SCHEDULE 3

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES, TOXINS OR SERA

PART 1

STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES

7. Without prejudice to any other requirements to keep records, where vaccines contain or might contain micro-organisms or microbial toxins, the licence holder shall keep a durable record, readily available for inspection by a person authorised by the licensing authority, of the origin, properties and characteristics of the cell cultures used in the production of those vaccines and shall ensure that that record is not destroyed for a period of five years from the date when the relevant production occurred.