

SCHEDULE 3

Regulation 9(6)

OFFENCES, PENALTIES ETC

Offences

1. Any person who, in breach of these Regulations, places a traditional herbal medicinal product on the market without holding a traditional herbal registration in respect of that product, or otherwise than in accordance with the terms of such a registration, 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 traditional herbal medicinal product, or who has in his possession a traditional herbal 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 traditional herbal registrations, any holder of a traditional herbal registration for a traditional herbal medicinal product who contravenes any condition of the registration shall be guilty of an offence.

4. Any person who is the holder of a traditional herbal registration who fails to implement an urgent safety restriction imposed on him by the licensing authority under regulation 8 shall be guilty of an offence.

5. Where the use, supply or marketing of a traditional herbal medicinal product is suspended in accordance with regulation 7, 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.

6. Any person who is or, immediately before its revocation or suspension, was the holder of a traditional herbal registration who fails to comply with a notice given to him under regulation 7(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.

7. Any holder of a traditional herbal registration who fails promptly to—

- (a) 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 23 of the 2001 Directive; or
- (b) introduce any changes or make any amendments that may be required in accordance with that Article or paragraphs 3.2(9) and 3.2.2.4(c) of Part I of Annex I to the 2001 Directive; or
- (c) provide information to the licensing authority as required by the third or fourth paragraphs of Article 23 of the 2001 Directive; or
- (d) submit any application to the licensing authority to make any changes or variation as required by that Article; or
- (e) notify the licensing authority if the traditional herbal medicinal product to which the registration relates has not been placed on the market in the United Kingdom for a period of three consecutive years pursuant to regulation 9(4);

shall be guilty of an offence.

8. Any holder of a traditional herbal registration who fails to forward to the licensing authority any data requested by the authority pursuant to the final paragraph of Article 23 of the Directive—

- (a) where the licensing authority have served a written notice on the holder under regulation 9(7) in relation to the request, within the time specified in that notice;

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(b) where there is no such notice, promptly,
shall be guilty of an offence.

9. Any holder of a traditional herbal registration who fails to forward to the licensing authority any data requested by the authority pursuant to regulation 9(5)—

(a) where the licensing authority have served a written notice on the holder under regulation 9(7) in relation to the request, within the time specified in that notice;

(b) where there is no such notice, promptly,
shall be guilty of an offence.

10. Any person who is the holder of a traditional herbal registration who fails to ensure appropriate and continued supplies pursuant to the second paragraph of Article 81 of the 2001 Directive shall be guilty of an offence.

11. Any holder of a traditional herbal registration who communicates to the general public information relating to pharmacovigilance concerns about the product to which the registration relates without having previously communicated, or without simultaneously communicating, such information to the licensing authority shall be guilty of an offence.

12. Any holder of a traditional herbal registration who fails to ensure that information relating to pharmacovigilance concerns about the product to which the registration relates which he communicates to the general public or the licensing authority is presented objectively and is not misleading shall be guilty of an offence.

13. Any person responsible for placing on the market a traditional herbal medicinal product authorised by the licensing authority who, at any time, does not have at his disposal an appropriately qualified person responsible for pharmacovigilance as required by Title IX of the 2001 Directive shall be guilty of an offence.

14. Any person responsible for placing a traditional herbal 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 Title IX of the 2001 Directive, shall be guilty of an offence.

15. Any person responsible for placing a traditional herbal medicinal product on the market who fails to make or maintain a detailed record of any suspected adverse reaction as required by Title IX of the 2001 Directive shall be guilty of an offence.

16. Any person who, while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Title IX of the 2001 Directive 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 traditional herbal medicinal product is answered fully and promptly; or
- (d) provide to the licensing authority any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post authorization safety studies,

as required by any provision of that Title, shall be guilty of an offence.

17.—(1) Any person who in the course of an application for the grant, renewal or variation of a traditional herbal registration for a traditional herbal medicinal product—

- (a) fails to provide to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the traditional herbal medicinal product as required by point (7) or (11) of the introduction to Annex I to the 2001 Directive; or
- (b) provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the traditional herbal medicinal product but which is false or misleading in a material particular,

shall be guilty of an offence.

(2) Any person who—

- (a) is responsible for placing a traditional herbal medicinal product on the market;
- (b) is the traditional herbal registration holder for a traditional herbal medicinal product; or
- (c) while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Title IX of the 2001 Directive is required to provide information to the licensing authority about a traditional herbal medicinal product,

who provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the traditional herbal medicinal product but which is false or misleading in a material particular shall be guilty of an offence.

18. Any holder of a traditional herbal registration who sells or supplies or procures the sale or supply of a traditional herbal medicinal product to which the traditional herbal registration 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 Title V of the 2001 Directive or of Schedule 5 to these Regulations, shall be guilty of an offence.

19. Where, in relation to a traditional herbal 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 Title V of the 2001 Directive or Schedule 5, any person, other than the holder of the traditional herbal registration 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.

20. 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.

21. Any person who—

- (a) sells or supplies a traditional herbal medicinal product in accordance with any of paragraphs 2 to 5 of Schedule 1; or
- (b) provides a specification for such a product for the purposes of paragraph 2 of that Schedule,

who provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the traditional herbal medicinal product but which is false or misleading in a material particular shall be guilty of an offence.

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Penalties

- 22.** 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

23.—(1) Where an offence is committed under any of paragraphs 14, 15, 16 or 17 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.

24. Where the holder of a traditional herbal registration 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 registration, it shall be a defence for him to prove—

- (a) that he had communicated the provisions relating to the registration 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 had not been complied with.

25.—(1) A person does not commit an offence under paragraphs 10, 17 or 21 if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.