Agenda for HPRA Information Day on Medical Devices

23rd May 2018 (08:15 Registration)

	ITEM	TIME
Session 1		09:00 – 10:30
1.1	Overview of implementation of the new EU device regulations (EUDR)	
	With the entry into force of the new EUDRs we are now in the implementation phase of the two Regulations on medical devices and in vitro *diagnostic medical devices. We aim to provide an overview of the system level issues impacting the implementation of these regulations and provide an update on addressing some of the key challenges at EU and national level.*	
1.2	Transitioning to the new legislation	
	Work is ongoing at EU level to ensure cooperation across the EU network to facilitate an efficient, proportionate and predictable implementation phase. An overview of the work of the implementation taskforce and the transition subgroup will be presented.	
Session 2		11:00 – 12:30
2	Practical impact of the regulations	
	A number of topics will be addressed in this session with regard to the expectations for economic operators, market surveillance, vigilance requirements and Eudamed.	
	Lunch 12:30 – 1:30	
Session 3		1:30 – 2:45
3.1	Classification and Clinical Developments	
	An overview of the process and ongoing work items in train for medical device and IVD classification as well as an update on the implementation of the clinical work items will be provided.	
3.2	Summary of practical considerations	2:45 – 3:00
	Some practical questions regarding preparation for the new regulations will be provided in this session.	
Session 4	Brexit panel discussion	3:00 – 4:00
	Our panel of representatives from the medtech sector and the Department of Foreign Affairs will discuss the challenges and opportunities posed by the UK exit from the EU on the Irish medtech sector. Representatives from Department of Foreign Affairs, Industry, IDA, Enterprise Ireland will discuss some of the key issues raised during the HPRA survey on Brexit and its impact on the Irish medtech sector.	
	Close out of meeting	4:15