SCHEDULES

SCHEDULE 7

Regulation 41

Qualified persons

PART 1

Qualification requirements for qualified person

1. A person must satisfy the requirements in paragraphs 2 and 8 or, alternatively, the requirements in paragraphs 7 and 8, of this Schedule before acting as a qualified person (but this is subject to Part 2).

2. The person must have a degree, diploma or other formal qualification which satisfies the requirements of this Part, in one of the following subjects—

(a) pharmacy;

(b) medicine;

(c) veterinary medicine;

(d) chemistry;

(e) pharmaceutical chemistry and technology; or

(f) biology,

but this paragraph is subject to paragraph 7.

3. A qualification satisfies the requirements of this Part if it is awarded on completion of a university course of study, or a course recognised as equivalent by the member State in which it is studied, which—

(a) satisfies the minimum requirements specified in paragraph 4; and

(b) extends over a period of at least four years of theoretical and practical study of a subject specified in paragraph 2 (but this is subject to paragraphs 5 and 6).

4.—(1) A course should include at least the following core subjects—

(a) experimental physics;

(b) general and inorganic chemistry;

(c) organic chemistry;

(d) analytical chemistry;

(e) pharmaceutical chemistry, including analysis of medicinal products;

(f) general and applied medical biochemistry;

(g) physiology;

(h) microbiology;

(i) pharmacology;

(j) pharmaceutical technology;

(k) toxicology; and

(l) pharmacognosy.

(2) The subjects mentioned in sub-paragraph (1) should be balanced in such a way as to enable the person to fulfil the obligations specified in Part 3 of this Schedule.

5. If the course referred to in paragraph 3 is followed by a period of theoretical and practical training of at least one year, including a training period of at least six months in a pharmacy open to the public and a final examination at university level, the minimum duration of the course is three and a half years.

6. If two university courses, or courses recognised as of university equivalent standard, co-exist, one of which extends over four years and the other over three years, the three-year course is to be treated as fulfilling the condition as to the duration of the course in paragraph 3, provided that the member State in which the courses take place recognises the formal qualifications gained from each course as being equivalent.

7. If the person's formal qualifications do not satisfy the requirements of this Part, the person may act as a qualified person if the licensing authority is satisfied, on the production of evidence, that the person has adequate knowledge of the subjects specified in paragraph 4(1).

8.—(1) The person must (subject to sub-paragraph (2)) have at least two years' practical experience in an undertaking authorised to manufacture medicinal products of—

(a) qualitative analysis of medicinal products;

(b) quantitative analysis of active substances; and

(c) the testing and checking necessary to ensure the quality of medicinal products.

(2) But—

(a) if the person has completed a university course lasting at least five years, the minimum period of practical experience under this paragraph is one year; and

(b) if the person has completed a university course lasting at least six years, the minimum period of practical experience under this paragraph is six months.

PART 2

Qualified persons with long experience

9.—(1) This paragraph applies to a person who has acted as a qualified person since the coming into force of Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products(**1**).

(2) A person to whom this paragraph applies may continue to act as a qualified person.

10.—(1) This paragraph applies to a person who—

(a) holds a degree, diploma or other formal qualification in a scientific discipline awarded on completion of a university course or course recognised as equivalent; and

(b) began the course before 21 May 1975.

(2) A person to whom this paragraph applies may act as a qualified person provided that sub-paragraph (3) (and, where applicable, paragraph 11) is satisfied.

(**1**) OJ No L 147, 9.6.1975, p.13, no longer in force.

(3) This sub-paragraph is satisfied if, for at least two years before 21 May 1985, the person has carried out one of the following activities in an undertaking authorised to manufacture medicinal products—

(a) production supervision;

(b) qualitative and quantitative analysis of active substances; or

(c) testing and checking, under the direct supervision of the qualified person in respect of the undertaking, to ensure the quality of the medicinal products.

11. If a person to whom paragraph 10 applies acquired the practical experience mentioned in paragraph 10(3) before 21 May 1965, the person must complete a further one year's practical experience of the kind specified in that paragraph immediately before the person may act as a qualified person.

PART 3

Obligations of qualified person

12. The qualified person is responsible for securing—

(a) that each batch of medicinal products manufactured in the United Kingdom 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 non-EEA State, irrespective of whether the products have been manufactured in 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.

13.—(1) This paragraph applies where—

(a) a medicinal product which has undergone the controls referred to in paragraph 12 in another member State is imported to the United Kingdom; 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 12.

14.—(1) This paragraph applies where—

(a) medicinal products are imported from a country other than an EEA State; and

(b) appropriate arrangements have been made 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 by the European Union, and

(ii) the controls referred to in paragraph 12(b) 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.

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.