

## SCHEDULE

Regulation 40

### Amendments to Regulation (EC) No 469/2009

#### Interpretation of Schedule

1. In this Schedule, a reference to an Article, paragraph, point or Annex is to that of Regulation (EC) No 469/2009.

#### Article 1: definitions

2. In Article 1, in relation to the definition of “maker”—
- (a) for “Union”, substitute “United Kingdom”;
  - (b) omit “third”;
  - (c) after “countries”, insert “outside the United Kingdom, the Isle of Man and the Member States of the European Union”; and
  - (d) renumber that definition as paragraph (k) and insert after the definition of “UK authorisation(1)”.

#### Article 5: effects of the certificate

3. In Article 5—
- (a) in paragraph 2(a)—
    - (i) in point (i)—
      - (aa) omit “third”; and
      - (bb) after “countries”, insert “outside the United Kingdom, the Isle of Man and the Member States of the European Union”;
    - (ii) in point (ii), for “Union”, substitute “United Kingdom”;
    - (iii) in point (iii)—
      - (aa) for “Member State of making”, substitute “United Kingdom”;
      - (bb) for “Member States”, substitute “the United Kingdom, the Isle of Man or one or more Member States of the European Union”;
    - (iv) in point (iv), for “Union”, substitute “United Kingdom”;
  - (b) in paragraph 2(b)—
    - (i) for “authority” to “take place”, substitute “comptroller”;
    - (ii) for “that Member State”, substitute “the United Kingdom”;
    - (iii) for “a”, where it appears before the last occurrence of “certificate”, substitute “that”;
  - (c) in paragraph 2(c), for “authority referred to in Article 9(1)”, substitute “comptroller”;
  - (d) in paragraph 2(d)—
    - (i) omit “third”;
    - (ii) after “countries”, insert “outside the United Kingdom, the Isle of Man and the Member States of the European Union”;
    - (iii) for “a logo, in the form set out in Annex -I, is affixed”, substitute “the words ‘UK export’ are affixed so as to be sufficiently clear and visible to the naked eye”;

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(1) The definition of “UK authorisation” is inserted by [S.I. 2019/801](#).

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

- (e) in paragraph 2(e), omit from “and” to the end of the sentence;
- (f) in paragraph 3, for “Union”, substitute “United Kingdom”;
- (g) in paragraph 5—
  - (i) omit point (c);
  - (ii) in point (d), omit from “granted” the first time it appears to “making” the second time it appears;
  - (iii) in point (e)—
    - (aa) omit “third”, both times it appears;
    - (bb) after “countries”, insert “outside the United Kingdom, the Isle of Man and the Member States of the European Union”;
- (h) in paragraph 6—
  - (i) for “authority”, substitute “comptroller”;
  - (ii) for “contained in Annex -Ia”, substitute “prescribed by rules made under section 123 of the Patents Act 1977”;
- (i) in paragraph 7—
  - (i) omit “third”;
  - (ii) after “country”, the first time it appears, insert “outside the United Kingdom, the Isle of Man and the Member States of the European Union”;
- (j) omit paragraph 8, including its footnote;
- (k) after paragraph 10, insert—

“11. The Secretary of State may by regulations make further provision as to the manner and form (including design and colour) of affixing the words “UK export” to the outer packaging of the product, or the medicinal product containing that product, referred to in paragraph 2(a)(i) of this Article, and, where feasible, to its immediate packaging.

12. Those regulations are to be made by statutory instrument which is subject to annulment pursuant to a resolution of either House of Parliament.”.

#### **Article 11: publication**

- 4. In Article 11(4)—
  - (a) for “authority referred to in Article 9(1)”, substitute “comptroller”;
  - (b) for “It”, substitute “The comptroller”.

#### **Article 21a: evaluation**

- 5. Omit Article 21a.

#### **Annex -I and Annex -I: logo and standard form**

- 6. Omit Annex -I and Annex -Ia.