HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for HPRA Webinar Series on Medical Devices and *In Vitro* Diagnostic Medical Devices (IVDs)

Monday 9 November – Friday 13 November, 11:00 am – 12:00 pm daily

Date	Content
9 November	
Session 1.1	Overview of the implementation of the MDR and IVDR
	With the MDR date of application just six months away, the focus of this session will be an update from a speaker from the European Commission on the status of implementation across the MDR and IVDR, including an update on NB designation.
Session 1.2	HPRA status update on national implementation
	The focus of this session will be an overview of the national work in place to ensure effective implementation of MDR and IVDR at national level.
10 November	
Session 2.1	IVDR classification – practical considerations
	With the new IVDR Classification guidance complete, this session will provide an insight into some of the practical considerations for the IVDR classification rules and some key implications for consideration.
Session 2.2	IVDR performance evaluation
	With EU work recommencing in this area, the aim of this session is to call out some of the key requirements for IVDs and performance evaluation.
11 November	
Session 3.1	Economic operators' obligations within the supply chain
	This session will provide a practical overview of economic operators' responsibilities and obligations throughout the supply chain.
Session 3.2	Eudamed and national registration requirements
	This session will provide an update on Eudamed's development. The HPRA will also summarise national registration requirements.

12 November

Session 4.1	HPRA application of market surveillance key activities
	This session will provide an overview of the competent authority perspective on lifecycle market surveillance.
Session 4.2	HPRA remote inspection activities
	This session will cover what to expect from a HPRA remote inspection.
Session 4.3	Distributor pilot inspections
	This session will provide a status update on distributor inspections as well as the key learnings from previous pilot inspections undertaken to date.

13 November

Session 5.1	Sufficient clinical data and equivalence for legacy devices
	This session will provide an update on European Commission Guidance documents MDCG 2020-5 and MDCG 2020-6 concerning sufficient clinical evidence for legacy devices and equivalence.
Session 5.2	Update on clinical work programme for 2021
	This session will outline the work programme of the CIE Working Group for 2020-2021 and the expected deliverables for work packages.