

---

STATUTORY INSTRUMENTS

---

**1983 No. 1729**

**The Medicines (Labelling) Amendment Regulations 1983**

**Amendment of regulations**

2. The Medicines (Labelling) Regulations 1976(1) shall be amended as follows—
- (a) in regulation 3(1) (interpretation) after the definition of “proprietary designation” there shall be inserted the following definition—
    - ““proprietary medicinal product” and “ready-made veterinary drug” have the same meanings as in sections 7(7) and 8(4) of the Act(2);”;
  - (b) at the end of paragraph 5 of Schedule 1 (standard particulars required in the labelling of containers and packages) there shall be inserted the words “and in the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug, the withdrawal period necessary before an animal which has been treated with the drug is slaughtered for the production of food and before products derived from such an animal are used as food.”;
  - (c) at the beginning of paragraphs 8 and 11 of Schedule 1 there shall be inserted the words “Except in the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug.”;
  - (d) after paragraph 11 of Schedule 1 (as amended) there shall be inserted the following paragraph—
    - (A) In the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug—
      - (a) the name and address of the holder of the product licence which relates to the drug, and
      - (b) if different therefrom, the name and address of the person responsible for the composition of the drug.”;

and

- (e) after paragraph 12 of Schedule 1 there shall be inserted the following paragraph—
  - “13. In the case of a veterinary drug which is a proprietary medicinal product or a ready-made veterinary drug, the species of animal for which the drug is intended and the method and the route of administration.”.

---

(1) relevant amending instrument is S.I. 1977/996.

(2) Sections 7(7) and 8(4) were inserted by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170 and amended by S.I. 1983/1724.