SCHEDULE 6

PARTICULARS THAT MUST ACCOMPANY AN APPLICATION FOR A MANUFACTURING AUTHORISATION

9. A description of the arrangements—

(a) for maintaining production or importation records;

(b) for maintaining records of analytical and other testing procedures applied in the course of manufacture, assembly or importation for ensuring compliance of materials used in the manufacture of any investigational medicinal products with the specification of such materials or medicinal products; and

(c) for keeping reference samples of materials used in the manufacture of any investigational medicinal products and of the investigational medicinal products.