

Ongoing Guidance development within MDCG Subgroups – October 2019*

**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
<i>** Stakeholders are observers in 11 MDCG subgroups and are consulted on a regular basis; further to that other MDCG subgroups are consulted as indicated</i>				
1. Notified Bodies Oversight (NBO)¹				
MDR + IVDR	<i>Q&A on Notified bodies –new questions to be added to the document already published</i>		2020	
MDR + IVDR	<i>Sampling of devices on a representative basis</i>	IVD, UDI, Nomenclature, CIE	2019	
MDR + IVDR	<i>Explanatory note on codes</i>	IVD	2019	
MDR + IVDR	<i>Batch verification on class D IVDs</i>	IVD	TBD	
MDR+IVDR	<i>Significant changes</i>	TBD	TBD	Task force to be set up
MDR	<i>Applicability of clinical evaluation consultation procedure</i>	CIE	TBD	Kick off meeting of the TF on 13/09/2019
2. Standards				
MDR + IVDR	<i>Commission Implementing Decision (Standardisation request)</i>	N/A	2019	

¹ Stakeholders are not part of this group as it covers requirements set out by designating authorities specifically for Notified Bodies; stakeholders are consulted on mature and final drafts.

3. Clinical Investigations and Evaluation (CIE)				
MDR	<i>Clinical Evaluation - Equivalence</i>	NBO	TBD	Currently under extended consultation within the Work Package
MDR	<i>Clinical evidence needed for medical devices previously certified under Directives 93/42/EC and 90/385/EC (legacy medical devices)</i>	NBO	TBD	Currently under extended consultation within the Work Package
MDR	<i>Clinical evaluation assessment report template</i>	NBO	TBD	
MDR	<i>Clinical investigation application</i>	N/A	2019	Input to EUDAMED CIE
MDR	<i>Clinical investigation assessment template</i>	N/A	2019	Input to EUDAMED CIE
MDR	<i>Processes and templates relative to CI and PS Assessments</i>	N/A	2019	Input to EUDAMED CIE
MDR	<i>Template Post-Market Clinical Follow-up Plan</i>	NBO, PMSV	2019	
MDR	<i>Template Post-Market Clinical Follow-up Plan Update</i>	NBO, PMSV	2019	
MDR	<i>SAE reporting EUDAMED requirements - form</i>	N/A	2019	Input to EUDAMED CIE
MDR	<i>Report form for Serious Adverse Events</i>	N/A	2019	Input to EUDAMED CIE
MDR	<i>Process flow for SAE reporting</i>	N/A	2019	Input to EUDAMED CIE
4. Post-Market Surveillance and Vigilance (PMSV)				
MDR + IVDR	<i>Post-Market Surveillance requirements</i>	CIE	TBD	Task Force to be set up

MDR + IVDR	<i>Vigilance requirements</i>	CIE	TBD	Task Force has been set up
MDR + IVDR	<i>Development of harmonised reporting forms for incidents</i>	CIE	TBD	Several Task Forces on-going
5. Market Surveillance (MS)²				
MDR	<i>Class I manufacturers</i>	CIE / PMSV	2019	
MDR + IVDR	<i>Update of PRRC document</i>	TBD	2020	
MDR + IVDR	<i>Authorised Representatives</i>	TBD	2020	Task force has been set up
MRD + IVDR	<i>In-house manufacturers</i>	IVD	TBD	Task force to be set up
6. Borderline & Classification (B&C)				
MDR	<i>Borderline with medicinal products (including general guidance, definitions of pharmacological, immunological and metabolic means of action and diagnosis, and consultation procedures of medicines authorities)</i>	NBO	TBD	
MDR	<i>Classification of medical devices</i>	NBO / NET	TBD	NET involved in drafting sections of the document
7. New Technologies				
MDR + IVDR	<i>Clinical Evaluation of Software</i>	CIE+IVD	2019	
MDR + IVDR	<i>Cybersecurity of Software</i>	N/A	TBD	

² Stakeholders are not part of this group as it covers requirements set out by competent authorities; stakeholders are consulted on mature and final drafts.

8. EUDAMED				
9. Unique Device Identification (UDI)				
MDR + IVDR	<i>Integration of UDI in manufacturers' QMS</i>	N/A	2019	
MDR + IVDR	<i>Guidelines on specific product types (contact lenses)</i>	N/A	2019	Part of bilateral cooperation with US
MDR + IVDR	<i>Formats of AICD and HRI parts of UDI carriers</i>	N/A	N/A	To be available and published by Oct 2019
MDR + IVDR	<i>List of values for certain data fields (clinical size + warnings and contraindications)</i>	CIE + IVD	N/A	
10. International Matters				
MDR + IVDR	<i>Taking into account MDSAP for NB</i>	NBO	TBD	
11. In vitro Diagnostic Medical Devices (IVD)				
IVDR	<i>Classification of IVDs</i>	BC, NBO	2019	
IVDR	<i>Performance evaluation</i>	CIE	TBD	
IVDR	<i>SSP template and guidance</i>	CIE	TBD	
IVDR	<i>Transfer of CTS to CS</i>	N/A	TBD	
IVDR	<i>Development of common specifications</i>	N/A	TBD	

IVDR	<i>Qualification of assays used in clinical trials of medicinal products</i>	N/A	TBD	In collaboration with competent authorities for medicinal products
12. Nomenclature				
MDR + IVDR	<i>Information package on EMDN (for website)</i>	N/A	N/A	To be published by Q4 2019
MDR + IVDR	<i>Rules and process for update of EMDN</i>	N/A	2019	
MDR + IVDR	<i>1st release of EMDN</i>	N/A	TBD	
MDR + IVDR	<i>Mapping CND-GMDN package</i>	N/A	N/A	To be possibly finalised by 2020 Q2. The outcome of this exercise is highly dependent on level of cooperation ensured by GMDN
MDR + IVDR	<i>Translation of EMDN</i>	N/A	TBD (validation)	Experts from MS; might be conducted by the translators in the course of the translation exercise
MDR + IVDR	<i>List of EMDN terms to be used for implant card purposes</i>	UDI	2019	
13. Annex XVI³				
MDR	<i>Qualification of devices listed in Annex XVI</i>	TBD	TBD	

³ Stakeholders are not part of this group as it covers requirements set out by competent authorities; stakeholders are consulted on mature and final drafts. text