STATUTORY INSTRUMENTS

2013 No. 532

The Medicines (Products for Human Use) (Fees) Regulations 2013

PART 6

Capital Fees for Assessment of Labels and Leaflets

Fees for assessment of a set of proposed changes to labels and leaflets

24.—(1) Unless paragraph (2) applies, where—

(a) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a United Kingdom marketing authorisation (other than a parallel import licence) is submitted to the licensing authority in accordance with Article 61(3) of the 2001 Directive; or

(b) a set of proposed changes to the labelling or the package leaflet of a medicinal product which is the subject of a parallel import licence is submitted to the licensing authority,

the fee payable by the holder of that authorisation or licence is the fee prescribed in Part 5 of Schedule 2 in connection with that change.

(2) Paragraph (1) does not apply where a change to the labelling or package leaflet of a medicinal product is proposed in connection with an application for the variation of the marketing authorisation for that product.