

SCHEDULES

SCHEDULE 11

Regulations 58(5);59(7); 60(11);66(8);
68(12); 104(4);105(9); 108(8);
110(9);130(11); 133(8); and 137

Advice and representations

PART 1

General procedures

Application of this Part

1.—(1) This Part of this Schedule applies to—

- (a) an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration;
- (b) an application to renew a UK marketing authorisation, certificate of registration or traditional herbal registration; and
- (c) a proposal to revoke, vary or suspend a UK marketing authorisation, certificate of registration or traditional herbal registration (including variation by the variation or removal of a condition to which a UK marketing authorisation or a certificate of registration is subject) other than a proposal to vary the authorisation, certificate or registration on the application of or by agreement with its holder.

(2) This Part is subject to Part 4 of this Schedule.

Requirement to consult the appropriate committee

2.—(1) The licensing authority must consult the appropriate committee if the authority proposes on grounds relating to safety, quality or efficacy—

- (a) to refuse to grant or renew a UK marketing authorisation or traditional herbal registration in response to the application; or
- (b) to revoke, vary or suspend a UK marketing authorisation or traditional herbal registration.

(2) The licensing authority must consult the appropriate committee if the authority proposes on grounds relating to safety or quality—

- (a) to refuse to grant or renew a certificate of registration in response to the application; or
- (b) to revoke, vary or suspend a certificate of registration.

(3) This paragraph is subject to paragraphs 3 and 4 (exceptions to requirement to consult).

(4) In this Schedule “the appropriate committee” in relation to any function means whichever of the bodies listed in paragraph (5) the licensing authority considers to be the appropriate body to perform that function.

(5) Those bodies are—

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- (a) the Commission; and
- (b) any expert committee appointed by the licensing authority.

Exceptions to requirement to consult

3.—(1) Paragraph 2 does not apply to a proposal to refuse to grant or renew a UK marketing authorisation, certificate of registration or traditional herbal registration if—

- (a) the licensing authority has asked the applicant to supply information that the licensing authority thinks is relevant to enable the application to be determined; and
 - (b) the information has not been supplied to the authority within the relevant period.
- (2) The relevant period is—
- (a) where the licensing authority has completed its initial full assessment of the application, the period of six months beginning with the date when the authority asked the applicant to supply the information mentioned in sub-paragraph (1); or
 - (b) where the licensing authority has completed its assessment of any supplemental information, the period of three months beginning with the date when the authority asked the applicant to supply the information mentioned in sub-paragraph (1).
- (3) The licensing authority may extend the relevant period if—
- (a) the applicant asks it to do so;
 - (b) the applicant provides the grounds for that request; and
 - (c) the licensing authority thinks that the grounds are exceptional.

4.—(1) Paragraph 2 does not apply to a proposal to suspend a UK marketing authorisation, certificate of registration or traditional herbal registration if the licensing authority thinks that, in the interests of safety, it is necessary to suspend the authorisation, certificate or registration with immediate effect for not more than three months.

(2) In that event the licensing authority must report the suspension to the appropriate committee forthwith.

- (3) Sub-paragraph (4) applies if, following a suspension to which this paragraph applies—
- (a) the licensing authority thinks that the authorisation, certificate or registration should be further suspended, or varied or revoked; or
 - (b) the appropriate committee advises that the authorisation, certificate or registration should be further suspended, or varied or revoked.

(4) The provisions of this Part of this Schedule (including this paragraph) apply accordingly to the suspension, variation or revocation.

Provisional opinion against authorisation

5.—(1) If the appropriate committee is consulted under paragraph 2(1) it may give a provisional opinion that on grounds relating to safety, quality or efficacy—

- (a) it may be unable to advise the licensing authority to grant or renew the UK marketing authorisation or traditional herbal registration;
- (b) it may be unable to advise the licensing authority to grant the authorisation or registration unless—
 - (i) it contains terms other than those in the application, or

- (ii) it is granted subject to conditions; or
 - (c) it may have to advise the licensing authority to revoke, vary or suspend the authorisation or registration.
- (2) If the Commission is consulted under paragraph 2(2), it may give a provisional opinion that, on grounds relating to safety or quality—
 - (a) it may be unable to advise the licensing authority to grant or renew the certificate of registration;
 - (b) it may be unable to advise the licensing authority to grant the certificate unless—
 - (i) it contains terms other than those in the application, or
 - (ii) it is granted subject to conditions; or
 - (c) it may have to advise the licensing authority to revoke, vary or suspend the certificate.
- (3) The appropriate committee must notify the applicant for the grant or renewal or (as the case may be) the holder of the authorisation, certificate or registration in writing of its provisional opinion.

Opportunity to make representations

- 6.—**(1) An applicant or holder notified under paragraph 5 may, by notice in writing to the appropriate committee, request the opportunity to make written or oral representations to the appropriate committee.
- (2) The applicant or holder must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

Written representations

- 7.—**(1) If the applicant or holder requests the opportunity to make written representations, the applicant or holder must provide the appropriate committee with those representations and any documents on which the applicant or holder wishes to rely in support of them—
- (a) before the end of the period of six months beginning with the date of the request; or
 - (b) before the end of such shorter period as the appropriate committee may specify in the notification under paragraph 5.
- (2) The appropriate committee may at the request of the applicant or holder extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 6.
- (3) The applicant or holder may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) The appropriate committee must—
- (a) take the representations made under this paragraph into account; and
 - (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

- 8.—**(1) If the applicant or holder requests the opportunity to make oral representations, the applicant or holder must provide the appropriate committee with a written summary of those representations and any documents on which the applicant or holder wishes to rely in support of them—

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- (a) before the end of the period of six months beginning with the date of the request; or
 - (b) before the end of such shorter period as the appropriate committee may specify in the notification under paragraph 5.
- (2) The appropriate committee may at the request of the applicant or holder extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 6.
- (3) The applicant or holder may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant or holder to make oral representations at a hearing before the committee.
- (5) The appropriate committee must—
- (a) take the representations made under this paragraph into account; and
 - (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

- 9.—(1) This paragraph applies if the applicant or holder—
- (a) does not request the opportunity to make written or oral representations to the appropriate committee within the period mentioned in paragraph 6;
 - (b) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or
 - (c) requests the opportunity to make oral representations, but—
 - (i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or
 - (ii) fails to make oral representations at a hearing before the appropriate committee.
- (2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

- 10.—(1) After receiving the appropriate committee's report under paragraph 7 or 8 or notification under paragraph 9 the licensing authority must—
- (a) decide whether to grant or renew the UK marketing authorisation, certificate of registration or traditional herbal registration;
 - (b) decide whether to grant or renew the authorisation, certificate or registration in accordance with the application; or
 - (c) decide whether to proceed with its proposal to revoke, vary or suspend the authorisation, certificate or registration,
- as the case may be.
- (2) If the appropriate committee has given a report under paragraph 7 or 8, the licensing authority must take the report into account in making its decision.
- (3) The licensing authority must notify the applicant or holder of—
- (a) its decision; and
 - (b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 10 notification

11.—(1) A person to whom a notification is given under paragraph 10 may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(2) The person must give the notification within the period of 28 days beginning with the day on which the notification under paragraph 10 is given or such longer period as the licensing authority may allow.

(3) The review must be conducted in accordance with Schedule 5.

(4) This paragraph does not apply if—

- (a) the person has not made any representations in accordance with paragraph 7 or 8; and
- (b) the decision of the licensing authority is in accordance with the advice of the appropriate committee.

Licensing authority decisions in other cases

12.—(1) This paragraph applies if the appropriate committee has not been consulted under paragraph 2(1) because the licensing authority proposes on grounds not relating to safety, quality or efficacy—

- (a) to refuse to grant or renew a UK marketing authorisation or traditional herbal registration in response to the application;
- (b) to grant or renew a UK marketing authorisation or traditional herbal registration otherwise than in accordance with the application; or
- (c) to revoke, vary or suspend a UK marketing authorisation or traditional herbal registration.

(2) This paragraph also applies if, having been consulted under paragraph 2(1), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(1), and the licensing authority proposes—

- (a) to determine the application for the UK marketing authorisation or traditional herbal registration in a way that differs from the appropriate committee's advice;
- (b) to revoke, vary or suspend the authorisation or registration against such advice; or
- (c) on grounds not relating to safety, quality or efficacy—
 - (i) to refuse to grant or renew the authorisation or registration,
 - (ii) to grant or renew the authorisation or registration otherwise than in accordance with the application, or
 - (iii) to revoke, vary or suspend the authorisation or registration.

(3) This paragraph also applies if the appropriate committee has not been consulted under paragraph 2(2) because the licensing authority proposes on grounds not relating to safety or quality—

- (a) to refuse to grant or renew a certificate of registration in response to the application;
- (b) to grant or renew a certificate of registration otherwise than in accordance with the application; or
- (c) to revoke, vary or suspend a certificate of registration.

(4) This paragraph also applies if, having been consulted under paragraph 2(2), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2), and the licensing authority proposes—

- (a) to determine the application for the certificate of registration in a way that differs from the appropriate committee's advice;
 - (b) to revoke, vary or suspend the authorisation against such advice; or
 - (c) on grounds not relating to safety or quality—
 - (i) to refuse to grant or renew the certificate,
 - (ii) to grant or renew the certificate otherwise than in accordance with the application, or
 - (iii) to revoke, vary or suspend the certificate.
- (5) The licensing authority must notify the applicant for the grant or renewal or (as the case may be) the holder of the authorisation, certificate or registration in writing of its proposal.
- (6) The notification must state—
- (a) the reasons for the proposal; and
 - (b) any advice of the appropriate committee and any reasons it has given for that advice.

Right to review or representations after paragraph 12 notification

- 13.—**(1) A person to whom a notification is given under paragraph 12 may—
- (a) notify the licensing authority in writing that the person wishes the licensing authority to submit the proposal to review upon oral representations, or
 - (b) make representations in writing to the licensing authority with respect to the proposal.
- (2) The person must give the notification or make the representations within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.
- (3) A review in accordance with sub-paragraph (1)(a) must be conducted in accordance with Schedule 5.
- (4) If the person makes written representations in accordance with sub-paragraph (1)(b) the licensing authority must take them into account before determining the matter.

PART 2

Type II variation applications, complex variation applications and new excipient variation applications

Application of this Part

- 14.** This Part applies—
- (a) to an application (a “Type II variation application”) to vary a UK marketing authorisation if the variation is a major variation of Type II within the meaning of Article 2(3) of [Commission Regulation \(EC\) No 1234/2008](#) of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products⁽¹⁾; and
 - (b) to an application to vary a traditional herbal registration that is—
 - (i) a complex variation application, or
 - (ii) a new excipient variation application.

(1) OJ No L 334, 12.12.2008, p.7.

15.—(1) In paragraph 14(b)(i) “complex variation application” means an application by the holder of the registration to vary it so that one or more of the following changes can be made to the product to which it relates—

- (a) a change in the product’s active ingredients by the addition of an active ingredient from a new source;
- (b) a change in the product’s excipients by the addition of a TSE risk excipient from a new source; or
- (c) a change by the addition of a vitamin or mineral from a new source, where no European Pharmacopoeia certificate of suitability for the vitamin or mineral is submitted with the application.

(2) For the purpose of sub-paragraph (1), an ingredient, vitamin or mineral is “from a new source” if its manufacturer as named in the application has not been named as its manufacturer in a marketing authorisation or traditional herbal registration granted for a medicinal product including the ingredient, vitamin or mineral.

(3) For the purpose of sub-paragraph (1), an excipient is a “TSE risk excipient from a new source” if—

- (a) it has been manufactured from raw materials of ruminant origin or such raw materials have been used in its manufacture; and
- (b) its manufacturer as named in the application has not been named as its manufacturer in a marketing authorisation or traditional herbal registration granted for a medicinal product that includes the excipient.

16.—(1) In paragraph 14(b)(ii) “new excipient variation application” means an application (other than a complex variation application) by the holder of the registration to vary it so that the formulation of the medicinal product to which it relates can be changed by the addition of a new excipient.

(2) For the purpose of sub-paragraph (1) “new excipient” means, subject to paragraphs (3) and (4), an ingredient of a medicinal product that is not an active ingredient and that has not been included in a medicinal product—

- (a) intended to be administered by the same route as the product to which the application relates; and
- (b) for which a marketing authorisation (other than a product licence of right) or traditional herbal registration has been granted.

(3) In the application of sub-paragraph (1) to a medicinal product intended to be administered orally, the reference to a new excipient does not include any ingredient specified in an enactment as an approved ingredient or additive in food or in a food product.

(4) In the application of sub-paragraph (1) to a medicinal product intended for external use only, the reference to a new excipient does not include any ingredient specified in an enactment as an approved ingredient or additive in a cosmetic product.

(5) In this paragraph “enactment” includes an enactment comprised in subordinate legislation or in any Directive, Regulation or Decision of the European Union.

17. This Part is subject to Part 4 of this Schedule.

Opportunity to make representations

18.—(1) This paragraph applies if the licensing authority notifies the applicant for a variation to which this Part applies that it has decided, on grounds relating to safety, quality or efficacy—

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- (a) to refuse to grant the application, or
 - (b) to grant it otherwise than in accordance with the application.
- (2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.
- (3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.
- (4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

- 19.**—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—
- (a) before the end of the period of six months beginning with the date of the request; or
 - (b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 18.
- (2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 18.
- (3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) The appropriate committee must—
- (a) take the representations made under this paragraph into account; and
 - (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

- 20.**—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—
- (a) before the end of the period of six months beginning with the date of the request; or
 - (b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 18.
- (2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 18.
- (3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.
- (5) The appropriate committee must—
- (a) take the representations made under this paragraph into account; and

- (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

- 21.—**(1) This paragraph applies if the applicant—
- (a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or
 - (b) requests the opportunity to make oral representations, but—
 - (i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or
 - (ii) fails to make oral representations at a hearing before the appropriate committee.
- (2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

- 22.—**(1) After receiving the appropriate committee's report under paragraph 19 or 20 or notification under paragraph 21 the licensing authority must confirm or alter its decision.
- (2) If the appropriate committee gives a report under paragraph 19 or 20, the licensing authority must take that into account in making its decision.
- (3) The licensing authority must notify the applicant or holder of—
- (a) its decision; and
 - (b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 22 notification

- 23.—**(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 22—
- (a) to refuse the application; or
 - (b) to grant it otherwise than in accordance with the application.
- (2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.
- (3) The applicant must give the notification within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.
- (4) The review must be conducted in accordance with Schedule 5.
- (5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 19 or 20.

PART 3

Referral to the Committee for Herbal Medicinal Products

Application of this Part

24.—(1) This Part applies if the licensing authority proposes to refer an application for a traditional herbal registration to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive.

(2) This Part is subject to Part 4 of this Schedule.

Opportunity to make representations

25.—(1) The licensing authority must notify the applicant of the authority's proposal.

(2) The applicant may by notice in writing to the licensing authority request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request within the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant or holder's request.

Written representations

26.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 25.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

27.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of six months beginning with the date of the request; or

- (b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 25.
- (2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of twelve months beginning with the date of the request under paragraph 24.
- (3) The applicant may submit additional written representations or documents after the end of the period for doing so only with the permission of the appropriate committee.
- (4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the appropriate committee.
- (5) The appropriate committee must—
 - (a) take the representations made under this paragraph into account; and
 - (b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

- 28.**—(1) This paragraph applies if the applicant—
- (a) requests the opportunity to make written representations, but fails to make those written representations within the period for doing so; or
 - (b) requests the opportunity to make oral representations, but—
 - (i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or
 - (ii) fails to make oral representations at a hearing before the appropriate committee.
- (2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority following report

- 29.**—(1) After receiving the appropriate committee's report under paragraph 26 or 27 or notification under paragraph 28 the licensing authority must decide whether to proceed with its proposal.
- (2) If the appropriate committee gives a report under paragraph 26 or 27, the licensing authority must take that into account in making its decision.
- (3) The licensing authority must notify the applicant or holder of—
- (a) its decision; and
 - (b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 29 notification

- 30.**—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 29 to refer the applicant to the Committee on Herbal Medicinal Products as proposed.
- (2) The applicant may notify the licensing authority in writing that the person wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification within the period of 28 days beginning with the day on which the licensing authority's notification is given or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the person has not made any representations in accordance with paragraph 26 or 27.

PART 4

Exceptions to Schedule

31. This Schedule does not apply to an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration if, at any time during the period beginning with the date on which the application is made and ending with the date on which the licensing authority gives a decision on the application, there is an authorisation, certificate or registration in force in respect of the medicinal product in question in any EEA State.

32. This Schedule does not apply to an application for the grant of a UK marketing authorisation, certificate of registration or traditional herbal registration if the application has been submitted to the licensing authority in accordance with Article 28 of the 2001 Directive.

33. This Schedule ceases to apply if at any time the matter in question is referred to the Committee for Medicinal Products for Human Use or the Committee for Herbal Medicinal Products under Article 30 or 31 of the 2001 Directive for the application of the procedure laid down in Articles 32 to 34 of that Directive.

34. This Schedule does not apply to an application for a UK marketing authorisation or certificate of registration if—

- (a) the licensing authority declines to assess the application on the ground that—
 - (i) an application for an authorisation or registration in respect of the same medicinal product is being examined in another EEA State, and
 - (ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or
- (b) the licensing authority rejects the application on the ground that—
 - (i) the medicinal product in question has an authorisation or registration in another EEA State, and
 - (ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive.

35. This Schedule does not apply to an application for a traditional herbal registration in relation to which either of the conditions in Article 16d(1) of the 2001 Directive is met if—

- (a) the licensing authority declines to assess the application on the ground that—
 - (i) an application for a registration in respect of the same medicinal product is being examined in another EEA State, and
 - (ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (3) of the 2001 Directive; or
- (b) the licensing authority rejects the application on the ground that—
 - (i) the medicinal product in question has a registration in another EEA State, and
 - (ii) the application to the licensing authority has not been submitted in accordance with Article 28(1) and (2) of the 2001 Directive.

36. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a UK marketing authorisation that—

- (a) was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure);
- (b) was granted before 1st January 1995 by member States in accordance with Article 4 of Council Directive [87/22/EEC](#) of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology⁽²⁾; or
- (c) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the authorisation.

37. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a certificate of registration that was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure).

38. This Schedule does not apply if the application or proposal relates to the renewal, revocation, suspension or variation of a traditional herbal registration that—

- (a) was granted in accordance with the provisions of Chapter 4 of Title III to the 2001 Directive (mutual recognition procedure and decentralised procedure); or
- (b) was subject to the procedure laid down in Articles 32 to 34 of the 2001 Directive following a referral under Article 30 or 31 of that Directive, unless the procedure was limited to certain specific parts of the registration.

39. This Schedule does not apply if—

- (a) the licensing authority refuse to grant an application for a traditional herbal registration;
- (b) the application was referred to the Committee for Herbal Medicinal Products in accordance with Article 16c(4) of the 2001 Directive; and
- (c) the Committee for Herbal Medicinal Products did not support the grant of the application.

(2) OJ No L 15, 17.1.1987. p.38.