SCHEDULES

SCHEDULE 12

Material to accompany an application for a traditional herbal registration

PART 1

General requirements

1. The name or corporate name and permanent address of the applicant and (where applicable) of the manufacturer of the medicinal product.

2. The name of the medicinal product. This may be—

(a) an invented name that is not liable to confusion with the product's common name; or

(b) a common or scientific name accompanied by a trademark or by the name of the person who is to be the holder of the traditional herbal registration.

3. Qualitative and quantitative particulars of the constituents of the medicinal product, including—

(a) where there is an international non-proprietary name recommended by the World Health Organisation for a constituent, a reference to that name; or

(b) otherwise, a reference to the relevant chemical or botanical name.

4. An evaluation of the potential environmental risks posed by the medicinal product, including an assessment of its environmental impact and a description of the proposed arrangements for limiting that impact on a case by case basis.

5. A description of the methods of manufacturing the medicinal product.

6. The therapeutic indications and contra-indications for the medicinal product and the adverse reactions associated with it.

7. The posology and pharmaceutical form of the medicinal product, its method and route of administration and its expected shelf life.

8. The reasons for any precautionary and safety measures to be taken for—

(a) the storage of the medicinal product;

(b) the administration of the medicinal product to patients; and

(c) the disposal of the medicinal product and any waste products,

with an indication of the potential risks presented by the medicinal product for the environment.

9. A description of the control methods employed by the manufacturer.

10. Results of pre-clinical (toxicological and pharmacological) tests in relation to the medicinal product and its constituent active substances.

11. A detailed summary of those results prepared and signed by an expert with appropriate technical or professional qualifications, which must be set out in a brief curriculum vitae.

12. A summary of the product characteristics for the medicinal product in accordance with Part 2 of this Schedule.

13. A mock-up, in accordance with Part 13 (packaging and leaflets) of—

(a) the outer packaging of the medicinal product;

(b) the immediate packaging of the medicinal product; and

(c) the package leaflet for the medicinal product.

14. A document showing that the manufacturer of the medicinal product is authorised to produce medicinal products in the manufacturer's own country.

15. Where the medicinal product consists of a combination of one or more herbal substances and one or more herbal preparations, or the medicinal product contains one or more vitamins or minerals—

(a) data on the traditional use of the medicinal product as a whole; and

(b) if any of the medicinal product's individual active ingredients are not sufficiently known, data on the traditional use of those active ingredients.

This covers (in particular)—

(c) evidence that the product is not harmful in the specified conditions of use; and

(d) evidence as to the pharmacological effects or efficacy of the product on the basis of long-standing use and experience.

16. Details of any authorisation or registration obtained by the applicant in another member State or a third country allowing the medicinal product to be placed on the market.

17. Details of any decision in another member State or a third country to refuse to grant an authorisation or registration allowing the medicinal product to be placed on the market, with the reasons for any such decision.

18. Bibliographical or expert evidence of the traditional use of the medicinal product or a product corresponding to the medicinal product.

For this purpose a product ("A") corresponds to a medicinal product ("B") if—

(a) product A has the same active ingredients as product B (regardless of the excipients used in either product);

(b) product A's intended purpose is the same as or similar to product B's intended purpose;

(c) product A has a strength and dosage equivalent to that of product B; and

(d) product A's route of administration is the same as or similar to product B's route of administration.

19. A bibliographic review of safety data.

20. An expert report on safety.