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 sold 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; "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 is either

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

(ii) 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 marketing authorization was made before the determination of the application for the marketing authorization for that drug or substance;

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

"herbal remedy" has the same meaning as in section 132(1) (general interpretation provisions) of the Act;

"homoeopathic medicinal product" means any medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;

"limited use drug" means a medicinal product in respect of which an application for a marketing authorization has been submitted, to which Section G of Part 4 of the Annex to Council Directive 75/318/EEC applies;

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

(a) that the medicinal product has not been manufactured or imported into the United Kingdom during the period of 12 months preceding the commencement of the relevant fee period; or

(b) where the medicinal product had been manufactured 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 marketing authorization (other than a product licence of right) has been granted in the five years preceding 31st December in the fee period preceding the relevant fee period;

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

"prescription only medicine" means a medicinal product (not being an anthroposophic product, a herbal remedy, 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) (medicinal products on prescription only) 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 sale 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 sale list medicine, does exceed £30,000 in the relevant calendar year;

"turnover" means the amount calculated in accordance with Part II of this Schedule.