List of active substances (or combinations of active substances) which HPRA can consider switching from POM to OTC – July 2014

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Substance(s)	Indication for Over the Counter Sale or Supply	Conditions Maximum Strength (MS) / Maximum Pack Size (MPS) / Maximum Period of Treatment (MPT) / Maximum Dose (MD) / Maximum Daily Dose (MDD) / Age / Other
Azelastine / Azelastine Hydrochloride	External use: For ophthalmic use for the treatment of seasonal allergic rhinitis and non-seasonal (perennial) allergic conjunctivitis.	0.5 mg/ml (MS) 3.0 mg/6 ml (MPS) For use in adults and children aged 12 years and older.
Diclofenac salts	External use: For local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.	Equivalent of 2.0% of Diclofenac (MS) 30.0 g (MPS) 7 Days (MPT) For use in adults and children aged 12 years and older
Felbinac	External use: For local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.	3.17% (MS) 30 g (MPS) 7 Days (MPT) For use in adults and children aged 12 years and older.
Penciclovir	External use: For the treatment of herpes simplex virus infections of the lips and face (Herpes labialis).	1% (MS) 2 g (MPS) For use in adults and children aged 12 years and older.
Rabeprazole / Rabeprazole Sodium	Oral use: For short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation).	10 mg (MS) 14 tablets (MPS) 4 weeks (MPT) For use in adults.

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Sumatriptan	Oral use: For the acute relief of migraine attacks, with or without aura, in patients who have a stable well established pattern of symptoms.	50 mg (MS) 2 tablets (MPS) 1 Day (MPT) 50 mg (MD) 100 mg (MDD) For use in adults aged 18 to 65 years. Pharmacist supply of sumatriptan should be made in accordance with a common dispensing guideline.
Tioconazole	External use: For the topical treatment of nail infections due to susceptible fungi (dermatophytes and yeasts) and bacteria.	28 % w/w (MS) 12 ml (MPS) After a 3-month use without improvement, a doctor should be consulted.
Triamcinolone	External use: For the treatment of symptoms of seasonal and perennial allergic rhinitis.	55 mcg per actuation (MS) 220 mcg (110 mcg per nostril) (MD) 220 mcg (110 mcg per nostril) (MDD) 3 months (MPT) For use in adults.
Combination of Clotrimazole / Hydrocortisone	External use: Topical treatment of skin infections by organisms sensitive to clotrimazole where co-existing symptoms of inflammation necessitate topical treatment with a combination of a corticosteroid and an antifungal. Once the inflammatory symptoms have disappeared, treatment can be continued with clotrimazole cream.	30 g (MPS) 7 Days (MPT) For use in adults and children aged 12 years and older.

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Combination of Miconazole / Hydrocortisone	External use: Topical treatment of skin infections by organisms sensitive to miconazole where co-existing symptoms of inflammation necessitate topical treatment with a combination of a corticosteroid and an antifungal. Once the inflammatory symptoms have disappeared, treatment can be continued with miconazole cream.	30 g (MPS) 7 Days (MPT) For use in adults and children aged 12 years and older.
Combination of Hydrocortisone / Lidocaine	External use: For the symptomatic relief of anal and perianal pruritis, pain and inflammation such as associated with haemorrhoids, anal fissures or loose stools.	0.2/1.0 % w/w (MS) 30 ml (MPS) For use in adults.
Combination of Urea / Hydrocortisone / Lactic Acid	External use: For use in the management of dermatoses characterised by hyperkeratosis and inflammation.	10.0 /1.0 / 5.0 % w/w (MS) 30 g (MPS) 7 days (MPT) For use in adults and children aged 12 years and older.