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

5. The holder of the authorisation shall provide such information as may be requested by the licensing authority for the purposes of these Regulations or the Act—

(a) about the products currently being manufactured or assembled under his authorisation; and

(b) of the operations being carried out in relation to such manufacture or assembly.