

Medicines (Orphan Drugs) (Exemption) Order

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MEDICINES ACT (CHAPTER 176, SECTION 9)

MEDICINES (ORPHAN DRUGS) (EXEMPTION) ORDER

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G.N. No. S 470/1991

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(31st March 2005)

Citation

1. This Order may be cited as the Medicines (Orphan Drugs) (Exemption) Order.

Definitions

2. In this Order, unless the context otherwise requires —

“advertisement” includes any notice, poster, circular, label, wrapper or document and any announcement made orally or by means of producing or transmitting light or sound;

“hospital” means a private hospital and includes a medical or dental clinic;

“orphan drug” means a medicinal product which —

- (a) has been identified by any doctor or dentist as an appropriate and essential remedy with no effective substitute available for the treatment of any rare disease;
- (b) has not been granted a product licence under the Act; and
- (c) has been approved by the competent health authorities either of the country of the origin or of any other country where the orphan drug has been used;

“rare disease” means a life-threatening and severely debilitating illness affecting less than 20,000 persons.

Importation and supply of orphan drugs

3. The licensing authority may permit any person to import or supply any orphan drug without a product licence if the drug is to be used by a doctor or dentist who has prescribed the drug for the treatment of a patient under his care.

Maintenance of records

- 4.—(1) Every person who is permitted by paragraph 3 to import any orphan drug shall maintain written records which shall include —

- (a) the quantity imported or supplied;
- (b) the date received or supplied; and
- (c) the name and address of the person to whom the drug is supplied.

- (2) All records to be maintained under this paragraph and documents which support