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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations replace the Medicines (Medicated Animal Feeding Stuff) Regulations 1988.

The Regulations continue to prohibit a person, in the course of a business carried on by him, from incorporating a medicinal product (which now includes intermediate feed as defined in regulation 2(1)) unless (additionally) it is a licensed product, and it is incorporated in accordance with a product licence, an animal test certificate or a veterinary written directions given by a veterinary surgeon or veterinary practitioner (regulation 3(1)(a) and (b)). In addition, a person can incorporate medicinal products in animal feeding stuffs if he is registered in the Register kept under the Regulations and, subject to specified conditions, intends to export such animal feeding stuffs (regulation 3(1)(c)).

The Regulations continue to prohibit a person, in the course of a business carried on by him, from selling or supplying any animal feeding stuff in which a medicinal product, not being a prescription only medicine (that is to say, a medicinal product which may be sold or supplied by retail only in accordance with a prescription given by a veterinary surgeon or veterinary practitioner), has been incorporated or from importing any such animal feeding stuff unless the medicinal product was incorporated in the animal feeding stuff in accordance with a product licence, an animal test certificate or a veterinary written direction (regulation 4(1) and (2)).

The Regulations continue to prohibit a person, in the course of a business carried on by him, from selling or supplying any animal feeding stuff in which a prescription only medicine has been incorporated or from importing any such animal feeding stuff except in accordance with a veterinary written direction, subject to certain exceptions (regulation 4(3) and (4)).

As medicinal products not licensed for incorporation in animal feeding stuff (or without an appropriate animal test certificate) can no longer be incorporated in animal feeding stuffs pursuant to a veterinary written direction, consequential provisions in respect of the sale or supply of feeding stuffs requiring a certificate of analysis or a certificate of compliance with a monograph have been deleted and the content of the veterinary written direction has been modified.

The Regulations continue to impose detailed requirements relating to registration in the Register, including provision for payment of fees and giving an undertaking to comply with a specified Code of Practice (regulation 1(2) and 6). (The Codes of Practice are priced publications and are available from MAFF Publications, London SE99 7TP). Additionally a defence is available to any person who, having exercised all due diligence, sells, supplies, imports or incorporates a medicinal product in an animal feeding stuff against a forged veterinary written direction (regulation 7).