SCHEDULE 9

Amendment of the General Product Safety Regulations 2005

**Amendment of regulation 33**

**6.**—(1) Regulation 33 is amended as follows.

(2) In the heading, omit "and Commission".

(3) At the beginning insert—

"(A1) The Secretary of State must establish and operate a database containing information relating to market surveillance and product safety.".

(4) Before paragraph (1) insert—

"(B1) The database referred to in paragraph (A1) must be designed so as to enable notifications required under paragraph (1), (2) or (4), or under Article 22 of Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, to be made to the Secretary of State through the database.".

(5) For paragraph (1), substitute—

"(1) An enforcement authority which has received a notification of a risk under regulation 9(1) shall immediately notify the Secretary of State of the risk through the database referred to in paragraph (A1).".

(6) In paragraph (2), after "Secretary of State", in the first place it occurs, insert "of the action taken through the database referred to in paragraph (A1)";

(7) Omit paragraph (3).

(8) In paragraph (4)—

(a) for "pharmaceutical" substitute "medicinal";

(b) after "Secretary of State", in the first place it occurs, insert "of the measure or action taken through the database referred to in paragraph (A1)"; and

(c) after "withdrawal of any such measure or action" insert "through the database referred to in paragraph (A1).

(9) Omit paragraphs (5) to (9).

(10) For paragraph (10)(b), substitute—

"(b) "medicinal product" has the meaning given to it in regulation 2 of the Human Medicines Regulations 2012(**1**).".

(**1**) S.I. 2012/1916, to which there are amendments not relevant to these Regulations.