STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 11

Amendment of Part 11 (Pharmacovigilance)

Amendment of regulation 177 (application of Part and interpretation)

139.—(1) Regulation 177 [M1] is amended as follows.

[[F1](2) After paragraph (1) insert—

"(1A) Schedule 12A applies in relation to medicinal products that are the subject of a UKMA(GB) ora THR(GB).".**]**

(3) In paragraph (2)—

(a) after "this Part" insert " and Schedule 12A ";

[F2](b) . . . . . .

[F3](c) . . . . . .

(4) In paragraph (3)—

(a) for "Schedule 33" substitute " Schedules 12A and 33 ";

[F4](b) . . . . . .

[F5](c) . . . . . .

[F6](5) . . . . . .

[[F7](6) In paragraph (5)—

(a) for "Schedule 33" substitute "Schedules 33 and 33A";

(b) in paragraph (c) of the definition of "relevant post-authorisation safety study", omit "and"; and

(c) after that definition, insert—

""signal" means, in relation to a UKMA(GB) or THR(GB), information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, which is judged to be of sufficient likelihood to justify verificatory action; and".**]**

Textual Amendments

F1 Reg. 139(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(a)**

F2 Reg. 139(3)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(b)**

F3 Reg. 139(3)(c) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(b)**

F4 Reg. 139(4)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(c)**

F5 Reg. 139(4)(c) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(c)**

F6 Reg. 139(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(d)**

F7 Reg. 139(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 107(e)**

Commencement Information

I1 Reg. 139 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 Regulation 177 was amended by S.I. 2013/1855 and 2014/1878.

[F8Amendment of regulation 179 (obligation on licensing authority to operate pharmacovigilance system)

139A. In regulation 179—

(a) in paragraph (1), after "pharmacovigilance system" insert "in relation to medicinal products for sale or supply in Great Britain";

(b) after paragraph (1) insert—

"(1A) The licensing authority must operate a pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland.";

(c) in paragraph (2) for "The pharmacovigilance system" substitute "Each pharmacovigilance system"; and

(d) in paragraph (3)(a) for "the pharmacovigilance system" substitute "each pharmacovigilance system".**]**

Textual Amendments

F8 Reg. 139A inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 108**

Commencement Information

I2 Reg. 139A in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 180 (obligation on licensing authority to audit pharmacovigilance system)

140.—(1) Regulation 180 is amended as follows.

(2) In paragraph (1),

[F9(a) after "its pharmacovigilance system" insert "relating to medicinal products for sale or supply in Great Britain" and**]**

[F10(b)**]** omit "and report the results of that audit to the European Commission".

[F11(2A) After paragraph (1) insert—

"(1A) The licensing authority must perform a regular audit of its pharmacovigilance system relating to medicinal products for sale or supply in Northern Ireland and report the results of that audit to the European Commission.".**]**

(3) In paragraph (2)—

(a) omit "results of the"; and

(b) for "reported to the European Commission" substitute " performed ".

[F12(4) After paragraph (2) insert—

"(3) The results of the audit referred to in paragraph (1A) must be reported to the European Commission—

(a) on the first occasion no later than 21st September 2021;

(b) every two years after the first occasion.".**]**

Textual Amendments

F9 Reg. 140(2)(a) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(a)(i)**

F10 Words in reg. 140(2) renumbered as reg. 140(2)(b) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(a)(ii)**

F11 Reg. 140(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(b)**

F12 Reg. 140(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 109(c)**

Commencement Information

I3 Reg. 140 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F13**Amendment of regulation 181 (delegation of obligations under Part 11)**

141. In regulation 181(1), for "to another EEA State" substitute "in connection with its pharmacovigilance system in relation to medicinal products for sale or supply in Northern Ireland to an EEA State".**]**

Textual Amendments

F13 Reg. 141 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 110**

Commencement Information

I4 Reg. 141 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 182 (obligation on holder to operate a pharmacovigilance system)

142.—(1) Regulation 182 [M2] is amended as follows.

(2) In paragraph (2)(a), **[**[F14]after "in the EU" insert "or United Kingdom"**]** .

[[F15](2A) In paragraph (2)(b), after "pharmacovigilance system master file" insert "and ensure it is permanently and immediately available for inspection electronically in the United Kingdom at the single point from which the reports referred to in regulation 187(4) are accessible".

(2B) After paragraph (2) insert—

"(2A) Where the person the holder has permanently and continuously at its disposal under paragraph (2)(a) ("the qualified person") does not reside and operate in the United Kingdom, the holder must nominate a contact person for pharmacovigilance at a national level who reports to the qualified person, resides and operates in the United Kingdom and has permanent access to the pharmacovigilance system master file.

(2B) Paragraph (2A) has effect from the day twelve months after IP completion day.".**]**

[[F16](3) For paragraph (3) substitute—

"(3) Without prejudice to the requirements set out in regulation 65C and Schedule 10A (variations to a UK marketing authorisation) the holder must keep the licensing authority informed at all times of the name and contact details of—

(a) the appropriately qualified person mentioned in paragraph (2)(a); and

(b) the nominated person mentioned in paragraph (2A).

(3A) The holder must—

(a) ensure that the pharmacovigilance system master file is accessible electronically from the single point within the United Kingdom from which the reports referred to in regulation 187(4) are accessible; and

(b) immediately notify the licensing authority of any change to the single point where the pharmacovigilance system master file may be accessed electronically.".**]**

(4) Omit paragraph (6).

Textual Amendments

F14 Words in reg. 142(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(a)**

F15 Reg. 142(2A)(2B) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(b)**

F16 Reg. 142(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 111(c)**

Commencement Information

I5 Reg. 142 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 Regulation 182 was amended by S.I. 2013/1855.

Amendment of regulation 184 (obligation on holder to audit pharmacovigilance system)

143. In regulation 184, after paragraph (2) insert—

"(3) The holder **[**F17of a UKMA(GB) or THR(GB)**]** must also comply with the requirements of paragraph 13 of Schedule 12A in relation to auditing the pharmacovigilance system.".

Textual Amendments

F17 Words in reg. 143 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 112**

Commencement Information

I6 Reg. 143 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 185 (recording obligations on the licensing authority)

144. In regulation 185(b), after "by" insert " a holder, ".

Commencement Information

I7 Reg. 144 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 186 (reporting obligations on the licensing authority)

[F18**145.** In regulation 186—

(a) in paragraph (1), for sub-paragraphs (d) and (e) substitute—

"(d) submit reports of serious suspected adverse reactions in Northern Ireland that it has recorded under regulation 185 in relation to—

(i) a UKMA(NI),

(ii) a UKMA(UK),

(iii) a THR(NI),

(iv) a THR(UK), or

(v) an Article 126a authorisation,

to the EMA before the end of the period of 15 days beginning on the day following the day on which the report was received; and

(e) submit reports of non-serious suspected adverse reactions in Northern Ireland that it has recorded under regulation 185 in relation to—

(i) a UKMA(NI),

(ii) a UKMA(UK),

(iii) a THR(NI),

(iv) a THR(UK), or

(v) an Article 126a authorisation,

to the EMA before the end of the period of 90 days beginning on the day following the day on which the report was received.";

(b) omit paragraph (4).**]**

Textual Amendments

F18 Reg. 145 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 113**

Commencement Information

I8 Reg. 145 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new regulation 187A (collaboration with the World Health Organisation)

146. After regulation 186 insert—

"**186A.** The licensing authority must collaborate with the World Health Organisation in matters of pharmacovigilance, and must in particular—

(a) take the necessary steps to promptly submit to the World Health Organisation appropriate and adequate information regarding the measures taken in the United Kingdom which may have a bearing on public health protection in other countries; and

(b) make available promptly all suspected adverse reaction reports occurring in the United Kingdom to the World Health Organisation.".

Commencement Information

I9 Reg. 146 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 187 (recording obligations on holders)

147.—(1) Regulation 187 is amended as follows.

[[F19](2) In paragraph (1) for "in the EEA or in third countries" substitute "in the United Kingdom or another country".**]**

(3) In paragraph (4), for "EEA" substitute " United Kingdom ".

Textual Amendments

F19 Reg. 147(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 114**

Commencement Information

I10 Reg. 147 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 188 (reporting obligations on holders)

148.—(1) Regulation 188 is amended as follows.

(2) In each place where it occurs, for "Eudravigilance database" substitute " licensing authority ".

(3) In paragraph (1)—

[[F20](za) for "Subject to paragraph (2), the holder" substitute "The holder of a UK marketing authorisation, traditional herbal registration or Article 126a authorisation";**]**

(a) in sub-paragraph (a)—

(i) for "EEA" substitute " United Kingdom ", and

(ii) for "third countries" substitute " countries other than the United Kingdom ";

(b) in sub-paragraph (b), for "EEA" substitute " United Kingdom ";

(c) in sub-paragraph (e), for "EMA and the competent authorities of the EEA States" substitute " licensing authority ".

[[F21](3A) After paragraph (1) insert—

"(1A) The holder of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation must, in relation to the product—

(a) submit electronically to the Eudravigilance database a report on all serious suspected adverse reactions that occur in the UK and other countries before the end of the period of 15 days beginning on the day on which the holder gained knowledge of the reaction;

(b) submit electronically to the Eudraviligance database a report on all non-serious suspected adverse reactions that occur in an EEA State or Northern Ireland before the end of the period of 90 days beginning on the day on which the holder gained knowledge of the reaction;

(c) collect follow-up information on reports submitted under sub-paragraphs (a) or (b) and submit it electronically to the Eudravigilance database by way of an update to the original report within the specified time period; and

(d) collaborate with the EMA and the competent authorities of the EEA States in the detection of duplicates of suspected adverse reaction reports.".**]**

[[F22](4) In paragraph (2)—

(a) after "holder" insert "of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation";

(b) for "paragraph (1)(a) or (b)" substitute "paragraph (1A)(a) or (b)"; and

(c) for "paragraph (1)(d)" substitute "paragraph (1A)(c)".

(4A) In paragraph (3) for "paragraph (4)" substitute "paragraph (4A)".**]**

(5) In paragraph (4)(a), omit "other than monitored publications".

[[F23](5A) After paragraph (4) insert—

"(4A) The holder of a UKMA(NI), a UKMA(UK), a THR(NI), a THR(UK) or an Article 126a authorisation must—

(a) monitor medical literature other than the monitored publications for reports of suspected adverse reactions to the product; and

(b) report suspected adverse reactions identified under sub-paragraph (a) in accordance with paragraph (1A).".**]**

(6) In paragraph (5), omit the definitions of "monitored active substance" and "monitored publication".

(7) Omit paragraph (6).

Textual Amendments

F20 Reg. 148(3)(za) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(a)**

F21 Reg. 148(3A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(b)**

F22 Reg. 148(4)(4A) substituted for reg. 148(4) (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(c)**

F23 Reg. 148(5A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 115(d)**

Commencement Information

I11 Reg. 148 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 189 (signal detection: licensing authority obligations)

149.—(1) Regulation 189 is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), for "in the Eudravigilance database" substitute " that it collects by virtue of operating its pharmacovigilance system under this Part "; and

(b) in sub-paragraph (d), for "regulations 59 to 61" substitute " regulations 59, 60 and 61 ".

[F24(3) In paragraphs (2) and (3), for "The licensing" insert "In relation to medicinal products subject to a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the licensing".**]**

Textual Amendments

F24 Reg. 149(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 116**

Commencement Information

I12 Reg. 149 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 190 (signal detection: holder obligation)

[F25**150.** For regulation 190(1) substitute—

"(1) The holder must inform—

(a) the licensing authority, and

(b) in respect of a UKMA(UK), a UKMA(NI), a THR(UK), a THR(NI) or an Article 126a authorisation, the EMA,

without delay if it detects any relevant changes in relation to the product.".**]**

Textual Amendments

F25 Reg. 150 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 117**

Commencement Information

I13 Reg. 150 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 191 (obligation on holder to submit periodic safety update reports: general requirements)

151.—(1) Regulation 191 is amended as follows.

(2) In paragraphs (1) and (7), **[**F26after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,"**]**.

(3) In paragraph (2), insert " UK " before "marketing authorisation".

F27(4) . . . . . .

(5) After paragraph (4) insert—

"(4A) A PSUR **[**F28in relation to a product authorised under a UKMA(GB)**]** must also include the content, and be submitted in the format, specified in Part 8 of Schedule 12A.".

(6) After paragraph (8), insert—

"(8A) In the case of a conditional marketing authorisation **[**F29in relation to a product authorised under a UKMA(GB)**]**, the holder must submit PSURs immediately upon the request of the licensing authority and at least every six months beginning with the date on which the authorisation for the medicinal product is granted or renewed by the licensing authority.".

[F30(7) In paragraph (10)—

(a) for sub-paragraph (b) substitute—

"(b) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has not yet been placed on the market within the EEA or Northern Ireland, at least every six months following authorisation until the placing on the market within the EEA or Northern Ireland, or

(ii) in relation to a product authorised under a UKMA(GB), the product has not yet been placed on the market in Great Britain, at least every six months following authorisation until the placing on the market within Great Britain; and";

(b) for sub-paragraph (c) substitute—

"(c) where—

(i) in relation to a product authorised under a UKMA(NI) or UKMA(UK), the product has been placed on the market within the EEA or Northern Ireland—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that;

(ii) in relation to a product authorised under a UKMA(GB), the product has been placed on the market in Great Britain—

(aa) at least every six months during the first two years following the initial placing on the market,

(bb) once a year for the following two years, and

(cc) every three years after that.".**]**

(8) Omit paragraph (11).

Textual Amendments

F26 Words in reg. 151(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(a)**

F27 Reg. 151(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(b)**

F28 Words in reg. 151(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(c)**

F29 Words in reg. 151(6) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(d)**

F30 Reg. 151(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 118(e)**

Commencement Information

I14 Reg. 151 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 192 (obligation to submit periodic safety reports: derogation from general requirements)

152.—(1) Regulation 192 is amended as follows.

(2) In paragraph (1)(a), insert " UK " before "marketing authorisation".

(3) In paragraph (3), **[**[F31]after "EMA" insert "and the licensing authority or, in the case of a holder of a UKMA(GB), to the licensing authority only,**]**

[[F32](4) In paragraph (9), after "paragraph (3)(a)" insert "from the holder of a UKMA(UK), UKMA(NI), THR(UK), THR(NI) or Article 126a authorisation".**]**

Textual Amendments

F31 Words in reg. 152(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 119(a)**

F32 Reg. 152(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 119(b)**

Commencement Information

I15 Reg. 152 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 193 (harmonisation of PSUR frequency or date of submission)

153.—(1) Regulation 193 is amended as follows.

[F33(2) In paragraph (1) substitute—

"(1) Where products that are subject to different authorisations or registrations contain the same active substance or the same combination of active substances, the frequency and dates of submission may be amended and harmonised in accordance with—

(a) Article 107c(4) of the 2001 Directive, where—

(i) any of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation; and

(ii) none of the authorisations or registrations is a UKMA(GB) or THR(GB); or

(b) paragraphs (2A), (3) and (4A), where—

(i) any of the authorisations or registrations is a UKMA(GB) or THR(GB); and

(ii) none of the authorisations or registrations is a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation.";**]**

[F34(2A) In paragraph (2), after "holder" insert "of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation".**]**

(3) **[**F35After paragraph (2) insert—**]**

[F36"(2A)**]** Where one or more of the grounds in paragraph (3) is met, the holder **[**F37of a UKMA(GB) or THR(GB)**]** may submit a request in writing to the licensing authority, or the licensing authority may in any event decide, to—

(a) determine a UK reference date from which submission dates are calculated in respect of products that fall under paragraph (1); or

(b) change the frequency and date of submission of the PSUR.".

(4) **[**F38After paragraph (4) insert—**]**

[F39"(4A)**]** Where the licensing authority makes a decision under paragraph (2) following a written request from a holder **[**F40of a UKMA(GB) or THR(GB)**]**, it must notify that holder in writing of its decision to approve or refuse the request.".

(5) In paragraph (5)—

[F41(a) after "of the 2001 Directive" insert "or paragraph (2A) (as the case may be)"**]**

[F42(b) after "EMA" insert "or licensing authority (as the case may be)"**]**

(6) **[**F43After paragraph (6) insert**]**—

[F44"(6A)**]** Subject to paragraph **[**F45(6B)**]**, in this regulation, "UK reference date" means a date determined by the licensing authority under paragraph (2)(a) in respect of medicinal products containing the same active substance or the same combination of active substances.

[F44(6B)**]** Until the licensing authority makes a decision under paragraph (2), any—

(a) Union reference date in respect of medicinal products containing the same active substance or the same combination of active substances; or

(b) date of submission and frequency of periodic safety reports in respect of such products,

published by the EMA under Article 107c(7) of the 2001 Directive, is deemed to be the UK reference date or, as the case may be, the required date or frequency of PSUR submission, in respect of those medicinal products.".

(7) After paragraph **[**[F46](6B)**]** insert—

"(7) The licensing authority must publish a list of—

(a) UK reference dates it determines under paragraph (2); and

(b) the required date of submission and frequency for PSURs in respect of medicinal products containing the same active substance or the same combination of active substances.

(8) Any change to the date of submission and frequency of PSURs as a result of the application of this regulation is to take effect after a 6 month period, such period beginning with the day after the licensing authority publishes that change under paragraph (7).".

Textual Amendments

F33 Reg. 153(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(a)**

F34 Reg. 153(2A) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(b)**

F35 Words in reg. 153(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)(i)**

F36 Words in reg. 153(3) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)(ii)**

F37 Words in reg. 153(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(c)(iii)**

F38 Words in reg. 153(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)(i)**

F39 Words in reg. 153(4) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)(ii)**

F40 Words in reg. 153(4) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(d)(iii)**

F41 Reg. 153(5)(a) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(i)**

F42 Reg. 153(5)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(e)(ii)**

F43 Words in reg. 153(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)(i)**

F44 Words in reg. 153(6) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)(ii)**

F45 Word in reg. 153(6) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(f)(iii)**

F46 Word in reg. 153(7) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 120(g)**

Commencement Information

I16 Reg. 153 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F47Amendment] of regulation 194 (responding to a single assessment of PSUR under Article 107e of the 2001 Directive)

[F48154. In regulation 194(1) after "medicinal product" insert "authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation".**]**

Textual Amendments

F47 Word in reg. 154 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 121(a)**

F48 Words in reg. 154 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 121(b)**

Commencement Information

I17 Reg. 154 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 195 (obligation on licensing authority to assess PSURs)

155.—(1) Regulation 195 [M3] is amended as follows.

(2) In the heading, omit "where EU single assessment procedure does not apply".

[F49(2A) Before paragraph (1) insert—

"(A1) This regulation applies in the circumstances specified in paragraphs (1) and (1A).".

(2B) In paragraph (1)—

(a) after "relating to a medicinal product" insert "authorised for sale or supply authorised under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation"; and

(b) in sub-paragraph (a)(i) omit "other than the United Kingdom".**]**

(3) **[**F50After**]** paragraph (1) **[**F51insert**]**—

[F52"(1A)**]** This regulation applies where PSURs relating to a medicinal product **[**F53authorised for sale or supply under a UKMA(GB) or THR(GB)**]** have been submitted to the licensing authority under regulations 191 to 192.".

(4) After paragraph (3) insert—

"(3A) If the licensing authority considers under paragraph (3)(b) that an authorisation or registration needs to be varied, it may require the holder to submit to the licensing authority, within a time period that the licensing authority specifies, an application for a variation, including—

(a) an updated summary of the product characteristics; and

(b) an updated package leaflet.".

F54(5) . . . . . .

Textual Amendments

F49 Reg. 155(2A)-(2B) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(a)**

F50 Word in reg. 155(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(i)**

F51 Word in reg. 155(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(ii)**

F52 Words in reg. 155(3) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(iii)**

F53 Words in reg. 155(3) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(b)(iv)**

F54 Reg. 155(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 122(c)**

Commencement Information

I18 Reg. 155 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 Regulation 195 was amended by S.I. 2014/1878.

[F55Amendment of regulation 196 (urgent action)

156ZA. In regulation 196—

(a) in the italic heading immediately preceding it, after "Urgent action" insert "and major safety review";

(b) in paragraph (1), for "The licensing authority must initiate the Section 4 procedure by informing" substitute "In the case of a medicinal product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation, the licensing authority must inform";

(c) omit sub-paragraph (2B);

(d) omit paragraphs (4) to (7);

(e) in paragraph (8), omit the definition of "EU urgent action procedure" and "Section 4 procedure".]

Textual Amendments

F55 Reg. 156ZA inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 123**

Commencement Information

I19 Reg. 156ZA in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F56Insertion of new regulation 196A (major safety review by the licensing authority)]

156. [F57After regulation 196 insert] substitute—

F58 "…

Major safety review by the licensing authority

[F59 **196A].**—(1) The licensing authority may conduct a major safety review where—

(a) on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities it considers—

(i) suspending or revoking a UK marketing authorisation or traditional herbal registration of a medicinal product or in respect of a class of medicinal products,

(ii) prohibiting the supply of a medicinal product or a class of medicinal products,

(iii) refusing the renewal of a UK marketing authorisation or traditional herbal registration, or

(iv) action is necessary to vary a UK marketing authorisation or traditional herbal registration or a class of such authorisations or registrations, including to impose new conditions; or

(b) it is informed by a holder that, on the basis of safety concerns, the holder has—

(i) interrupted the sale or supply, or offer of sale or supply, of the product to which a UK marketing authorisation or traditional herbal registration relates,

(ii) taken action to have that product's authorisation or registration cancelled or intends to do so, or

(iii) not applied for the renewal of that product's authorisation or registration.

(2) If the licensing authority conducts a review under paragraph (1), it must—

(a) announce the initiation of that review on the UK web-portal as soon as reasonably practicable;

(b) include in that announcement—

(i) an outline of its reasons for conducting a major safety review, the medicinal products concerned and, where applicable, the active substances concerned, and

(ii) the proposed structure and time-scale of the review;

(c) notify a holder if the product to which that holder's authorisation or registration relates is within the scope of the review; and

(d) publish the outcome of that review, including any recommendations it is making, or action it is proposing to take, as soon as reasonably practicable after the conclusion of that review.

(3) A holder who is notified under paragraph (2)(c)—

(a) must provide to the licensing authority such information as the licensing authority notifies that holder it requires, within such time period as the licensing authority specifies; and

(b) may, where such information contains confidential data relevant to the subject matter of the review, because the data relates to a manufacturing process or trade secret, notify the licensing authority that that data is provided in confidence.

(4) Where the licensing authority proposes that action should be taken in respect of any UK marketing authorisation or traditional herbal registration—

(a) during the conduct of the major safety review, because urgent action is necessary to protect public health; or

(b) upon the conclusion of such a review,

it may exercise its powers under Part 5 or 7 (as the case may be) in relation to that authorisation or registration.".

Textual Amendments

F56 Reg. 156 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(a)**

F57 Words in reg. 156 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(b)**

F58 Words in reg. 156 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(c)(i)**

F59 Words in reg. 156 renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 124(c)(ii)**

Commencement Information

I20 Reg. 156 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F60Amendment] of regulation 197 (EU urgent action procedure)

157. [F61In] regulation 197 [F62, in paragraph (1), after "class of medicinal products" insert "authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation"] .

Textual Amendments

F60 Word in reg. 157 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125(a)**

F61 Word in reg. 157 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125(b)**

F62 Words in reg. 157 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 125(c)**

Commencement Information

I21 Reg. 157 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 198 (post-authorisation safety studies: general provisions)

158.—(1) Regulation 198 is amended as follows.

(2) In paragraph (2),

[[F63](a) "the competent authorities" to the end becomes sub-paragraph (a);

(b) in sub-paragraph (a), at the end insert "and the licensing authority, where the product is subject to a marketing authorisation, traditional herbal registration or Article 126a authorisation for sale or supply in Northern Ireland;"

(c) after sub-paragraph (a) insert—

"(b) the licensing authority, where the product is subject to a marketing authorisation or traditional herbal registration for sale or supply in Great Britain only."**]**.

(3) In paragraph (3)—

(a) in sub-paragraph (c),

[[F64](i) "for "the relevant competent authorities" substitute—

"(i) "for "the relevant competent authorities" substitute—

"(i) the relevant competent authorities and the licensing authority, where paragraph (2)(a) applies;

(ii) the licensing authority where paragraph (2)(b) applies,"

(ii) "any new information" to the end becomes full-out words;"**]**

(b) in sub-paragraph (d),

[[F65](i) "the competent authorities of the EEA States in which the study was conducted" becomes paragraph (i);

(ii) in paragraph (i), after "the study was conducted" insert "and the licensing authority, where paragraph (2)(a) applies;"

(iii) after paragraph (i) insert—

"(ii) the licensing authority, where paragraph (2)(b) applies,";

(iv) "before the end of the period" to the end becomes full-out words.**]**

Textual Amendments

F63 Words in reg. 158(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(a)**

F64 Words in reg. 158(3)(a)(i) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(i)**

F65 Words in reg. 158(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 126(b)(ii)**

Commencement Information

I22 Reg. 158 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 199 (submission of draft study protocols for required studies)

159.—(1) Regulation 199 is amended as follows.

[[F66](2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation is a UKMA(GB),

before the study is commenced.".**]**

[[F67](3) In paragraph (4)—

(a) after "protocol is submitted" insert "only";

(b) after "paragraphs (2) and (3)(a)" insert "(and is not submitted to the Pharmacovigilance Risk Assessment Committee)".**]**

[F68](4) . . . . . .

[F68](5) . . . . . .

[F68](6) . . . . . .

Textual Amendments

F66 Reg. 159(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(a)**

F67 Reg. 159(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(b)**

F68 Reg. 159(4)-(6) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 127(c)**

Commencement Information

I23 Reg. 159 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 200 (amendment to study protocols for required studies)

160.—(1) Regulation 200 is amended as follows.

[[F69](2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation for the product is a UKMA(GB),

before their implementation.".**]**

[[F70](3) In paragraph (4)—

(a) after "protocol is submitted" insert "only";

(b) after "paragraphs (2) and (3)(a)" insert "(and is not submitted to the Pharmacovigilance Risk Assessment Committee)".**]**

[F71](4) . . . . . .

F72(5) . . . . . .

Textual Amendments

F69 Reg. 160(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(a)**

F70 Reg. 160(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(b)**

F71 Reg. 160(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(c)**

F72 Reg. 160(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 128(c)**

Commencement Information

I24 Reg. 160 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 201 (submission and evaluation of final study reports for required studies)

161.—(1) Regulation 201 is amended as follows.

[F73(2) In paragraph (2) for "to the body specified in paragraph (3)" to the end substitute—

"to—

(a) the body specified in paragraph (3) and the licensing authority (where not otherwise required by paragraph (3)), where the authorisation for the product is a UKMA(NI) or UKMA(UK);

(b) the licensing authority, where the authorisation for the product is a UKMA(GB),

a final study report and an abstract of the study results.".**]**

F74(3) . . . . . .

(4) In paragraph (4), **[**F75omit "for reports falling under paragraph (3)(a)" and "for reports falling under paragraph (3)(b)**]**

Textual Amendments

F73 Reg. 161(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(a)**

F74 Reg. 161(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(b)**

F75 Words in reg. 161(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 129(c)**

Commencement Information

I25 Reg. 161 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[F76Amendment of regulation 202 (follow up of final study reports)

162. In regulation 202(1), after "This regulation applies" insert "in respect of a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation".**]**

Textual Amendments

F76 Reg. 162 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 130**

Commencement Information

I26 Reg. 162 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new regulation 202A (medicinal products subject to additional monitoring)

163. After regulation 202 insert—
"Medicinal products subject to additional monitoring

Licensing authority power in relation to medicinal products subject to additional monitoring

202A.—(1) The licensing authority may establish a list of medicinal products that are subject to additional monitoring.

(2) The list referred to in paragraph (1) is to include the names and active substances of—

(a) medicinal products authorised in the United Kingdom that contain a new active substance which, on 1st January 2011, was not contained in any medicinal product authorised in the United Kingdom;

(b) any biological medicinal product not covered by sub-paragraph (a) that was authorised in the United Kingdom after 1st January 2011;

(c) medicinal products that are authorised pursuant to these Regulations, subject to the conditions referred to in regulation 50I, 59(2)(b) or (c), 60 or 61(4).

(3) If the licensing authority considers it appropriate, medicinal products that are authorised pursuant to these Regulations, subject to the conditions referred to in regulation 59(2)(a), (d), (e) or (f), 61(5) or 183(2), may also be included in the list referred to in paragraph (1).

(4) For medicinal products included in the list referred to in paragraph (1)—

(a) the summary of product characteristics and the package leaflet must include a symbol and statement as follows: "▼ This medicinal product is subject to additional monitoring"; and

(b) that symbol must be proportional to the font of the subsequent standardised text, and each side of the triangle must have a minimum length of 5 millimetres.

(5) In the cases referred to in paragraph (2)(a) and (b), the licensing authority must, unless paragraph (6) applies, remove a medicinal product from the list after five years, beginning with the day after the UK reference date referred to in regulation 193.

(6) In the cases referred to in paragraph (2)(c) and (3), the licensing authority must remove a medicinal product from the list once the condition or obligation under a provision specified in those paragraphs has been fulfilled.

(7) Until the licensing authority publishes a list of medicinal products under paragraph (1), the reference to that list is instead to be read as a reference to the list referred to in Article 23 of Regulation (EC) No 726/2004, as that list may be amended from time to time.".

Commencement Information

I27 Reg. 163 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 203 (obligations on licensing authority in relation to national medicines web-portal)

164.—(1) Regulation 203 is amended as follows.

(2) In paragraph (1), omit from "linked" to the end.

[[F77](3) In paragraph (2), after sub-paragraph (d) insert—

"(da) the list published by the licensing authority under, or which applies by virtue of, regulation 202A;".**]**

Textual Amendments

F77 Reg. 164(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 131**

Commencement Information

I28 Reg. 164 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

[[F78]Amendment] of regulation 204 (obligation on licensing authority in relation to public announcements)

165. [[F79]In**]** regulation 204 **[**[F80], in paragraph (1), after "pharmacovigilance concerns" insert "which relate to products authorised under a UKMA(NI) or UKMA(UK)**]**.

Textual Amendments

F78 Word in reg. 165 heading substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132(a)**

F79 Word in reg. 165 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132(b)**

F80 Words in reg. 165 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 132(c)**

Commencement Information

I29 Reg. 165 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 205 (obligations on holders in relation to public announcements)

166.—(1) Regulation 205 is amended as follows.

(2) In paragraph (2), **[**[F81]after "bodies listed in paragraph (3)" insert "where the product is subject to a UKMA(NI), UKMA(UK), THR(NI), THR(UK) or Article 126a authorisation, or the licensing authority where the product is subject to a UKMA(GB) or THR(GB),"**]**

[F82](3) . . . . . .

Textual Amendments

F81 Words in reg. 166(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 133(a)**

F82 Reg. 166(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 133(b)**

Commencement Information

I30 Reg. 166 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 205A (further obligations in respect of pharmacovigilance activities)

167. After regulation 205 insert—

"Further obligations in respect of pharmacovigilance activities

Further obligations in respect of pharmacovigilance activities

205A.—(1) Schedule 12A **[**[F83]applies in relation to medicinal products for sale or supply under a UKMA(GB) or THR(GB) and**]** makes further provision as to the obligations of a holder and the licensing authority in respect of the performance of pharmacovigilance activities under this Part.

(2) **[**[F84]The Secretary of State**]** may by regulations **[**[F85]in respect of Great Britain**]** amend Schedule 12A.

(3) Regulations under paragraph (2) may make provision regarding the performance of pharmacovigilance activities under this Part as to—

(a) the content and maintenance of the pharmacovigilance system master file kept by the holder;

(b) the minimum requirements for the quality system for the performance of pharmacovigilance activities by the holder and the licensing authority;

(c) the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;

(d) the minimum requirements for the monitoring of data recorded by the licensing authority pursuant to regulation 185 (recording obligations on the licensing authority) to determine whether there are new risks or whether risks have changed;

(e) the format and content of electronic transmission of suspected adverse reactions by a holder;

(f) the format and content of electronic periodic safety reports and risk management plans; and

(g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.".

Textual Amendments

F83 Words in reg. 167 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 134(a)**

F84 Words in reg. 167 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 134(b)(i)**

F85 Words in reg. 167 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 134(b)(ii)**

Commencement Information

I31 Reg. 167 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of new Schedule 12A (further provision as to performance of pharmacovigilance activities)

168. Schedule 6 inserts a new Schedule 12A after Schedule 12 to the 2012 Regulations.

Commencement Information

I32 Reg. 168 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 205B (guidance in respect of good pharmacovigilance practice and post authorisation efficacy studies)

169. After new regulation 205A insert—
"Guidance in respect of pharmacovigilance

Guidance in respect of good pharmacovigilance practice and post authorisation efficacy studies

205B.—(1) The licensing authority may publish—

(a) guidance on good pharmacovigilance practices for both the licensing authority and UK marketing authorisation holders;

(b) scientific guidance on post authorisation efficacy studies.

(2) Subject to paragraph (3), the guidance issued by the Commission under Article 108a of the 2001 Directive on the matters specified in paragraph (1)(a) and (b) continues to apply until the date on which the licensing authority publishes guidance under paragraph (1).

(3) The licensing authority—

(a) may determine that provisions of the guidance specified in paragraph (2) no longer apply, or apply subject to specified modifications, from a date that it specifies; and

(b) must, if it so determines, publish its determination.

(4) Guidance published under paragraph (1), or which applies by virtue of paragraph (2) (as modified by any determination under paragraph (3), as the case may be), is to be taken into account in consideration of whether there has been any failure to comply with a provision in this Part, or Schedule 12A, to which the guidance is relevant.".

Commencement Information

I33 Reg. 169 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 206 (infringement notices)

170.—(1) Regulation 206 [M4] is amended as follows.

[[F86](2) In paragraph (3), after "paragraph (1)" insert "in relation to a product authorised for sale or supply under a UKMA(NI), UKMA(UK), THR(NI) or THR(UK)".

(3) In paragraph (4) after sub-paragraph (a) insert—

"(aa) Schedule 12A;".**]**

Textual Amendments

F86 Reg. 170(2)(3) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 135**

Commencement Information

I34 Reg. 170 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M4 Regulation 206 was amended by S.I. 2013/1855.

Amendment of regulation 207 (offences)

171. In regulation 207(1), after "other than" insert " Schedule 12A (further requirements in respect of pharmacovigilance activities) and ".

Commencement Information

I35 Reg. 171 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 208 (false and misleading information)

[F87]**172.** . . . . . .

Textual Amendments

F87 Reg. 172 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 136**

PROSPECTIVE

Amendment of regulation 209 (penalties)

[F88]173. . . . . . .

Textual Amendments

F88 Reg. 173 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 136**

PROSPECTIVE

Omission of regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004)

[F89]174. . . . . . .

Textual Amendments

F89 Reg. 174 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 136**

Amendment of regulation 210A (offences in relation to pharmacovigilance obligations under the Implementing Regulation)

175.—(1) Regulation 210A [M5] is amended as follows.

(2) In the heading, **[**[F90]after**]** "the Implementing Regulation **[**[F91]insert "and Schedule 12A"**]**.

(3) In paragraph (1)—

[[F92](a) in sub-paragraph (a), at the beginning insert "in relation to a UKMA(NI), UKMA(UK), THR(NI) THR(UK) or Article 126a authorisation,";

(b) after sub-paragraph (a) insert—

"(aa) in relation to a UKMA(GB) or THR(GB), fails to comply with any requirement or obligation contained in a provision of Schedule 12A listed in paragraph (2A); or".**]**

(4) **[**[F93]After paragraph (2) insert**]**—

[[F94]"(2A)**]** The provisions of Schedule 12A mentioned in paragraph (1)(a) are—

(a) Part 1 (pharmacovigilance system master file);

(b) Parts 2 and 3 (minimum requirements for the quality systems in the performance of pharmacovigilance activities);

(c) Part 6 (transmission of reports of suspected adverse reactions);

(d) paragraph 24 (update of risk management plans);

(e) Part 8 (periodic safety update reports); and

(f) Part 9 (post-authorisation safety studies).

F95(3) . . . . . .

F95(4) . . . . . .".

[F96(5) In paragraph (4), after "Implementing Regulation" insert ", or of paragraph 26(8) or 29(1) of Schedule 12A,".**]**

Textual Amendments

F90 Word in reg. 175(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(a)(i)**

F91 Words in reg. 175(2) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(a)(ii)**

F92 Reg. 175(3)(a)(b) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(b)**

F93 Words in reg. 175(4) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)(i)**

F94 Words in reg. 175(4) renumbered (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)(ii)**

F95 Words in reg. 175(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(c)(iii)**

F96 Reg. 175(5) inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 137(d)**

Commencement Information

I36 Reg. 175 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M5 Regulation 210A was inserted by S.I. 2013/1855.

PROSPECTIVE

Amendment of regulation 211 (persons liable)

F97**176.** . . . . . .

Textual Amendments

F97 Reg. 176 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 138**

Amendment of regulation 212 (transitional arrangements)

[[F98]**177.** In regulation 212, omit "182, 186, 188, 191, 192".**]**

Textual Amendments

F98 Reg. 177 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 139**

Commencement Information

I37 Reg. 177 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 33 (transitional arrangements: pharmacovigilance)

178. In Schedule 33, omit paragraphs 1, 2 and **[**[F99]5**]** to 10.

Textual Amendments

F99 Word in reg. 178 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 140**

Commencement Information

I38 Reg. 178 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Status:
This version of this part contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, PART 11.