SCHEDULE 3

OFFENCES, PENALTIES ETC.

Offences

10. Any person who, while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Chapter 3 of Title II of Council Regulation (EEC) No. 2309/93, or Chapter Va of Council Directive 75/319/EEC fails to—

(a) establish or maintain a system for collecting and collating information about suspected adverse reactions;

(b) prepare for the licensing authority a report on any such reactions; or

(c) ensure that a request from the licensing authority for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a relevant medicinal product is answered fully and promptly,

as required by any provision of any such Chapter, shall be guilty of an offence.