

SCHEDULE 34

Amendment of Regulation (EC) No 1223/2009 and related amendments

Amendment of Article 23

21. In Article 23 (communication of serious undesirable effects)—

(a) in paragraph 1—

(i) for “competent authority” substitute “Secretary of State”;

(ii) omit the words from “of the Member State” to “occurred”;

(b) in point (a) for “him”—

(i) in the first place in which it occurs substitute “the responsible person or the distributor”;

(ii) in the second place in which it occurs substitute “that responsible person or distributor”

(c) in point (c) for “him” substitute “that responsible person or distributor”;

(d) for paragraph 2 substitute—

“**2.** The Secretary of State must immediately inform all other competent authorities of any information notified to the Secretary of State under paragraph 1.”;

(e) for paragraph 3 substitute—

“**3.** Where a distributor reports serious undesirable effects of a cosmetic product to the Secretary of State, the Secretary of State must immediately inform the responsible person.”;

(f) for paragraph 4 substitute—

“**4.** Where end users or health professionals report serious undesirable effects of a cosmetic product to any competent authority that is not the Secretary of State, that competent authority must immediately inform the Secretary of State who must then immediately inform the responsible person.

Where end users or health professionals report serious undesirable effects of a cosmetic product to the Secretary of State, the Secretary of State must immediately inform all other competent authorities and the responsible person.”.