STATUTORY INSTRUMENTS

2014 No. 1878

The Human Medicines (Amendment) (No. 2) Regulations 2014

Insertion of Schedule 8A

26. After Schedule 8 (material to accompany a UK marketing authorisation) insert—

"SCHEDULE 8A Regulation 50(1A)

Material to accompany an application for a parallel import licence

1. The name or corporate name and permanent address of the applicant.

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 parallel import licence holder.

3. Details of the product to be imported if requested by the licensing authority.

4. Details of the UK reference product.

5. If requested by the licensing authority, 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.

6. If requested by the licensing authority, 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.

7. If requested by the licensing authority, 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.

8. If requested by the licensing authority, a summary of the product characteristics for the medicinal product in accordance with Part 2 of Schedule 8.

9. 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."