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

3. The holder of the authorisation shall place the quality control system referred to in Article 11(1) of Commission Directive 2003/94/EC under the authority of the person notified to the licensing authority in accordance with paragraph 6(3) of Schedule 6 as being responsible for quality control.