TOPRA Stakeholder Workshop:
The practical implementation of MDR Article 117 and EMA guidance on 'Drug-Device Combination Products'

MONDAY 02 December	
18.30 – 19.30	Welcome drinks reception

TUESDAY 03 December	
08:45	Welcome
Aim of the meeting: to listen and learn from different perspectives to enable consistent, risk-based approaches to implementation of new legislation across stakeholder groups and wide range of DDCs Session Chairs: Janine Jamieson, EU Editor, IPQ Publications and Liz Baker, Group Manager, Licensing Division, MHRA	
Legislative Background and State of Play Guidance & Resources	
09:00	Introduction Speaker: Janine Jamieson, EU Editor, IPQ Publications, Sweden
09:10	EMA guidance • EMA Q&A Feedback and additional questions being prepared • Training activities within EMA/HMA network on combination products • Advice for applicants from May 2020 Speaker: Ivana Hayes, Seconded National Expert (Regulatory Affairs), European Medicines Agency (EMA), the Netherlands
09:20	Perspective of an assessor involved in Clinical trials and EMA activities • Clinical trials and clinical evidence requirements for DDC products • Implications of regulations and DDC guidance for ATMPs • Innovative technologies Speaker: Ilona Reischl, CAT Vice-chair and Clinical Trials Assessor, Federal Office for Safety in Health Care (BASG), Austria
09:30	QWP/BWP draft guideline on DDCs and MAA • Possible major changes from the draft guidance? • Challenging areas, timelines and interaction with Commission • Advice and reassurance for companies preparing to submit MAAs in 2020 Speaker: Abigail Moran, Senior Pharmaceutical Assessor, MHRA and Rapporteur QWP/BWP, UK
09:40	Notified Body perspective • TEAM-NB update- how many NBs offering NBOp services now/prior to May 2020? • Guidance on data submission expectations to enable Pharma Industry to prepare • Consistency of approach across all NBs, incl. support from MDCG

	Speaker: Julia Frese, co-chair Department Manager, Centre of Combination Products, TÜV SÜD Product Service GmbH and chair Team NB taskforce article 117, Team-NB, Germany
09:50	Panel discussion Discussion and questions focusing on responding to previous presentations Session presenters listed above and additional panellist • Petra van Leeuwen, Project manager, DEKRA Certification BV and chair Team NB taskforce article 117, Team-NB, the Netherlands
10:30	Coffee break
Challenges, preparations and advice - industry perspective	
11:00	Introduction Session chair: Margareth Jorvid, CEO, Regulatory Affairs & Quality Assurance, Methra Uppsala AB, Sweden
11:10	Pharma Industry collaboration perspective • Communications and collaborations to date • Major challenges for big pharma, integral and non-integral delivery devices • Overview of preparations for guidance implementation Speaker: Bjorg Hunter, Regulatory Manager, Devices, GSK, UK
11:25	SME perspective • Developing new products with partners • Major challenges for SMEs • Experience and advice on preparations Speaker: Maren von Fritschen, Director Regulatory Affairs, EUCOPE, Belgium
Reflections on the morning's presentations	
11:40	Panel discussion Discussion and questions focusing on responding to previous presentations and toward potential directions and solutions
12:30	Lunch
Hot Topics: • Content of NBOp • Platform technologies • Variations	
13:30	Introduction Session chair: Mark Chipperfield, Principal Consultant and Director, Corvus Device, UK
13:40	Platform technologies • Working with different platforms – pharma, supplier • Importance of supplier agreements for providing necessary data • EBE/EFPIA position paper Speaker: Andrew Lennard, Reg Affairs CMC, External Engagement & Policy, Amgen

13:55	Variations – substantial changes • Risk based approach based on control strategy for entire DDC • Frequency of variations with devices vs pharma Speaker: Amanda Matthews, Senior Director, Regulatory CMC for Combination Products & Medical Devices, Pfizer, UK
14:10	Content of NBOp: TEAM-NB perspective • Risk- based assessment and experience to date • Expected review of compatibility data by NB vs CA • Relevant ISO standards and international product type guidance (FDA) Speaker: Jon Sutch, Drug/Device Combination Expert, BSI, UK
14:25	Panel discussion Discussion and questions focusing on responding to previous presentations and toward potential directions and solutions Session presenters listed above plus other invited speakers
15:30	Tea break
Stakeholder Discussion and Conclusions	
16:00	Summary of key points – Tim Chesworth, Senior Director Regulatory Affairs - Medical Devices & Combination Products, AstraZeneca, UK
16:10	All speaker panel debate – Towards solutions for smooth implementation
16:50	Wrap-up – Janine, Margareth and Tim and on behalf of TOPRA MedTech SPIN
17:00	Close