## SCHEDULE 1

Regulation 4(2)

## EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 4

### Interpretation

**1.** In this Schedule—

"first level nurse" means a person registered in Sub-Part 1 of the Nurses' Part of the professional register;

"professional register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(**1**);

"registered midwife" means a person registered in the Midwives' Part of the professional register;

"relevant register" means—

(a) in relation to a first level nurse or registered midwife, the professional register,

(b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954 or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976, and

(c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(**2**) relating to—

(i) chiropodists and podiatrists;

(ii) physiotherapists;

(iii) radiographers: diagnostic or therapeutic,

that register;

"supplementary prescriber" means—

(a) a first level nurse,

(b) a pharmacist,

(c) a registered midwife, or

(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—

(i) chiropodists and podiatrists;

(ii) physiotherapists;

(iii) radiographers: diagnostic or therapeutic,

against whose name is recorded in the relevant register, an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber.

**2.** Regulation 4(1) shall not apply to a traditional herbal medicinal product supplied in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor, dentist or supplementary prescriber and for use by his individual patients on his direct personal responsibility, in order to fulfil the special needs of those patients, but such supply shall be subject to the conditions specified in paragraph 3.

(**1**) S.I.2002/253.
(**2**) S.I. 2002/254.

**3.** The conditions mentioned in paragraph 2 are that—

(a) the traditional herbal medicinal product is supplied to a doctor, dentist or supplementary prescriber or for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist, in accordance with paragraph 2;

(b) no advertisement or representation relating to the traditional herbal medicinal product is issued with a view to it being seen generally by the public in the United Kingdom and that no advertisement relating to that product, by means of any catalogue, price list or circular letter is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the supply is in response to a bona fide unsolicited order;

(c) the manufacture or assembly of the traditional herbal medicinal product is carried out under the supervision of such staff and such precautions are taken as are adequate to ensure that the product is of the character required by and meets the specifications of the doctor, dentist or supplementary prescriber who requires it;

(d) written records as to the manufacture or assembly in accordance with sub-paragraph (c) are made and maintained and are available to the licensing authority or the enforcement authority on request by them or either of them;

(e) if the traditional herbal medicinal product is manufactured or assembled in the United Kingdom, or imported into the United Kingdom from a third country, the product—

(i) is manufactured, assembled or imported by the holder of a manufacturer's licence which relates specifically to the manufacture, assembly or import of traditional herbal medicinal products to which paragraph 2 applies; or

(ii) has been manufactured, assembled or imported as an investigational medicinal product by the holder of a manufacturing authorization granted by the licensing authority for the purposes of regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**3**); and

(f) the traditional herbal medicinal product is distributed by way of wholesale dealing by the holder of a wholesale dealer's licence.

**4.**—(1) Subject to the following sub-paragraphs, regulation 4(l) shall not apply to anything done—

(a) in relation to England and Wales, by a doctor or dentist which relates to a traditional herbal medicinal product specially prepared by him, or to his order, for administration—

(i) to one or more patients of his, or

(ii) where that doctor or dentist is a member of a group of doctors or dentists working together to provide primary medical or general services to one or more patients of any other doctor or dentist of that group,

and consists of procuring the manufacture or assembly of a stock of the product with a view to administering the product to such patients;

(b) in relation to Scotland and Northern Ireland, by a doctor or dentist which relates to a traditional herbal medicinal product specially prepared by him, or to his order, for administration—

(i) to one or more patients of his, or

(**3**) S.I. 2004/1031.

(ii) where that doctor or dentist is a member of a group of doctors or dentists working together to provide general medical or dental services to one or more patients of any other doctor or dentist of that group,

and consists of procuring the manufacture or assembly of a stock of the product with a view to administering the product to such patients; or

(c) in a registered pharmacy, a hospital or health centre and is done there by or under the supervision of a pharmacist, and consists of procuring the manufacture or assembly of a stock of traditional herbal medicinal products with a view to dispensing them in accordance with paragraph 2.

(2) The exemption conferred by sub-paragraph (1) shall not apply to procuring the manufacture of traditional herbal medicinal products unless those products are to be manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture or assembly of traditional herbal medicinal products to which paragraph 2 applies.

(3) The exemption conferred by sub-paragraph (1) shall not apply to anything done by a doctor or dentist in relation to a stock held by him of such traditional herbal medicinal products in excess of a total of 5 litres of fluid and 2.5 kilograms of solids of all traditional herbal medicinal products to which that sub-paragraph relates.

**5.**—(1) Regulation 4(1) shall not apply to the placing on the market by way of supplying of any traditional herbal medicinal product to which this paragraph relates if the conditions of sub-paragraph (2) are satisfied.

(2) The conditions referred to in sub-paragraph (1) are—

(a) that the traditional herbal medicinal product is sold or supplied to a person exclusively for use by him in the course of a business carried on by him for the purposes of administering it or causing it to be administered to one or more human beings otherwise than by selling it;

(b) that, if sold or supplied through the holder of a wholesale dealer's licence, the traditional herbal medicinal product is sold or supplied to such a person, and for such use by him, as is described in head (a) above;

(c) that, where the manufacture or assembly of the traditional herbal medicinal product is procured, it is procured by such a person, and for such use by him, as is described in head (a) above;

(d) that no advertisement or representation relating to the traditional herbal medicinal product is issued with a view to it being seen generally by the public in the United Kingdom and that no advertisement relating to that product, by means of any catalogue, price list or circular letter, is issued by, at the request or with the consent of, the person selling that product by retail or by way of wholesale dealing or supplying it in circumstances corresponding to retail sale, or the person who manufactures it, and that the supply is in response to a bona fide unsolicited order;

(e) that the traditional herbal medicinal product is prepared by or under the supervision of a pharmacist; and

(f) that the traditional herbal medicinal product is manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture of traditional herbal medicinal products to which paragraph 2 applies.

**6.** Any person who sells or supplies a traditional herbal medicinal product in accordance with any of paragraphs 2 to 5 shall maintain, and keep for a period of at least 5 years, a record showing—

(a) the source from which that person obtained that product;

(b) the person to whom and the date on which the sale or supply was made;

(c) the quantity of each sale or supply;

(d) the batch number of the batch of that product from which the sale or supply was made; and

(e) details of any suspected adverse reaction to the product so sold or supplied of which he is aware.

**7.** A person required to maintain the records mentioned in paragraph 6 shall—

(a) notify the licensing authority of any suspected adverse reaction such as is mentioned in head (e) of that paragraph which is a serious adverse reaction; and

(b) make available for inspection at all reasonable times by the licensing authority the records mentioned in that paragraph.