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.

Scope and application of this Schedule

2. Subject to paragraphs 6 and 7, Part 2 applies to—

(a) any application for the grant of a traditional herbal registration for a traditional herbal medicinal product except one made pursuant to the procedure in Article 28 of the 2001 Directive;

(b) any application to renew a traditional herbal registration for a traditional herbal medicinal product; and

(c) any proposal to revoke, vary or suspend a traditional herbal registration for a traditional herbal medicinal product, other than a variation on the application of the holder of that traditional herbal registration.

3. Subject to paragraphs 6 and 7, Part 3 applies to any application to vary a traditional herbal registration for a traditional herbal medicinal product which is a complex or a new excipient variation application.

4. Subject to paragraphs 6 and 7, Part 4 applies where the licensing authority propose to refer an application for the grant of a traditional herbal registration for a traditional herbal medicinal product to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive.

5. Subject to paragraphs 6 and 7, Part 5 applies where—

(a) an applicant for a traditional herbal registration for a traditional herbal medicinal product, or for the variation or renewal of such a traditional herbal registration; or

(b) the holder of a traditional herbal registration for a traditional herbal medicinal product,

gives notice under paragraphs 12, 17 or 20 of his wish to appear before or be heard by a person appointed by the licensing authority.

6. This Schedule shall cease to apply if at any time the relevant matter is, by virtue of any relevant Community provision, referred to the Committee for Herbal Medicinal Products for the application of the procedure laid down in Articles 32 to 34 of the 2001 Directive.

7. This Schedule does not apply—

(a) if an application relates to a traditional herbal medicinal product in respect of which either of the conditions set out in Article 16d(1) are fulfilled and—

(i) the licensing authority declines to assess the application because an application for an EC traditional herbal registration in another EEA State is being examined in

that State and the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or

(ii) the licensing authority rejects the application where the traditional herbal medicinal product in question has an EC traditional herbal registration in another EEA State and the application has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive;

(b) if the application or proposal relates to the renewal, revocation, suspension or variation of a traditional herbal registration which has been granted—

(i) in accordance with the provisions of Title III, Chapter 4 of the Directive; or

(ii) which has not been so granted, but which has been subject to the procedure laid down in Articles 32 to 34 of the Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the traditional herbal registration; or

(c) if the licensing authority refuse to grant the traditional herbal registration applied for following a referral to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) where the Committee for Herbal Medicinal Products has not supported the grant of the application.