

SCHEDULE 7

STANDARD PROVISIONS FOR MANUFACTURING AUTHORISATIONS

PART 2

PROVISIONS WHICH MAY BE INCORPORATED IN AN AUTHORISATION RELATING TO THE MANUFACTURE OR ASSEMBLY OF INVESTIGATIONAL MEDICINAL PRODUCTS

6. The holder of the authorisation shall—
 - (a) inform the licensing authority before making any material alteration in the premises or plant used under his authorisation, or in the operations for which they are used; and
 - (b) inform the licensing authority of any change that he proposes to make in any personnel named in his authorisation as respectively—
 - (i) responsible for supervising the production operations, or
 - (ii) responsible for quality control of the investigational medicinal products being manufactured or assembled including the person named as the qualified person for the purposes of regulation 43 and paragraph 14.