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

Survey for health service providers (individual health professionals, health institutions and medical device procurement bodies)

Final, 05/08/2024 (deadline extended)

Background

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) – through the European Health and Digital Executive Agency (HaDEA) – has commissioned a "**Study supporting the monitoring of the availability of medical devices on the EU market**" to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG), in collaboration with Areté and Civic Consulting.

The **general objective** of the study, which started in December 2022 and runs for 36 months, is **to support the monitoring of 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[1] **from the perspectives of key stakeholders**. Large stakeholder consultations, including the stakeholder group of health service providers, are foreseen in the context of this study.

To be able to monitor the availability of medical devices (MDs) incl. in vitro diagnostic medical devices (IVDs) on the European market, it is vital to gather **quantitative information from health service providers like individual health professionals (i.e. medical doctors or other health professionals) and health institutions (i.e. hospitals or medical device procurement bodies) based in EU Member States is key. The main aim of this survey is to identify areas of MDs/IVDs where unavailability occurred in the last 6 months and/or will occur in the coming 1-2 years**. The questions relate to the availability of MDs and IVDs on the European market in the context of the implementation of Medical Devices and In vitro Diagnostic Medical Devices Regulations[1]; budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions are **not the subject of this survey**. The supply problems reported in this survey should have lasted several months.

Notes: this survey is independent of manufacturers' reporting obligations[2] in case of interruption or discontinuation of the supply of certain devices as stipulated by Regulation (EU) 2024/1860[3]. The information gained from this survey will identify and raise awareness of areas of MDs/IVDs where unavailability occurs without any legal or official implications regarding the reported shortages.

We kindly ask you to participate in the survey and provide your input on this matter. In general it may take about 10 minutes to complete the survey – but this is dependant on the amount of different types of MDs or IVDs where problems related to the purchasing or supply occur.

The survey (set of questions and its methodology) was developed by the study team together with the MDCG Task Force on Certification Capacity Monitoring and supported by representatives of health service providers.

The results will be fed into the study's public dashboard and will be analysed in study reports. **Your data will only be used in aggregated form and will not be forwarded to a third party.**

Participation in the survey

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation – MDR), Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (In Vitro Diagnostic Medical Device Regulation – IVDR)

[2] According to Article 10a Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746: Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.

[3] Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

We hope to reach as many health professionals and health institutions (e.g. hospitals and their procurement bodies, etc.) as possible and want to keep your workload in relation to completing the survey to a minimum.

Kindly provide **only ONE answer per person or institution (if possible)**. If you are replying on behalf of representative associations or on behalf of several institutions, please indicate this.

You can download the survey questionnaire from the menu on your right.

Instructions on how to answer to the survey:

- Navigate through the questionnaire using the next and forward buttons at the end of each page. To change replies, it is sufficient to go back to the question and modify it.
- A draft of the survey in progress can be saved using the dedicated button at the end of each page on the right. If you wish to pause the survey, do not forget to save your input by clicking on the button "Save as draft" before closing your session. This will generate a personalised link to your draft of the survey. Re-loading the page after a time-out will not recover previous answers. We advise you to save the progress made and click on the new link provided by EUSurvey once you are ready to finish the survey.
- For some questions, additional instructions are provided in italics. Additional instructions will appear in case of errors in an answer field (e.g. "This is not a valid e-mail address.").
- Fields marked with (*) are mandatory. In case mandatory replies are missing, an error message in red (e.g. "This field is required.") is displayed in the relevant section of the question when you move forward in the questionnaire.
- To submit your replies, please continue to the very last page and then click on the "submit" button at the bottom of the page. After submitting the questionnaire, this message will be displayed: "We thank you for the time spent taking this survey. Your response has been recorded". A summary of your replies is provided and can be downloaded as a PDF or printed.

You can find a glossary of the terms used in this survey here.

Survey deadline: 31 October 2024 (23:59 CET)

Data protection and consent to participate

Any personal or institution specific information (raw data) collected in the survey will be kept strictly confidential. Only aggregated survey outcomes will be published in the data dashboard and analysis reports.

The project leader, the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), is responsible for the project management as well as the concept behind and analysis of the survey, Areté is providing support with consultation activities (implementation in the EUSurvey tool, distributing surveys, data collection and pseudonymisation) while the third project partner (Civic Consulting) has no access to data.

This survey is run via the online tool EUSurvey. The raw data entered in the survey are stored on the servers of the European Commission's Data Centre pursuant to the Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission. More information is available at https://ec.europa.eu/eusurvey/home/privacystatement

For processing and subsequent publication, the data will be entered in aggregated form in the dashboard tool (using MS PowerBI). Before publication in the dashboard, the aggregated survey results are subject to review by DG SANTE and the MDCG Taskforce on Notified Body capacity monitoring. It is guaranteed that it will not be possible to trace back individuals or institutions in the aggregated data.

With the submission of your data/information, you agree to these terms. We follow the EC privacy statement: https://ec.europa.eu/info/law/better-regulation/specific-privacy-statement_en

Contact

If you have enquiries, please contact the study team lead, Ms Friederike Windisch (medical.devices@goeg.at).

Survey

The survey consists of four parts:

Survey part	Survey content	Survey question numbers
A	**About you** and your organisation/institution	1–4
B	Availability of CE-marked **medical devices**:	5–6
C	Availability of CE-marked **in vitro diagnostic medical devices**	7–8
D	Any **other issues**	9–13

The questions marked with a red asterisk * are mandatory and have to be completed.

A: About you and your organisation/institution

1. **Please provide your contact details.**

   We value your privacy. We may contact you in case we have any questions about your submission or to send you survey results. Full anonymity is guaranteed. Further invitations to participate in potential future survey rounds may be sent directly to the email address provided. We will not share your personal contact details; they will be deleted as soon as they are no longer needed to process the results.

1.1 Name of the person completing the survey: *[first name and surname]* *

1.2 Contact details: e-mail address: *[free text]* *

1.3 Representativity *

I am replying to this survey *[single choice]*

- representing myself
- representing the organisation/institution, I am working for

  Please select:
  - hospital
  - several hospitals, namely …. *[enter free text]*
  - (private) practice, focus clinic, primary care centre
  - medical society or healthcare professionals' association I am member of /I am working for
  - procurement body
  - municipality I am working for
  - other: *[free text]*

1.4 If applicable: Name of the organisation/institution on behalf of which you are replying to this survey (e.g. hospital(s) / (private) practice, focus clinic, primary care centre / medical society, health care professionals' association / procurement body / municipality): *[free text]*

1.5 By proceeding with the survey, you agree to the publication of your answers/information in an aggregated form.

[I agree] *

2. **Country of work** *

Please indicate the country/ies where you or your institution is based

[list of EU-27 Member States, Iceland, Liechtenstein and Norway and option "several – please specify (free text)" and "other – please specify (free text)"]

3. **Role** *

What is your main role? *[single choice]*

- Clinician[4]
- Hospital pharmacist
- Nurse
- Laboratory professional
- Staff of medical society or healthcare professionals' association
- Staff of procurement body
- Other health professional: *[free text]*
- Other: *[free text]*

[4] A clinician is a medical doctor having direct contact with patients rather than being involved with theoretical or laboratory studies.

4. **Main area of work** *
Where do you mainly work? *[single choice]*
- University hospital
- General training hospital
- General non-training hospital
- Private practice, focus clinic, primary care centre
- Nursing home / long-term care / mobile nursing care
- Medical society office or healthcare professionals' association office
- Procurement body administration
- Other: *[free text]*

B: Availability of CE-marked medical devices** (MDs)

** **Definition 'medical device':** Any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: (-) diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease, (-) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, (-) investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state, (-) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations; and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: (-) devices for the control or support of conception (-) products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point. [Source: MDR (EU) 2017/745]

5. **PAST: Availability problems with CE-marked MDs in the last six months:** *
Did you or the organisation(s)/institution(s) you are representing have problems* related to the purchasing / being supplied with relevant medical devices **in the last six months**? *[yes/no]*

* This question relates to the availability of medical devices on the European market in the context of the implementation of the Medical Devices Regulation (MDR); budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions are not the subject of this survey. The supply problem should have lasted several months.

- **If yes:**
  - Which **types** of CE-marked medical devices were **concerned**? *[drop down EMDN codes[3] or option to enter several ranges of devices based on EMDN codes]*

    [3] The European Medical Device Nomenclature (EMDN) is a nomenclature system for coding medical devices. Among its various uses, it is utilised by manufacturers for the registration of medical devices in EUDAMED - the European Database on Medical Devices.
    - Please specify the problem(s) per type of MD selected:
      - **Suppliers** *[single choice]*
        - Very few suppliers on the EU market
        - Only one supplier and no alternatives
        - No more suppliers on the EU market
        - No information available
        - Other: *[free text]*
      - Is an **alternative CE-marked medical device** available in your country? *[yes/no/I don't know]*
        - If yes: *[multiple choices]*
          - Effectiveness:
            - An alternative CE-marked MD is as effective as the original. *[yes/no/ I don't know]*

- Price:
  - An alternative CE-marked MD is available but is more expensive. *[yes/no/ I don't know]*
  - An alternative CE-marked MD is available and is less expensive. *[yes/no/ I don't know]*
- Safety:
  - An alternative CE-marked MD is available but is less safe for the patient (e.g increase in the number of incidents observed). *[yes/no/ I don't know]*
  - An alternative CE-marked MD is available but requires training. *[yes/no/ I don't know]*
  - An alternative CE-marked MD is available but needs to be fitted with other equipment(s). *[yes/no/ I don't know]*
- Usage:
  - An alternative CE-marked MD is available but offers fewer options regarding its use (on label). *[yes/no/ I don't know]*
  - An alternative CE-marked MD is available but used off label. *[yes/no/ I don't know]*

– If no:

- Is an alternative CE-marked MD available in other EU countries? *[yes/no/I don't know]*

– Are **alternative treatments or medical procedures** available? *[yes/no/ I don't know]*

– [optional] Which **risk class** does this type of CE-marked MD belong to? *[single choice]*

– Class I
– Class Ir/s/m
– Class IIa
– Class IIb
– Class III

○ [optional] *[free text for further explanations]*

6. **FUTURE: Availability problems with CE-marked medical devices in the coming 1-2 years***

Do you or the organisation(s)/institution(s) you are representing foresee problems* related to the purchasing / being supplied with specific types of medical devices **in the coming 1-2 years**? *[yes/no/I don't know]*

* This question relates to the availability of medical devices on the European market in the context of the implementation of the Medical Devices Regulation; budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions are not the subject of this survey.

- **If yes:**
  - Which **types** of CE-marked medical devices will be concerned? *[drop down EMDN codes[3] or option to enter several ranges of devices based on EMDN codes]*
    - Please specify the expected problems per type of MD selected: *[multiple choices]*
      – Availability in the European Union:
        – A specific MD will be taken off the European market and no suitable alternative will be available worldwide.
        – An alternative MD is unlikely to be available on the European market but is / will remain available in other countries (e.g. USA, Japan, China).

- Effectiveness:
  - An alternative CE-marked MD is likely to be available but will not be as effective.
- Price:
  - An alternative CE-marked MD will likely be available but more expensive.
- Safety:
  - An alternative CE-marked MD will likely be available but less safe for the patient.
  - An alternative CE-marked MD will likely be available but will require training to reduce the risk.
  - An alternative CE-marked MD will likely be available but will need to be fitted with other equipment(s).
- Usage:
  - An alternative CE-marked MD will likely be available but will offer fewer options regarding its use (on label)
  - An alternative CE-marked MD will likely be available but used off label
- Other: *[please specify, free text]*

▪ [optional] Which **risk class** does this type of CE-marked MD belong to? *[single choice]*
- Class I
- Class Ir/s/m
- Class IIa
- Class IIb
- Class III

○ [optional] *[free text for further explanations]*

C: Availability of CE-marked in vitro diagnostic medical devices** (IVDs)

** **Definition "in vitro diagnostic medical device'**: Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following: a) concerning a physiological or pathological process or state; b) concerning congenital physical or mental impairments; c) concerning the predisposition to a medical condition or a disease; d) to determine the safety and compatibility with potential recipients; e) to predict treatment response or reactions; f) to define or monitoring therapeutic measures. Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices [Source: IVDR (EU) 2017/746]

7. **PAST: Availability problems with CE-marked IVDs in the last six months***
Did you or the organisation(s)/institution(s) you are representing have problems* related to the purchasing / being supplied with relevant in vitro diagnostic medical devices **in the last six months**? *[yes/no/not applicable]*

* This question relates to the availability of in vitro diagnostic medical devices on the European market in the context of the implementation of the In Vitro Diagnostic Medical Device Regulation (IVDR); budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions are not the subject of this survey. The supply problem should have lasted several months.

- **If yes:**
  - Which **types** of CE-marked in vitro diagnostic medical devices were **concerned**? *[drop down EMDN codes* or option to enter several ranges of devices based on EMDN codes]*

* The European Medical Device Nomenclature (EMDN) is a nomenclature system for coding medical devices (incl. in vitro diagnostics). Among its various uses, it is utilised by manufacturers for the registration of in vitro diagnostic medical devices in EUDAMED – the European Database on Medical Devices.

- Please specify the problem(s) per type of IVD selected:
  - **Suppliers** *[single choice]*
    - Very few suppliers on the EU market
    - Only one supplier and no alternatives
    - No more suppliers on the EU market
    - No information available
    - Other: *[free text]*
  - Is an **alternative CE-marked IVD** available in your country? *[yes/no/ I don't know]*
    - If yes: *[multiple choices]*
      - Effectiveness:
        - An alternative CE-marked IVD is as effective as the original. *[yes/no/ I don't know]*
      - Price:
        - An alternative CE-marked IVD is available but is more expensive. *[yes/no/ I don't know]*
        - An alternative CE-marked IVD is available and is less expensive. *[yes/no/ I don't know]*
      - Safety:
        - An alternative CE-marked IVD is available but is less safe for the patient (e.g increase in the number of incidents observed). *[yes/no/ I don't know]*
        - An alternative CE-marked IVD is available but requires training. *[yes/no/ I don't know]*
        - An alternative CE-marked IVD is available but needs to be fitted with other equipment(s). *[yes/no/ I don't know]*
      - Usage:
        - An alternative CE-marked IVD is available but offers fewer options regarding its use (on label). *[yes/no/ I don't know]*
        - An alternative CE-marked IVD is available but used off label. *[yes/no/ I don't know]*
    - If no:
      - Is an alternative CE-marked IVD available in other EU countries? *[yes/no/I don't know]*
- [optional] Which **risk class** does this type of CE-marked IVD belong to? *[single choice]*
  - Class A
  - Class A Sterile
  - Class B
  - Class C
  - Class D
- [optional] *[free text for further explanations]*

8. **FUTURE: Availability problems with CE-marked IVDs in the coming 1-2 years***
   Do you or the organisation(s)/institution(s) you are representing foresee problems* related to the purchasing / being supplied with specific types of in vitro diagnostic medical devices **in the coming 1-2 years**? *[yes/no/I don't know]*

* This question relates to the availability of in vitro diagnostic medical devices on the European market in the context of the implementation of the In Vitro Diagnostic Medical Device Regulation (IVDR); budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions are not the subject of this survey.

- If yes:
  - Which **types** of CE-marked IVDs will be concerned? *[drop down EMDN codes[3] or option to enter several ranges of devices based on EMDN codes]*
    - Please specify the expected problems per type of IVD selected: *[multiple choices]*
      - Availability in the European Union:
        - A specific IVD will be taken off the European market and no suitable alternative will be available worldwide.
        - An alternative IVD is unlikely to be available on the European market but is / will remain available in other countries (e.g. USA, Japan, China).
      - Effectiveness:
        - An alternative CE-marked IVD will likely be available but will not be as effective.
      - Price:
        - An alternative CE-marked IVD will likely be available but more expensive.
      - Safety:
        - An alternative CE-marked IVD will likely be available but less safe for the patient.
        - An alternative CE-marked IVD will likely be available but will require training.
        - An alternative CE-marked IVD will likely be available but will need to be fitted with other equipment(s).
      - Usage:
        - An alternative CE-marked IVD will likely be available but will offer fewer options regarding its use (on label).
        - An alternative CE-marked IVD will likely be available but used off label.
      - Other: *[please specify, free text]*
    - [optional] Which **risk class** does this type of CE-marked IVD belong to? *[single choice]*
      - Class A
      - Class A sterile
      - Class B
      - Class C
      - Class D
      -
  - [optional] *[free text for further explanations]*

D: Any other issues

9. Is there **anything else** that you would like to share with us regarding the availability of MDs and IVDs? *[free text]*
10. Do you have any **concerns or suggestions** as to **alleviate possible shortages** of MDs/IVDs? *[free text]*
11. Would you be **interested in and available for a follow-up interview**? *[yes/no]*
12. If you know of any further (national) **contacts** or any **relevant literature** that could be useful for this study, please feel free to provide details. *[free text- open field: "further contacts"; open field: "relevant literature"]*

13. Is there **anything relevant** to the topic that we forget to ask and should ask in follow-up interviews? *[free text]*

We thank you for your participation. Your contribution is highly appreciated!

If you have any questions about the survey or our study, please do not hesitate to contact us:
medical.devices@goeg.at