SCHEDULES

[F1SCHEDULE 33A

Transitional provision in relation to EU Exit

Textual Amendments

F1 Sch. 33A inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), reg. 1, **Sch. 7** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 193**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 3

Transitional provision in respect of conversion of EU marketing authorisations in force immediately before IP completion day

Conversion of EU marketing authorisations in force before IP completion day

6.—(1) This paragraph applies in relation to an EU marketing authorisation which was in force immediately before IP completion day.

(2) An EU marketing authorisation to which this paragraph applies—

(a) insofar as it authorises sale or supply of a medicinal product in Great Britain, has effect on and after IP completion day as a UKMA(GB) granted under regulation 49(1) of these Regulations (but, insofar as it authorises sale or supply of a medicinal product in Northern Ireland, continues to operate in Northern Ireland as an EU marketing authorisation); and

(b) is referred to in this Part as a "converted EU marketing authorisation".

(3) If the holder of an EU marketing authorisation to which this paragraph applies notifies the licensing authority in writing before the end of the period of 21 days beginning with IP completion day that it does not wish to be the holder of a converted EU marketing authorisation, the licensing authority must revoke the converted EU marketing authorisation with effect from the date of receipt of the notification.

(4) A converted EU marketing authorisation—

(a) is treated as if it had been granted by the licensing authority under regulation 49(1) on the same terms as those on which the EU marketing authorisation was granted, including any conditions or restrictions subject to which the EU marketing authorisation was granted and which remain in force immediately before IP completion day;

(b) is treated, for the purposes of regulations 65 or 65B (validity of UK marketing authorisation), as if it had been granted by the licensing authority on the date that the EU marketing authorisation took effect;

(c) is treated for the purposes of regulation 67(1) (failure to place on the market) as if it had been granted on IP completion day, and the period of three years referred to in regulation 67(2) is treated as having started on IP completion day;

(d) is treated for the purposes of determining the relevant fee period for the purposes of Schedule 4 to the Fees Regulations (periodic fees for marketing authorisations) as if it had been granted by the licensing authority on the date that the EU marketing authorisation took effect;

(e) is treated, for the purposes of the reference to the date of grant in regulation 27A(a) of the Fees Regulations (fees for renewals of a marketing authorisation) as if it had been granted on the date that the EU marketing authorisation took effect;

(f) retains, for the purposes of regulation 51A(1) and (6), the benefit of any remaining periods of data or marketing exclusivity (if any) from which the holder benefitted immediately before IP completion day;

(g) retains the benefit of any decision by the EMA to exempt the holder from Articles 14(4) or (5) of Regulation (EC) No 726/2004 (failure to place on the market), and that decision is treated as if it had been made by the licensing authority under regulation 67(3); and

(h) remains subject to—

(i) any suspension of the EU marketing authorisation that is in force immediately before IP completion day,

(ii) any post-authorisation obligations imposed after it was granted, and which remain in force immediately before IP completion day, and

(iii) any variation to its terms which were granted or accepted before IP completion day.

(5) For the purposes of this paragraph, an EU marketing authorisation is in force, even if that authorisation is suspended immediately before IP completion day.

(6) A converted EU marketing authorisation to which this paragraph applies which—

(a) was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006; and

(b) remains such a conditional marketing authorisation immediately before IP completion day,

has effect on and after IP completion day as a UK marketing authorisation granted under regulation 58F.

(7) A converted EU marketing authorisation to which this paragraph applies which relates to a medicinal product which—

(a) was designated as an orphan medicinal product by the European Commission pursuant to Article 5 of the Orphan Regulation; and

(b) remains in the Community register of Orphan Medicinal Products as referred to in that Article immediately before IP completion day,

has effect on and after IP completion day as a UK marketing authorisation granted under regulation 58C and retains, for the purposes of regulation 58D, the benefit of any period of marketing exclusivity from which the holder benefitted immediately before IP completion day under Article 8 of the Orphan Regulation.

Classification of converted EU marketing authorisations

7. For the purposes of regulation 62 (classification of UK marketing authorisation), it is a term of a converted EU marketing authorisation that the product to which the authorisation relates is to be available—

(a) in a case where the product was classified in its EU marketing authorisation immediately before IP completion day as a prescription only medicine, the product is to be available only on prescription;

(b) in a case where the product was not so classified and the licensing authority has determined that the product should be available on general sale, the product is to be available on general sale; or

(c) in any other case, the product is to be available only from a pharmacy.

Obligations of licensing authority in connection with converted EU marketing authorisations

8.—(1) The licensing authority must, before the end of the period of 7 days beginning with IP completion day, notify the holders of converted EU marketing authorisations—

(a) that the EU marketing authorisation is converted to a UK marketing authorisation; and

(b) that the holder may notify the licensing authority in accordance with paragraph 6(3) that it does not wish to be the holder of a UK marketing authorisation.

(2) The licensing authority must, as soon as reasonably practicable after the end of the period referred to in paragraph 6(3), publish a list of converted EU marketing authorisations.

(3) The list mentioned in sub-paragraph (2) must specify which converted EU marketing authorisations have been revoked in accordance with paragraph 6(3).

Obligations of holders of converted EU marketing authorisations

9.—(1) A holder of a converted EU marketing authorisation must submit to the licensing authority, before the end of the period of one year beginning with IP completion day, the information described in sub-paragraph (3).

(2) The obligation in sub-paragraph (1) is subject to any requirement imposed by the licensing authority to provide that information before the end of a shorter period specified by the licensing authority under paragraph 10(1).

(3) The information which must be submitted in accordance with sub-paragraph (1) (referred to in this paragraph as the "baseline data") is—

(a) such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing for this purpose and published by the licensing authority on or before IP completion day;

(b) notification of whether or not the product to which the converted EU marketing authorisation relates—

(i) is on the market in the United Kingdom at the time the notification is given, or

(ii) if not, whether the product has been on the market in the United Kingdom at any time on or after IP completion day and if so, the date on which it was withdrawn from the United Kingdom market.

(4) In this Part, the date on which the holder of a converted EU marketing authorisation complies with the obligation in sub-paragraph (1), or with any requirement imposed by the licensing authority under paragraph 10(1) to provide all of the baseline data before the end of a period shorter than the period of one year beginning with IP completion day, is referred to as "the data submission date".

Powers of licensing authority in connection with provision of information

10.—(1) If the licensing authority requests a holder of a converted EU marketing authorisation to submit all or part of the baseline data at any time before the expiry of the period of one year beginning with IP completion day, the holder must supply the information within the time period specified by the licensing authority in its request.

(2) If the licensing authority requests a holder of a converted EU marketing authorisation to provide any other information relating to the EU marketing authorisation, the holder must supply the information within the time period specified by the licensing authority in its request.

Variations of converted EU marketing authorisations notified or applied for before IP completion day

11.—(1) This paragraph applies where, before IP completion day—

(a) a holder of a converted EU marketing authorisation has notified the EMA of, or made an application to the EMA for, a variation of the EU marketing authorisation to which the converted EU marketing authorisation applies under Chapter III of Regulation (EC) No 1234/2008, or has made an application to the EMA for an extension of that EU marketing authorisation in accordance with Article 19 of that Regulation;

(b) the procedures specified in Article 17 of that Regulation (measures to close the procedures of Articles 14 to 16) have not concluded, or, in the case of an extension, no final decision has been made by the European Commission in relation to the application; and

(c) the holder of the converted EU marketing authorisation wishes the variation to be made to the converted EU marketing authorisation.

(2) Where the variation is a minor variation of Type IA—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at any time on or after the time at which it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) the holder of the converted EU marketing authorisation must (subject to paragraph 13), include in the baseline data—

(i) a summary of the variation, and

(ii) if the notification has been rejected by the EMA, an indication of that fact; and

(c) the variation to the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing before the end of the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(3) Where the variation is a minor variation of Type IB—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at any time on or after the time at which it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) if the variation has not been rejected by the EMA, the holder of the converted EU marketing authorisation must (subject to paragraph 13) include a copy of the notification in the baseline data; and

(c) the variation to the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing before the end of the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(4) Sub-paragraph (5) applies where—

(a) the variation is a major variation of Type II or an extension; and

(b) before IP completion day the Committee for Medicinal Products for Human Use gave a positive final opinion in relation to the application with which the United Kingdom concurred.

(5) Where this sub-paragraph applies—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at any time on or after the time at which it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) the holder of the converted EU marketing authorisation must (subject to paragraph 13) include a copy of the application in the baseline data; and

(c) the licensing authority must either—

(i) treat the variation as accepted, and, if the variation affects the terms of the converted EU marketing authorisation, amend those terms accordingly; or

(ii) notify the holder of the converted EU marketing authorisation before the end of the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(6) Sub-paragraph (7) applies where—

(a) the variation is a major variation of Type II or an extension; and

(b) before IP completion day the Committee for Medicinal Products for Human Use had not given any opinion in relation to the application, or had given a negative final opinion in relation to it, or had given a positive final opinion but the United Kingdom recorded a divergent opinion.

(7) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must submit to the licensing authority—

(i) the application for the variation; and

(ii) (subject to paragraph 13) the baseline data; and

(b) the licensing authority must consider the application in accordance with Schedule 10A.

(8) In this paragraph and paragraph 12, "minor variation of Type IA", "minor variation of Type IB", "major variation of Type II" and "extension" have the meanings given in paragraph 1 of Schedule 10A.

Variations of converted EU marketing authorisations submitted to EMA after IP completion day but before the data submission date

12.—(1) This paragraph applies where a holder of a converted EU marketing authorisation—

(a) notifies the EMA of, or applies to the EMA for, a variation of the EU marketing authorisation to which the converted EU marketing authorisation relates during the period beginning with IP completion day and ending on the day before the data submission date; and

(b) wishes the variation to be made in relation to the converted EU marketing authorisation.

(2) Where the variation is a minor variation of Type IA—

(a) the variation may be implemented in relation to the converted EU marketing authorisation at the same time as it may be implemented in relation to the EU marketing authorisation to which the converted EU marketing authorisation relates;

(b) the holder of the converted EU marketing authorisation must (subject to paragraph 13), include in the baseline data—

(i) a summary of the variation, and

(ii) if the notification has been rejected by the EMA, an indication of that fact; and

(c) the variation to the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing within the period of 30 days beginning with the data submission date that the variation is rejected, in which case the holder must cease to apply the rejected variation immediately after receipt of the notification.

(3) Where the variation is a minor variation of Type IB, a major variation of Type II or an extension which has not been rejected by the EMA—

(a) the holder of the converted EU marketing authorisation must submit to the licensing authority—

(i) the notification of, or application for, the variation, and

(ii) (subject to paragraph 13) the baseline data; and

(b) the licensing authority must consider the application in accordance with Schedule 10A.

Variations of converted EU marketing authorisations sought in advance of the data submission date

13.—(1) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a notification of, or an application for, a variation to the authorisation before the data submission date, the holder must—

(a) submit the notification or application to the licensing authority; and

(b) unless sub-paragraph (2) applies, provide to the licensing authority at the same time such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing by the licensing authority for this purpose and published on or before IP completion day.

(2) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a notification of, or an application for, a variation to the authorisation before the data submission date but does not provide the information described in sub-paragraph (1)(b) with the notification or application, the licensing authority may agree to consider the notification or application if it is satisfied that—

(a) the variation may be necessary on urgent safety grounds;

(b) the variation may be necessary in order to maintain supplies of a particular medicinal product to patients in the United Kingdom; or

(c) there are other good reasons for considering the variation in advance of the submission of the information described in sub-paragraph (1).

(3) Where the licensing authority considers a notification of, or an application for, a variation in advance of the data submission date in accordance with this paragraph, the references in paragraphs 11(2)(c), (3)(c) and (5)(c)(ii) and 12(2)(c) to the data submission date are to be read as references to the date on which—

(a) the notification of, or the application for, the variation is submitted to the licensing authority in accordance with sub-paragraph (1); or

(b) the licensing authority notifies the holder that it will consider the notification or application, in accordance with sub-paragraph (2), without the information referred to in sub-paragraph (2)(b).

Applications for renewals of converted EU marketing authorisations made before IP completion day

14.—(1) This paragraph applies where a holder of a converted EU marketing authorisation has, before IP completion day, made an application to the EMA for renewal of the EU marketing

authorisation in accordance with Article 14 of Regulation (EC) No 726/2004 but no final decision has been made in relation to that application by the European Commission before IP completion day.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the application for renewal to the licensing authority with the baseline data; and

(b) the licensing authority must—

(i) where before IP completion day the Committee for Medicinal Products for Human Use has given a positive final opinion in relation to the application with which the United Kingdom concurred, treat the renewal application as accepted for the purposes of regulation 66 (application for renewal of authorisation), or

(ii) where before IP completion day the Committee for Medicinal Products for Human Use has not given any opinion or has given a negative final opinion in relation to the application, or where a positive final opinion has been given but the United Kingdom recorded a divergent opinion, treat the application as an application made in relation to the converted EU marketing authorisation under regulation 66 and consider the application in accordance with that regulation.

Applications for renewals of conditional marketing authorisations made before IP completion day

15.—(1) This paragraph applies where before IP completion day—

(a) a holder of a converted EU marketing authorisation which was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006 has made an application to the EMA for renewal of the authorisation in accordance with Article 6 of that Regulation; but

(b) no final decision has been made in relation to that application by the European Commission.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the application for renewal to the licensing authority with the baseline data; and

(b) the licensing authority must—

(i) where before IP completion day the Committee for Medicinal Products for Human use has given a positive final opinion in relation to the application with which the United Kingdom concurred, treat the renewal application as accepted for the purposes of regulation 66B, or

(ii) where before IP completion day the Committee for Medicinal Products for Human Use has not given any opinion or has given a negative final opinion in relation to the application, or where a positive final opinion has been given but the United Kingdom recorded a divergent opinion, treat the application as an application made in relation to the converted EU marketing authorisation under regulation 66B (renewal of conditional marketing authorisation) and consider the application in accordance with that regulation.

Applications for renewals of converted EU marketing authorisations made after IP completion day

16.—(1) This paragraph applies where a holder of a converted EU marketing authorisation is due to make an application for renewal of the authorisation in accordance with regulation 66 (application for renewal of authorisation) during the period of one year beginning with IP completion day.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the baseline data so that it is received by the licensing authority at the same time as the application for renewal is made;

(b) the licensing authority must consider the renewal application in accordance with regulation 66; and

(c) the converted EU marketing authorisation remains in force until the licensing authority notifies the holder of its decision on the renewal application.

Applications for renewals of conditional marketing authorisations made after IP completion day

17.—(1) This paragraph applies where the holder of a converted EU marketing authorisation which was granted as a conditional marketing authorisation within the meaning of Article 1 of Regulation (EC) No 507/2006 is due to make an application for renewal of the authorisation in accordance with regulation 66B during the period beginning with IP completion day and ending on the data submission date.

(2) Where this paragraph applies—

(a) the holder of the converted EU marketing authorisation must (subject to paragraph 18) submit the baseline data so that it is received by the licensing authority at the same time as the application for renewal is made;

(b) the licensing authority must consider the renewal application in accordance with regulation 66B (renewal of conditional marketing authorisation); and

(c) the authorisation remains in force until the licensing authority notifies the holder of its decision on the renewal application.

Renewals of converted EU marketing authorisations sought in advance of the data submission date

18.—(1) If a holder of a converted EU marketing authorisation submits an application for renewal in accordance with regulation 66 or 66B before the data submission date, it must, unless sub-paragraph (2) applies, provide to the licensing authority with the application such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing by the licensing authority for this purpose and published on or before IP completion day.

(2) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a renewal application before the data submission date but does not provide the information described in sub-paragraph (1) with the application, the licensing authority may agree to consider the application if it is satisfied that—

(a) the renewal may be necessary on urgent safety grounds;

(b) the renewal may be necessary in order to maintain supplies of a particular medicinal product to patients in the United Kingdom; or

(c) there are other good reasons for considering the renewal in advance of the data submission date.

Article 61(3) notifications made before IP completion day in relation to converted EU marketing authorisations

19.—(1) This paragraph applies where, before IP completion day—

(a) a holder of a converted EU marketing authorisation has, in accordance with Article 61(3) of the 2001 Directive, notified the EMA of a proposed change to an aspect of the labelling or the package leaflet of the EU marketing authorisation to which the converted EU marketing authorisation relates; but

(b) the period of 90 days referred to in Article 61(3) has not elapsed and the EMA has not objected to the proposed change.

(2) Where this paragraph applies, and where the holder wishes the proposed change to apply in relation to the converted EU marketing authorisation—

(a) the holder may put the change into effect in relation to the converted EU marketing authorisation at the same time as it may be put into effect in relation to the EU marketing authorisation;

(b) the holder must (subject to paragraph 21) include with the baseline data—

(i) a copy of the notification, and

(ii) an indication of whether the EMA has opposed the proposed change; and

(c) the proposed change to the labelling or the package leaflet of the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing within the period of 30 days beginning with the data submission date that the proposed change is opposed, in which case the holder must cease to apply the opposed change immediately after receipt of the notification.

Article 61(3) notifications made in relation to converted EU marketing authorisations after IP completion day but before the data submission date

20.—(1) This paragraph applies where, during the period beginning with IP completion day and ending on the day before the data submission date, a holder of a converted EU marketing authorisation notifies the EMA in accordance with Article 61(3) of the 2001 Directive of a proposed change to an aspect of the labelling or the package leaflet of the EU marketing authorisation to which the converted EU marketing authorisation relates.

(2) Where this paragraph applies, and where the holder wishes the proposed change to apply in relation to the converted EU marketing authorisation—

(a) the holder of the converted EU marketing authorisation may put the change into effect at the same time as it may be put into effect in relation to the EU marketing authorisation;

(b) the holder must (subject to paragraph 21) include with the baseline data—

(i) a copy of the notification, and

(ii) an indication of whether the EMA has opposed the proposed change; and

(c) the proposed change to the labelling or the package leaflet of the converted EU marketing authorisation is deemed to be accepted unless the licensing authority notifies the holder in writing within the period of 30 days beginning with the data submission date that the proposed change is opposed, in which case the holder must cease to apply the opposed change immediately after receipt of the notification.

Article 61(3) notifications sought in advance of the data submission date

21.—(1) If a holder of a converted EU marketing authorisation wishes to notify the licensing authority of a proposed change to an aspect of the labelling or the package leaflet of the EU marketing authorisation to which the converted EU marketing authorisation relates in advance of the data submission date, the holder must—

(a) submit the notification of the proposed change to the licensing authority; and

(b) unless sub-paragraph (2) applies, at the same time provide the licensing authority with such information concerning the product to which the converted EU marketing authorisation relates as may be specified in writing by the licensing authority for this purpose and published on or before IP completion day.

(2) If a holder of a converted EU marketing authorisation wishes the licensing authority to consider a proposed change before the data submission date but does not provide the information described in sub-paragraph (1)(b) with the notification, the licensing authority may agree to consider the notification if it is satisfied that—

(a) the proposed change may be necessary on urgent safety grounds;

(b) the proposed change may be necessary in order to maintain supplies of a particular medicinal product to patients in the United Kingdom; or

(c) there are other good reasons for considering the proposed change in advance of the data submission date.

(3) Where the licensing authority considers a proposed change in accordance with this paragraph, the references in paragraph 19(2)(c) and 20(2)(c) to the data submission date are to be read as references to the date on which—

(a) the proposed change is notified to the licensing authority in accordance with sub-paragraph (1); or

(b) the licensing authority notifies the holder that it will consider the notification, in accordance with sub-paragraph (2), without the information referred to in sub-paragraph (1)(b).

Place of establishment for converted EU marketing authorisation holder established in EEA state before IP completion day

22.—(1) Subject to sub-paragraph (2), a person who—

(a) holds a converted EU marketing authorisation on IP completion day (whether or not it is suspended); and

(b) was, immediately before IP completion day, established in an EEA State, and remains established there on and after IP completion day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 49(3) or 66(2) (as the case may be), notwithstanding the amendments made to those provisions by the EU Exit Regulations.

(2) But sub-paragraph (1) continues to apply to a person after the end of the specified period only if the person has, before the end of that period, notified the licensing authority in writing of—

(a) a named individual who resides and operates in the United Kingdom who the licensing authority may contact in respect of any matter relating to the converted EU marketing authorisation during the transitional period; and

(b) that individual's address, telephone number and email address.

(3) In this paragraph—

"the specified period" means 4 weeks beginning with IP completion day; and

"the transitional period" means the period of 24 months beginning with IP completion day.

Temporary exemption as to packaging requirements for converted EU marketing authorisations

23.—(1) A holder of a converted EU marketing authorisation does not commit an offence under regulation 268 during the period of 36 months beginning with IP completion day to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 by reason only of the fact that the outer or immediate packaging, or the package leaflet, do not include the correct information as to—

(i) the name and address of the holder of the UK marketing authorisation, or, where applicable, the name of the holder's representative,

(ii) the number of the UK marketing authorisation, or

(iii) the name and address of the manufacturer of the product; and

(b) the outer and immediate packaging, or the package leaflet, do not include the correct information specified in paragraph (a)(i) to (iii) solely because—

(i) the number of the marketing authorisation is the number of the EU marketing authorisation to which the converted EU marketing authorisation relates, or

(ii) the UK marketing authorisation holder has established itself in the United Kingdom before the end of the period of 24 months beginning with IP completion day in order to comply with regulation 49(3), and the information specified in paragraph (a)(i) or (iii) is no longer correct as a consequence of that establishment in the United Kingdom.

(2) Sub-paragraph (1) only applies if—

(a) the packaging and package leaflet met the requirements of Part 13 as to the matters specified in sub-paragraph (1)(a)(i) to (iii) immediately before IP completion day; and

(b) the holder of the converted EU marketing authorisation, having been notified of the number of the UK marketing authorisation and having established itself in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, during the period referred to in sub-paragraph (1).

Referrals made under Article 20 of Regulation (EC) No 726/2004 that have not concluded or been implemented before IP completion day

24.—(1) Sub-paragraph (2) applies where—

(a) the European Commission has requested the opinion of the EMA in accordance with Article 20(2) of Regulation (EC) No 726/2004 in relation to a specified matter; but

(b) no final decision has been adopted by the European Commission in accordance with Article 20(3) of that Regulation immediately before IP completion day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 68 (revocation, variation and suspension of UK marketing authorisation) as soon as reasonably practicable.

(3) In making a decision under regulation 68 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before IP completion day in relation to the specified matter as a consequence of its involvement in the procedure under Article 20 of Regulation (EC) No 726/2004;

(b) any relevant decision made, or agreement reached, before IP completion day, where the United Kingdom participated as a member State in the making of that decision or agreement, under any procedure provided for in the Council Decision of 28 June 1999 laying down the procedure for the exercise of implementing powers conferred on the Commission; and

(c) any advice it receives from the appropriate committee pursuant to the procedures in Schedule 11.

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 68 in accordance with sub-paragraph (2) in a case where the Committee for Medicinal Products for Human Use has given a final opinion in relation to the specified matter.

(5) Where this sub-paragraph applies, the licensing authority may treat the opinion as if it were the opinion of the appropriate committee for the purposes of paragraph 5 of Schedule 11.

(6) Sub-paragraph (7) applies where—

(a) the European Commission has requested the opinion of the EMA in accordance with Article 20(2) of Regulation (EC) No 726/2004 in relation to a specified matter;

(b) a final decision has been adopted by the European Commission in accordance with Article 20(3) of that Regulation immediately before IP completion day; but

(c) the necessary steps to give effect to the decision referred to in paragraph (b) have not been taken before IP completion day.

(7) Where this sub-paragraph applies, the licensing authority must, where a Commission decision or opinion requires steps to be taken in respect of an EU marketing authorisation that is a converted EU marketing authorisation, take the steps necessary as a result of the decision or opinion to suspend, revoke or vary a converted EU marketing authorisation as soon as reasonably practicable.

(8) In this paragraph, "specified matter" means a matter in relation to which the opinion of the EMA has been requested by the European Commission under Article 20(2) of Regulation (EC) No 726/2004 before IP completion day that might result in the suspension, revocation or variation of an EU marketing authorisation which is a converted EU marketing authorisation.

Enforcement

25. If a holder of a converted EU marketing authorisation fails to comply with an obligation imposed on the holder by or under this Part, the licensing authority may suspend the authorisation until the holder complies with the obligation.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, PART 3.