

## SCHEDULE 6

### PARTICULARS THAT MUST ACCOMPANY AN APPLICATION FOR A MANUFACTURING AUTHORISATION

6.—(1) The name and address and qualifications and experience of the qualified person who is to carry out the duties referred to in regulation 43(2).

(2) In the case of an authorisation relating to manufacture or assembly, the name and qualifications and experience of the production manager or other person whose duty it will be to supervise the production operations at each of the premises referred to in paragraph 4 of this Schedule, and the name and function of the person to whom he is responsible.

(3) In the case of an authorisation relating to manufacture or assembly—

- (a) the name and degrees, diplomas or other qualifications and experience of the person to be in charge of quality control over all the premises referred to in paragraph 4 of this Schedule;
- (b) the extent of the authority to be delegated to him to reject unsatisfactory batches of investigational medicinal products, and
- (c) the name and function of the person to whom he is responsible.