IRISH MEDICINES BOARD

Notice Information: - Advisory
13 June 2014

Part 1. Product Information

a)	Title:	Safety Advisory Notice on Barium selenate injectables
b)	Product Name/Type:	BVP Barium Selenate Injection 50, VPA 10956/008/002 & BVP Barium Selenate Injection 100, VPA 10956/008/003. Selenate Long Acting 50 mg/ml suspension, VPA 10960/073/001
c)	Product Classification:	Prescription-only medicine
d)	Authorisation Number:	VPA 10956/008/002, 10956/008/003 & 10960/073/001
e)	Authorisation Holder:	BVP Animal Care, Cross Vetpharm Group

Part 2. Target Audience

a)	Target Audience:	Veterinary Practitioners and distributors of veterinary medicines

Part 3. Problem/Issue

a)	Problem/Issue:	Further to a binding decision of the European Commission on 28 March 2014 that the marketing authorisation of all long acting formulations containing barium selenate for injection that are indicated for all food producing species be suspended on the basis that the benefit-risk balance is negative, the marketing authorisations of all products containing the substance in Ireland have been suspended. Please be advised that no new batches of these products will be available in Ireland, until the suspension has been lifted.

Part 4. Background Information

a)	Background Information:	The decision of the European Commission is attached http://ec.europa.eu/health/documents/community-register/html/vo24894.htm The decision follows the outcome of a referral procedure to the European Medicines Agency which led to a scientific evaluation of injectable barium selenate veterinary medicines marketed in the EU which was conducted by the Committee for Medicinal Products for Veterinary Use http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/04/WC500142028.pdf

Part 5. Keywords

a)	Keywords:	Barium selenate, veterinary medicines, referral, suspension