SCHEDULE 1

EXEMPTIONS AND EXCEPTIONS FROM THE PROVISIONS OF REGULATION 4

Interpretation

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(**1**); and

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

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