SCHEDULE 1

Regulation 3(2)

EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 3

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

2. The conditions mentioned in paragraph 1 are that—

(a) the relevant medicinal product is supplied to a doctor or dentist or for use in a registered pharmacy, a hospital or a health centre under the supervision of a pharmacist, in accordance with paragraph 1;

(b) no advertisement or representation relating to the relevant 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 sale or supply is in response to a bona fide unsolicited order;

(c) the manufacture or assembly of the relevant 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 or dentist 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) the relevant medicinal product is manufactured, assembled or imported by the holder of an authorization referred to in Article 16 of Council Directive 75/319/EEC which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; and

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

3.—(1) Subject to the following sub-paragraphs, regulation 3(1) shall not apply to anything done—

(a) by a doctor or dentist which relates to a relevant medicinal product specially prepared by him, or to his order, for administration to one or more patients of his or, 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

(b) 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 relevant medicinal products with a view to dispensing them in accordance with paragraph 1.

(2) The exemption conferred by sub-paragraph (1) shall not apply to procuring the manufacture of relevant 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 relevant medicinal products to which paragraph 1 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 relevant medicinal products in excess of a total of 5 litres of fluid and 2.5 kilograms of solids of all relevant medicinal products to which that sub-paragraph relates.

4.—(1) Regulation 3(1) shall not apply to the placing on the market by way of supplying of any relevant medicinal product to which this paragraph relates if the conditions of sub-paragraph (3) are satisfied.

(2) The relevant medicinal products to which this paragraph relates are relevant medicinal products which are for use by being administered to one or more human beings and which may be lawfully sold by retail or supplied in circumstances corresponding to retail sale, otherwise than in accordance with a prescription by a doctor or dentist.

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

(a) that the relevant 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 adminstered 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 relevant 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 relevant 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 relevant 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 sale or supply is in response to a bona fide unsolicited order;

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

(f) that the relevant medicinal product is manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture of relevant medicinal products to which paragraph 1 applies.

5.—(1) Regulations 3(1) shall not apply to a radiopharmaceutical for human use(**1**) —

(a) which is prepared at the time at which it is intended to be administered; and

(b) which is prepared, in accordance with the manufacturer's instructions and by the person by whom it is to be administered, exclusively from a kit, generator or precursor (or from more than one of these) in respect of which a marketing authorization is in force; and

(c) the administration of which is not or will not be a contravention of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978(**2**).

(2) In this paragraph—

"generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

(**1**) See article 2 of Council Directive 89/343/EEC.
(**2**) S.I. 1978/1006.

"kit" means any preparation to be reconstituted or combined with radionuclides in a final radiopharmaceutical, usually prior to its administration;

"precursor" means a radionuclide produced for the radio-labelling of another substance prior to its administration, other than a radionuclide which is incorporated in or produced from a generator or is included in a radiopharmaceutical;

"radiopharmaceutical" means any relevant medicinal product which when ready for use contains one or more radionuclides included for a medicinal purpose.

6. Any person who sells or supplies a relevant medicinal product in accordance with any of paragraphs 1 to 4 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.