Implementation of MDCG position paper MDCG 2022-14

IVD WG meeting

12 October 2023

European Commission

2.2 MDCG 2022-14 – Actions to increase notified bodies' capacities (1/2)

1. Make use of hybrid audits

- MDCG 2022-17 MDCG Position Paper on 'hybrid audits' — completed
- Updated Team-NB position paper on hybrid audits published — completed
- Synergy between the two documents to be ensured by NBCG-Med — on going
- Finalisation of NBCG-Med paper — on going

2. Leveraging evidence from previous assessments conducted under the Directives

- Notified bodies developing a framework for leveraging evidence from previous assessments conducted with regard to requirements under the Directives — on going
- On-going NBO discussion on a first proposal from notified bodies — on going

3. Appropriate surveillance of 'legacy devices'

- MDCG 2022-15 on appropriate surveillance under Article 110 IVDR — completed
- MDCG 2022-4 Rev. 1 on appropriate surveillance under Article 120 MDR — completed
- Further revision of MDCG 2022-4 following adoption of MDR amendment in process — on going

4. Review MDCG guidance documents

- Review of a number of guidance documents on-going or planned, including **MDCG 2019-13 on sampling**, MDCG 2020-3 on MDR significant changes (completed), NBOG BPG 2017-2 on requirements for NB personnel, **MDCG 2020-16 on classification of IVDs**, MDCG 2019-9 and **2022-9 on SS(C)P** — on going

5. EUDAMED machine-to-machine

- 6-12 months after Eudamed's full functionality — planned

2.2 MDCG 2022-14 – Actions to increase notified bodies' capacities (2/2)

6. Foster NBs capacity + Rationalise and streamline NB internal procedures — continuous

- Call on notified bodies to streamline their administrative procedures — planned
- Support to NBCG-Med technical secretariat (founded under EU4Health programme) — on going
- EU4Health action on capacity building of notified bodies and preparedness of manufacturers (NoBoCap) — on going

7. COM Delegated Acts to modify frequency of complete re-assessment of notified bodies

- COM Delegated Regulations amending MDR and IVDR as regards the frequency of complete re-assessments of notified bodies adopted by COM on 1 December 2022 and published on the OJEU on 8 March 2023 — completed

8. Speed-up the assessment, designation and notification process

- MDCG 2022-13 on designation, re-assessment and notification — completed
- Development of templates and forms to support the designation process on-going — on going
- Gaining further momentum in the designation process — on going

9. Add codes to designation of notified bodies

- Lifting limitations/conditions or changes within the codes not qualifying as scope extensions — completed
- Further revision of MDCG 2022-13 to add process concerning changes to the designation — on going

10. Revision of section III.6 of MDCG 2019-6

- MDCG 2019-6 Rev.4 – section III.6 updated — completed

11. Status of MDCG guidance documents

- Distinction between different types of guidance documents — continuous
- Reasonable time to be given to integrate new guidance in the relevant systems and/or to apply them — continuous

2.2 MDCG 2022-14 – Actions to access notified bodies and increase preparedness of manufacturers

12. Make standard fees publicly available and take into account interest of SMEs

- MDCG 2023-2 List of standard fees — completed
- Take into account interest of SMEs (section 1.2.8 of Annex VII MDR / IVDR) — on going

13. Allocate notified bodies capacity for SME manufacturers

- NB analysis of available capacity per codes — on going
- EU4Health action on capacity building of notified bodies and preparedness of manufacturers — on going

14. Call on manufacturers to ensure timely compliance to MDR/IVDR (MDCG 2022-11)

- MDCG 2022-11 under revision for discussion at MDCG in October — continuous

15. Structured dialogue before and during the conformity assessment process

- Exchanges of technical information and regulatory guidance between the notified body and the manufacturer (i.e. on "what nee to be fulfilled") are allowed before (i.e. before application) as well as during the conformity assessment process – clarified by NBO Sub-group — completed
- NWIP to be agreed by NBO on revision of MDCG 2019-6 to provide further clarification to notified bodies and industry , e.g. possible questions to be asked ahead of application submission. — on going

16. Increase preparedness of manufacturers

- EU4Health action on capacity building of notified bodies and preparedness of manufacturers (NoBoCap) – action to be supported by the EEN — on going
- Notified bodies developing common guidelines for manufacturers: BPGs for the Submission of Technical Documentation under MDR and under IVDR available — completed
- Industry associations are invited to promote and ensure awareness of economic operators of the legal requirements — continuous

2.2 MDCG 2022-14 – Other actions to facilitate transition to the Regulations

17. Practical application of Article 61 MDR + certificates subject to conditions

- Preparatory work during summer 2022 – with the involvement of notified bodies — completed
- MDCG TF on certificates subject to conditions working to develop a horizontal framework – notified bodies involved in the work and currently carrying out a dedicated survey on the matter — on going

18. Orphan devices

- Work of MDCG orphan device TF with extended membership to find tailored solutions — on going
- NWIP for MDCG endorsement: Guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the MDR
- Orphan devices support programme, focussed on paediatrics – action funded under EU4Health 2023 programme — planned

19. Consultation of medicines authorities

- Call on medicines authorities to accept and efficiently process consultations — continuous