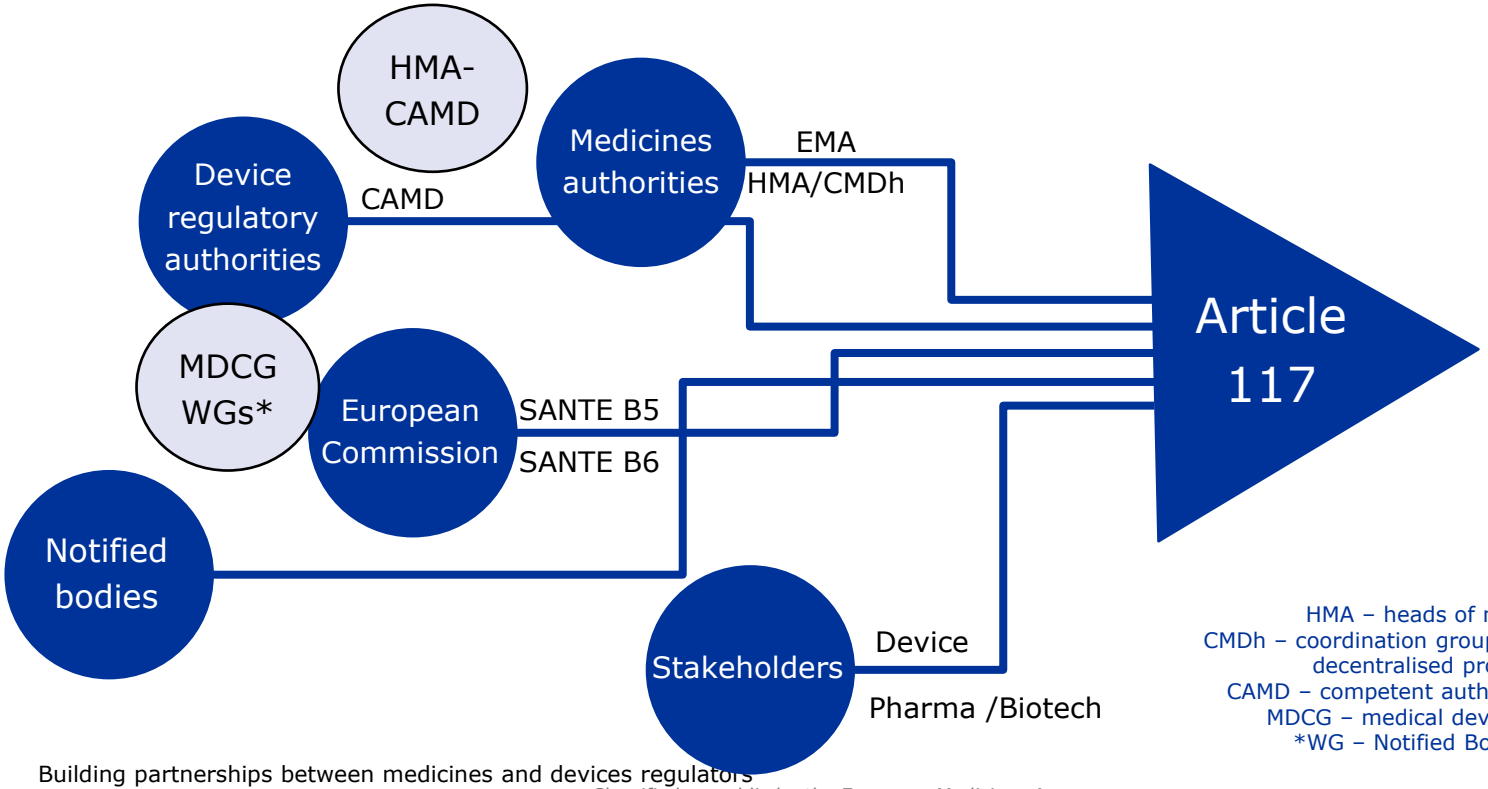
Follow-up on the practical arrangements regarding integrated drug-device combination products

5th industry stakeholder platform for R&D support virtual meeting
16 November 2020

Presented by Armin Ritzhaupt, PhD, MPH
European Medicines Agency

Wide-ranging collaborations for implementation



HMA – heads of medicines agencies
CMDh – coordination group for mutual recognition and decentralised procedures – human
CAMD – competent authorities for medical devices
MDCG – medical device coordination group
*WG – Notified Body Oversight (NBO)

Approach to MDR Article 117 (1/2)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 May 2019
EMA/CHMP/QWP/BWP/259165/2019
Committee for Medicinal Products for Human Use (CHMP)

Guideline on the quality requirements for drug-device combinations

Draft

Core precept:

- **EMA/NCAs:** evaluate device specific aspects relevant to the quality, safety and efficacy of the medicinal product
- **Notified Bodies:** assess the relevant GSPRs

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

21 October 2019 Rev.1
EMA/37991/2019
Human Medicines Evaluation Division

Questions & Answers on Implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)

- Revised set of Q&As under review and discussion with EC/NBO
- Further updates in progress

Approach to MDR Article 117 (2/2)

The European Association Medical Devices - Notified Bodies

Editor : Team-NB	Adoption date : 01/04/2020	Version 1

Team-NB Position Paper

on Documentation Requirements for Drug Device Combination Products

Falling in the Scope of Article 117 of MDR 2017/745.

EBE-EFPIA Position Paper

An Industry Perspective on Article 117 of the EU Medical Device Regulation: Labelling Requirements for Prefilled, Non-Reusable, Integral Drug-Delivery Device Combination Products

Date: 8 August 2019

EBE-EFPIA Reflection Paper

An Industry Perspective on Article 117 of the EU Medical Devices Regulation and the Impact on how Medicines are Assessed

Version 1 of 12 July 2018

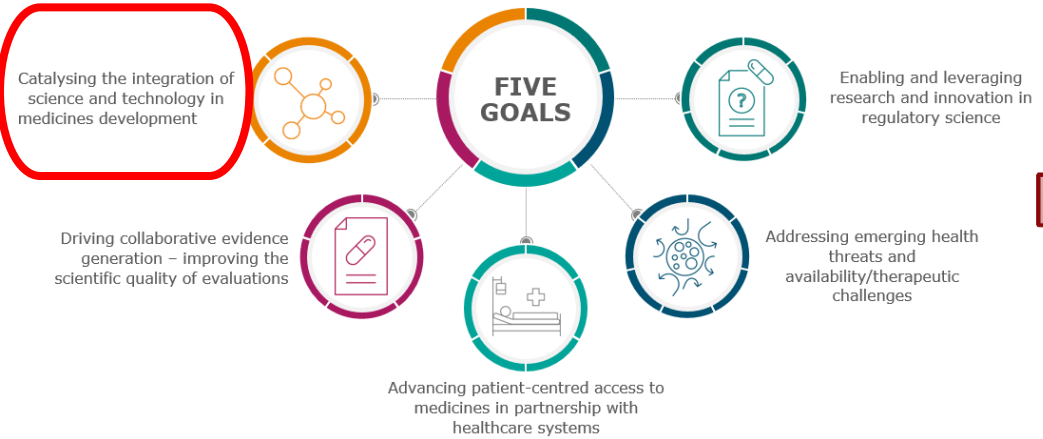
Ongoing guidance development within MDCG Subgroups – October 2020*

*This is not an exhaustive list of ongoing work performed by MDCG subgroups

Scope	Group Deliverables	Consult prior to MDCG**	Planned MDCG Endorsement	Additional Comments
** Stakeholders are observers in 13 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated				
1. Notified Bodies Oversight (NBO)[1]				
MDR + IVDR	*Q&A on requirements notified bodies –new questions to be added to MDCG 2019-6*	Notified bodies	2020	
MDR + IVDR	*Q&A related to MDCG 2020-4*		2020	
MDR+IVDR	*Updates of guidance documents and templates on the designation and re-assessment process*	Notified bodies	2021	
MDR + IVDR	*Updates of guidance documents and templates on qualification and authorisation of personnel*	Notified bodies	2021	
MDR + IVDR	*Guidance on Certifications according to Article 16 MDR/IVDR)*		2021	Jointly with the Market Surveillance WG
MDR	*Guidance on appropriate surveillance according to Article 120(3)*		2021	
MDR	*Guidance on NB opinions on the conformity of the device part according to Article 117 MDR*	B&C		

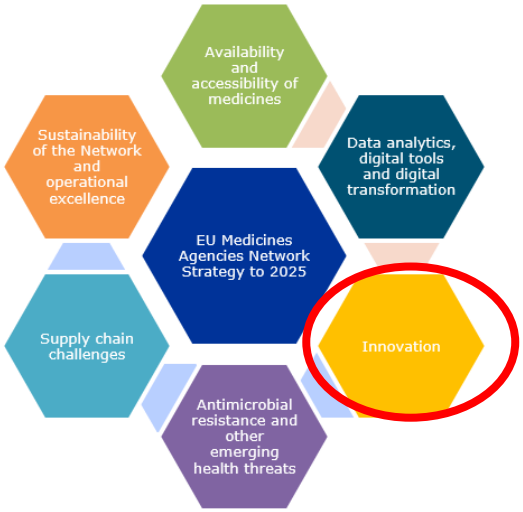
Regulatory Science Strategy and EU Medicines Agencies Network Strategy to 2025

RSS 2025



Unified actions

EMANS 2025



- Strong alliances with experts from medical device authorities and others (Member States, European Commission, EMA, industry associations).
- Better understanding of medical device regulation and their mechanism of actions

Next steps

- **EMA virtual half-day workshop 27 Nov 2020**
  ➔ Focus on Article 117 implementation
- **EMA guidance**:
  - further Q&A updates in agreement with EC/MDCG/MS
  - QWP/BWP guideline anticipate finalisation soon
- **EC-NBO taskforce on combination products**
- Progress RSS / joint network strategy to 2025

EMA's mission

Protect human and animal health

Stimulate and foster EU Innovation

Continue dialogue with all involved stakeholders

Thank you for your attention

Further information

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