
EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Prescription Only Medicines (Human Use) Order 1997 (“the principal Order”) which specifies the description and classes of medicines (“prescription only medicines”) which, subject to exemptions specified in the Order, may be sold or supplied only in accordance with the prescription of an “appropriate practitioner”, and may be administered only in accordance with the directions of such a practitioner.

Article 2 substitutes a revised Article 12 of the principal Order, so as to extend the exemption from section 58(2)(a) of the Medicines Act 1968 for the sale or supply of a prescription only medicine in the course of the business of a hospital for the purpose of being administered in accordance with written directions, to cases where the directions are given by any appropriate practitioner (other than veterinary surgeons and veterinary practitioners). It also provides that where conditions apply as to the cases or circumstances in which an extended formulary nurse prescriber or a supplementary prescriber may give a prescription, those conditions also apply in relation to the written directions given by those prescribers in accordance with the exemption.

Article 3 amends Schedule 3A to the principal Order so as to change the permitted use or route of administration for the following substances, when prescribed or administered by an extended formulary nurse prescriber: erythromycin (to include oral use), fusidic acid (to extend to all external uses), hycosine butylbromide (to include transdermal administration), hycosine hydrobromide (to remove transdermal administration), metronidazole (to include rectal administration), prednisolone sodium phosphate (to include oral use). Article 3 also adds to the list of substances which may be prescribed by extended formulary nurse prescribers, subject to certain conditions, the following substances: amitriptyline hydrochloride, azithromycin dihydrate, carbamazepine, clavulanic acid, conjugated oestrogens (equine), diclofenac potassium, diclofenac sodium, erythromycin ethyl succinate, erythromycin stearate, estradiol, estriol, etonogestrel, flumazenil, gabapentin, glucagon hydrochloride, glucose, imipramine hydrochloride, lignocaine hydrochloride, lymecycline, nortriptyline hydrochloride, prednisolone, salbutamol sulphate, sodium fusidate, terbutaline sulphate.

Article 4 amends Part III of Schedule 5 of the principal Order so as to add diamorphine and morphine to the list of substances that may be parenterally administered by registered midwives.

A Regulatory Impact Assessment in relation to this Order has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.