RESPECT OF FEES FOR VARIATIONS

Amendments to the Fees Regulations 2009

2. The Fees Regulations 2009 are amended as specified in regulations 3 to 8.

Amendment to regulation 18

3. In regulation 18 (fees for variations of authorizations, registrations, licences and authorisations), in paragraph (1) omit sub-paragraph (a).

Insert of new regulation 18A

4. After regulation 18 insert—

“Fees for a variation to the terms of a marketing authorization

18A.—(1) Unless regulation 51 (revocation and savings) applies, the fee for an application under regulation 4 (applications for the grant, removal or variation of a United Kingdom marketing authorization) of the Marketing Authorisations Regulations

⁽⁶⁾ 1968 c.67; section 129(6) was extended by section 1(3)(b) of the Medicines Act 1971.

⁽⁷⁾ S.I. 2009/389.

⁽⁸⁾ S.I. 1994/3144; relevant amending instruments are S.I. 2003/2321, 2004/3224 and 2005/1094.

for a variation of a United Kingdom marketing authorization is the fee mentioned in paragraph (2).

- (2) The fee referred to in paragraph (1) is—
 - (a) the fee prescribed in paragraphs 35A to 39 of Schedule 1 in connection with the application;
 - (b) in respect of an inspection of a site made in connection with the application, the fee payable in accordance with regulations 27 to 29 and 31.
- (3) Unless regulation 28 applies, the fee in paragraph (1) is payable by the applicant.”.

Amendment to regulation 20

5. In regulation 20 (applications for multiple variations), in paragraphs (1) and (2) omit the words “marketing authorization”, in each place they occur.

Insert of new regulation 20A

6. After regulation 20, insert—

“Applications for variations to the terms of a marketing authorization

20A.—(1) In this regulation and Part 4 of Schedule 1—

“Major Variation (Type II) Group Application” means an application for several variations to one marketing authorization and—

- (a) at least one of the variations is a major variation of type II;
- (b) subject to paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No 1234/2008;
- (c) the variations do not include a variation—
 - (i) of a kind referred to in paragraph 1 (extension of the marketing authorisation) or paragraph 3 (minor variation of type IB and consequential variations) of Annex III to EC Regulation No 1234/2008;
 - (ii) which relates to a change which is referred to in paragraph 23 of Schedule 1 (Type II Complex Variation Application); or
 - (iii) of a marketing authorization so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 1 (Extended Type II Complex Variation Application); and
- (d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB;

“Major Variation (Type II) Complex Group Application” means an application for several variations to one marketing authorization and—

- (a) at least one of the variations relates to one or more of the changes referred to in paragraph 23 of Schedule 1 (Type II Complex Variation Application);
- (b) subject to paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No 1234/2008;
- (c) the variations do not include a variation of—
 - (i) a kind referred to in paragraph 1 or paragraph 3 of Annex III to EC Regulation No 1234/2008; or

(ii) a marketing authorization so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 1; and

(d) the variations may include one or more minor variations of type IA or one or more minor variations of type IB or one or more major variations of type II;

“Major Variation (Type II) Extended Complex Group Application” means an application for several variations to one marketing authorization and—

(a) at least one of the variations is a variation to a marketing authorization so that the medicinal product is indicated for a use referred to in paragraph 9(a) or (b) of Schedule 1;

(b) subject to paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No 1234/2008;

(c) the variations do not include a variation of a kind referred to in paragraph 1 of Annex III to EC Regulation No 1234/2008; and

(d) subject to paragraph (c), the variations may include minor variations of type IA, minor variations of type IB or other major variations of type II or a variation relating to a change referred to in paragraph 23(a), (b) or (c) of Schedule 1;

“major variation of type II” has the meaning given in Article 2(3) of EC Regulation No 1234/2008;

“Minor Variation (Type IB) Group Application” means an application for several variations to one marketing authorization and—

(a) at least one of the variations is a minor variation of type IB;

(b) subject to paragraph (c), the variations fall within the scope of Article 7(2)(b) of EC Regulation No 1234/2008;

(c) the variations do not include—

(i) a variation of a kind referred to in paragraph 1 or paragraph 2 of Annex III of EC Regulation No 1234/2008; or

(ii) a major variation of type II; and

(d) the variations may include one or more minor variations of type IA;

“minor variation of type IA” has the meaning given in Article 2(2) of EC Regulation No 1234/2008;

“minor variation of type IB” has the meaning given in Article 2(5) of EC Regulation No 1234/2008; and

“work sharing” means the worksharing procedure within the meaning of Article 20 of EC Regulation No 1234/2008.

(2) In a case where a recommendation on the classification of a variation is made in accordance with Article 5 of EC Regulation No 1234/2008, the fee payable for the application made in respect of that variation shall be the appropriate fee for the classification given to the variation or, as the case may be, the appropriate fee which arises as a consequence of the classification given to the variation.

(3) Unless paragraph (4) applies, a separate fee is payable in respect of each application to vary each term of a marketing authorization.

(4) A separate fee is not payable for each application to vary a term of a marketing authorization which—

(a) falls within the same type of group application; or

(b) the licensing authority—

- (i) in consultation with other Member States concerned, have agreed, in accordance with Article 7(2)(b) of EC Regulation No 1234/2008, should be subject to the procedure for grouping of variations within the meaning of that Article; and
 - (ii) have agreed fall, or should be treated as falling, within the same type of group application.
- (5) For the purposes of paragraph (4) the reference to a group application means an application which is a—
- (a) Minor Variation (Type IB) Group Application;
 - (b) Major Variation (Type II) Group Application;
 - (c) Major Variation (Type II) Complex Group Application; or
 - (d) Major Variation (Type II) Extended Complex Group Application.
- (6) A separate fee is not payable for a variation which is wholly consequential upon another variation of a provision of a marketing authorization which is applied for in the same application.”.

Amendments to Schedule 1

7.—(1) Schedule 1 (capital fees for applications for, and variations to, marketing authorizations, licences and certificates) is amended as follows.

(2) In paragraph 2 (general: categories of Applications and Variations) omit the reference to “BROMI variations guidance” and the meaning given to that reference.

(3) Omit paragraph 4 (BROMI variations).

(4) In paragraph 5 (complex application), for sub-paragraph (q)(i) substitute—

“(i) for an extension of a marketing authorization within the meaning of Article 2(4) of EC Regulation No 1234/2008; and”.

(5) In paragraph 22 (Type IB and Type II Applications)—

(a) in sub-paragraph (1), for ““minor variation” of Type IB” to the end of that sub-paragraph substitute—

““minor variation of type IB” within the meaning of Article 2(5) of EC Regulation No 1234/2008”;

(b) in sub-paragraph (2), for paragraph (f) substitute—

“(f) an application for an extension of a marketing authorization within the meaning of Article 2(4) of EC Regulation No 1234/2008”; and

(c) in sub-paragraph (3), for ““minor variation” of Type IA” to the end of that sub-paragraph substitute—

““minor variation of type IA” within the meaning of Article 2(2) of EC Regulation No 1234/2008”.

(6) In paragraph 23 (Type II Complex Variation Application)—

(a) in sub-paragraph (a), for “Annex II to [Commission Regulation \(EC\) No. 1084/2003](#)” substitute “Annex I to EC Regulation No 1234/2008”;

(b) in sub-paragraph (b), from “major variation” to “No. 1084/2003” substitute—

““major variation of type II” within the meaning of Article 2(3) of EC Regulation No 1234/2008;” and

- (c) in sub-paragraph (c)(ii), from “is not a variation” to the end of that sub-paragraph substitute “is not a minor variation of type IA or minor variation of type IB within the meaning of Article 2 of EC Regulation 1234/2008”.
- (7) Omit paragraph 35 (marketing authorizations).
- (8) After paragraph 35, insert—

“Variations to the terms of marketing authorizations

35A.—(1) Subject to paragraphs 36 to 39 and 46, 47A and 48, the fee payable under regulation 18A(1) in connection with an application for a variation to the terms of a marketing authorization of a kind described in column 1 of the appropriate table is—

- (a) if the application is in an eCTD format application, the fee specified in the corresponding entry in column 2 of the appropriate table;
- (b) if the fee is not in an eCTD format application, the fee specified in the corresponding entry in column 3 of that table.

(2) In paragraph (1), the appropriate table is—

- (a) in respect of an application for a variation of a marketing authorization which is within the scope of EC Regulation No 1234/2008(9), Table 1;
- (b) in respect of a UK national variation application, Table 2;
- (c) in respect of a reclassification variation application, Table 3.

(3) In Table 1, “reference authority” has the meaning given in Article 20(2)(b) of EC Regulation No 1234/2008.

(4) In Table 2, “UK national variation application” means a variation to a notification of, or an application for, a variation to the terms of a marketing authorization which is not within the scope of EC Regulation No 1234/2008 and which—

- (a) is a change set out in the document entitled UK National MA Variations Guidance published by the licensing authority and available on its website on 30 November 2009(10); and
- (b) complies with the procedures and conditions to be fulfilled as set out in that document,

and the expressions “National Type 1B Application”, “National Type II Application”, “National Type II Complex Variation Application”, “National Type II Extended Complex Variation Application”, “National Type IB Minor Variation Group Application”, “National Type II Major Variation Group Application” and “National Type II Major Variation Complex Group Application” shall be construed accordingly.

Table 1

Fees for applications for variations of marketing authorizations falling within the scope of EC Regulation No 1234/2008

<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
<i>Kind of variation</i>	<i>Fee payable if in eCTD format</i>	

(9) See Article 1 of the Regulation.

(10) A copy of the guidance can be downloaded from the licensing authority’s website at www.mhra.gov.uk or obtained by writing to the licensing authority at Market Towers, 1, Nine Elms Lane, London, SW8 5NQ or by sending an email to info@mhra.gsi.gov.uk.

*Fee payable for
application not in
eCTD format*

1. Application for a single kind variation

(a)	Type IB Application where—		
	(i) the UK is a concerned Member State	£296	£314
	(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£588	£616
(b)	Type II Application where—		
	(i) the UK is a concerned Member State	£786	£824
	(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£952	£998
(c)	Type II Complex Variation Application where—		
	(i) the UK is a concerned Member State	£8,892	£9,327
	(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£15,418	£16,170
(d)	Extended Type II Complex Variation Application where—		
	(i) the UK is a concerned Member State	£27,442	£28,780
	(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£38,360	£40,232

2. Applications for a Group

(a)	Minor Variation (Type IB) Group Application where—		
	(i) the UK is a concerned Member State	£666	£700
	(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£1,311	£1,380
(b)	Major Variation (Type II) Group Application where—		
	(i) the UK is a concerned Member State	£1,767	£1,860
	(ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing	£2,137	£2,250

- (c) Major Variation (Type II) Complex Group Application where—
- (i) the UK is a concerned Member State £10,099 £10,150
- (ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing £16,320 £17,160
- (d) Major Variation (Type II) Extended Complex Group Application where—
- (i) the UK is a concerned Member State £28,120 £29,600
- (ii) the UK is the reference Member State or the licensing authority is the reference authority for work sharing £39,140 £41,200

Table 2**Fees for UK national variation applications**

<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
<i>Kind of national variation</i>	<i>Fee payable if in eCTD format</i>	<i>Fee payable for application not in eCTD format</i>
1. National Type 1B Application	£296	£314
2. National Type II Application	£786	£824
3. National Type II Complex Variation Application	£8,892	£9,328
4. National Type II Extended Complex Variation Application	£27,442	£28,780
5. National Type IB Minor Variation Group Application	£666	£700
6. National Type II Major Variation Group Application	£1,767	£1,860
7. National Type II Major Variation Complex Group Application	£10,099	£10,150
8. National Type II Major Variation Extended Complex Group Application	£28,120	£29,600

Table 3**Fees for reclassification variation applications**

<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
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<i>Kind of reclassification variation</i>	<i>Fee payable if in eCTD format</i>	<i>Fee payable for application not in eCTD format</i>
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Application falling within the category described in—		
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(a) paragraph 15(a)	£12,834	£13,460
(b) paragraph 15(b)	£8,736	£9,160”.

(9) In paragraph 37 (reclassification of marketing authorizations), in sub-paragraph (1) for “regulation 18(1)” substitute “regulation 18A(1)”.

(10) In paragraph 46 (identical variations) omit—

(a) “unless paragraphs 47 to 48 apply”; and

(b) “the variation of a marketing authorization.”.

(11) After paragraph 46 insert—

“Reduced fees for Type IB and Type II Applications, Minor Variation (Type IB) Group Applications and a Major Variation (Type II) Group Applications

46A.—(1) Unless paragraph 47A or 48 applies, where more than one application of a type referred to in paragraph (2) is made at the same time by the same marketing authorization holder and all of the applications are for identical kinds of variations, the fee payable under regulation 18A(1)—

(a) in connection with the first application considered by the licensing authority is the appropriate amount specified in this Part of the Schedule;

(b) in connection with each of the other applications is 50% of that amount.

(2) The type of application referred to in paragraph (1) is a—

(a) Type IB Application;

(b) Type II Application;

(c) Minor Variation (Type IB) Group Application; or

(d) Major Variation (Type II) Group Application”.

(12) Omit paragraph 47 (complex variation application).

(13) After paragraph 47 insert—

“Reduced Fees for identical Type II Complex Applications, Extended Type II Complex Variation Applications, Major Variation (Type II) Complex Group Applications and Major Variation (Type II) Extended Complex Group Applications

47A.—(1) Where more than one application of a type referred to in paragraph (2) is made at the same time by the same marketing authorization holder and all of the applications are for identical kinds of variations, the fee payable under regulation 18A(1)—

(a) in connection with the first application considered by the licensing authority, is the appropriate amount specified in this Part of the Schedule;

(b) in connection with each of the other applications in respect of which no further medical, scientific or pharmaceutical assessment is required, is the amount which would be payable if the application was a Type II Application.

(2) The type of application referred to in paragraph (1) is a—

(a) Type II Complex Variation Application;

- (b) Extended Type II Complex Variation Application;
- (c) Major Variation (Type II) Complex Group Application; or
- (d) Major Variation (Type II) Extended Complex Group Application.”.”

(14) In paragraph 48 (multiple reclassification variations applications) for “regulation 18(1)” substitute “regulation 18A(1)”.

(15) In paragraph 49 (a set of changes) for paragraphs (2) and (3) substitute—

“(2) If the proposed changes in respect of a product to which the fee in sub-paragraph (1)

(a) applies are submitted in accordance with the National Guidance on labels and leaflets self-certification, the fee payable under regulation 22(1) is £199.

(3) For the purposes of this paragraph—

(a) changes are submitted in accordance with the National Guidance on labels and leaflets self-certification if they are of a type described in the National Guidance on labelling and patient information leaflets for self-certification and comply with the conditions set out in relation to those changes in that Guidance; and

(b) the “National Guidance on labelling and patient information leaflets for self-certification” means the documents entitled “Guidance on changes to labelling and patient information for self-certification” and “Guidance on changes to labelling for self certification – compliance with article 56(a) – inclusion of Braille on the labelling” published by the licensing authority and available on its website on 9 November 2009(11).”.

Amendments to Schedule 7

8.—(1) In Schedule 7 (interpretation), paragraph 1 is amended as follows.

(2) Omit the definition of “[Commission Regulation \(EC\) No. 1084/2003](#)” and its meaning.

(3) After the definition of “[Council Regulation \(EEC\) No. 2309/93](#)”, insert—

““[EC Regulation No 1234/2008](#)” means [Commission Regulation \(EC\) No. 1234/2008](#) concerning the examination of variations to the terms of marketing authorizations for medicinal products for human use and veterinary medicinal products(12);”.

(4) For the definition of “concerned Member State” substitute—

““concerned Member State” means for the purpose of—

(a) regulation 12 and Part 2 of Schedule 1 (capital fees for Applications for Authorizations, Licences, Registrations and Certificates), an EEA State, the competent authorities of which receive an application to obtain recognition, according to the procedure laid down in Title III, Chapter 4 of the 2001 Directive, of a United Kingdom marketing authorization;

(b) regulation 18A and Part 4 of Schedule 1 (capital fees for applications for variations of authorizations, Licences and Registrations), an EEA State, the competent authority of which has received an application for a variation to the terms of a marketing authorization under the procedure laid down in [EC Regulation No 1234/2008](#) for a medicinal product in respect of which an authorization was granted by that competent authority, other than the reference Member State;”.

(5) In the definition of “variation”, in sub-paragraph (a), for “Article 3(1) of [Commission Regulation \(EC\) No. 1084/2003](#)” substitute “Article 2(1) of [EC Regulation No 1234/2008](#)”.

(11) Copies of the documents can be downloaded from the licensing authority’s website at www.mhra.gov.uk or obtained by writing to the licensing authority at Market Towers, 1, Nine Elms Lane, London, SW8 5NQ or by sending an email to .

(12) OJ No. L 334, 12.12.2008 p.7.

PART 3

CONSEQUENTIAL AMENDMENTS

The Marketing Authorisations Regulations 1994

9.—(1) The Marketing Authorisations Regulations 1994 are amended as follows.

(2) In regulation 1 (citation, commencement and interpretation), in paragraph (2)—

(a) after the definition of “Regulation (EC) No 726/2004” insert—

““Regulation (EC) No 1234/2008” means Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products”; and

“in the definition of “the relevant Community provisions” after “Regulation (EC) No 726/2004;” insert “Regulation (EC) No 1234/2008;”.

(3) In Schedule 2 (procedural provisions relating to the grant, renewal, variation, revocation and suspension of United Kingdom marketing authorizations) in paragraph 1 (interpretation) for the definition of “Type II variation application” substitute—

““Type II variation application” means an application for a variation to the terms of a marketing authorisation which falls within the meaning of a major variation of type II in Article 2(3) of Commission Regulation (EC) No 1234/2008”.

(4) In Schedule 3 (offences, penalties etc) in paragraph 3A for “1085/2003” substitute “1234/2008”.

PART 4

SAVINGS

Savings

10.—(1) The Fees Regulations 2009 and the Marketing Authorisations Regulations 1994, as in force before the coming into force of these Regulations, shall continue to apply to valid notifications or applications for variations made immediately before 1st January 2010.

(2) The amendments of the Fees Regulations 2009 made by these Regulations shall not affect any proceedings instituted under those Regulations for the recovery of any fees due as debts to the Crown and, for the purposes of those proceedings, the provisions so referred to shall continue to apply as if they had not been amended.

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Signed by authority of the Secretary of State for Health

30th November 2009

Mike O'Brien
Minister of State,
Department of Health
Michael McGimpsey

30th November 2009

Minister for Health, Social Services and Public
Safety

Bob Blizzard

Frank Roy

7th December 2009

Two of the Lords Commissioners of Her
Majesty's Treasury
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Products for Human Use) (Fees) Regulations 2009 ([S.I. 2009/389](#)) (“the Fees Regulations 2009”). The Fees Regulations 2009 make provision for the fees payable relating to marketing authorizations, licences and certificates in respect of medicines for human use.

These Regulations amend the provisions relating to fees which are payable for an application to vary the terms of marketing authorisations for medicinal products. These Regulations do not increase the rate of fees payable but amend provisions regarding the grouping of variations in respect of which a fee may be payable to vary marketing authorizations which were granted in accordance with Directive [2001/83/EC](#) of the European Parliament and of the Council on the Community code relating to medicinal products for human use and in accordance with national procedures under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 ([S.I. 1994/3144](#)).

[Commission Regulation \(EC\) No 1234/2008](#) concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ No. L334, 12.12.2008 p.7) establishes a new framework regarding the classification into different categories of variations to marketing authorisations depending on level of risk to the public and the impact on the quality, safety and efficacy of the medicinal product concerned.

Part 2 of these Regulations amends the Fees Regulations 2009 in respect of those provisions relating to the payment of fees for an application to vary the terms of a marketing authorization. Regulations 4 and 7(8) respectively insert a new regulation 18A and new paragraph 35A of Schedule 1 in respect of the specified fee payable. Separate fees are specified in respect of an application for variation to the terms of a marketing authorization which is within the scope of EC Regulation No 1234/2008 and an application for variation to the terms of a marketing authorization which is not within the scope of that Regulation and which is a change made in accordance with the “UK National MA Variations Guidance” published by the MHRA on behalf of the licensing authority and available on the MHRA website on 30 November 2009.

Regulation 6 inserts a new regulation 20A which makes provision relating to the application and classification of groups of variations. Regulations 4, 6 and 7(7) relate to the procedural changes and the ability to group variations to the terms of marketing authorizations laid down in [Commission Regulation \(EC\) No 1234/2008](#). Regulation 6(6) provides that a separate fee is not payable for a variation which is wholly consequential upon another variation.

Regulations 3, 5, 7(1) to (7), (9), (10), (12), (14) and (15) make amendments which are a consequence of the new groupings of variations in respect of which fees are payable and as a consequence of the “Guidance on changes to labelling and patient information for self-certification” and “Guidance on changes to labelling for self certification – compliance with article 56(a) – inclusion of Braille on the labelling” published by the MHRA on behalf of the licensing authority and available on the MHRA website on 9 November 2009.

Regulation 7(11) and (13) respectively insert new paragraph 46A and paragraph 47A of Schedule 1 to provide a reduction of the fee payable in cases where there are duplicate group applications to vary marketing authorizations.

Regulation 9 makes consequential amendments to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 ([S.I. 1994/3134](#)) so as to refer to [Commission Regulation \(EC\) No 1234/2008](#).

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Regulation 10 makes savings provisions.

An impact assessment of the effect that this instrument will have on business and the voluntary sector is available from the MHRA at Market Towers, 1 Nine Elms Lane, London, SW8 5NQ.