IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 01 August 2007

Part 1. Product Information

a)	Title:	Botulinum Toxin
b)	Product Name/Type:	Botox, Dysport & Neurobloc
c)	Reference:	MIMS Publication - August 2007

Part 2. Problem/Issue

a) Problem/Issue:

Botulinum toxins (Types A and B) are proteins produced by the bacterium Clostridium botulinum. These toxins act by preventing release of acetylcholine at the neuromuscular or other cholinergic junctions and produce a reversible partial denervation of the injected muscles or eccrine glands. Botulinum toxins Type A or B are the active substances in three medicinal products authorised for sale in Ireland (Botox, Dysport & Neurobloc). Heathcare professionals are reminded that these products should only be used by physicians with appropriate experience for the approved indications as outlined below: 1. Botox (Type A) is indicated for the management of: Blepharospasm, hemifacial spasm and associated focal dystonias. Cervical dystonia (spasmodic torticollis). Focal spasticity, associated with dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsypatients, two years of age or older. of the wrist and hand in adult post stroke patients. Persistent severe primary hyperhidrosis of the axillae, which interferes with the activities of daily living and is resistant to topical treatment 2. Dysport (Type A) is indicated for the treatment of: -Spasticity of the arm in patients following a stroke. -Dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older -Spasmodic torticollis -Blepharospasm -Hemifacial spasm 3. NeuroBloc (Type B) is indicated for the treatment of cervical dystonia (torticollis). It should be noted that the dosage units for each botulinum toxin product are specific to that product and are not interchangeable with those used to quantify the dose of other botulinum toxin products. The product information for the above-mentioned products has recently been updated to reflect the following important safety information: Serious adverse events related to the distant spread of botulinum toxin, including muscle weakness, dysphagia and aspiration, have been reported very rarely with all botulinum toxin products, some of which had a fatal outcome. There is a need for extreme caution when administering botulinum toxin products to patients with neurological disorders or a history of dysphagia or aspiration. The benefit-risk ratio of botulinum toxin is acceptable when used for approved indications. In order to minimize the risk of serious reactions due to spread of toxin, it is essential that the precautions and warnings and the recommended administration guidance (including the recommendation to use the minimum effective dose and titrate according to individual requirements) is strictly followed, as outlined in the product information. Patients or caregivers should be informed about the risk of spread of toxin and be advised to seek immediate medical care if swallowing, speech or respiratory disorders arise. Healthcare professionals are requested to continue to report any suspected adverse reactions associated with the use of botulinum toxin in the usual way. Adverse reaction report forms can be downloaded from the publications section of the IMB website at www.imb or completed on-line via the Adverse Reaction Form.

Part 3. Keywords

a) Keywords:

botulinum toxin Botox, Dysport & Neurobloc