Agenda of the 1st Workshop of the EUnetHTA Task Force on HTA and Medical Devices

May 29th, 2018 in Vienna at 8.45- 17.30

Meeting Venue: **Gesellschaft der Ärzte, Frankgasse 8, 1090 Wien**, Room: **Hauptsaal**

Moderated by **Julia Chamova**

8.45-9.15	Registration, welcome coffee	30 min
9.15–9.30	Welcome and introduction to aim of Workshop Claudia Wild, LBI HTA	15 min

Session 1	***From CE marking to patient access*** *Presentations*	60 min
9.30-9.50	The EU legal framework for medical devices: Overview of the two Regulations DG GROW, Vincent Houdry	
9.50-10.10	EU cooperation on HTA beyond 2020 - European Commission Proposal to strengthen EU cooperation on HTA DG SANTE, Ioana Siska	
10.10-10.30	HTA and market access for medical devices: Common ground for evidence generation for market access and reimbursement Stefan Sauerland, IQWiG	
10.30-11.00	Coffee break	30 min

Session 2	***Clinical investigations of MDs and possible link to HTA*** ***Presentations and moderated discussion***	**60 min**
11.00-11.15	Update from the Clinical Investigation and Evaluation Working Group on the guidance and templates under development Tom Melvin, HPRA/Health Products Regulatory Authority	
11.15-11.30	EUnetHTA templates and guidelines Zoe Garrett, NICE	
11.30-12.00	Discussion: Questions of moderator and audience	

Session 3	***Possible synergies between the regulatory and HTA issues in the field of medical devices: European and national examples to learn from.*** *Panel session with 5-minute-inputs and a moderated discussion*	75 min
12.00-12.10	Collaboration between regulators and HTA bodies in UK Mirella Marlow, NICE Graeme Tunbridge, MHRA/Medicines and Healthcare products Regulatory Agency	
12.10-12.20	Collaboration between regulators and HTA bodies in Ireland: Market Surveillance Patricia Harrington, HIQA Tom Melvin, HPRA/Health Products Regulatory Authority	
12.20-12.30	Exploring regulatory-HTA synergies for medical devices – EUnetHTA's role Chantal Belorgey, HAS Jean-Claude Ghislain, ANSM - Direction scientifique et de la stratégie européenne	

12.30-13.15	Moderated panel discussion: How can we use national and European experiences for building synergies between regulatory and HTA issues in the field of medical devices? Questions from the audience	
12.15-13.15	Lunch	60 min

Session 4	***Working with the new regulation: The role and perspective of Notified Bodies: certification, clinical evaluation and implementation, training needs.*** *Panel session with 5-minute-inputs and a moderated discussion*	60 min
14.15-14.25	Authority perspective on the new requirements for Notified Bodies Rainer Edelhäuser, ZLG Central Authority of the Laender for Health Protection Regarding Medicinal Products and Medical Devices, Germany, Current Chair of NBOG	
14.25-14.35	The Notified Bodies perspective Françoise Schlemmer, Director Team NB - the European Association for Medical Devices of Notified Bodies Christine Quinton, responsable pôle de certification G-MED chez LNE Université de Rouen	
14.35-14.45	Building bridges between HTA and Notified Bodies in Spain redETS (Spanish Network of HTA) Leonor Varela, AVALIA-T. Mariá Jesús Carenas Fernández, Head of Products Evaluation Service at the NB area at AEMPS	
14.45-15.15	Moderated panel discussion: 3 questions to the panel and questions from the audience	
15.15-15.45	Coffee break	30 min

Session 5	***Post-market follow-up, registries and possible link to HTA*** *Presentations and moderated discussion*	90 min
15.45-16.00	Post-market follow-up data Vincent Houdry, DG GROW	
16.00-16.15	EUnetHTA WP5B1: Post-launch evidence generation involving existing registries François Meyer, HAS	
16.15-16.30	EUnetHTA WP5B2: A tool to assess registry quality Mirella Marlow, NICE	
16.30-17.15	Discussion: Questions of moderator and audience	

17.15-17.30	Wrap up and outlook to next activities Claudia Wild, LBI HTA	15 min