SCHEDULES

SCHEDULE 8

Material to accompany an application for a UK marketing authorisation

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 marketing authorisation holder.

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 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. The results of the following in relation to the medicinal product and its constituent active substances—

(a) pharmaceutical (physico-chemical, biological or microbiological) tests;

(b) pre-clinical (toxicological and pharmacological) tests; and

(c) clinical trials.

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 applicant's pharmacovigilance system which shall include the following elements—

(a) proof that the applicant has at the applicant's disposal an appropriately qualified person responsible for pharmacovigilance;

(b) the member States in which the appropriately qualified person resides and carries out his or her tasks;

(c) the contact details of the appropriately qualified person;

(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Part 11; and

(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.

13. The risk management plan, together with a summary, that—

(a) describes the risk management system which the applicant will introduce for the medicinal product concerned; and

(b) shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

14. Where any clinical trials have been carried out outside the European Union, a statement to the effect that the trials met the ethical requirements of the Clinical Trials Directive.

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

16. 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.

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

18. Where an application for authorisation for the medicinal product to be placed on the market is under consideration in a member State or States—

(a) a list of the member State or States concerned; and

(b) in relation to each application, a copy of—

(i) the summary of the product characteristics proposed by the applicant, and

(ii) the package leaflet proposed by the applicant.

19. Where an authorisation for the medicinal product to be placed on the market has been granted by a member State or by a third country—

(a) a copy of that authorisation;

(b) a summary of the safety data, including the data contained in the periodic safety update reports, where available; and

(c) any suspected adverse reaction reports.

20. Where an authorisation for the medicinal product to be placed on the market has been granted by a member State in accordance with the 2001 Directive, a copy of—

(a) the summary of the product characteristics approved by the competent authority of the member State; and

(b) the package leaflet approved by that competent authority.

21. Where an authorisation for the medicinal product to be placed on the market has been refused by a member State or by a third country, details of that decision and of the reasons for it.

22. A copy of any designation of the medicinal product as an orphan medicinal product under Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products(**1**) together with a copy of the relevant Agency opinion.

(**1**) OJ No L 18, 22.1.2000, p.1, as amended by Regulation (EC) No 596/2009 (OJ No L 188, 18.7.2009, p.14.