STATUTORY RULES OF NORTHERN IRELAND

2012 No. 134

The Medicines (Products for Human Use) (Fees) Regulations 2012

PART 6

Capital Fees for Assessment of Labels and Leaflets

Meaning of "set of proposed changes"

21. For the purposes of this Part and Part 5 of Schedule 2, a "set of proposed changes" means a number of proposed changes to the labelling or package leaflet of a medicinal product, where—

(a) if there is more than one version of the labelling or package leaflet for that product, those changes all relate to the same version; and

(b) those changes are submitted to the licensing authority at the same time.

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

22.—(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 authorization (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 authorization 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 authorization for that product.

Time for payment of fees under regulation 22

23. All sums payable by way of fees under regulation 22(1) must be paid by the time that the proposed changes are submitted to the licensing authority.