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

13. The holder of the authorisation, for the purpose of enabling the licensing authority to ascertain whether there are any grounds—

(a) for suspending, revoking or varying any authorisation or licence granted under these Regulations or Part II of the Act;

(b) amending the clinical trial authorisation in accordance with regulation 23 or 24; or

(c) suspending or terminating any clinical trial in accordance with regulation 31,

shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the holder of the authorisation, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for an authorisation or licence.