SCHEDULE 1

Marketing authorisations **[**F1in Great Britain**][**F2in Northern Ireland**]**

Textual Amendments

F1 Words in Sch. 1 heading inserted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(7)(a)**

F2 Words in Sch. 1 heading inserted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(13)(a)**

PART 7

Labelling and package leaflets

Approval by the Secretary of State

45. The Secretary of State, when issuing a marketing authorisation, must approve all containers, packaging, labels and package leaflets.

Reference to being authorised E+W+S

46. A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words "UK authorised veterinary medicinal product" or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in the United Kingdom.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Reference to being authorised N.I.

46. A label and package leaflet of an authorised veterinary medicinal product may contain in legible characters the words "**[**F4UK(NI)**]** authorised veterinary medicinal product" or, if the marketing authorisation provides, other wording specified in the authorisation indicating that the product is authorised in **[**F5Northern Ireland**]**.

Extent Information

E3 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F4 Word in Sch. 1 para. 46 substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(13)(i)(i)**

F5 Words in Sch. 1 para. 46 substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(13)(i)**(ii)

Language

47.—(1) All labels and package leaflets must be in English, but may contain other languages provided that the information given is identical in all the languages.

(2) This requirement does not apply in the case of a product imported by a veterinary surgeon and administered by or under the responsibility of that same veterinary surgeon.

Labelling with all the information on the immediate packaging E+W+S

48.—(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters—

(a) the name, strength and pharmaceutical form of the veterinary medicinal product;

(b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and, if appropriate, "To be supplied only on veterinary prescription";

(g) the contents by weight, volume or number of dose units;

(h) the marketing authorisation number;

(i) the name and address of the marketing authorisation holder **[**[F3], the local representative designated under paragraph 18 of this Schedule**]** or, if there is a distributor authorised in the marketing authorisation, that distributor;

(j) a suitably labelled space to record discard date (if relevant);

(k) the target species;

(l) the distribution category;

(m) the words "Keep out of reach of children";

(n) storage instructions;

(o) the in-use shelf-life (if appropriate);

(p) for food-producing species, the withdrawal period for each species or animal product concerned;

(q) any warning specified in the marketing authorisation;

(r) disposal advice;

(s) full indications;

(t) dosage instructions;

(u) contra-indications;

(v) further information required in the marketing authorisation;

(w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.

(2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F3 Words in Sch. 1 para. 48(1)(i) inserted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(7)(b)**

Labelling with all the information on the immediate packaging N.I.

48.—(1) If it is reasonably practicable to do so, the following must be provided on the immediate packaging, in legible characters—

(a) the name, strength and pharmaceutical form of the veterinary medicinal product;

(b) the name and strength of each active substance, and of any excipient if this is required under paragraph 2 of the summary of product characteristics;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and, if appropriate, "To be supplied only on veterinary prescription";

(g) the contents by weight, volume or number of dose units;

(h) the marketing authorisation number;

(i) the name and address of the marketing authorisation holder or, if there is a distributor authorised in the marketing authorisation, that distributor;

(j) a suitably labelled space to record discard date (if relevant);

(k) the target species;

(l) the distribution category;

(m) the words "Keep out of reach of children";

(n) storage instructions;

(o) the in-use shelf-life (if appropriate);

(p) for food-producing species, the withdrawal period for each species or animal product concerned;

(q) any warning specified in the marketing authorisation;

(r) disposal advice;

(s) full indications;

(t) dosage instructions;

(u) contra-indications;

(v) further information required in the marketing authorisation;

(w) if the product is one that requires a dose to be specified for the animal being treated, a space for this.

(2) If all this is on the immediate packaging, there is no need for any outer packaging or a package leaflet.

Extent Information

E4 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Products with immediate and outer packaging

49.—(1) If it is not reasonably practicable to have all the required information on the immediate packaging then this paragraph applies.

(2) The immediate packaging must have at least the following information—

(a) the name of the veterinary medicinal product, including its strength and pharmaceutical form;

(b) the name and proportion of each active substance, and of any excipient if knowledge of the excipient is needed for safety reasons;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription";

(g) the words "Keep the container in the outer carton".

(3) In addition, the immediate packaging must have as much of the required information as is reasonably practicable.

(4) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product in accordance with the following paragraph.

Package leaflets

50.—(1) If it is not reasonably practicable to have all the required information on the immediate packaging or all of this information on the outer packaging, there must be a package leaflet supplied with the product, containing all the required information except for the batch number and the expiry date, and including the name of both the marketing authorisation holder and, if different, the name of the distributor named in the marketing authorisation.

(2) If there is a package leaflet, the immediate packaging and the outer packaging must both refer the user to it.

(3) A package leaflet must relate solely to the veterinary medicinal product with which it is included.

(4) It must be written in plain English.

(5) Only a package leaflet approved in the marketing authorisation may be included with the veterinary medicinal product.

Ampoules

51.—(1) In the case of ampoules or other unit dose forms, where the container cannot bear legibly the required information, only the following information must be shown on the immediate packaging—

(a) the name of the veterinary medicinal product;

(b) the name and strength of the active ingredient;

(c) the route of administration (if not immediately apparent);

(d) the batch number;

(e) the expiry date;

(f) the words "For animal treatment only" and if appropriate, "To be supplied only on veterinary prescription".

(2) The outer packaging must contain all the required information if it is reasonably practicable to do this, and if it is not reasonably practicable to do this a package leaflet must be supplied with the product, except that the ampoule need not refer to the package leaflet.

Small containers other than ampoules

52. As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the required information, all the required information must appear on the outer packaging or outer packaging and package leaflet, but the immediate packaging must be labelled with the batch number and the expiry date and, if there is room, the other information in the preceding paragraph.

Homeopathic remedies

53.—(1) A homeopathic remedy registered under these Regulations must be labelled in accordance with this paragraph.

(2) There must be no specific therapeutic indication on the labelling or in any information relating to it.

(3) The labelling (or labelling and package leaflet) must contain the following and no other information—

(a) the words "homeopathic remedy without approved therapeutic indications for veterinary use";

(b) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the pharmacopoeia used (if the homeopathic remedy is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks);

(c) the name and address of the registration holder and (on the package leaflet) of the manufacturer;

(d) the method and, if necessary, route of administration;

(e) the expiry date;

(f) the pharmaceutical form;

(g) the contents of the pack;

(h) any special storage precautions;

(i) the target species;

(j) any necessary special warnings;

(k) the batch number; and

(l) the registration number.

Variations

54. The Secretary of State may permit variations in the above in any individual marketing authorisation if this is necessary for public or animal health purposes or the protection of the environment.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 7.