

SCHEDULE 1

Marketing authorisations

PART 4

Variations of marketing authorisations on the application of the holder

Administrative variations

35.—(1) The holder of a marketing authorisation may apply for a minor change in a marketing authorisation to be made without the Secretary of State considering any scientific data (an “administrative variation”).

(2) If the Secretary of State grants an administrative variation, and subsequently establishes that this should have been a variation requiring consideration of scientific data, she shall notify the marketing authorisation holder, require him to submit an application for a variation enabling data to be assessed and revoke the administrative variation.