SCHEDULES

SCHEDULE 7

Qualified persons

PART 3

Obligations of qualified person

12.—[F1(1)] [F2In Great Britain, the qualified person] is responsible for securing—

(a) that each batch of medicinal products manufactured in [F3Great Britain] has been manufactured and checked in accordance with these Regulations and the requirements of the [F4UK marketing authorisation], certificate of registration or traditional herbal registration [F5, or an equivalent authorisation,] relating to those products; F6... [F7and]

(b) in the case of [F8medicinal products imported from a country other than approved country for import, irrespective of whether the products have been manufactured in the United Kingdom or an approved country for import], that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the [F9UK marketing authorisation], certificate of registration or traditional herbal registration [F10, or an equivalent authorisation,] relating to those products; [F11and]

F12(c) . . . . . .

[F13(2) In this paragraph "equivalent authorisation" means, in respect of a medicinal product that does not have a UK marketing authorisation, certificate of registration or traditional herbal registration, such equivalent authorisation or registration granted by an appropriate authority for the licensing of medicinal products in an approved country for import.]

Textual Amendments

F1 Sch. 7 para. 12 renumbered as Sch. 7 para. 12(1) (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in Sch. 7 para. 12(1) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(a)(ia)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(a)**)

F3 Words in Sch. 7 para. 12(1)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(a)(ii)(zaa)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(b)**)

F4 Words in Sch. 7 para. 12(1)(a) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(ii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in Sch. 7 para. 12(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(ii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Word in Sch. 7 para. 12(a) omitted (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **17(a)** and word in Sch. 7 para. 12(a) omitted (N.I.) (9.2.2019) by virtue of The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **17(a)**

F7 Word in Sch. 7 para. 12(1)(a) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(ii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in Sch. 7 para. 12(1)(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iii)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in Sch. 7 para. 12(1)(b)(iii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iii)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in Sch. 7 para. 12(1)(b) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iii)(cc)**; 2020 c. 1, Sch. 5 para. 1(1)

F11 Sch. 7 para. 12(c) and preceding word inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **17(b)** and Sch. 7 para. 12(c) and preceding word inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **17(b)**

F12 Sch. 7 para. 12(1)(c) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)

F13 Sch. 7 para. 12(2) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(a)(v)**; 2020 c. 1, Sch. 5 para. 1(1)

[F14 12A.—(1) In Northern Ireland, the qualified person is responsible for securing—

(a) that each batch of medicinal products manufactured in Northern Ireland has been manufactured and checked in accordance with these Regulations and the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(b) in the case of medicinal products imported from a country other than an EEA State, irrespective of whether the products have been manufactured in Northern Ireland or an EEA State, that each batch has undergone—

(i) a full qualitative analysis,

(ii) a quantitative analysis of all the active substances, and

(iii) all other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to those products; and

(c) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive and not intended to be exported to a country other than an EEA State, that the features specified in paragraph 18A of Schedule 24 have been affixed on the packaging.**]**

[F15(2) This paragraph does not apply in relation to listed NIMAR products in Northern Ireland.**]**

Textual Amendments

F14 Sch. 7 para. 12A inserted (31.12.2020) by S.I. 2019/775, regs. 1, **32(3)(aa)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Sch. 7 para. 12A(2) inserted (1.1.2022) by The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021 (S.I. 2021/1452), regs. 1(2), **26**

13.—(1) This paragraph applies **[**[F16]in Northern Ireland**]** where—

(a) a medicinal product which has undergone the controls referred to in **[**[F17]paragraph 12A in a member State is imported to Northern Ireland**]**; and

(b) each batch of the product is accompanied by control reports signed by another qualified person in respect of the medicinal product.

(2) Where this paragraph applies, the qualified person is not responsible for carrying out the controls referred to in paragraph **[**[F18]12A**]**.

Textual Amendments

F16 Words in Sch. 7 para. 13(1) inserted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**)

F17 Words in Sch. 7 para. 13(1)(a) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**)

F18 Word in Sch. 7 para. 13(2) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(b)(iii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(e)**)

14.—(1) This paragraph applies where—

(a) medicinal products are imported **[**[F19]into Great Britain from a country other than an approved country for import or into Northern Ireland**]** from a country other than an EEA State; and

[[F20](b) appropriate arrangements have been made, in the case of import into Great Britain by the licensing authority with the country from which those products are imported and, in the case of a product for import into Northern Ireland by the European Union with that country, to ensure that—

(i) the manufacturer of the medicinal products applies standards of good manufacturing practice at least equivalent to those laid down—

(aa) in the case of a product for sale or supply in Great Britain, in the Good Manufacturing Practice Directive, as supplemented by the guidelines and principles which apply under, or by virtue of, regulation C17, and

(bb) in the case of a product for sale or supply in Northern Ireland, by the European Union;

(ii) the controls referred to in paragraph 12(b) or 12A(b) (as appropriate) have been carried out in that country.**]**

(2) Where this paragraph applies, the qualified person is not responsible for carrying out the controls referred to in paragraph 12 **[**[F21]or 12A**]**.

[[F22](3) The licensing authority must publish a list of the countries with whom it has made appropriate arrangements under sub-paragraph (1)(b) ("approved country for batch testing list").

(4) A country may be included in the approved country for batch testing list subject to any condition or restriction that the licensing authority considers appropriate, including as to categories of medicinal product, and any such condition or restriction must be included in the list.

(5) In order to satisfy itself of the matters specified in sub-paragraph (1)(b)(i) and (ii), the licensing authority may, in particular, take into account—

(a) the country's rules for good manufacturing practice;

(b) the regularity of inspections to verify compliance with good manufacturing practice;

(c) the effectiveness of enforcement of good manufacturing practice;

(d) the regularity and rapidity of information provided by that country relating to non-compliant manufacturers;

(e) any on-site review of that country's regulatory system undertaken by the licensing authority;

(f) any on-site inspection of a manufacturing site in that country observed by the licensing authority;

(g) any other relevant documentation available to the licensing authority.

(6) The licensing authority must—

(a) review any appropriate arrangements it has made under sub-paragraph (1)(b) to determine if that country still satisfies the requirements of sub-paragraph (1)(b)(i) and (ii), and whether any condition or restriction in those arrangements remains appropriate;

(b) if it is not so satisfied, remove that country from the approved country for batch testing list or, as the case may be, amend or remove that condition or restriction; and

(c) undertake such a review at least every three years beginning with the date on which the country is included in that list.**]**

Textual Amendments

F19 Words in Sch. 7 para. 14(1)(a) inserted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(c)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(i)**)

F20 Sch. 7 para. 14(1)(b) substituted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(c)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(ii)**)

F21 Words in Sch. 7 para. 14(2) inserted (31.12.2020) by S.I. 2019/775, **reg. 32(3)(c)(iia)** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 22(f)(iii)**)

F22 Sch. 7 para. 14(3)-(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **32(3)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

15.—(1) The qualified person is responsible for ensuring, in relation to a medicinal product, that documentary evidence is produced that each batch of the product satisfies the requirements of paragraph 12.

(2) The documentary evidence referred to in sub-paragraph (1) must be kept up to date and must be available for inspection by the licensing authority for a period of at least five years.

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