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Status on implementation of MDR

Helena Dzojic
Head of department for medical devices
Swedish Medical Products Agency

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Disclaimer….

Work in progress!

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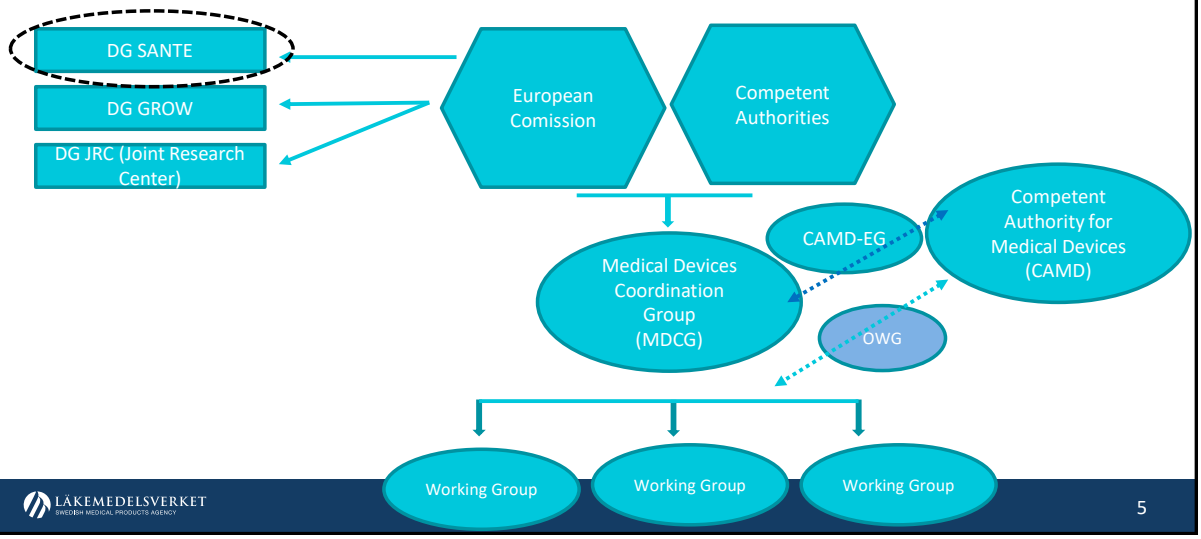
Agenda

1. Governance EU level - collaboration between EU COM, CAMD, CA CEG and MDCG
2. State of play - working on prioritizing the most urgent topics until May 26´th 2020
   - Joint Action Plan
     1. EUDAMED delay
     2. Guidance material – prioritization until May
     3. Capacity of Notified Bodies
     4. Access to the market
3. State of play in Sweden
4. Questions?

- **1.**
- **Governance EU level - collaboration between EU COM, CAMD, CA CEG and MDCG**

Governance: EU level



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Currently the MDCG has 13 working groups

1. **Notified bodies oversight (NBO):** Shares experiences and exchanges views on issues relating to notified bodies & drafts technical recommendations etc.
2. **Standards**: General issues relating to standardization & Harmonisation of standards to MDR and IVDR.
3. **Clinical investigation and evaluation (CIE):** Develops and promotes homogenous interpretation and implementation with regard to clinical evaluation and investigation.
4. **Post-market surveillance and vigilance (PMSV):** Exchange guidance, information, discuss actual incident cases, review current reporting practices.
5. **Market Surveillance**: Enforcement activities and administrative measures by CAs in relation to surveillance and control of devices put on the market.
6. **Borderline and classification (B&C)**: Advises on the qualification of a product as a medical device & Matters related to the appropriate type of classification for a given medical device.
7. **New technologies**: Advises on software, cybersecurity, and other issues related to new technologies & Identifies upcoming issues including new and emerging technologies in the area of medical devices including IVDs.
8. **EUDAMED**: Facilitates the implementation of the EUDAMED database.
9. **Unique device identification (UDI):** Facilitates the implementation of UDI.
10. **International matters:** Prepares a common European view on IMDRF issues and discuss other international issues & Monitors international regulation trends.
11. **In vitro diagnostic medical devices (IVD):** Develops and promotes homogenous interpretation and implementation with regard to IVDs.
12. **Annex XVI:** Common specifications for those groups of products listed in Annex XVI
13. **Nomenclature**

12. februar 2020 7

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2.
State of play: Roadmap

Guidance documents so far…

- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
  Published MDCG guidance documents
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/spread-word_en
  Factsheets in all MSs languages
- https://ec.europa.eu/growth/sectors/medical-devices_en
  Latest news from EU COM

	Target	Message
1	General	Are you ready for the changes in EU medical devices legislation? The updated Medical Devices section on the website of the European Commission has everything you need to prepare. Check it out now.
2	MD Manufacturers	Have you prepared for the new EU Medical Devices Regulation? The European Commission has produced a factsheet with key information. Download it here.
3	IVD Manufacturers	Have you prepared for the new EU In-vitro Diagnostic Medical Devices Regulation? The European Commission has produced a factsheet with key information. Download it here.
4	International	Are you looking for information on how the changes in EU medical devices legislation will affect your country? The updated Medical Devices section on the website of the European Commission has the information you need. Access it here now.
5	General/newsletter	Stay up to date with all the latest developments related to medical devices and in vitro diagnostic medical devices in the EU. Sign up for a newsletter from DG GROW here.
6	By sector	Are you ready for the changes in EU medical devices legislation? The updated Medical Devices section on the website of the European Commission has information targeted at the procurement ecosystem. Access it here now.
		Are you aware of the changes in EU medical devices legislation? The updated Medical Devices section on the website of the European Commission has information targeted at competent authorities in non-EU/EEA countries. Access it here now.
		Are you ready for the changes in EU medical devices legislation? The updated Medical Devices section on the website of the European Commission has information targeted at authorised representatives, importers and distributors. Access it here now.
		Are you ready for the changes in EU medical devices legislation? The updated Medical Devices section on the website of the European Commission has information targeted at healthcare professionals and health institutions. Access it here now.

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CAMD Roadmap

- Implementation Taskforce established to produce and deliver a single European Implementation Roadmap
- Roadmap published on 7th November 2017, being continuously updated
- It defines key priorities to be delivered, identifies groups involved in this work and sets priority levels
- Work has been ongoing. Defined in plans with definitive deliverables, timelines, leaders etc.

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Status of the current updated roadmap

	Technical areas/work streams	Total Assignments			
1	Clinical Evaluation & Clinical Investigation (MD); Performance Evaluation & Performance Studies (IVD)	27	6	7	14
2	Scope & Classification	7	4	1	2
3	Notified Bodies & Conformity Assessment	17	9	4	3
4	Post-Market Surveillance & Vigilance for both MD and IVD	14	5	5	4
5	Eudamed & UDI	23	10	4	9
6	Market Surveillance	24	2	4	18
7	IVD-specific Issues	16	5	3	8
8	Over-arching & Cross-cutting Priorities	17	2	7	8
	Total	**145**	**43**	**35**	**66**

Status: December 2019 - Colours are provisional and discussion is ongoing

3.
Joint Action Plan

Joint Action Plan

- EPSCO meeting in December 2019 – need for a readiness check!
- The Commission and the Member States are preparing a plan on common action (immediate and long term actions) to ensure progress in the implementation of the new regulations before they apply.
- Input from OWG for immediate actions:
  - EUDAMED delay
  - Need of guidance documents
  - Capacity of Notified Bodies – market access after May 2020

3.1
EUDAMED delay

EUDAMED – European electronic database for medical devices

- COM announced 29th October 2019 that EUDAMED will be delayed.
- Therefore EUDAMED's launch will be done together for medical devices and in-vitro medical devices, at the original date foreseen for in-vitro medical devices i.e. May 2022.
- The date of application of the MDR remains May 2020.
- Possible interim steps before the final EUDAMED launch in 2022 is still to be determined.

3.2
Guidance material

Prioritized guidance material - draft

1. Guidance on transitional provisions
2. Guidance related to Eudamed delay
3. Guidance on clinical requirements

3.3
Market access

Market access

- Notified bodies – system and capacity challenges.(ange status för MDR/IVDR)
- National derogations – Art 59
- If using national solutions and Art. 59 we need to ensure common approach between all Member States.

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State of play - Sweden

- National implementation

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Usefull Links and guidelines:

- https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745R(02)&from=SV
  Corrigendum
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en
  General information from EU Commission
- https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en
  Published guidance documents
- https://lakemedelsverket.se/malgrupp/Foretag/Medicinteknik---ny-lagstiftning/
  Samlad information på LV hemsida.
- https://lakemedelsverket.se/overgripande/Publikationer/Nyhetsbrev/Medicinteknik/
  Nyhetsbrev från Medicinteknik, prenumerera gärna