SCHEDULES

SCHEDULE 9

Undertakings by non-EEA manufacturers

11.—(1) The manufacturer must implement a system for recording and reviewing complaints in relation to medicinal products to which a marketing authorisation relates, together with an effective system for recalling promptly and at any time the medicinal products in the distribution network.

(2) The manufacturer must record and investigate all complaints described in sub-paragraph (1) and must immediately inform the licensing authority of any defect which could result in a recall from sale, supply or export or in an abnormal restriction on such sale, supply or export.