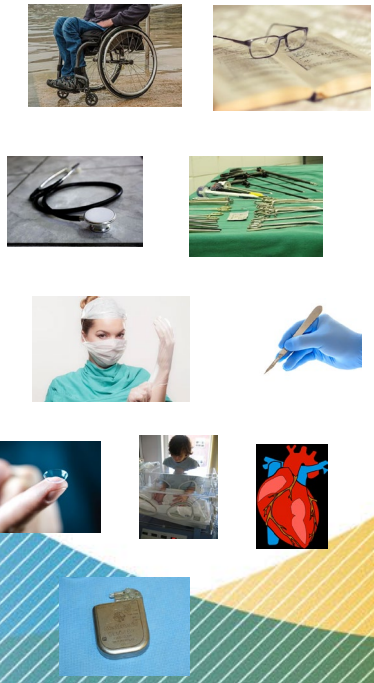
Study supporting the monitoring of availability of medical devices on the EU market (HaDEA/2021/P3/03)

EU4Health Programme



BEHEALTH 2023 - Panel discussion 5. MDR and IVD Regulation, challenges for NBs and market operators

Friederike Windisch, Austrian National Public Health Institute

24 October 2023

Areté The Agri-food Intelligence Company

CIVIC CONSULTING

Gesundheit Österreich GmbH

Study supporting the monitoring of availability of medical devices on the EU market

Commissioned by:
The European Commission's Directorate-General for Health and Food Safety (DG SANTE) via the European Health and Digital Executive Agency (HaDEA) - **HADEA/2021/P3/03**

Aim: To support monitoring and analyzing the availability of medical devices and in vitro diagnostic medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic medical devices Regulations **from the perspectives of key stakeholders**

Geographic scope: 30 countries (27 EU Member States plus Iceland, Liechtenstein and Norway)

Duration:
2 December 2022 – 1 December 2025 (36 months)

Study team:

- **Project lead:** Gesundheit Österreich GmbH (GÖG) / Austrian National Public Health Institute
- **Project partners:** Areté, Civic Consulting
- **Supported by an Expert Advisory Group:** Four MD experts providing methodological and thematic support

Contact: Ms Friederike Windisch (project manager), Ms Nina Zimmermann (deputy project manager) → medical.devices@goeg.at

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Consultation activities and presentation of results

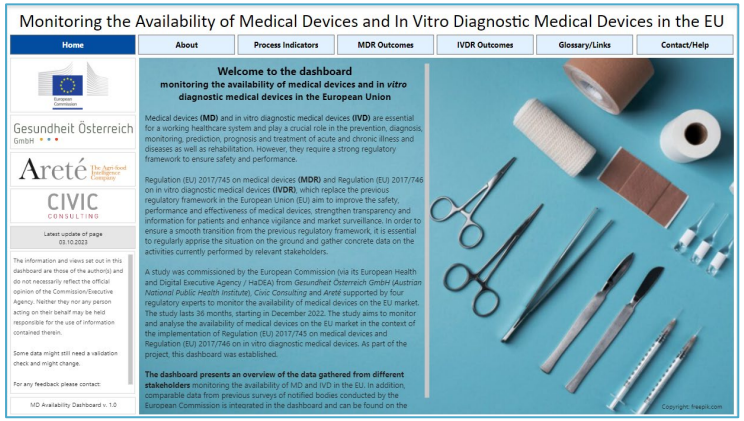
Surveys

Interviews

MDCG Taskforce Meetings

Results are presented in aggregated form in a **publicly available** and **regularly updated** dashboard

Note: First publication planned for November 2023



Source Icons:
https://www.flaticon.com/de/kostenlose-icons/fragebogen
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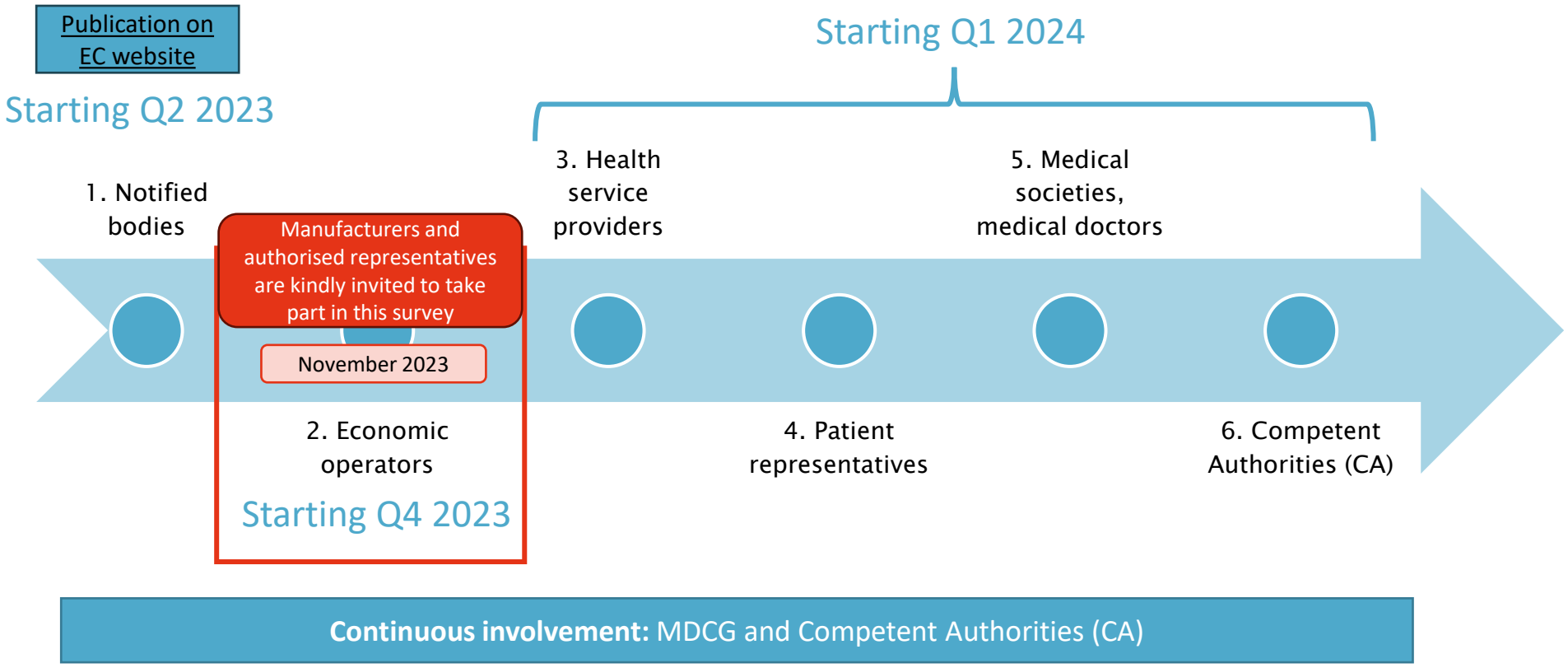
Overview of ongoing and planned survey activities with the key stakeholders



Source: GÖG

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Manufacturer survey – content

Supporting tools:
- Brief glossary
- Webinars for manufacturers and authorised representatives planned
- Q&A document

MD

- About the company (e.g. country, roles, SME, etc.)
- AIMDD/MDD – e.g.
  - no. of devices with (AI)MDD certificates; no. of (AI)MDD certificates;
  - no. of devices planned to transition to MDR and reasons why not
- Notified body (NB) – e.g.
  - If they have written agreements with a NB and reasons why not; no. of written agreements
  - If the NB refused applications and reasons for refusal
- MDR implementation – e.g.
  - Applications: No. of applications filed per Annex; How many devices are still under review?
  - Certificates: No. of devices covered by certificates in total & per class & new devices; no. of certificates per Annex
- Estimates – e.g.:
  - Yearly average cost for certification
  - Percentage of total portfolio that requires a MDR certificate with an already received MDR certificate;
  - Applications planned for new devices in the next 12-18 months
- Discontinued devices
- Preparedness of manufacturers

IVD – same questions

AR – separate questions

Link to the survey for manufacturers and authorised representatives:
https://ppri.goeg.at/Study_MD_Availability (accessible in November 2023)

Thank you very much for your attention!

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(project manager)

Please contact the study team in case of questions, suggestions or comments!
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