EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 September 2024
EMA/415588/2024

Webinar on orphan medical devices

Agenda – 23 September 2024 (14:00 – 16:30 CEST), registration page

Chair: Silvy da Rocha Dias – EMA, Head of Expert Panels and Groups Office

Item	Agenda	Mins
1.	Welcome - Alberto Ganan (EMA); Flora Giorgio (EC)	5′
	PART I **Guidance on the clinical evaluation of orphan medical devices (MDCG 2024-10): General considerations**	
2.	General overview: Orphan device criteria and clinical evaluation considerations Donal O'Connor; Gearóid McGauran (HPRA)	20′
3.	The involvement of the expert panels Peter Bischoff-Everding (EC)	5′
4.	Manufacturers' views on the challenges addressed by the new guidance Jana Russo (MedTech Europe); Ralf Klein (EUROM VI)	10′
5.	Healthcare professionals' views on the application of the new guidance Elena Arbelo (ESC)	10′
6.	Q&A	15′
	Break	5′
	PART II **Guidance on the clinical evaluation of orphan medical devices (MDCG 2024-10): Procedural considerations**	
7.	Notified body activities and responsibilities Rene Bombien (TÜV SÜD); Richard Holborow (BSI)	15′
8.	Involvement of expert panels: advice on orphan device status and clinical evidence • Early advice pursuant to MDR Article 61(2) — Iordanis Sidiropoulos (EMA) — 10′ • Advice to manufacturers and notified bodies in cases where the clinical evaluation is in an advanced stage or completed — Miguel Antunes (EMA) — 10′ • Perspectives from the experts — Tom Melvin (Expert Panels) — 15′ • Submission portal: how to submit a request — Michael Vogl (EMA) — 5′	40′
9.	Q&A	15′
10.	Conclusions - Alberto Ganan (EMA); Flora Giorgio (EC)	10′

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List of speakers

Guest speakers

Donal O'Connor - Health Products Regulatory Authority (HPRA), Clinical Manager Medical Devices

Elena Arbelo – European Society of Cardiology (ESC), Chair of the Advocacy and Quality Improvement Committee – European Heart Rhythm Association (EHRA); Associate Professor Hospital Clínic

Gearóid McGauran - Health Products Regulatory Authority (HPRA), Medical Officer Medical Devices Department

Jana Russo - MedTech Europe, Manager Medical Devices

Ralf Klein – EUROM VI - Medical Technology Committee, Vice-chair; Chair of the RA Forum medical technology SPECTARIS Association; Owner and Managing Director of Radimed GmbH Bochum

Rene Bombien - TÜV SÜD, Chief Medical Officer

Richard Holborow – British Standards Institution (BSI), Global Head of Clinical Compliance

Tom Melvin – Medical Device Expert Panels, Advisor; Associate Professor of Medical Device Regulatory Affairs, School of Medicine, Trinity College Dublin, the University of Dublin

European Commission speakers

Flora Giorgio – European Commission, Head of Unit Medical Devices, SANTE D3

Peter Bischoff-Everding – European Commission, Legal Officer Medical Devices, SANTE D3

European Medicines Agency speakers

Alberto Ganan – European Medicines Agency, Head of Committees and Quality Assurance Department

Iordanis Sidiropoulos – European Medicines Agency, Scientific Officer Expert Panels and Groups Office

Michael Vogl – European Medicines Agency, Scientific Officer Expert Panels and Groups Office

Miguel Antunes – European Medicines Agency, Scientific Officer Expert Panels and Groups Office