SCHEDULE 2

PROCEDURAL PROVISIONS RELATING TO THE GRANT, RENEWAL, VARIATION, REVOCATION AND SUSPENSION OF TRADITIONAL HERBAL REGISTRATIONS

PART 1

INTERPRETATION AND APPLICATION

Interpretation

1. In this Schedule—

"active ingredient from a new source" means an active ingredient in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that active ingredient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted;

"complex variation application" means an application by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of a medicinal product comprising one or more of the following changes—

(a) a change in that product's active ingredients which involves the addition of one or more active ingredients which are active ingredients from a new source;

(b) a change in that product's excipients which involves the addition of one or more TSE risk excipients from a new source; or

(c) a change which involves the addition of one or more vitamins or minerals which are vitamins or minerals from a new source where no European Pharmacopoeia certificate of suitability covering those vitamins or minerals has been submitted with the application;

"new excipient" means any ingredient of a medicinal product, other than an active ingredient, that has not previously been included in a medicinal product which is intended to be administered by the same route of administration as the product in question and in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted, except that—

(a) in the case of a medicinal product intended to be administered orally, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in food or in a food product; and

(b) in the case of a medicinal product intended for external use only, the expression does not include any ingredient specified in any enactment (including an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Community) as an approved ingredient or additive in a cosmetic product;

"new excipient variation application" means an application, other than a complex variation application, by a traditional herbal registration holder to vary a traditional herbal registration which relates to a change in the formulation of the medicinal product to add a new excipient;

"the time allowed" means the period of twenty-eight days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case;

"TSE risk excipient from a new source" means an excipient which has been manufactured from raw materials of ruminant origin or which has had raw materials of ruminant origin used in its manufacture and in respect of which—

(a) the application names as manufacturer a manufacturer not previously named as the manufacturer of that excipient included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted; and

(b) no European Pharmacopoeia certificate of suitability covering the excipient has been submitted with the application;

"vitamin or mineral from a new source" means a vitamin or mineral in respect of which the application names as manufacturer a manufacturer not previously named as the manufacturer of that vitamin or mineral included in a medicinal product in respect of which a marketing authorization (other than a product licence of right) or a traditional herbal registration has previously been granted.