SCHEDULE 1

Marketing authorisations

PART 6

Mutual recognition and multiple applications

Application for a marketing authorisation where one already exists in another member State

42.—(1) If a veterinary medicinal product has already received a marketing authorisation in another member State at the time of application, and the holder of the marketing authorisation applies for a marketing authorisation in the United Kingdom, the following procedure ("the mutual recognition procedure") applies.

(2) The applicant must submit to the Secretary of State a dossier identical to the one submitted to the competent authority of the member State in which the veterinary medicinal product has been authorised ("the reference member State").

(3) If there is a marketing authorisation current in more than one member State the applicant must identify which member State is acting as the reference member State.

(4) If the applicant is applying in more than one member State he must supply the Secretary of State with a list of all the States in which he is applying.

(5) The Secretary of State must obtain an assessment report from the reference member State and, where appropriate, an explanation of any extension of the period of data protection.

(6) Within 90 days after receipt of the assessment report, the Secretary of State must, subject to the following provisions, either—

(a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or

(b) notify the reference member State that he will not approve them, and provide the reference member State with a detailed statement of the reasons.

(7) He may only refuse an application on the grounds of serious risk to human or animal health or the environment.

(8) If he approves the assessment report, the summary of product characteristics, the labelling and the package leaflet he must ensure that he is in a position to decide whether or not to grant a marketing authorisation within 30 days of approving them.

(9) If the Secretary of State is notified by the reference member State that—

(a) not all member States concerned have within 90 days approved the assessment report, summary of product characteristics, labelling or package leaflet; and

(b) the reference member State has sent a detailed statement of the reasons to the other member States involved in the application, the applicant and the coordination group for action in accordance with Article 33(3) of Directive 2001/82/EC,

the Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(10) The Secretary of State may grant the marketing authorisation even though not all member States have agreed to grant it, but must revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.

Application in another member State

43.—(1) When the Secretary of State has granted a marketing authorisation for a veterinary medicinal product and he is notified by the marketing authorisation holder that he has applied to have that veterinary medicinal product authorised in another member State, he must prepare an assessment report for the product within 90 days of the notification and send it to the member State or States concerned.

(2) If the other member State (or, if there is more than one, all of them) agrees with the assessment report, the summary of product characteristics, the labelling and the package leaflet he need take no further action.

(3) If not all the other member States concerned so agree within a further 90 days he must send a detailed statement setting out why they have disagreed to the other member States, the applicant and the coordination group for action in accordance with Article 33(3) of Directive 2001/82/EC.

(4) The Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

Application for a marketing authorisation in multiple member States where a marketing authorisation does not exist in any member State

44.—(1) If an applicant wishes to apply for a marketing authorisation in more than one member State, and a marketing authorisation does not exist in any member State for the product ("the decentralised procedure"), he must—

(a) apply simultaneously in all the relevant member States;

(b) submit a dossier to the Secretary of State that is identical to the dossier being submitted to all the other member States;

(c) include a list of all member States in which he has applied; and

(d) nominate one of them to act as the reference member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet for consideration by the other member States ("the concerned member States").

(2) If the United Kingdom is the reference member State, the Secretary of State must prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet within 120 days of the receipt of a valid application and must send them to the other concerned member States and to the applicant.

(3) If the United Kingdom is not the reference member State, within 90 days after receipt of the assessment report and drafts of the summary of product characteristics, labelling and package leaflet from the reference member State, the Secretary of State must, subject to the following provisions, either—

(a) approve the assessment report, the summary of product characteristics, the labelling and the package leaflet, and inform the reference member State accordingly; or

(b) notify the reference member State that he will not approve it, and provide the reference member State with a detailed statement of the reasons.

(4) He may only refuse an application on the grounds of serious risk to human or animal health or the environment.

(5) If all the member States involved agree the assessment report, the summary of product characteristics, the labelling and the package leaflet within 90 days, the Secretary of State must ensure that he is in a position to decide whether or not to grant a marketing authorisation within 30 days.

(6) If, within 90 days, not all the member States have agreed the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human

or animal health or to the environment, the Secretary of State (if the United Kingdom is the reference member State) must send a detailed statement of the reasons to the other member States involved in the application, the applicant, and the coordination group to act in accordance with Article 33(3) of Directive 2001/82/EC.

(7) If reference has been made to the coordination group by any member State, the Secretary of State must within 30 days comply with the decision of the coordination group or, if the coordination group refers the matter to the Agency, the decision of the Commission.

(8) If the Secretary of State wishes to do so, he may grant the marketing authorisation even though not all member States have agreed to grant it, but must revoke or vary the authorisation if this is necessary to comply with the decision of the Commission when it is received.