HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for HPRA Information Day on Medical Devices

23rd October 2014, 08:30 – 16:00 (07:30 Registration)

(Note: This agenda may be subject to change)

	ITEM	TIME
	Registration from 07:30	
Session 1	**Changing the regulatory environment**	08:30 – 10:45
	Chair – Joan Gilvarry (Director of Human Products Monitoring, HPRA)	
1.1	The Health Products Regulatory Authority	08:30 – 08:50
	Pat O'Mahony (Chief Executive, HPRA)	
1.2	Perspectives on current and future developments for medical devices	08:50 – 10:45
	John Brennan (Director Regulations and Industrial Policy, EUCOMED) *Caroline Conneely (National Decontamination Quality Lead Quality and Patient Safety Division, Health Service Executive)* *Ronnie McDermott, Equipment management, HSE* *Erik Hansson (Deputy Head, Unit B2, DG SANCO, European Commission.* *Mairead McGuinness MEP (Vice-President, European Parliament)* *John Wilkinson (Director of Devices, MHRA, UK)*	
	Wrap up/take home messages	
	Coffee 10:45 – 11:15	
Session 2	**Developing initiatives**	11:15 – 13:00
	Chair – John Lynch (Director of Compliance, HPRA)	
2.1	Life cycle approach to market surveillance of medical devices	11:15 – 11:45
	Lorraine Nolan (Director of Human Products Authorisation and Registration, HPRA)	
2.2	Innovation of medical devices and health products in Ireland	11:45 – 12:05
	Colman Casey, (Director, Health Innovation Hub, University College, Cork)	
2.3	Initiatives on research and innovation by HPRA – current and future	12:05 – 12:25
	Mike Morris, (Director of Scientific Affairs, HPRA)	

	Wrap up/take home messages	25 mins
	Lunch 13:00 – 14:15	
Session 3	**Parallel session 3a – Medical device perspectives in clinical practice**	14:15 – 16:00
	Chair – Joan Gilvarry (Director of Human Products Monitoring, HPRA)	
3a.1	Preparing for the new Regulations for healthcare providers	
	Cathal Brennan (Medical Device Assessor, HPAR Dept, HPRA)	
3a.2	Medical Device safety/vigilance	
	Paddy Murphy (Product Manager, Medical Devices, HPM Dept, HPRA)	
3a.3	HPRA medical device communications	
	Orla Keane (Product Manager, Medical Devices, HPM Dept, HPRA)	
	Wrap up/take home messages	
	Parallel session 3b – Medical device perspectives for industry	14:15 – 16:00
	Chair - Lorraine Nolan (Director of Human Products Authorisation and Registration, HPRA)	
3b.1	Preparing for the new Regulations – responsibilities of economic operators	
	Nicola Hickie (Medical Device Assessor, HPAR Dept, HPRA)	
3b.2	Vigilance reporting – current and future requirements	
	Anne Tobin (Medical Device Vigilance Manager, HPM Dept, HPRA)	
3b.3	Market surveillance activities – HPRA approach	
	Maria Carleton (Operations Manager, HPAR Devices, HPRA) *Paul Moody (Inspector, Compliance Dept, HPRA)*	
	Wrap up/take home messages	