SCHEDULES

SCHEDULE 3

Applications for licences under Part 3

Wholesale dealer's licences

3.—(1) This paragraph applies to an application for a wholesale dealer's licence.

(2) The application must contain—

(a) the name and address of the applicant;

(b) the name and address of the person (if any) making the application on the applicant's behalf;

(c) the address of each of the premises where medicinal products are to be stored, or from which they are to be distributed; and

(d) the name, address and qualifications of the responsible person **[**F1or the responsible person (import)**]**.

(3) The application must also contain—

(a) details of the distribution by way of wholesale dealing to which the licence is to relate;

(b) a statement of whether the medicinal products to which the distribution relates are the subject of—

[F2(i) in the case of a product for sale or supply in Great Britain, a UK marketing authorisation,

(ia) in the case of a product for sale or supply in Northern Ireland, a marketing authorisation,**]**

(ii) a certificate of registration,

(iii) a traditional herbal registration, or

(iv) **[**F3in the case of a product for sale or supply in Northern Ireland,**]** an Article 126a authorisation;

[F4(v) an authorisation granted by an authority in a country other than the United Kingdom to sell or supply the medicinal product in that other country;**]**

(c) a statement of whether the medicinal products to which the distribution relates are—

(i) prescription only medicines,

(ii) pharmacy medicines, or

(iii) medicines subject to general sale;

(d) a statement of whether the medicinal products to which the distribution relates are—

(i) special medicinal products, F5...

[F6(ia) EAMS medicinal products,**]**

(ii) sold or supplied pursuant to regulation 174 (supply in response to spread of pathogenic agents **[**F7etc), or**]**

[[F8](iii) to be distributed by means of export from Great Britain to an approved country for import;**]**

(e) a statement of whether the medicinal products dealt in under the licence are to be used—

(i) for administration to human beings, or

(ii) as ingredients in the preparation of medicinal products for administration to human beings;

(f) an indication of the range of medicinal products to be stored at each of the premises mentioned in the application;

(g) a statement of the facilities and equipment available at those premises for storing and distributing medicinal products;

(h) a description of the arrangements at those premises for ensuring, so far as practicable, the turn-over of stocks of medicinal products (whether by the maintenance of records or by other means);

(i) details of an emergency plan which satisfies the requirements of regulation 43(7)(b), and

(j) a description of the arrangements for keeping records relating to products received or dispatched.

[[F9](4) In sub-paragraph (2)(d)—

"the responsible person" means the person who has the functions described in regulation 45(2);

"the responsible person (import)" means the person who has the functions described in regulation 45AA(4).**]**

Textual Amendments

F1 Words in Sch. 3 para. 3(2)(d) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

F2 Sch. 3 para. 3(3)(b)(i)(ia) substituted for Sch. 3 para. 3(3)(b)(i) by S.I. 2019/775, regs. 1, **18(4)(b)(i)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(c)(i)**)

F3 Words in Sch. 3 para. 3(3)(b)(iv) inserted (31.12.2020) by S.I. 2019/775, **reg. 18(4)(b)(ii)** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 12(c)(ii)**)

F4 Sch. 3 para. 3(3)(b)(v) inserted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F5 Word in Sch. 3 para. 3(3)(d)(i) omitted (31.12.2020) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Sch. 3 para. 3(3)(d)(ia) inserted (15.4.2022) by The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022 (S.I. 2022/352), regs. 1(2), **13** (with reg. 19)

F7 Words in Sch. 3 para. 3(3)(d)(ii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

F8 Sch. 3 para. 3(3)(d)(iii) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(c)(iii)** (as amended by S.I. 2020/1488, **reg. 1 Sch. 2 para. 12(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Sch. 3 para. 3(4) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **18(4)(d)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Wholesale dealer's licences.