
STATUTORY INSTRUMENTS

2016 No. 190

The Medicines (Products for Human
Use) (Fees) Regulations 2016

PART 6

Capital Fees for Assessment of Labels and Leaflets

Meaning of “set of proposed changes”

24. 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.