STATUTORY INSTRUMENTS

2003 No. 696

The Prescription Only Medicines (Human Use) Amendment Order 2003

Insertion of articles 3B and 3C of the principal Order

6. After article 3A of the principal Order, insert the following articles—

"**Prescribing and administration by supplementary prescribers**

3B.—(1) Subject to paragraph (2), a supplementary prescriber may—

(a) give a prescription for a medicinal product referred to in article 3; or

(b) if that medicinal product is for parenteral administration—

(i) administer that medicinal product, or

(ii) give directions for the administration of that medicinal product,

only where he complies with the conditions as to the cases or circumstances in which he may do so specified in paragraph (3).

(2) Paragraph (1) does not apply if—

(a) the supplementary prescriber is a district nurse/health visitor prescriber and the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in Schedule 3; or

(b) the supplementary prescriber is an extended formulary nurse prescriber and—

(i) the medicinal product prescribed or administered, or in respect of which he gives directions for administration, falls within a description or class of medicinal products specified in article 3A(1), and

(ii) he satisfies any applicable condition specified by virtue of article 3A(3).

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

(a) the supplementary prescriber is acting in accordance with the terms of a clinical management plan which—

(i) relates to the patient for whom the product is prescribed or to whom it is, or is to be, administered,

(ii) is in effect at the time the prescription or direction is given or, as the case may be, the product is administered, and

(iii) includes the particulars specified in Schedule 3B;

(b) at the time the prescription or directions are given or, as the case may be, the product is administered—

(i) a product licence, a marketing authorization or a homoeopathic certificate of registration has effect in respect of the product, or

(ii) the product is, or is to be, administered in the course of a clinical trial and—

(a) the trial is the subject of a clinical trial certificate, or

(b) a clinical trial exemption has effect in relation to the supply of the product for the purposes of the trial; and

(c) the supplementary prescriber has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan.

Exemptions from conditions in respect of the cases or circumstances in which an extended formulary nurse prescriber or supplementary prescriber may administer a medicinal product

3C. The conditions specified by virtue of article 3A(3) and in article 3B(3) shall not apply in relation to the administration of a medicinal product by an extended formulary nurse prescriber or a supplementary prescriber where—

(a) that person is acting in accordance with the directions of another person who is an appropriate practitioner, or

(b) that administration is exempt from the restriction in section 58(2)(b) (restriction on administration) by virtue of any of the subsequent provisions of this Order.”.