
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (“the principal Regulations”). They provide that holders of wholesale dealer’s licences who import medicinal products for the purpose of sale and supply in specified circumstances where marketing authorisations are not required under The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144) must meet specified requirements. These are equivalent to those imposed on people exempt from the requirement to hold a product licence by virtue of The Medicines (Exemption from Licences) (Importation) Order 1984 (S.I. 1984/673).

The requirements are imposed in a new paragraph 8B of Schedule 3 to the principal Regulations which is inserted by regulation 3(4). Under the new paragraph, holders of wholesale dealer’s licences relating to exempted products (as defined in regulation 2(3) which inserts the new definition into regulation 2(1) of the principal Regulations) must only sell or supply such products in specified circumstances and where they have complied with the provisions set out in regulation 3(4) of these Regulations. The provisions require notification of the licensing authority concerning the importation of the products, record-keeping and set maximum quantities for import.

Under regulation 3(3) (which inserts a new paragraph 8(7A) into Schedule 3), exempted products are also not required to undergo controls carried out by a qualified person.

An assessment of the cost to business has been carried out and these Regulations impose no new costs on business.