



PPRI MD Webinar

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

23 May 2023, 11-12am

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Online via Zoom



CIVIC
CONSULTING

Gesundheit Österreich
GmbH 



Key data

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**

Project structure:

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

Project manager:

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

Key contacts DG SANTE/HaDEA:

Ms Chiara Tripepi (HaDEA), Ms Maria Chiara Orlandi (DG SANTE)

Duration:

2 December 2022 – 1 December 2025 (36 months)

Study objectives

Note: In the context of this study, “availability of medical devices on the EU market” relates to the terminology “making available on the market”, as applied in MDR /IVDR.

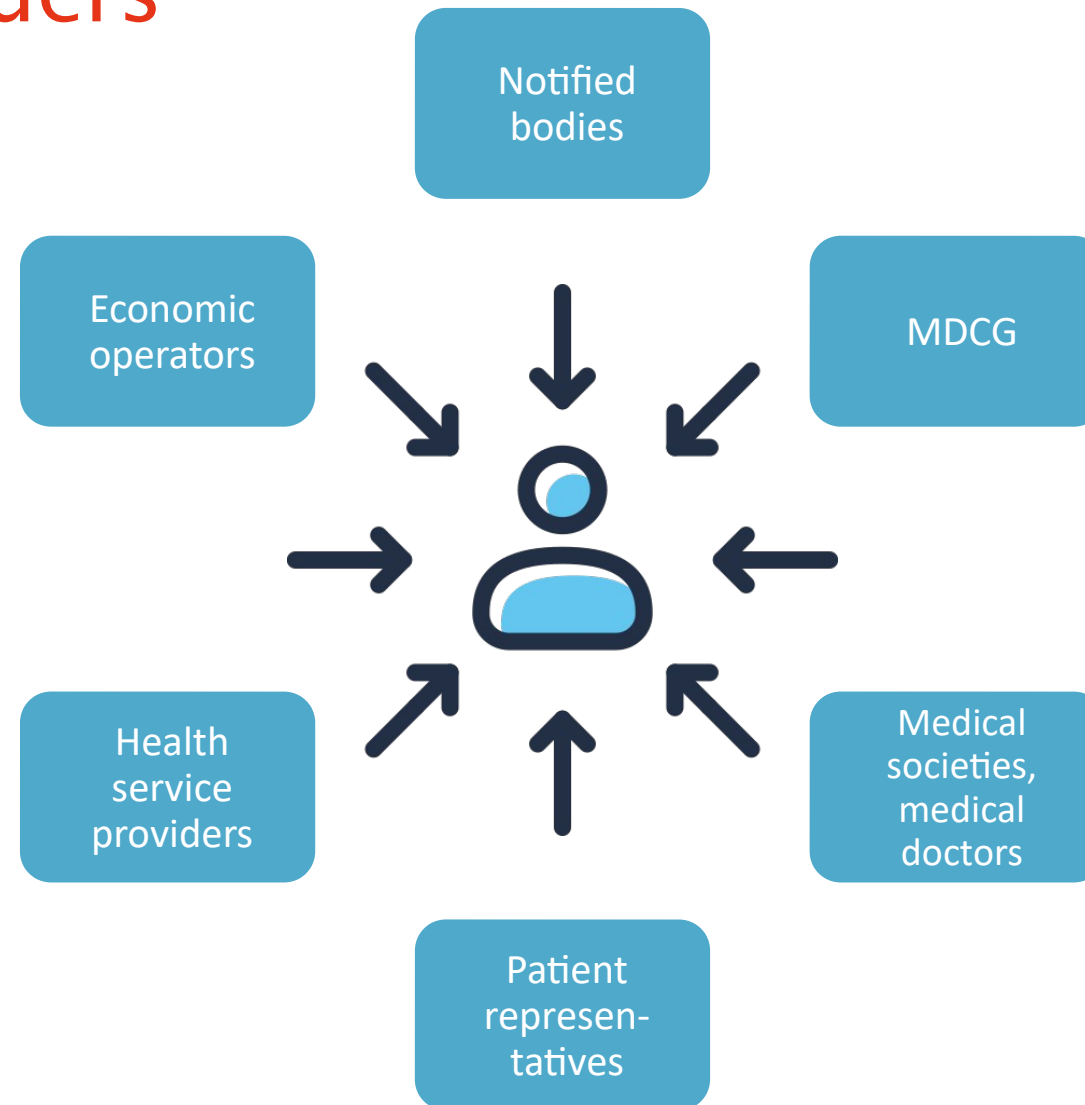
General objective

To support **monitoring and analysing the availability of 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**

Five specific objectives (SO):

- **SO1:** To **map all relevant stakeholders** which play a crucial role in ensuring the availability of medical devices on the European market (**Stakeholder mapping**)
- **SO2:** To **identify the relevant data and information** needed and to identify appropriate data sources (**Identification of quantitative and qualitative data needs**)
- **SO3:** To **design a dashboard**, including relevant indicators, and draft reports that describe the outcomes of the data collection in a user-friendly layout (**Data compilation and presentation**)
- **SO4:** To analyse per stakeholder group the **barriers** and **opportunities**. The analyses will look into the underlying cause, the phase in the life-cycle of the product (before / during certification) and the risk class/type of devices in the light of current developments at the time of the surveys (**Analysis**)
- **SO5:** To **develop a set of fit-for-purpose solutions** to address barriers and opportunities related to availability of MD at regular intervals, with reference to the new EU Regulations and their developments and in close cooperation with HaDEA/DG SANTE, the Expert Advisory Group and the MDCG taskforce (**Recommendations**).

Key stakeholders

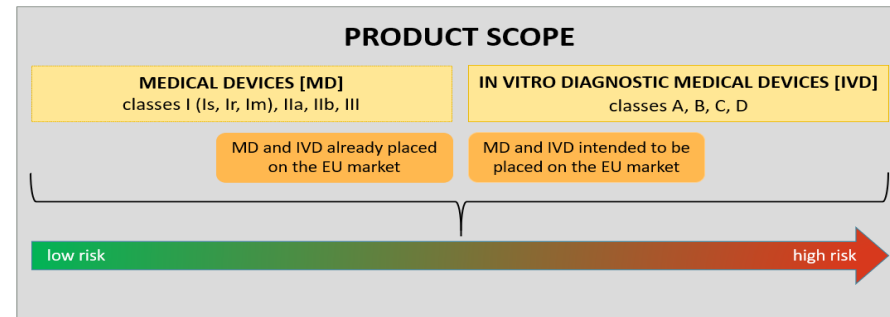


Source: GÖG

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Scope of the study

Product scope:



Source: GÖG

- **Product types:** medical devices (MD) and in vitro diagnostic medical devices (IVD)
- **Market status:** devices placed on the market (available under the new regulations) and those intended to be placed on the market in future (not yet available under the new regulations) and also taking into account legacy and new devices
- **Risk classes:** devices belonging to all risk classes, but with a focus on devices requiring the involvement of NB
- **Focus** will be set on special product groups (e.g. orphan and/or niche devices) and those at risk of shortage.

Geographic scope: 30 countries (27 EU Member States plus Iceland, Liechtenstein and Norway as new regulations cover the EEA)

Consultation activities and presentation of results



Surveys



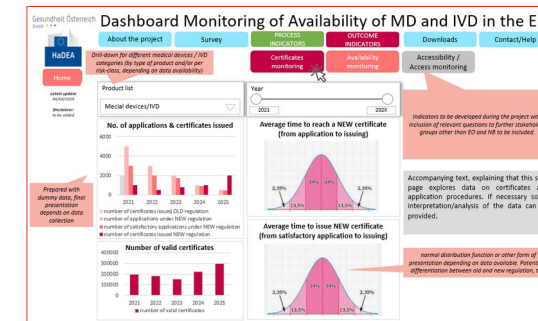
Interviews



MDCG Taskforce Meetings

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

Note: First publication planned for July 2023



Source: GÖG

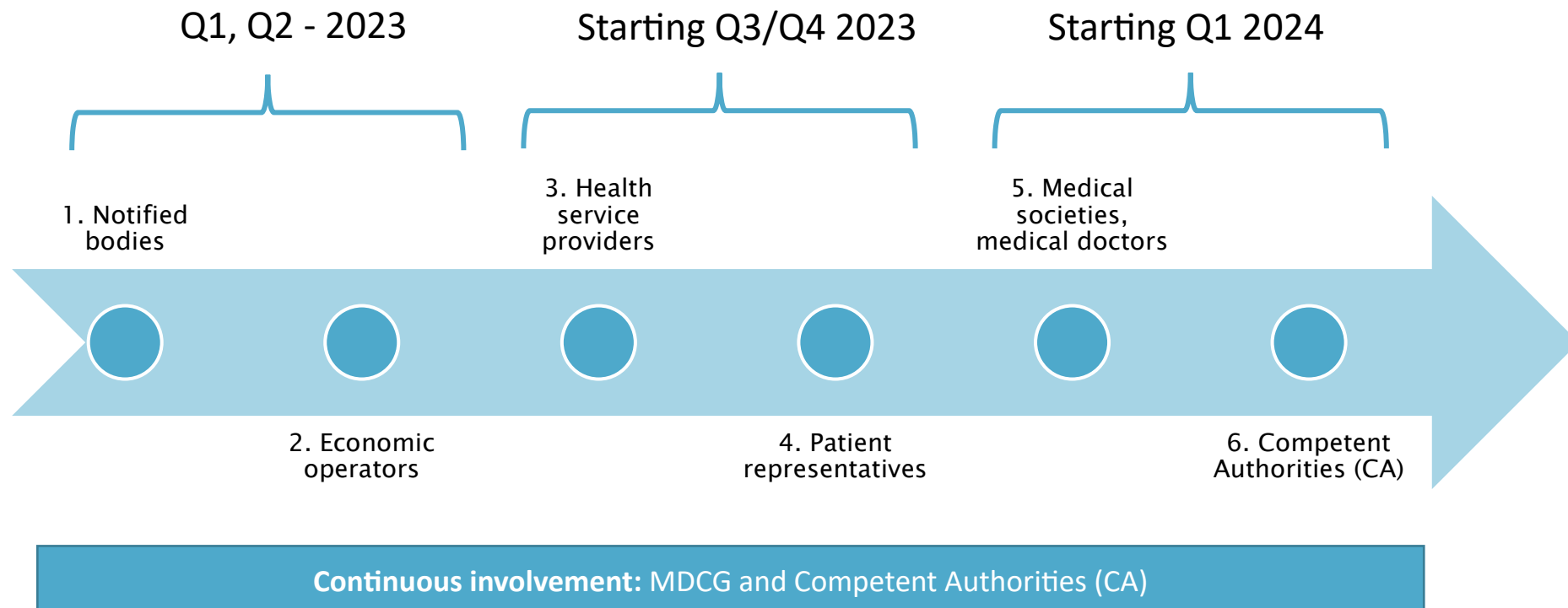
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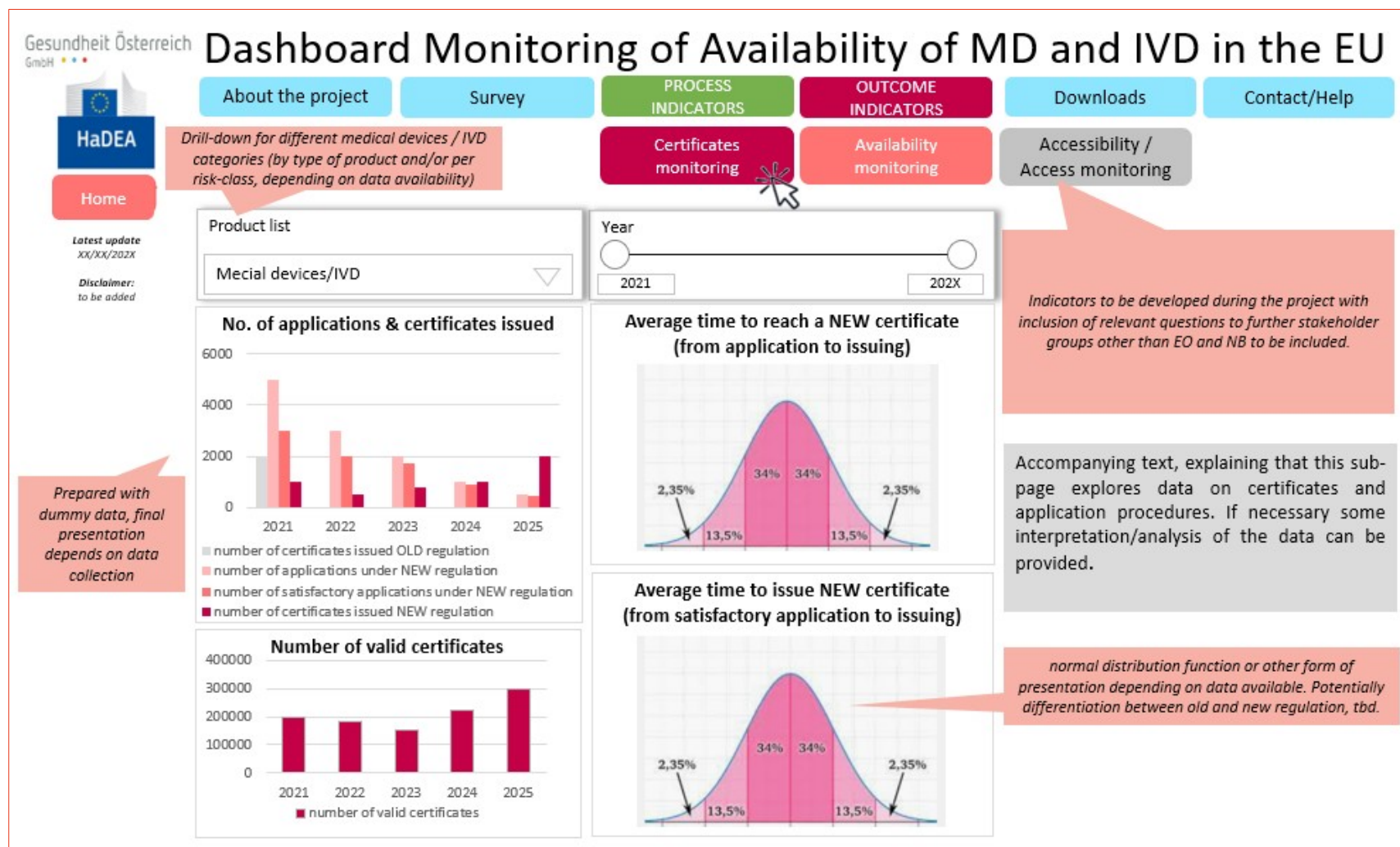
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Overview of planned survey activities



Source: GÖG

Dashboard mock-up



Source: GÖG

Supporting tools

- [Brief glossary](#)
- **Contact e-mail address:** medical.devices@goeg.at

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

Thank you very much for your attention!



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