SCHEDULE 7 Regulation 228(2)

Insertion of new Schedule 33A (transitional provision)

1. After Schedule 33 insert—

"SCHEDULE 33A Regulation 347A

Transitional provision in relation to EU Exit

PART 1

Interpretation

1. In this Schedule—

"the COMP" means the Committee for Orphan Medicinal Products of the EMA, established under Article 4 of the Orphan Regulation;

"converted EU marketing authorisation" has the meaning given in paragraph 6(1) and (2);

"the Paediatric Regulation" means Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, as it has effect in EU law(**1**);

"the Paediatric Committee" means the committee of the EMA established under Article 3 of the Paediatric Regulation;

"the Pharmacovigilance Risk Assessment Committee" means the Committee of the EMA established by Article 56(1)(aa) of Regulation (EC) No 726/2004; and

"Regulation (EC) No 507/2006" means Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council, as it has effect in EU law(**2**).

PART 2

Manufacturing, wholesale dealing and brokering

Wholesale dealer's licence used to distribute a medicinal product imported from an EEA State before exit day

2.—(1) Subject to sub-paragraphs (2) and (3), a person ("P") who is the holder of a wholesale dealer's licence which—

(a) was granted before exit day by the licensing authority;

(b) was in force immediately before exit day and remains in force on exit day (whether or not it is suspended); and

(c) was used by P to distribute a medicinal product, which was imported from an EEA State, by way of wholesale dealing, or to possess a medicinal product imported from an EEA State for such a purpose,

(**1**) OJ No. L 387, 27.12.2006, p. 1.
(**2**) OJ No. L 92, 30.3.2006, p. 6.

is deemed on and after exit day to hold a wholesale dealing licence granted under Part 3 (manufacture and distribution of medicinal products and active substances) that permits the operation of importing medicinal products from an approved country for import for the purposes specified in paragraph (c).

(2) After the end of the period of 6 months beginning with exit day, P is deemed to continue hold a wholesale dealer's licence that permits the operation of importing medicinal products from an approved country for import by virtue of sub-paragraph (1) only if, before the end of that period, P has notified the licensing authority in writing of—

(a) P's intention to continue to import medicinal products from an approved country for import; and

(b) either—

(i) P's intention to appoint a responsible person (import) who will carry out the functions under regulation 45AA(4) (requirement as to responsible persons where licence holder imports from an approved country for import) in respect of the licence, or

(ii) that P will only import medicinal products from an approved country for import to which an exemption in regulation 45AA(2) applies.

(3) Unless P has notified the licensing authority as provided for in sub-paragraph (2)(b)(ii), after the end of the period of 2 years beginning with exit day, P is deemed to continue to hold a wholesale dealer's licence that permits the operation of importing medicinal products from an approved country for import by virtue of sub-paragraph (1) only if, before the end of that period, P has notified the licensing authority in writing of the name, address and qualifications of a person who—

(a) is included in the register under regulation 45AB(1); and

(b) will carry out the functions under regulation 45AA(4) in respect of the licence.

(4) From exit day, until the date on which P notifies the licensing authority of the information specified in sub-paragraph (3), the responsible person in respect of that licence under regulation 45 must carry out the functions under regulation 45AA(4).

(5) As soon as reasonably practicable after receipt of the information specified in paragraph (3), the licensing authority must provide P with written notice that the responsible person (import) is named on the licence.

(6) Where P has notified the licensing authority as provided for in sub-paragraph (2)(b)(ii), the licensing authority must, as soon as reasonably practicable, notify P in writing that the wholesale dealer's licence includes import of a medicinal product from an approved country for import limited to medicinal products to which an exemption in regulation 45AA(2) applies.

Approved country for import list on exit day (regulation 18A)

3.—(1) For the purposes of regulation 18A(1) (approved country for import), during the transitional period, the licensing authority must publish an approved country for import list that includes each EEA State in it.

(2) The licensing authority must not, before the end of the transitional period, exercise its power under regulation 18A(3) to remove an EEA State from the approved country for import list.

(3) In this paragraph, "the transitional period" is the period of two years beginning with exit day.

Qualified persons and approved country for batch testing list on exit day (Schedule 7)

4.—(1) Sub-paragraph (2) applies to a person who—

(a) is acting as a qualified person immediately before exit day; and

(b) satisfies the requirements of Part 1 of Schedule 7 (qualification requirements for qualified persons) immediately before exit day as they had effect at that time.

(2) The person is to be treated on and after exit day as continuing to satisfy the requirements of Part 1 of Schedule 7 if the person would otherwise fail to do so as a result of amendments made to that Part by the EU Exit Regulations.

(3) For the purposes of paragraph 14(1)(b) of Schedule 7 (obligations of qualified person), for the transitional period, the licensing authority is deemed to have made appropriate arrangements with—

(a) each EEA State;

(b) Australia;

(c) Canada;

(d) Israel;

(e) Japan;

(f) New Zealand;

(g) Switzerland; and

(h) the United States of America,

and the licensing authority must, on exit day, publish a list that includes those countries under paragraph 14(3) of Schedule 7.

(4) The licensing authority may, in respect of any country specified in sub-paragraph (3)(b) to (h), include that country in the list subject to a condition or restriction as provided for in paragraph 14(4) of Schedule 7, insofar as that condition or restriction was reflected in the appropriate arrangements that existed immediately before exit day under Article 51(2) of the 2001 Directive.

(5) The licensing authority must not, before the end of the transitional period, exercise its powers under paragraph 14(6) of Schedule 7 to remove an EEA State from the list it publishes.

(6) In this regulation, "the transitional period" is the period of two years beginning with exit day.

List of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day (regulation 45O(6) to (9))

5.—(1) For the purposes of regulation 45O(6) (requirements for registration as an importer, manufacturer or distributor of active substances), for the transitional period, the licensing authority must publish a list that includes the following countries—

(a) each EEA State;

(b) Australia;

(c) Brazil;

(d) Israel;

(e) Japan;

(f) Switzerland; and

(g) the United States of America.

(2) The licensing authority must not, before the end of the transitional period, exercise its power under regulation 45O(9) to remove an EEA State from the list it publishes.

(3) In this paragraph, "the transitional period" is the period of two years beginning with exit day.

PART 3

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

Conversion of EU marketing authorisations in force before exit day

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

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

(a) has effect on and after exit day as a UK marketing authorisation granted under regulation 49(1) of these Regulations; 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 exit 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 exit 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 exit day, and the period of three years referred to in regulation 67(2) is treated as having started on exit 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 51(1) and (2), the benefit of any remaining periods of data or marketing exclusivity (if any) from which the holder benefitted immediately before exit 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 exit day,

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

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

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

has effect on and after exit 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 exit day,

has effect on and after exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit day

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

14.—(1) This paragraph applies where a holder of a converted EU marketing authorisation has, before exit 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 exit 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 exit 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 exit 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 exit day

15.—(1) This paragraph applies where before exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit day in relation to converted EU marketing authorisations

19.—(1) This paragraph applies where, before exit 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 exit day but before the data submission date

20.—(1) This paragraph applies where, during the period beginning with exit 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 exit 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 exit day

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

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

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

"the transitional period" means the period of 21 months beginning with exit 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 33 months beginning with exit 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 21 months beginning with exit 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 exit 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 exit 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 exit 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 exit 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 exit 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 exit day; but

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

PART 4

Transitional provision in respect of UK marketing authorisations, parallel import licences and parallel distribution notices

Place of establishment for UK marketing authorisation holder or parallel import licence holder established in an EEA State before exit day

26.—(1) Subject to sub-paragraphs (2) and (3), any person—

(a) who—

(i) holds a UK marketing authorisation immediately before exit day which remains in force on exit day (whether or not it is suspended),

(ii) holds a parallel import licence immediately before exit day which remains in force on exit day (whether or not it is suspended),

(iii) has made an application for, or to renew, a UK marketing authorisation or parallel import licence before exit day, which has not been determined before that date, or

(iv) makes such an application on or after exit day but before the end of the transitional period; and

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

is to be treated, for the transitional period, as satisfying the requirements of regulation 49(3), 66(2) or 66A(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 only if the person has 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 UK marketing

authorisation or parallel import licence, or application for a UK marketing authorisation or parallel import licence (as the case may be), during the transitional period; and

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

(3) A person must notify the licensing authority under sub-paragraph (2)—

(a) where sub-paragraph (1)(a)(i) to (iii) applies, within the period of 4 weeks beginning with exit day; or

(b) where sub-paragraph (1)(a)(iv) applies, at the time of making the application.

(3) This paragraph does not apply to a UK marketing authorisation that is a converted EU marketing authorisation within the meaning of paragraph 6.

(4) In this paragraph "the transitional period" means the period of 21 months beginning with exit day.

Temporary exemption as to packaging requirements: change of place of establishment

27.—(1) Subject to sub-paragraph (2), a person to whom paragraph 26 applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets: holder of authorisation etc) during the transitional period to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 (packaging and leaflets) by reason only of the fact that the outer or immediate packaging, or the package leaflet (as the case may be), 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 that 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 UK marketing authorisation holder has established itself in the United Kingdom before the end of the period of 21 months beginning with exit day in order to comply with regulation 49(3), and

(ii) the information specified in paragraph (a)(i) to (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 paragraph (1)(a)(i) to (iii) immediately before exit day; and

(b) the UK marketing authorisation holder, 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, as the case may be, during the transitional period.

(3) In this paragraph "the transitional period" means the period of 33 months beginning with exit day.

Conversion of parallel distribution notices in to parallel import licences

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

(a) a person holds a parallel distribution notice, issued by the EMA, for a medicinal product in respect of which there is an EU marketing authorisation;

(b) that distribution notice, and that EU marketing authorisation, are in force immediately before exit day; and

(c) that parallel distribution notice specifies the United Kingdom as a member state of destination in respect of that medicinal product.

(2) Subject to sub-paragraph (3), a person who falls within sub-paragraph (1) is deemed, on and after exit day, to have a parallel import licence granted under Part 5 in respect of the medicinal product specified in the parallel distribution notice.

(3) A person who falls within sub-paragraph (1) continues to hold a parallel import licence pursuant to sub-paragraph (2) only if that person notifies the licensing authority—

(a) before the end of the period of 21 days beginning with exit day, of each medicinal product, and each country from which it is intended to import that product on or after exit day; and

(b) of any other information that the licensing authority requests, within such time period as the licensing authority may specify.

(4) The licensing authority must as soon as reasonably practicable after receipt of the information specified in sub-paragraph (3), issue a parallel import licence to the holder of the parallel distribution notice.

Inclusion of the batch testing condition in relevant UK marketing authorisations, and batch testing of biological medicinal products in the EEA before exit day (regulation 60A)

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

(a) a marketing authorisation was in force before exit day,

(b) that authorisation is in force as a UK marketing authorisation on exit day (whether or not it is suspended); and

(c) that authorisation is for a medicinal product of a type that is specified in regulation 60A(2)(a) to (e) (condition as to the submitting of samples and other information to the appropriate authority).

(2) Where this sub-paragraph applies, the UK marketing authorisation is deemed to include the batch testing condition on and after exit day.

(3) Sub-paragraph (4) applies where a holder of a UK marketing authorisation has, before exit day, submitted to a competent authority of an EEA State samples for testing from a batch of a medicinal product ("the relevant batch") that—

(a) is the subject of that authorisation; and

(b) is of a type specified in regulation 60A(2)(a) to (e).

(4) Where this sub-paragraph applies, the holder of the UK marketing authorisation is deemed to have satisfied the batch testing condition in respect of the relevant batch if, before exit day—

(a) the competent authority of that EEA State examines the sample from the relevant batch; and

(b) that authority declared it to be in conformity with the approved specifications (within the meaning of Article 114 of the 2001 Directive) before exit day.

(5) The appropriate authority—

(a) must include each EEA State on the list it publishes under regulation 60A(5) on exit day; and

(b) must not, before the end of the transitional period, exercise its powers under regulation 60A(8) to remove an EEA State from the list it publishes under regulation 60A(5).

(6) For the purposes of regulation 60A(9), the appropriate authority must, on exit day—

(a) include Switzerland and Israel in the list it publishes under that paragraph; and

(b) include in respect of those countries any conditions or restrictions in the arrangement with those countries that affect the applicability of the batch testing exemption.

(7) In this paragraph—

(a) "the transitional period" means the period of 21 months beginning with exit day; and

(b) "the batch testing condition" and "the batch testing exemption" have the same meaning as in regulation 60A.

Existing data and marketing exclusivity and global marketing authorisations

30.—(1) Sub-paragraph (2) applies in relation to a UK marketing authorisation which, immediately before exit day, is part of a global marketing authorisation with one or more EU marketing authorisations or marketing authorisations granted by the competent authority of an EEA state.

(2) Where this sub-paragraph applies, the provisions of regulation 48(5) (definitions for Part 5), in so far as they describe a global marketing authorisation by reference to UK marketing authorisations only, do not affect the periods of data and marketing exclusivity to which the holder of a UK marketing authorisation to which this paragraph applies is entitled immediately before exit day.

Applications for EU marketing authorisations made before exit day

31.—(1) Sub-paragraph (2) applies where, before exit day—

(a) an application has been made to the EMA for an EU marketing authorisation; but

(b) no final decision has been made by the European Commission in relation to the grant of an EU marketing authorisation under Article 10 of Regulation (EC) No 726/2004.

(2) Where this sub-paragraph applies, the applicant may apply to the licensing authority for the grant of a UK marketing authorisation by submitting to the licensing authority—

(a) a copy of the application for the EU marketing authorisation; and

(b) if requested by the licensing authority, such material or information that the licensing authority reasonably considers necessary for dealing with the application.

(3) Sub-paragraph (4) applies where, before exit day and in relation to an application to which sub-paragraph (2) applies, a final opinion favourable to the granting of an EU marketing authorisation has been given by the Committee for Medicinal Products for Human Use and the United Kingdom concurred with that opinion.

(4) Where this sub-paragraph applies, the licensing authority must grant a UK marketing authorisation in response to an application as described in sub-paragraph (2) as soon as reasonably practicable after it is received.

(5) Sub-paragraph (6) applies where before exit day, in relation to an application to which sub-paragraph (2) applies—

(a) no final opinion favourable to the granting of an EU marketing authorisation has been given by the Committee for Medicinal Products for Human Use; or

(b) such an opinion has been given but the United Kingdom recorded a divergent opinion.

(6) Where this sub-paragraph applies, the licensing authority must consider an application made under sub-paragraph (2) in accordance with Part 5 of these Regulations (marketing authorisations).

Place of establishment for UK marketing authorisation holder established in EEA state before exit day (pre-exit EU marketing authorisation applications)

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

(a) who applied to the EMA for an EU marketing authorisation before exit day;

(b) to whom the licensing authority grants a UK marketing authorisation on or after exit day in response to that application in accordance with paragraph 31; and

(c) who was, immediately before exit day, established in an EEA State, and remains established there on and after exit day,

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

(2) Sub-paragraph (1) applies to a person only if, when submitting a copy of the application for the EU marketing authorisation to the licensing authority in accordance with paragraph 31, the person notifies the licensing authority in writing of—

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

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

(3) In this paragraph, "the transitional period" means the period which beginning with the date on which the licensing authority grants a UK marketing authorisation as described in paragraph 31(4) and ending 21 months after exit day.

Packaging in relation to UK marketing authorisations granted in response to application for EU marketing authorisation made before exit day

33.—(1) Subject to sub-paragraph (2), a person to whom paragraph 32(1) applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets: holder of authorisation etc) during the transitional period to the extent that—

(a) the packaging and package leaflet do not comply with the requirements of Part 13 (packaging and leaflets) 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 marketing authorisation, or, where applicable, the name of the holder's representative,

(ii) the number of the 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 application for the EU marketing authorisation related, or

(ii) the UK marketing authorisation holder has established itself in the United Kingdom before the end of the period of 21 months beginning with exit 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 exit day; and

(b) the UK marketing authorisation holder, being aware of the number of the UK marketing authorisation and having established in the United Kingdom, does not otherwise need to make any changes to the outer or immediate packaging, or the package leaflet, as the case may be, during the transitional period.

(3) In this paragraph, "the transitional period" means the period beginning with the date on which the licensing authority grants a UK marketing authorisation as described in paragraph 31(4) and ending 33 months after exit day.

Applications made for a UK marketing authorisation before exit day to which Chapter 4 of Title III of the 2001 Directive applied

34.—(1) Sub-paragraph (2) applies where an application for a UK marketing authorisation has been made before exit day and—

(a) regulation 58(6) and (7) of the 2012 Regulations (applications to be determined under Chapter 4 of Title III of the 2001 Directive) applied to that application before exit day; but

(b) a decision as specified in Article 28(5) of the 2001 Directive has not been adopted by the licensing authority before exit day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) where the procedure specified in Article 28(4) of the 2001 Directive has concluded before exit day in relation to that application, grant a UK marketing authorisation in respect of that application as soon as reasonably practicable, and in any event before the end of the period of 30 days, beginning with exit day; or

(b) where the procedure specified in Article 28(4) of the 2001 Directive has not concluded before exit day, determine that application in accordance with Part 5 of these Regulations (marketing authorisations) as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they no longer want the application to proceed.

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must have regard to—

(a) any relevant information obtained by it before exit day in relation to the application as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a reference member state or concerned member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive; and

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

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a UK marketing authorisation in the time period specified in regulation 58(1) (consideration of application) as if it had applied to that application on the date on which the application was submitted.

Transitional provision in respect of Plasma Master Files

35.—(1) This paragraph applies in relation to a UK marketing authorisation or EU marketing authorisation—

(a) which was granted before exit day;

(b) the application for which made reference to a Plasma Master File within the meaning of paragraph 1.1(a), first indent, of Part III of Annex I to the 2001 Directive which was certified by the EMA in accordance with paragraph 1.1(c) of that Part of the Annex; and

(c) which remains in force as a UK marketing authorisation on and after exit day.

(2) A holder of the UK marketing authorisation to which this paragraph applies may, subject to complying with the obligations in sub-paragraph (3), continue to refer to the Plasma Master File as certified by the EMA, notwithstanding the modifications to paragraph 1.1(c) of Part III of Annex I to the 2001 Directive in Schedule 8B, subject which that paragraph is to be read on and after exit day.

(3) The holder of a UK marketing authorisation to which this paragraph applies must notify the licensing authority of—

(a) the outcome of the annual update and recertification of the Plasma Master File by the EMA within 4 weeks beginning with the completion of that update and recertification;

(b) any application for changes to the terms of the Plasma Master File which the holder seeks from the EMA, within 4 weeks beginning with the date of the application; and

(c) the outcome of any application referred to in paragraph (b), within 4 weeks beginning with the date on which the holder is notified of that outcome.

(4) The licensing authority may at any time review the terms of a Plasma Master File to which reference is made in accordance with sub-paragraph (2), with a view to exercising its powers under these Regulations in relation to the UK marketing authorisation.

Suspensions of UK marketing authorisations that have effect immediately before exit day that were imposed under Chapter 4 of Title III of the 2001 Directive or Regulation (EC) No 726/2004

36. Where, immediately before exit day, a marketing authorisation, which is a UK marketing authorisation on exit day, has been suspended pursuant to the procedures in Chapter IV of Title III of 2001 Directive or Regulation (EC) No 726/2004, the suspension—

(a) continues to have effect on and after exit day in accordance with the terms on which it was imposed; and

(b) is to be treated as if it had been imposed by the licensing authority under Part 5 (marketing authorisations).

Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of an EU marketing authorisation or a UK marketing authorisation that have not concluded before exit day

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

(a) a specified matter has been referred under Article 31 of the 2001 Directive before exit day; but

(b) that procedure has not concluded before exit 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 exit day in relation to the specified matter as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive; 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 or the Co-ordination Group for Mutual Recognition and Decentralised Procedures (as the case may be) has given a final opinion in relation to the matter referred under Article 31 of the 2001 Directive.

(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 (advice and representations).

(6) Sub-paragraph (7) applies where—

(a) a specified matter has been referred under Article 31 of the 2001 Directive before exit day;

(b) that referral has concluded before exit day; but

(c) the licensing authority has not, before exit day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(7) Where this sub-paragraph applies, the licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the UK marketing authorisation—

(a) as soon as reasonably practicable; and

(b) in the case of a UK marketing authorisation that is not a converted EU marketing authorisation, within the period specified in Article 34(3) of the 2001 Directive (if relevant).

(8) In this paragraph—

"concluded before exit day", in relation to an Article 31 referral, means—

(a) a Commission decision as provided for in Article 34(3) of the 2001 Directive has been taken before exit day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 31 referral procedure, has been given before exit day; and

"specified matter" means—

(a) a matter referred under Article 31 of the 2001 Directive before exit day that concerns a proposal to suspend, revoke or otherwise vary a UK marketing authorisation or an EU marketing authorisation; but

(b) does not include a referral made under Article 107i of the 2001 Directive.

PART 5

Transitional provision in relation to variations of marketing authorisations other than converted EU marketing authorisations

Application or notification made before exit day in respect of a variation under Chapter IIa of Regulation (EC) No 1234/2008 (variations to purely national marketing authorisations)

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

(a) an application or notification in respect of a variation to a UK marketing authorisation has been submitted to the licensing authority under Chapter IIa of Regulation (EC) No 1234/2008 before exit day; but

(b) the procedures specified in Article 13e of that Regulation (measures to close the variation procedures in Chapter IIa of that Regulation) have not concluded before exit day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) determine which of the provisions specified in Schedule 10A that are relevant to that application or notification need to be taken on or after exit day, having regard to the steps that have already been undertaken under Chapter IIa of Regulation (EC) No 1234/2008 before exit day;

(b) assess the application or notification in accordance with the provisions of that Schedule the authority has determined are relevant to the application, as if the application or notification had been made under them; and

(c) take all reasonable steps to ensure that it assesses the notification or application in accordance with any relevant time period specified in that Schedule, as if the application had been made under the provisions in that Schedule before exit day.

(3) Paragraphs 15 and 16 of Schedule 10A apply to any variation that falls under sub-paragraph (1)(a) or (b).

Application or notification made before exit day in respect of a variation under Chapter II of Regulation (EC) No 1234/2008 (variations to marketing authorisations granted in accordance with Chapter 4 of the 2001 Directive)

39.—(1) This paragraph applies where an application or notification in respect of a variation to a marketing authorisation has been submitted to the licensing authority, as a relevant authority, under Chapter II of Regulation (EC) No 1234/2008 before exit day.

(2) If the procedures specified in Article 11(1) of Regulation (EC) No 1234/2008 have not concluded before exit day, the licensing authority must—

(a) assess the application or notification in accordance with regulation 65C and Schedule 10A to these Regulations, as if the application or notification had been made under those provisions; and

(b) make such an assessment having regard to the matters specified in sub-paragraph (5).

(3) If the procedures specified in Article 11(1) of Regulation (EC) No 1234/2008 have concluded before exit day—

(a) the licensing authority must take the steps specified in Article 11(2) of Regulation (EC) No 1234/2008 within the time limit specified in Article 23(1) of that Regulation; and

(b) paragraphs 15 and 16 of Schedule 10A apply to the variation.

(4) In making a determination under sub-paragraph (2), the licensing authority must—

(a) determine which steps of the procedures specified in Schedule 10A that are relevant to that application or notification need to be taken on or after exit day, having regard to the matters specified in sub-paragraph (5); and

(b) take all reasonable steps to ensure that it assesses the notification or application in accordance with any time period specified in that Schedule, as if the application had been made under the provisions in that Schedule before exit day.

(5) In making a determination under sub-paragraph (2), the licensing authority must have regard to—

(a) any recommendation in relation to that application or notification given before exit day pursuant to Article 5 of Regulation (EC) No 1234/2008;

(b) any relevant information obtained by it before exit day, as a relevant authority, in relation to the application or notification by virtue of any procedure provided for in Chapter II of that Regulation; and

(c) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a relevant authority, including any matter referred under the procedure specified in Article 13 of that Regulation.

Application or notification in respect of a variations made before exit day under Article 20 of Regulation (EC) No 1234/2008 (work-sharing procedure)

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

(a) an application or notification in respect of a variation to a UK marketing authorisation has been submitted to the licensing authority, as a relevant authority or the reference authority, under Article 20 of Regulation (EC) No 1234/2008;

(b) the marketing authorisation is one to which Chapter II or IIa of that Regulation applied; and

(c) the procedure in Article 20(8) has not been completed before exit day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) determine which of the provisions specified in Schedule 10A that are relevant to that application or notification need to be taken on or after exit day, having regard to the steps that have already been undertaken under Article 20 of Regulation (EC) No 1234/2008 before exit day;

(b) assess the application or notification in accordance with the relevant provisions in that Schedule, as if the application or notification had been made under them; and

(c) take all reasonable steps to ensure that it assesses the notification or application in accordance with any relevant time period specified in that Schedule, as if the application had been made under the provisions in that Schedule before exit day.

(3) In making a determination or assessment under sub-paragraph (2), the licensing authority must have regard to—

(a) any opinion given by the reference authority before exit day in relation to that application;

(b) any relevant information obtained by it before exit day, as a reference authority or relevant authority, in relation to the application or notification by virtue of any procedure provided for in regulation 20 of Regulation (EC) No 1234/2008; and

(c) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a relevant authority.

(4) Paragraphs 15 and 16 of Schedule 10A apply to any variation that falls under sub-paragraph (1).

PART 6

Transitional provision in relation to the Paediatric Regulation

Transitional provision in relation to applications made to EMA before exit day under the Paediatric Regulation

41.—(1) Where a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before exit day, that plan, including any modifications agreed by the EMA before exit day, has effect on and after exit day as an agreed paediatric investigation plan.

(2) Sub-paragraph (3) applies where—

(a) a paediatric investigation plan has been submitted to the EMA with a request for agreement before exit day;

(b) the proposed paediatric plan is valid in accordance with the provisions of Article 15(2) of the Paediatric Regulation; but

(c) the EMA has not adopted a decision to agree the plan before exit day.

(3) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the paediatric investigation plan with which the United Kingdom concurred has been given by the Paediatric Committee before exit day, treat the plan as an agreed paediatric investigation plan;

(b) where an opinion against agreeing the paediatric investigation plan with which the United Kingdom concurred has been given by the Paediatric Committee before exit day, decide that it cannot agree the plan under regulation 50B(5) (agreement and modification of paediatric investigation plan); or

(c) where before exit day no opinion in relation to the paediatric investigation plan has been given by the Paediatric Committee, or where such an opinion has been given but the United Kingdom recorded a divergent opinion, treat it as a request for agreement under regulation 50B(1) and determine that request as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they do not want the application to proceed as a request for agreement of a paediatric investigation plan under these Regulations.

(4) Sub-paragraph (5) applies where—

(a) a paediatric investigation plan has been agreed by the EMA in accordance with the Paediatric Regulation before exit day;

(b) the person to whom the EMA's decision to agree the plan was addressed has, before exit day, made a proposal under Article 22 of the Paediatric Regulation to modify the plan, or to request a waiver; but

(c) the EMA has not adopted a decision to agree to the modification or waiver before exit day.

(5) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the modification or waiver with which the United Kingdom concurred has been given by the Paediatric Committee before exit day, agree to the modification or waiver as if it had been requested under regulation 50B(6);

(b) where an opinion against agreeing the modification or waiver with which the United Kingdom concurred has been given by the Paediatric Committee before exit day, decide that it cannot agree to the modification or waiver as if it had been requested under regulation 50B(6); or

(c) where before exit day no opinion in relation to the modification or waiver has been given by the Paediatric Committee, or where such an opinion has been given but the United Kingdom recorded a divergent opinion, treat the proposal as one made under regulation 50B(6) and consider it accordingly, unless the applicant notifies the licensing authority in writing that they do not want the proposal to proceed as a proposal under regulation 50B(6).

(6) Where the EMA has adopted a decision to grant, and has not revoked, a waiver of the obligation to produce the information in Article 7(1)(a) of the Paediatric Regulation before exit day, that waiver has effect on and after exit day as a waiver granted by the licensing authority under regulation 50D (waiver of production of information in a paediatric investigation plan).

(7) Sub-paragraph (8) applies where—

(a) an application has been made to the EMA for a waiver of the obligation to produce the information in Article 7(1)(a) of the Paediatric Regulation before exit day;

(b) the application has been accepted as valid by the EMA; but

(c) the EMA has not adopted a decision to grant the waiver before exit day.

(8) Where this sub-paragraph applies, the licensing authority must—

(a) where an opinion favourable to agreeing the waiver with which the United Kingdom concurred has been given by the Paediatric Committee before exit day, grant the waiver under regulation 50D(2);

(b) where an opinion against agreeing the waiver with which the United Kingdom concurred has been given by the Paediatric Committee before exit day, decide that it cannot grant the waiver under regulation 50D(2); or

(c) where before exit day no opinion in relation to the waiver has been given by the Paediatric Committee, or where such an opinion has been given but the United Kingdom recorded a divergent opinion, treat the proposal as one made under regulation 50D and consider it accordingly, unless the applicant notifies the licensing authority in writing that they do not want the proposal to proceed as a proposal under regulation 50D.

PART 7

Transitional provision in relation to orphan medicinal products

Transitional provision in relation to applications made to EMA before exit day for orphan medicinal products

42.—(1) This sub-paragraph applies where—

(a) before exit day—

(i) an application has been made to the EMA for an EU marketing authorisation in relation to a medicinal product which has been approved as an orphan medicinal product by the European Commission pursuant to Article 5 of the Orphan Regulation and which appears in the Orphan Register, but

(ii) no final decision has been made by the European Commission in relation to maintaining the product's inclusion in the Orphan Register following the grant of an EU marketing authorisation, and

(b) on or after exit day, the licensing authority is granting or considering an application for a UK marketing authorisation in relation to the product in accordance with paragraph 31(4) or (6).

(2) Where sub-paragraph (1) applies, the licensing authority must—

(a) where an opinion favourable to the maintenance of the inclusion of the medicinal product in the Orphan Register with which the United Kingdom concurred has been given by the COMP before exit day in relation to the application, decide for the purposes of regulation 58C(1)(a) (consideration of applications relating to orphan medicinal products) that the orphan criteria are met in relation to the product, or

(b) where no opinion favourable to such maintenance has been given by the COMP before exit day in relation to the application, or where such an opinion has been given but the United Kingdom recorded a divergent opinion, reach its own view for the purposes of regulation 58C(1)(a) as to whether the orphan criteria are met in relation to the product.

(3) In this paragraph, "Orphan Register" means the Community register of Orphan Medicinal Products as referred to in Article 5 of the Orphan Regulation.

PART 8

Transitional provision in respect of homoeopathic medicinal products

List of countries for the purposes of the definition of "homoeopathic medicinal product" on exit day

43.—(1) For the purposes of the definition of "homoeopathic medicinal product" in regulation 8 (general interpretation: accepted Pharmacopoeias for homoeopathic manufacturing procedures), during the transitional period, the licensing authority must publish a list of countries that includes each EEA State in it.

(2) The licensing authority must not, before the end of the transitional period, remove an EEA State from the list described in sub-paragraph (1).

(3) In this paragraph, "the transitional period" is the period of two years beginning with exit day.

Place of establishment for holders of certificates of registration established in EEA before exit day

44.—(1) Subject to sub-paragraph (2), any person—

(a) who—

(i) holds a certificate of registration immediately before exit day which remains in force on exit day (whether or not it is suspended),

(ii) has made an application for, or to renew, a certificate of registration before exit day, which has not been determined by the licensing authority before that date, or

(iii) makes such an application on or after exit day but before the end of the transitional period; and

(b) who was, immediately before exit day, established in an EEA State and who remains there on and after that day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 103(4) or 108(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 only if the person has 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 certificate of registration, or application for a certificate of registration, during the transitional period; and

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

(3) A person must notify the licensing authority under sub-paragraph (2)—

(a) where sub-paragraph (1)(a)(i) or (ii) applies, within the period of 4 weeks beginning with exit day; or

(b) where sub-paragraph (1)(a)(iii) applies, at the time of making the application.

(4) In this paragraph "the transitional period" means the period of 21 months beginning with exit day.

Temporary exemption as to packaging requirements: change of place of establishment

45.—(1) Subject to sub-paragraph (2), a person to whom paragraph 44 applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets) during the transitional period in relation to a product to the extent that—

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

(i) the name and address of the holder of the certificate of registration,

(ii) the number of the certificate of registration, or

(iii) the name and address of the manufacturer of the product if different from the holder of the certificate of registration; 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 holder of the certificate of registration has established itself in the United Kingdom before the end of the period of 21 months beginning with exit day in order to comply with regulation 103(4) or 108(2), and

(ii) the information specified in paragraph (a)(i) to (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 exit day; and

(b) the certificate of registration holder, 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, as the case may be, during the transitional period.

(3) In this paragraph "the transitional period" means the period of 33 months beginning with exit day.

Applications made for a certificate of registration for a registrable homoeopathic product before exit day to which Chapter 4 of Title III of the 2001 Directive applied

46.—(1) Sub-paragraph (2) applies where an application for a certificate of registration has been made before exit day and—

(a) regulation 104(5) and (6) (applications to be determined under Chapter 4 of Title III of the 2001 Directive) applied to that application before exit day; but

(b) a decision as specified in Article 28(5) of the 2001 Directive has not been adopted by the licensing authority before exit day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) where the procedure specified in Article 28(4) of the 2001 Directive has concluded before exit day in relation to that application, grant a certificate of registration in respect of that application as soon as reasonably practicable, and in any event before the end of the period of 30 days, beginning with exit day; or

(b) where the procedure specified in Article 28(4) of the 2001 Directive has not concluded before exit day, determine that application in accordance with Part 6 of these Regulations as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they no longer want the application to proceed.

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must have regard to—

(a) any relevant information obtained by it before exit day in relation to the application as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive; and

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a reference member state or concerned member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive.

(4) In making a determination under sub-paragraph (2)(b), the licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a certificate of registration in the time period specified in regulation 104(1) as if it had applied to that application on the date on which the application was submitted.

Suspensions of certificates of registration that have effect immediately before exit day that were imposed under Chapter 4 of Title III of the 2001 Directive

47. Where, immediately before exit day, a certificate of registration has been suspended pursuant to the procedures in Chapter IV of Title III of 2001 Directive, the suspension—

(a) continues to have effect on and after exit day in accordance with the terms on which it was imposed; and

(b) is to be treated as if it had been imposed by the licensing authority under Part 6 of these Regulations (certification of homoeopathic medicinal products).

Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of a certificate of registration that have not concluded before exit day

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

(a) a specified matter has been referred under Article 31 of the 2001 Directive before exit day; but

(b) the procedure has not concluded before exit day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 110 (revocation, variation and suspension of certificate of registration) as soon as reasonably practicable.

(3) In making a decision under regulation 110 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before exit day in relation to the specified matter as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

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

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 110 in accordance with sub-paragraph (2) in a case where the Co-ordination Group for Mutual Recognition and Decentralised procedures has given an opinion in relation to the matter under Article 31 of the Directive.

(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) a specified matter has been referred under Article 31 of the 2001 Directive before exit day;

(b) the referral has concluded before exit day; but

(c) the licensing authority has not, before exit day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(7) The licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the certificate of registration within the time period specified in Article 34(3) of the 2001 Directive where the decision or opinion requires steps to be taken in relation to a certificate of registration.

(8) In this paragraph—

"concluded before exit day", in relation to an Article 31 referral, means—

(a) a Commission decision as provided for in Article 34(3) of the 2001 Directive has been taken before exit day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 31 referral procedure, has been given before exit day;

"specified matter" means—

(a) a matter referred under Article 31 of the 2001 Directive before exit day that concerns a proposal to suspend, revoke or otherwise vary a certificate of registration; but

(b) does not include a referral made under Article 107i of the 2001 Directive.

PART 9

Transitional provision in respect of traditional herbal registrations

Place of establishment for holders of traditional herbal registrations established in EEA before exit day

49.—(1) Subject to sub-paragraph (2), any person—

(a) who—

(i) holds a traditional herbal registration immediately before exit day which remains in force on exit day (whether or not it is suspended),

(ii) has made an application for, or to renew, a traditional herbal registration before exit day, which has not been determined by the licensing authority before that date, or

(iii) makes such an application on or after exit day but before the end of the transitional period; and

(b) who was, immediately before exit day, established in an EEA State and who remains there on and after that day,

is to be treated, for the transitional period, as satisfying the requirements of regulation 127(3) or 133(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 only if the person notifies 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 traditional herbal registration, or application for a traditional herbal registration, during the transitional period; and

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

(3) A person must notify the licensing authority under sub-paragraph (2)—

(a) where sub-paragraph (1)(a)(i) or (ii) applies, within the period of 4 weeks beginning with exit day; or

(b) where sub-paragraph (1)(a)(iii) applies, at the time of making the application.

(4) In this paragraph "the transitional period" means the period of 21 months beginning with exit day.

Temporary exemption as to packaging requirements: change of place of establishment

50.—(1) Subject to sub-paragraph (2), a person to whom paragraph 49 applies does not commit an offence under regulation 268 (offence relating to packaging and package leaflets) during the transitional period in relation to a product to the extent that—

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

(i) the name and address of the holder of the traditional herbal registration, or, if applicable, the holder's representative,

(ii) the number of the traditional herbal registration, 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 holder of the traditional herbal registration has established itself in the United Kingdom before the end of the period of 21 months beginning with exit day in order to comply with regulation 127(3) or 133(2), and

(ii) the information specified in paragraph (a)(i) to (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 exit day; and

(b) the holder of the traditional herbal registration, 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, as the case may be, during the transitional period.

(3) In this paragraph "the transitional period" means the period of 33 months beginning with exit day.

List of approved countries for traditional use of a herbal medicinal product on exit day

51.—(1) For the purpose of regulation 125A (list of approved countries for traditional use of a herbal medicinal product), the licensing authority must, for the transitional period, include each EEA State in the list it publishes under regulation 125A(1).

(2) The licensing authority must not, before the end of the transitional period, exercise its power under regulation 125A(3) to remove an EEA State from the list.

(3) In this paragraph, the transitional period is two years beginning with exit day.

Applications made for a traditional herbal registration before exit day to which Chapter 4 of Title III of the 2001 Directive applied

52.—(1) Sub-paragraph (2) applies where an application for a traditional herbal registration has been made before exit day and—

(a) regulation 130(12) and (13) (applications to be determined under Chapter 4 of Title III of the 2001 Directive) applied to that application before exit day; but

(b) a decision as specified in Article 28(5) of the 2001 Directive has not been adopted by the licensing authority before exit day.

(2) Where this sub-paragraph applies, the licensing authority must—

(a) where the procedure specified in Article 28(4) of the 2001 Directive has concluded before exit day in relation to that application, grant a traditional herbal registration in respect of that application as soon as reasonably practicable, and in any event before the end of the period of 30 days, beginning with exit day; or

(b) where the procedure specified in Article 28(4) of the 2001 Directive has not concluded before exit day, determine that application in accordance with Part 7 of these Regulations as soon as reasonably practicable, unless the applicant notifies the licensing authority in writing that they no longer want the application to proceed.

(3) In making a determination under sub-paragraph (2)(b), the licensing authority must have regard to—

(a) any relevant information obtained by it before exit day in relation to the application as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a reference member state or concerned member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

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

(4) In making a determination under sub-paragraph (2)(b), the licensing authority must take all reasonable steps to ensure that it makes a decision to grant or refuse a traditional herbal registration in the time period specified in regulation 130(1) as if it had applied to that application on the date on which the application was submitted.

Suspensions of traditional herbal registrations that have effect immediately before exit day that were imposed under Chapter 4 of Title III of the 2001 Directive

53. Where, immediately before exit day, a traditional herbal registration has been suspended pursuant to the procedures in Chapter IV of Title III of 2001 Directive, the suspension—

(a) continues to have effect on and after exit day in accordance with the terms on which it was imposed; and

(b) is to be treated as if it had been imposed by the licensing authority under Part 7 of these Regulations (traditional herbal registrations).

Referrals made under Article 31 of the 2001 Directive concerning the suspension, variation or revocation of a traditional herbal registration that have not concluded before exit day

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

(a) a specified matter has been referred under Article 31 of the 2001 Directive before exit day; but

(b) the procedure has not concluded before exit day.

(2) Where this sub-paragraph applies, the licensing authority must make a decision in respect of the specified matter in accordance with regulation 135 (revocation, variation and suspension of traditional herbal registration) as soon as reasonably practicable.

(3) In making a decision under regulation 135 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before exit day in relation to the specified matter as a consequence of its involvement in any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Chapter 4 of Title III of the 2001 Directive;

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

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 135 of these Regulations in accordance with sub-paragraph (2) in a case where the Co-ordination Group for Mutual Recognition and Decentralised procedures has given an opinion in relation to the matter under Article 31 of the Directive.

(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) a specified matter has been referred under Article 31 of the 2001 Directive before exit day;

(b) the referral has concluded before exit day; but

(c) the licensing authority has not, before exit day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(7) Where this sub-paragraph applies, the licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the traditional herbal registration within the time period specified in Article 34(3) of the 2001 Directive where the decision or opinion requires steps to be taken in relation to a traditional herbal registration.

(8) In this paragraph—

"concluded before exit day", in relation to an Article 31 referral, means—

(a) a Commission decision as provided for in Article 34(3) of the 2001 Directive has been taken before exit day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 31 referral procedure, has been given before exit day; and

"specified matter" means—

(a) a matter referred under Article 31 of the 2001 Directive before exit day that concerns a proposal to suspend, revoke or otherwise vary a traditional herbal registration; but

(b) does not include a referral made under Article 107i of the 2001 Directive.

Proposals to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products and the procedure in Part 3 of Schedule 11 that were on-going at exit day

55.—(1) This paragraph applies where—

(a) the licensing authority has proposed to refer an application for a traditional herbal registration to the Committee on Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive before exit day; but

(b) that application has not been determined in accordance with Part 7 of these Regulations before exit day.

(2) Where the licensing authority has received an opinion of the Committee for Herbal Medicinal Products before exit day in relation to the application, it must take that decision in to account and determine that application.

(3) Where the licensing authority has not received an opinion of the Committee for Herbal Medicinal Products before exit day, notwithstanding the amendments made to Part 3 of Schedule 11 by the EU Exit Regulations, it may—

(a) proceed to determine the application, taking into account any proceedings that took place before exit day under Part 3 of Schedule 11 (prior to its amendment by the EU Exit Regulations), or any opinion of the Committee on Herbal Medicinal Products in relation to the application that is given on or after exit day; or

(b) it may refer the matter under regulation 130A in order to obtain the findings and advice of the appropriate committee before determining the application.

PART 10

Transitional provision in respect of pharmacovigilance

Interpretation of Part

56. In this Part, references to a "holder" are to the holder of a UK marketing authorisation or a traditional herbal registration.

Temporary exemption as to the location of an appropriately qualified person for pharmacovigilance

57.—(1) Sub-paragraph (2) applies to a holder of a UK marketing authorisation or traditional herbal registration—

(a) which was granted before exit day;

(b) that remains in force on exit day as a UK marketing authorisation or traditional herbal registration (as the case may be); and

(c) in respect of which, the holder had an appropriately qualified person for pharmacovigilance in respect of that authorisation or registration who, immediately before exit day, resided and operated in an EEA State.

(2) Where this sub-paragraph applies to a holder, that holder is to be treated as satisfying the requirements of regulation 182(2)(a), notwithstanding the amendments made to that provision by the EU Exit Regulations, for the transitional period, insofar as that holder would otherwise not meet those requirements solely because the appropriately qualified person responsible for pharmacovigilance in respect of that authorisation or registration resides and operates in an EEA State.

(3) In this regulation "the transitional period" means the period of 21 months beginning with exit day.

Referrals made under Article 107i of the 2001 Directive concerning the evaluation of data from pharmacovigilance activities which are not concluded before exit day

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

(a) a specified matter has been referred under Article 107i of the 2001 Directive (urgent Union procedure) before exit day; but

(b) that procedure has not concluded before exit 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 or 135 (revocation, variation and suspension of UK marketing authorisation or traditional herbal registration) as soon as reasonably practicable.

(3) In making a decision under regulation 68 or 135 in accordance with sub-paragraph (2), the licensing authority must have regard to—

(a) any relevant information obtained by it before exit day in relation to the specified matter as a consequence of its involvement in any procedure provided for by, or referred to in, Section 4 of Chapter 3 of the 2001 Directive;

(b) any relevant decision made, or agreement reached, before exit day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for by, or referred to in, Section 4 of Chapter 3 of the 2001 Directive; and

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

(4) Sub-paragraph (5) applies if the licensing authority is making a decision under regulation 68 or 135 in accordance with sub-paragraph (2) in a case where the Committee for Medicinal Products for Human Use or the Co-ordination Group for Mutual Recognition and Decentralised Procedures (as the case may be) has given a final opinion in relation to the 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 (advice and representations).

(6) In making a determination under regulation 68 or 135 in accordance with sub-paragraph (2), the licensing authority may adopt or have regard to any decision made, or agreement reached, in relation to the specified matter under Section 4 of Chapter 3 of the 2001 Directive on or after exit day, notwithstanding that the United Kingdom did not participate in the making of that decision or agreement.

(7) Sub-paragraph (8) applies where—

(a) a specified matter has been referred under Article 107i of the 2001 Directive before exit day; and

(b) that referral has concluded before exit day; but

(c) the licensing authority has not, before exit day, taken the steps necessary to give effect to that decision or that opinion (as the case may be).

(8) Where this sub-paragraph applies, the licensing authority must take the steps necessary as a result of the decision or opinion to suspend, revoke or vary the UK marketing authorisation or traditional herbal registration—

(a) as soon as reasonably practicable, and, where relevant, within the time period specified in Article 34(3) of the 2001 Directive where a Commission decision requires steps to be taken in relation to a UK marketing authorisation that is not a converted EU marketing authorisation, or traditional herbal registration; or

(b) as soon as reasonably practicable, where a Commission decision or opinion requires steps to be taken in respect of a UK marketing authorisation that is a converted EU marketing authorisation.

(9) In this paragraph—

"concluded before exit day", in relation to an Article 107i referral, means—

(a) a Commission decision as provided for in Article 107k of the 2001 Directive has been taken before exit day; or

(b) an opinion of the Co-ordination Group for Mutual Recognition and Decentralised Procedures, which constituted the end of the Article 107i referral procedure in accordance with Article 107k(2), has been given before exit day;

"specified matter" means a referral made under Article 107i of the 2001 Directive on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities.

Matters on-going at exit day in respect of periodic safety update reports

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

(a) a holder has submitted a periodic safety update report under regulation 191 before exit day;

(b) that periodic safety report is, immediately before exit day, to be assessed in accordance with the single assessment procedure in Article 107e of the 2001 Directive;

(c) the procedure described in Article 107e(3) of the 2001 Directive has been completed before exit day; but

(d) the licensing authority has not yet taken the steps described in regulation 194 before exit day.

(2) Where this sub-paragraph applies, notwithstanding the revocation of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive) by the EU Exit Regulations, the licensing authority must take the steps specified in regulation 194 in respect of the UK marketing authorisation or traditional herbal registration as soon as reasonably practicable.

(3) Sub-paragraph (4) applies where—

(a) a holder has submitted a periodic safety update report under regulation 191 before exit day;

(b) that periodic safety report is, immediately before exit day, to be assessed in accordance with the single assessment procedure in Article 107e of the 2001 Directive; and

(c) the procedure described in Article 107e(3) of the 2001 Directive has not been completed before exit day.

(4) Where this sub-paragraph applies, the licensing authority—

(a) may notify a holder falling within sub-paragraph (3)(a) of the need to provide to it such further information that the licensing authority specifies; and

(b) must, subject to sub-paragraph (5), assess the periodic safety update report in accordance with regulation 195 (obligations on licensing authority to assess PSURs) (as amended by the EU Exit Regulations) as soon as reasonably practicable.

(5) Information required under sub-paragraph (4)(a) must be provided before the end of whatever period the licensing authority may specify.

(6) In making a determination under regulation 195, where sub-paragraph (4) applies, the licensing authority may adopt or have regard to—

(a) any relevant information obtained by it before exit day in relation to the periodic safety report and the assessment of that report as a consequence of its involvement in any procedure provided for in Section 2 of Chapter III of the 2001 Directive;

(b) any relevant decision made, or agreement reached, in relation to the periodic safety update report or its assessment before exit day, where the United Kingdom participated as a member state in the making of that decision or agreement, under any procedure provided for in Section 2 of Chapter III of the 2001 Directive;

(c) any decision made, or agreement reached, in relation to that marketing authorisation or certificate of registration under Section 2 of Chapter III of the 2001 Directive on or after exit day, notwithstanding that the United Kingdom did not participate in the making of that decision or agreement.

Matters on-going at exit day in relation to draft study protocols under Article 107n and 107o of the 2001 Directive (submission of, and amendment to, draft study protocols for required studies)

60.—(1) Where the Pharmacovigilance Risk Assessment Committee has, before exit day—

(a) issued a letter endorsing a draft study protocol under Article 107n(2)(a) of the 2001 Directive;

(b) informed a holder that the study is a clinical trial under Article 107n(2)(c) of the 2001 Directive; or

(c) informed a holder of its endorsement of a substantial amendment to that protocol under Article 107o of the 2001 Directive,

the licensing authority is deemed to have accepted the draft study protocol, or the amended draft study protocol, or made that decision (as the case may be) under regulation 199(5) (submission of draft study protocols for required studies) or 200(5)(b) (amendment to study protocols for required studies).

(2) Where sub-paragraph (1) applies, the licensing authority may request the holder to provide to it any information in relation to the procedures under Article 107n or 107o of the 2001 Directive within a specified time period, and that holder must provide that information within that time period.

(3) Sub-paragraph (4) applies where, before exit day—

(a) a holder is proposing to, or, pursuant to Article 21a or 22a of the 2001 Directive, is under a duty to, undertake a non-interventional post-authorisation safety study; and

(b) the procedure specified in Article 107n or 107o of the 2001 Directive has not concluded before exit day.

(4) Where this sub-paragraph applies, on and after exit day, the holder must—

(a) submit any further information that has been required of it by the Pharmacovigilance Risk Assessment Committee to the licensing authority; and

(b) submit to the licensing authority such further information that it may request in relation to the procedures under Article 107n or 107o of the 2001 Directive within a time period specified by the licensing authority, whether or not that information has already been submitted to, or received from, that Committee before exit day,

and the licensing authority must assess that information in accordance with regulation 199 or 200 (as the case may be).

(5) In this paragraph, "not concluded before exit day" means that—

(a) a holder is proposing to, or, pursuant to Article 21a or 22a of the 2001 Directive, is under a duty to, undertake a non-interventional post-authorisation safety study;

(b) the Pharmacovigilance Risk Assessment Committee has not taken any of the steps specified in sub-paragraph (1)(a) to (c).

Matters on-going at exit day in respect of the follow up of final study reports

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

(a) a final study report has been submitted to the Pharmacovigilance Risk Assessment Committee under Article 107p of the 2001 Directive; but

(b) that committee has not, before exit day, made recommendations under Article 107q(1) of the 2001 Directive.

(2) Where this sub-paragraph applies—

(a) the licensing authority may, on or after exit day, request the holder to submit to it the information specified in regulation 201(2) (submission and evaluation of final study reports for required studies), and such further information relating to the final study report, or the procedure provided for in Chapter 4 of Title IX of the 2001 Directive, as the licensing authority may require; and

(b) that holder must, in any event, undertake the steps specified in regulation 201(5) in respect of that final study report.

(3) Sub-paragraph (4) applies where—

(a) regulation 202(1) (follow-up of final study reports) applied before exit day in respect of a final study report; but

(b) the licensing authority has not, before exit day, taken the steps specified in regulation 202(2).

(4) Where this paragraph applies, notwithstanding the revocation of regulation 202 by the EU Exit Regulations, the licensing authority must take the steps specified in regulation 202(2) in accordance with the time period specified in that paragraph.

(5) Sub-paragraph (6) applies where—

(a) regulation 202(3) applied before exit day; but

(b) the holder has not taken the steps specified in regulation 202(4) before exit day.

(6) Where this sub-paragraph applies, notwithstanding the revocation of regulation 202—

(a) the holder must take the steps specified in regulation 202(4); and

(b) the licensing authority must determine that application for a variation in accordance with Part 5 (marketing authorisations) or 7 (traditional herbal registrations).

PART 11

Transitional provision in respect of Part 12

Approved country health professional list on exit day (regulation 214(6A))

62.—(1) For the purposes of regulation 214(6A), for the transitional period, the licensing authority must include on the list published under that paragraph, professions of equivalent professional status to an appropriate practitioner under regulation 214(3) to (5D) in each EEA State.

(2) In this paragraph, "transitional period" is the period of one year beginning with exit day.

PART 12

General provision in relation to transitional provisions

Licensing authority power to require information

63.—(1) Notwithstanding any other power to require information under this Schedule, the licensing authority may require in writing that a holder of, or an applicant for, a UK marketing authorisation, parallel import licence, manufacturing licence, wholesale dealing licence, certificate of registration or traditional herbal registration provides it with any information which—

(a) is relevant to the exercise of the licensing authority's functions under this Schedule; and

(b) is either in the holder's or applicant's possession or is information which the holder or applicant may reasonably access,

within such time period as the licensing authority specifies in that written request.

(2) If the holder of an authorisation, licence, certificate or registration mentioned in sub-paragraph (1) fails to comply with a request made pursuant to that sub-paragraph, the licensing authority may suspend the authorisation, licence, certificate or registration until the holder complies with the obligation.

(3) Nothing in this Schedule requires a person to supply information in contravention of requirements imposed under the data protection legislation (within the meaning of Part 1 of the Data Protection Act 2018(**3**)).".

(**3**) 2018 c. 12.