SCHEDULE 3

Regulation 7 (4)

OFFENCES, PENALTIES ETC.

Offences

1. Any person who, in breach of the relevant Community provisions or of these Regulations, places a relevant medicinal product on the market without holding a Community or United Kingdom marketing authorization in respect of that product, or otherwise than in accordance with the terms of such an authorization, shall be guilty of an offence.

2. Any person who, in the course of a business carried on by him, sells, supplies, manufactures or assembles, or procures the sale, supply, manufacture or assembly of, a relevant medicinal product, or who has in his possession a relevant medicinal product, knowing or having reasonable cause to believe that the product was or is intended to be placed on the market contrary to paragraph 1 shall be guilty of an offence.

3. Without prejudice to any other sanction which may be available for the enforcement of conditions attaching to marketing authorizations, any holder of a marketing authorization for a relevant medicinal product who contravenes any condition of the authorization shall be guilty of an offence.

4. Where the use, supply or marketing of a relevant medicinal product is suspended in accordance with regulation 6 or Council Regulation (EEC) No. 2309/93, any person who sells, supplies or markets, or procures the sale, supply or marketing of, that product knowing, or having reasonable cause to believe, that such use, supply or marketing is suspended, shall be guilty of an offence.

5. Any person who is or, immediately before its revocation or suspension, was the holder of a marketing authorization who fails to comply with a notice given to him under regulation 6(5) (notice to take all reasonably practicable steps to publish information concerning revocation or suspension or to recover possession of products affected) shall be guilty of an offence.

6. Any holder of a marketing authorization who fails promptly to—

(a) update information concerning the product or any connected matter as required by Article 4 of the 1965 Directive or Article 6 of Council Regulation (EEC) No. 2309/93; or

(b) take any steps reasonably necessary to take account of technical and scientific progress for the purposes of making any changes or amendments as required by Article 9a of the 1965 Directive or Article 15.1 of Council Regulation (EEC) No. 2309/93; or

(c) introduce any changes or make any amendments that may be required in accordance with those Articles; or

(d) provide information to the EMEA, the Commission or the licensing authority as required by Article 15.2 of Council Regulation (EEC) No. 2309/93; or

(e) submit any application to the licensing authority or the Community to make any changes or variation as required by Article 9a of the 1965 Directive or Article 15.3 of Council Regulation (EEC) No. 2309/93,

shall be guilty of an offence.

7. Any person responsible for placing on the market a relevant medicinal product authorized by the Community or by the licensing authority who, at any time, does not have at his disopsal an appropriately qualified person responsible for pharmacovigilance as required by Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93 or Chapter Va of Council Directive 75/319/EEC shall be guilty of an offence.

8. Any person responsible for placing a relevant medicinal product on the market who fails to report to the licensing authority any suspected adverse reaction, or to submit to the licensing authority any records of suspected adverse reactions as required by Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93 or Chapter Va of Council Directive 75/319/EEC, shall be guilty of an offence.

9. Any person responsible for placing a relevant medicinal product on the market who fails to make or maintain a detailed record of any suspected adverse reaction as required by Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or Chapter Va of Council Directive 75/319/EEC shall be guilty of an offence.

10. Any person who, while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or Chapter Va of Council Directive 75/319/EEC fails to—

(a) establish or maintain a system for collecting and collating information about suspected adverse reactions;

(b) prepare for the licensing authority a report on any such reactions; or

(c) ensure that a request from the licensing authority for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a relevant medicinal product is answered fully and promptly,

as required by any provision of any such Chapter, shall be guilty of an offence.

11. Any holder of a marketing authorization who sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorization relates—

(a) the labelling of which, or any package leaflet accompanying which, does not comply with; or

(b) without a package leaflet required to be provided by virtue of,

the applicable requirements of Council Directive 92/27/EEC or of Schedule 5 to these Regulations, shall be guilty of an offence.

12. Where, in relation to a relevant medicinal product—

(a) the labelling of the product, or any package leaflet accompanying the product, does not comply with; or

(b) the product is not accompanied by a package leaflet required to be provided by virtue of,

the applicable requirements of Council Directive 92/27/EEC or Schedule 5, any person, other than the holder of the marketing authorization for that product, who in the course of a business carried on by him, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence.

13. Any person who fails to keep any record required under paragraph 6 of Schedule 1, or to give notice or make it available for inspection as and when required under paragraph 7 of that Schedule, shall be guilty of an offence.Penalties

Penalties

14. Any person guilty of an offence under any of the preceding paragraphs shall be liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum;

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

Miscellaneous

15.—(1) Where an offence is committed under any of paragraphs 8, 9 or 10 by a person mentioned in those paragraphs who is acting as the employee or agent of another person, the employer or principal of that person shall be guilty of the same offence.

(2) Where a Scottish partnership is guilty of an offence under these Regulations in respect of any act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner in the partnership, he, as well as the partnership, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

16. Where the holder of a marketing authorization is charged with an offence under these Regulations in respect of anything which has been manufactured or assembled to his order by another person and had been so manufactured or assembled as not to comply with the provisions of that authorization, it shall be a defence for him to prove—

(a) that he had communicated the provisions relating to the authorization to that other person; and

(b) that he did not know, and could not by the exercise of reasonable care have known, that those provisions has not been complied with.