



IRISH MEDICINES BOARD

## Agenda

### New Variations Regulation Information Day 2010

**Date:** 22 January 2010  
**Location:** Crowne Plaza Hotel, Santry, Dublin 9  
**Time:** Registration will take place from 8.30am to 9.30am  
Information Day will begin at 9.30am

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**Session 1: Chairperson: Pat O'Mahony, Chief Executive; IMB**

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**Topic 1: *General Introduction***

**Speaker:** Ann O'Connor, Director of Human Products Authorisation and Registration  
**Time:** 9.30am – 9.40am (10 mins)

**Topic 2: *European Commission (EC) Procedural Guideline & summary of the main procedural changes***

**Speaker:** Larry O'Dwyer, Senior Pharmaceutical Assessor  
**Time:** 9.40am – 10.15am (35 mins)

**Topic 3: *The EC Classification Guideline***

**Speaker:** Mary O'Grady Quality Assessment Manager (Veterinary Medicines); Kevin Blake, Safety Assessment Manager (Human Products Safety Monitoring)  
**Time:** 10.15am-10.50pm (35 mins)

**Q&A session** 10.50am-11.10am (20mins)

**Tea/Coffee:** 11.10am-11.35am

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**Session 2: Chairperson: Ann O'Connor, Director of Human Products Authorisation and Registration**

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**Topic 4: *CMD Best Practice (European aspect) focus on application of variation procedures in MRP, work-sharing, and the article 5 procedure for the classification of 'unforeseen' variations.***

**Speaker:** Dr. Jayne Crowe, Senior Medical Officer  
**Time:** 11.35am – 12.10am (35mins)

**Topic 5: *The role of the European Medicines Agency in the new Variations Regulation***

**Speaker:** Sonia Ribeiro, Regulatory Affairs Advisor, European Medicines Agency  
**Time:** 12.10pm-12.45pm (35mins)

**Q&A session** 12.45pm-1.00pm (15mins)

**Lunch** 1.00pm-2.15pm

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**Session 3: Chairperson: Dr. Mike Morris, Senior Scientific Advisor**

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**Topic 6: *Practical advice on submission of applications (with focus on Do & Tell and Type 1A immediate applications)***

**Speaker:** Conor O'Donovan, Executive Pharmaceutical Assessor  
**Time:** 2.15pm-2.50pm (35mins)

**Topic 7: *Submission of variations to the IMB***

**Speaker:** Kevin Horan, IT Manager  
**Time:** 2.50pm-3.25pm (35mins)

**Topic 8: *Fees for variations***

**Speaker:** Rita Purcell, Director of Finance and Corporate Affairs  
**Time:** 3.25pm-3.35pm (10mins)

**Q&A session** 3.35pm-4.00pm (25mins)

**Close of meeting: *IMB (4.00pm)***  
Pat O'Mahony