

## SCHEDULE 2

### CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS TO, MARKETING AUTHORIZATIONS, LICENCES, AUTHORISATIONS, REGISTRATIONS AND CERTIFICATES

#### PART 6

##### Capital Fees for Regulatory Assistance Given by the United Kingdom Acting as Reference Member State Relating to the Assessment of Applications for the Renewal of Specified Marketing Authorizations

###### **Regulatory assistance**

**51.** Unless paragraph 52 applies, the fee payable under regulation 26(1) in connection with regulatory assistance provided by the United Kingdom acting as reference Member State where an application is made to the licensing authority for the renewal of a United Kingdom marketing authorization in relation to a medicinal product which has been subject to the procedures specified in regulation 26(2), is—

- (a) £10,465 if the application for renewal relates to a medicinal product which, at the time the United Kingdom marketing authorization was granted, contained a new active ingredient and that renewal is the first renewal in relation to which the United Kingdom is to provide regulatory assistance acting as reference Member State; or
- (b) £807 in any other case.

###### **Regulatory assistance – same manufacturer**

**52.—(1)** This paragraph applies if more than one application falling within regulation 26(1) is made by the same applicant at the same time, each of which relates to medicinal products which have the same active ingredient or combination of ingredients, dosage form, therapeutic indications and Periodic Safety Update Reports, and the United Kingdom marketing authorizations for those products have the same date for renewal.

(2) The fee payable under regulation 26(1) for applications to which sub-paragraph (1) applies is—

- (a) if the applications fall within paragraph 51(a)—
  - (i) £10,465 for the first application considered by the licensing authority; and
  - (ii) £807 for each other application;
- (b) if the applications fall within paragraph 51(b)—
  - (i) £807 for the first application considered by the licensing authority; and
  - (ii) £405 for each other application.