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## EXPLANATORY NOTE

These Regulations consolidate, with amendments, the provisions of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1977 and its amending instruments, which are revoked. They also supersede the Medicines (General Sale List) Order 1977 (S.I. 1977/2129) to the extent that that order imposed limits on the pack size of medicinal products on a general sale list.

The provisions consolidated relate to the following matters:—

- (a) requirements as to the safekeeping of certain veterinary drugs, the location of automatic machines for the sale of medicinal products, and the keeping of records by persons lawfully conducting a retail pharmacy business and by certain sellers of veterinary drugs;
- (b) restrictions as to the classes of persons to whom there may be sold prescription only medicines and pharmacy medicines, and exemptions from those restrictions; and
- (c) enforcement by local authorities and the Pharmaceutical Society of sections 53 and 54 of the Medicines Act 1968 (sale of medicinal products on a general sale list and from automatic machines) and enforcement of regulations under section 66 of that Act relating to dealings with medicinal products.

The principal changes made by these regulations in relation to those matters are the removal of a provision whereby certain prescription only medicines could be sold to state registered physiotherapists by way of wholesale dealing, and the inclusion of an exemption from the requirement that a person lawfully conducting a retail pharmacy business keep certain records of sales and supplies of prescription only medicines, when the sale or supply is for the purposes of a drug testing scheme, or in response to certain orders from doctors under National Health Service arrangements in Scotland or Northern Ireland.

Under section 53 of the Medicines Act 1968, medicinal products on a general sale list may be sold or supplied by retail elsewhere than at a registered pharmacy only if certain conditions are fulfilled. These regulations prescribe conditions relating to the quantity of certain such products (both those for human use and veterinary drugs) that may be sold or supplied by retail in any one container or package. The limits imposed are similar to those which subsisted under the Medicines (General Sale List) Order 1977.

Regulation 9 makes it an offence to contravene regulations 3, 4, 6 or 7 of these regulations. A person who contravenes regulation 5 will be guilty of an offence under section 67(2) of the Medicines Act 1968 and a person who contravenes regulation 8 will thereby contravene section 53 of that Act and be guilty of an offence under section 67(5).