SCHEDULE 3

PERIODIC FEES FOR LICENCES

PART I

INTERPRETATION

1. In this Schedule

"anthroposophic product" means a medicinal product prepared in accordance with the methods of anthroposophic medicine which is or supplied as an anthroposophic product and is so described by the person who sells or supplies that medicinal product;

"complex application" has the same meaning as in Schedule 1 except that it relates only to an application for a product licence;

"derivative", in relation to a limited use drug or a new active substance, means a medicinal product—

(a) which contains the same active ingredient or combination of active ingredients as that drug or substance but which either—

(i) is a different dosage form of that drug or substance, or

(ii) is of the same dosage form as, but of a different strength of active ingredient to, or of a different combination of active ingredients to, that drug or substance; and

(b) in respect of which an application for a product licence was made before the determination of the application for the product licence for that drug or substance;

"general sales list medicine" means a medicinal product (not being an anthroposophic product, a herbal product or a homoeopathic product) of a description or falling within a class specified in an Order made under section 51(1) of the Act;

"herbal product" means a medicinal product which is a herbal remedy as defined in section 132(1) of the Act;

"homoeopathic product" means a medicinal product prepared in accordance with the methods of homoeopathic medicine or similar methods which is sold or supplied as a homoeopathic product and is so described by the person who sells or supplies that medicinal product;

"limited use drug" means a medicinal product in respect of which an application for a product licence has been submitted, to which paragraph 5 of Chapter III of Part 3 of the Annex to the Council Directive 75/318/EEC applies;

"maintenance fee" means the periodic fee payable where the licence holder has notified the licensing authority that the medicinal product to which the product licence relates, being a prescription only medicine, a pharmacy medicine or a general sales list medicine, is not expected either to be manufactured anywhere under the terms of that product licence, or to be imported into the United Kingdom during the relevant licence fee period; and

(a) that during the period of 15 months preceding the commencement of the relevant licence fee period the medicinal product has not been either manufactured anywhere under the terms of that product licence, or imported into the United Kingdom; or

(b) where the medicinal product had been either manufactured anywhere under the terms of that product licence, or imported into the United Kingdom during the period referred to in (a) above, that turnover did not exceed £1,000 during the relevant calendar year;

"new active substance" means a medicinal product which is not a limited use drug and which contains an active ingredient which has not previously been included as an active ingredient

in a medicinal product in respect of which a product licence, other than a product licence of right, has been granted in the United Kingdom—

(a) in the five years preceding the coming into force of these Regulations; or

(b) in the five years preceding 31st December in the licence fee period preceding the relevant licence fee period.

"pharmacy medicine" means a medicinal product (not being an anthroposophic product, a herbal product or a homoeopathic product) which is neither a prescription only medicine nor a general sales list medicine;

"prescription only medicine" means a medicinal product (not being an anthroposophic product, a herbal product, a homoeopathic product, a new active substance or a derivative of a new active substance) of a description or falling within a class specified in an order made under section 58(1) of the Act;

"reduced rate fee" means the periodic fee payable where the turnover relating to a medicinal product, being a prescription only medicine, a pharmacy medicine or a general sales list medicine, does not exceed £30,000 in the relevant calendar year;

"standard fee" means the periodic fee payable where the turnover relating to a medicinal product, being a prescription only medicine, a pharmacy medicine or a general sales list medicine, does exceed £30,000 in the relevant calendar year;

"turnover" means the amount calculated in accordance with paragraphs 1 and 2 of Part II of this Schedule.