



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

Study overview and survey results of the survey with **health service providers (HSP)**

8 May 2025

Disclaimer

- This document was produced in the frame of the SC 2021 P3 03 under the DG SANTE Framework contract (FWC SANTE/2021/OP/0002) for evaluation, impact assessment, monitoring and other related services in relation to health and food policies.
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- The study team has aggregated the data received from survey participants to prepare this presentation but cannot be held responsible for the quality and accuracy of the data.

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MD

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List of abbreviations (1)

Abbreviation	Meaning
AIMDD	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
CA(s)	Competent Authority / Competent Authorities
CE	Conformité Européenne
CED	Council of European Dentists
CPME	Standing Committee of European Doctors
DG SANTE	Directorate-General for Health and Food Safety
EAHP	European Association of Hospital Pharmacists
EC	European Commission
EHPPA	European Hospital Public Procurer Association
EMDN	European Medical Device Nomenclature
EU	European Union
EUDAMED	European Database on Medical Devices
FWC	Framework contract
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
HOPE	European Hospital and Healthcare Federation
HSP	Health service provider(s)

List of abbreviations (2)

Abbreviation	Meaning
IVDs	In-vitro diagnostic medical device(s)
IVDD	Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices
IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (In Vitro Diagnostic Medical Device Regulation)
MDCG	Medical Device Coordination Group
MD(s)	Medical device(s)
MDD	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (Medical Device Regulation)
NB(s)	Notified body / bodies
PGEU	Pharmaceutical Group of the European Union
PPT	MS Power Point
Q	Question
SC	Special contract
TF	Task Force
ZINN	Zorg Inkoop Netwerk Nederland

1. Introduction

1.1. About the study

- Study supporting the monitoring of availability of medical devices on the EU market
- Scope of the study
- Dashboard
- Links to relevant documents in the context of this study

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)
- **Aim:** To support monitoring and analyzing 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
- **Duration:** 2 December 2022 – 1 December 2025 (36 months)
- **Study team** (contact: medical.devices@goeg.at):



Gesundheit
Österreich GmbH

Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG) → project lead



Areté



Civic Consulting

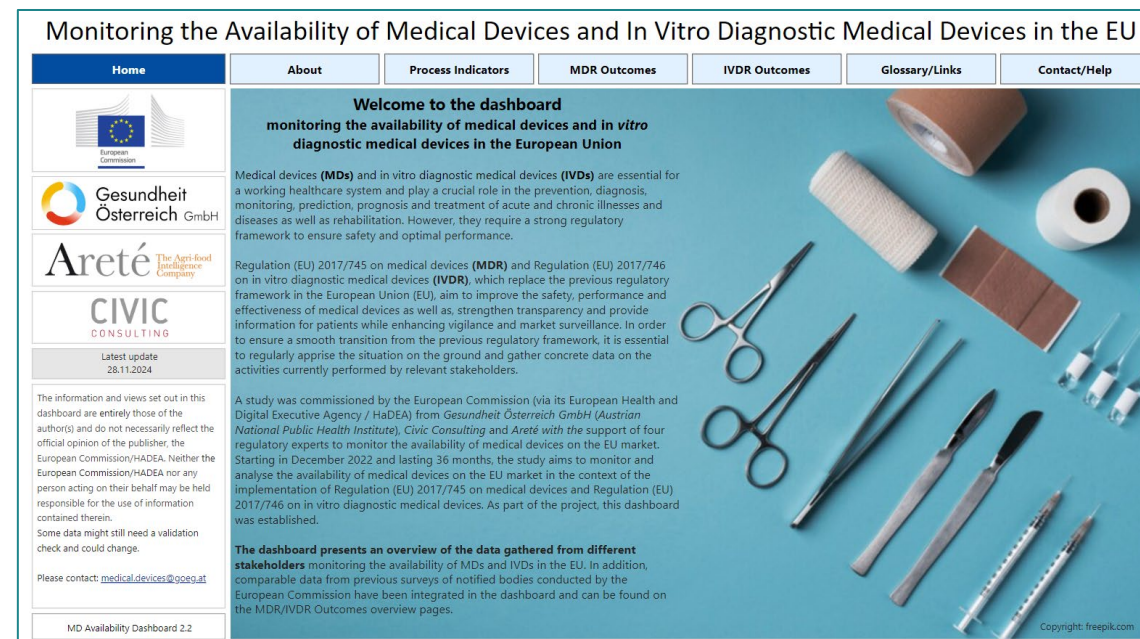
Supported by experts from the medical devices sector

Scope of the study

- **Product scope:**
 - **Product types:** medical devices (MDs) and in vitro diagnostic medical devices (IVDs)
 - **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 notified bodies
 - **Focus** will be set on special product groups (e.g. orphan and/or niche devices) and those at risk of shortage.
- **Geographic scope:** 31 countries (27 EU Member States plus Iceland, Liechtenstein, Norway and Turkey)

Dashboard

- NB survey results are presented in the study-related dashboard
- Available at: [Study supporting the monitoring of availability of medical devices on the EU market - European Commission \(europa.eu\)](https://study.supportingthemonitoringofavailabilityofmedicaldevicesontheEUmarket-europa.eu)



Links to relevant documents in the context of this study

- [One-pager about the study](#)
- [Endorsement letter](#)
- [Study-related glossary](#)
- [Dashboard](#)
- [Instructions for use for the dashboard](#)

1.2. About the survey with health service providers

- Acknowledgements
- Survey development and management
- Survey methodology
- Survey timeline
- Survey structure and content

Acknowledgements

The study team would like to sincerely thank the following institutions for the support in the health service provider survey:

- The Directorate General for Health and Food Safety at the European Commission (**DG SANTE**) and the European Health and Digital Executive Agency (**HaDEA**);
- Members of the **MDCG TF on certification capacity monitoring**;
- **Experts** who were available for exploratory interviews (see next slide for information on the organizations);
- **Experts and representatives** of the following organizations (in alphabetical order) for the review of a draft version and piloting the survey: Council of European Dentists, EuroPHARMAT, GÖG
- All **health service providers (individual health professionals, health institutions and medical procurement bodies)** of medical devices and in vitro diagnostic medical devices who took part in the survey.

Survey development and management

- **Survey development:** Six exploratory interviews with different health service providers were conducted (Biomedical Alliance, Council of European Dentists (CED), Danish Regions, European Association of Hospital Pharmacists (EAHP) and EuroPHARMAT, General Hospital Vienna, Mercurhosp) to prepare the survey. The final survey questions were developed by the study team in close consultation with DG SANTE/HaDEA and the MDCG TF on certification capacity monitoring. The draft survey was reviewed and piloted by a few health service providers before the official launch.
- **Survey dissemination:** The survey link was shared via (inter)national associations of health service providers (Biomedical Alliance in Europe, Council of European Dentists, EAHP, Pharmaceutical Group of the European Union (PGEU), Standing Committee of European Doctors (CPME), European Hospital and Healthcare Federation (HOPE), European Hospital Public Procurer Association (EHPPA) etc.), the European Commission, competent authorities for medical devices and IVDs and social media (LinkedIn).

Survey methodology

- **Aim:** to gather data from health service providers about availability of devices in the context of the implementation of MDR and IVDR
- **Target groups:**
 - individual health professionals
 - health institutions and
 - medical device procurement bodies
- **Survey period:** 14/08/2024 - 31/10/2024
- **Limitations:**
not representative, target groups are hard to reach via survey




- **Online survey** (EU survey tool)

The screenshot displays the 'Monitoring the availability of medical devices on the EU market - survey for health service providers' interface. At the top, there is a checkbox to 'Save a backup on your local computer (disable if you are using a public/shared computer)'. The title is followed by a subtitle '(individual health professionals, health institutions and medical device procurement bodies)'. A yellow box indicates 'Fields marked with * are mandatory'. A disclaimer states that the European Commission is not responsible for the content of questionnaires created using the EUSurvey service. Below this is a 'Pages' section with a progress bar showing the current position at 'Introduction to the survey'. The progress bar includes links for 'Introduction to the survey', 'Background', 'Participation in the survey', 'Data protection and contacts', 'Survey structure', and 'A - Participant info'. The 'Introduction to the survey' page is currently active, showing a question about problems related to purchasing or being supplied with medical devices (MDs) or in vitro diagnostic medical devices (IVDs) in the last six months, and a question about future availability of medical devices or in vitro diagnostic medical devices in the coming 1-2 years. On the right side, there are links for 'Standard', 'Accessibility Mode', 'Languages' (with a dropdown menu set to 'English'), 'Contact' (with a 'Contact Form' link), 'Download PDF version', and 'Report abuse'.

Survey timeline for the HSP survey



Survey structure and content



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 Arété 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 Regulations¹ 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 Regulations¹; 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 obligations² in case of interruption or discontinuation of the supply of certain devices as stipulated by Regulation (EU) 2024/1860³. 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 dependent 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 MDC 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 on In vitro Diagnostic Medical Device Regulation – IVDs.
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 EuAMED, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

EU Medical Devices Availability Study – Survey for HSP, 05/08/2024
1

Background and introduction

Survey (Q1-Q13)

About

ABOUT: About you and your organization/institution (Q1-Q4)

MD

MD: Availability of CE-marked medical devices (Q5-Q6)

IVD

IVD: Availability of CE-marked in vitro diagnostic medical devices (Q7-Q8)

AOB

Any other issues: Concerns or suggestions, literature ect. (Q9-Q13)

[Link](#) to the final survey (as PDF) including detailed questions

Abbreviations: IVD = in vitro diagnostic medical device, MD = medical device(s), Q = question

2. Results

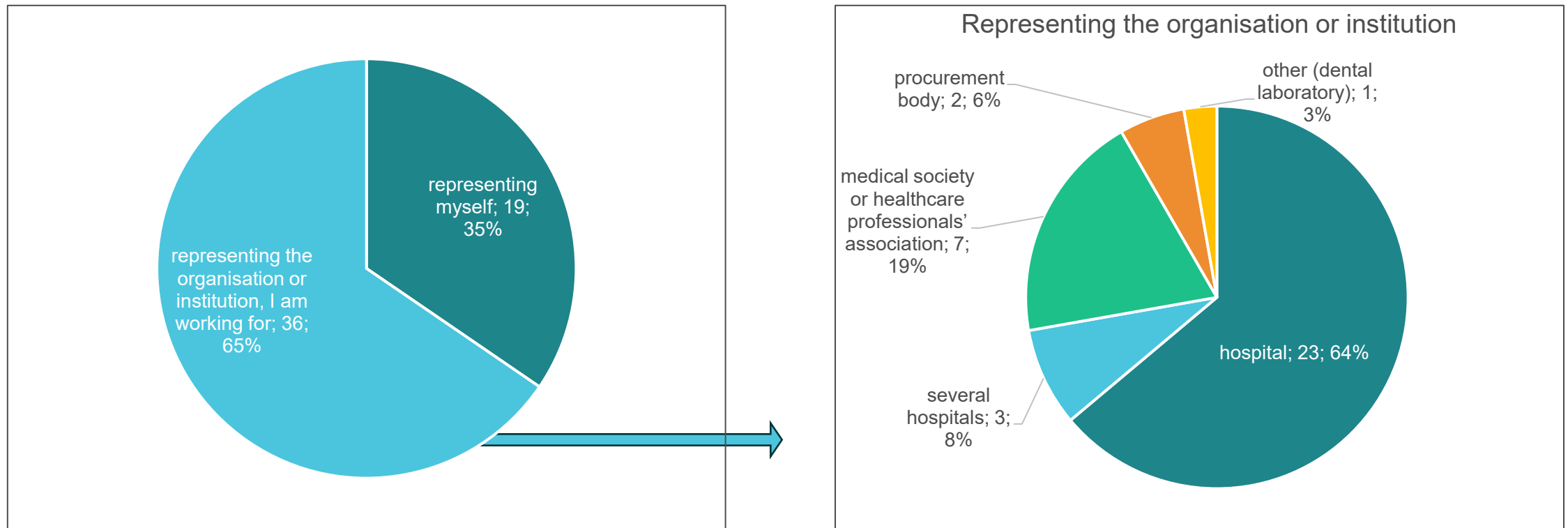
2.1. About the survey participants (responses)

Questionnaire part A including questions 1 to 4

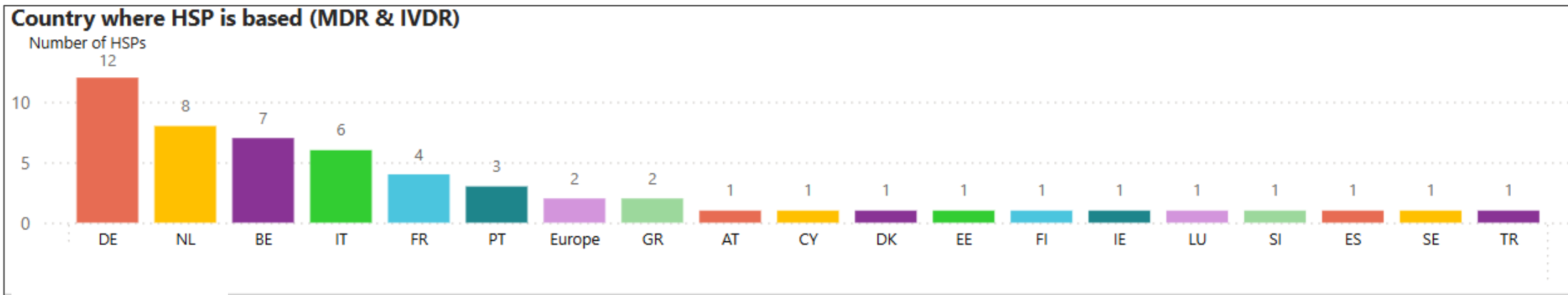
Note: Answers to question 1 (contact details) are not provided in this presentation.

About the responding organisations/institutions

In total, **65 responses** were received; 10 responses had to be excluded: double submission (n=1), not in the geographic scope (n=7), invalid replies (n=2); **55 replies were considered for data analysis.**



Country where the HSP is based

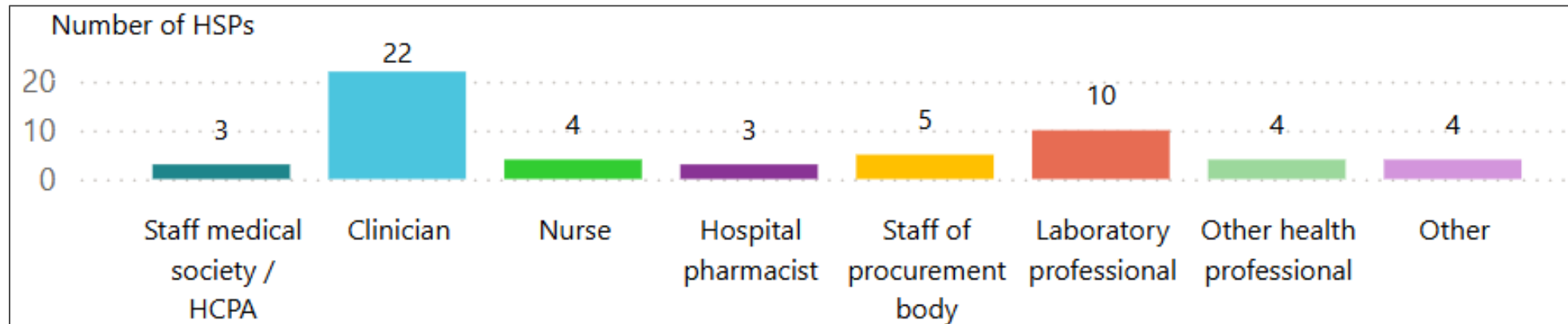


Europe = representative organisation on EU level

List of country abbreviations:

DE = Germany, NL = The Netherlands, BE = Belgium, IT = Italy, FR = France, PT = Portugal, GR = Greece, AT = Austria, CY = Cyprus, DK = Denmark, EE = Estonia, FI = Finland, IE = Ireland, LU = Luxembourg, SI = Slovenia, ES = Spain, SE = Sweden, TR = Turkey

Main role of respondents



Other than health professional:
Head of quality assurance, Head of
Purchasing Department, Quality
management, Head of Department for
medical technology

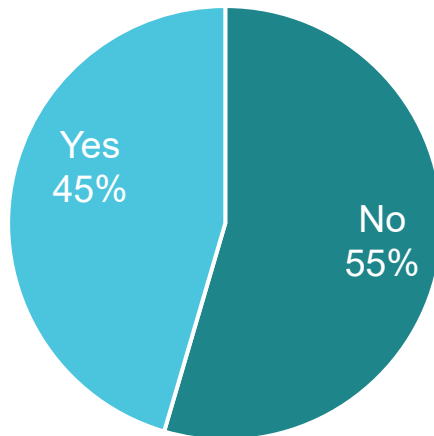
2.2. Survey results for medical devices

Questionnaire part B including questions 5-6

HSP survey – results (n = 55)

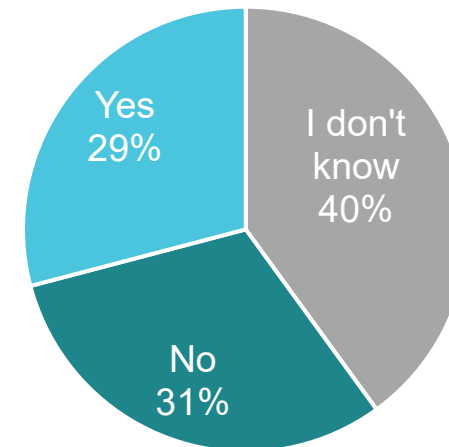
MD PAST:

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?**



MD FUTURE:

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?**



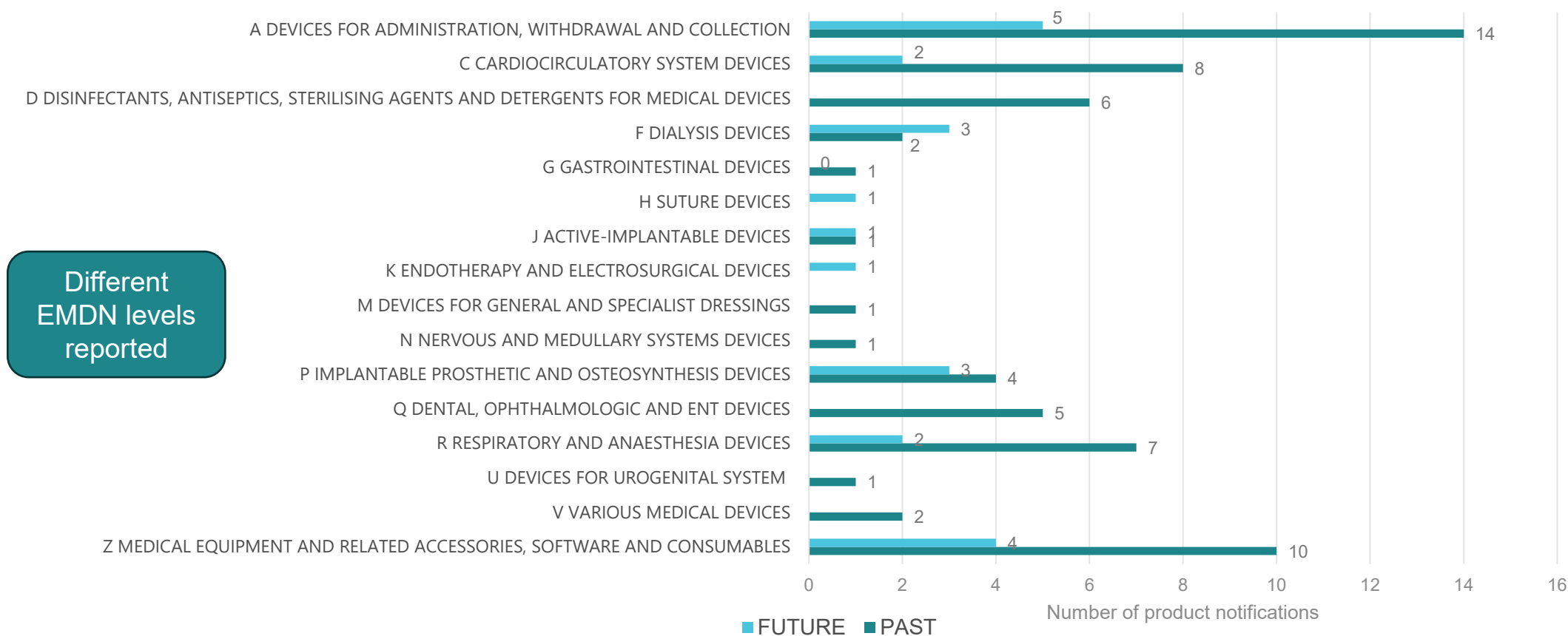
* Related to the availability of medical devices on the European market in the context of the implementation of the Medical Devices Regulation (MDR); budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage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

HSP survey – MD reported

	PAST: Problems* related to the purchasing / being supplied with relevant medical devices in the last six months	FUTURE: Problems* related to the purchasing / being supplied with specific types of medical devices in the coming 1-2 years
Medical devices	63 product notifications	22 product notifications

* Related 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 were not the subject of this survey.

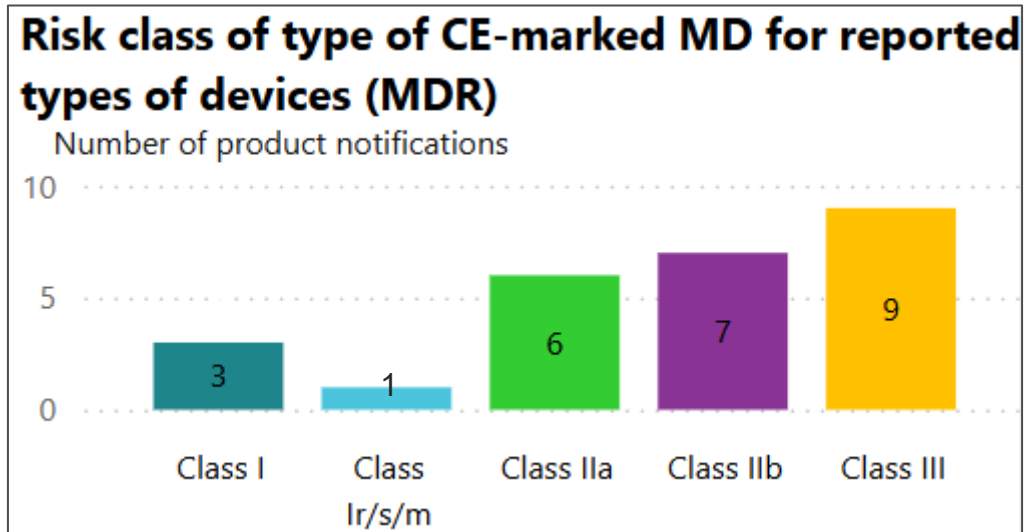
HSP survey – MDs reported by EMDN group



PAST

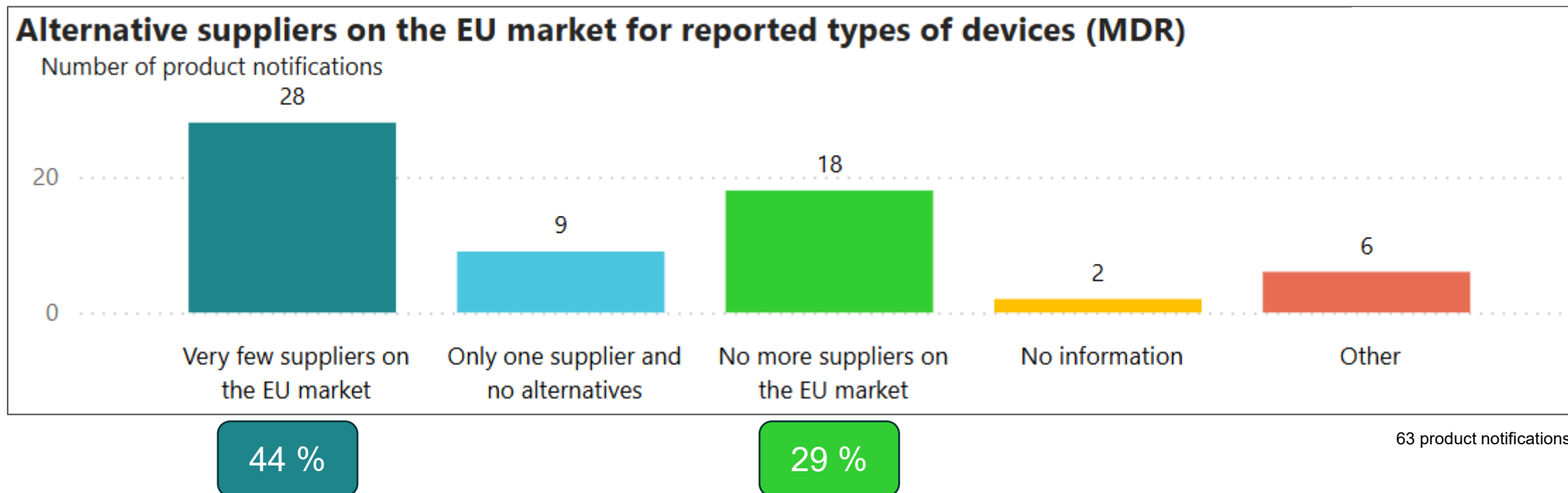
HSP survey – MDs reported by risk class

Optional
question



Note:
Out of 63 product notifications, 26 included
information on the risk class of the reported MDs.

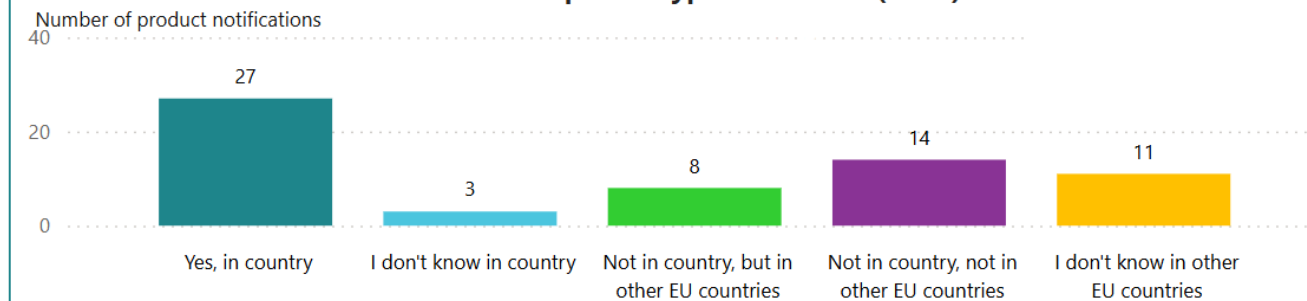
HSP survey – supplier situation



HSP survey – alternatives available?

In total 63 product notifications

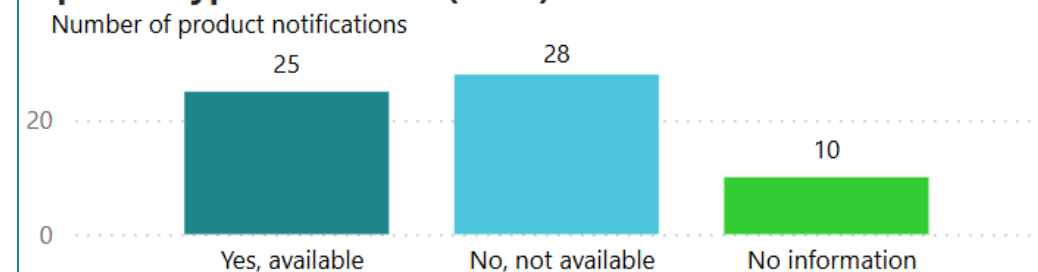
Alternative CE-marked MD available for reported types of devices (MDR)



43 %

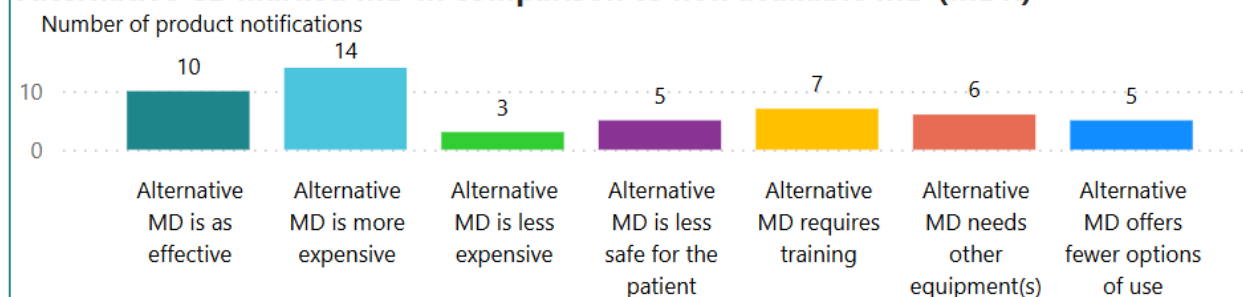
22 %

Alternative treatments or medical procedures available for reported types of devices (MDR)



44 %

Alternative CE-marked MD in comparison to non available MD (MDR)



HSP survey – PAST: Most frequent reported MDs

MD

Most frequent reported MDs (EMDN level 3)

A0201 - SINGLE-USE SYRINGES	6
A0102 - BIOPSY NEEDLES AND KITS	4
Q0101 - DEVICES FOR CONSERVATIVE DENTISTRY AND ENDODONTICS	4
C0190 - DEVICES FOR VASCULAR PROCEDURES - VARIOUS	2
C0301 - EXTRACORPOREAL ASSISTED CIRCULATION DEVICES	2
R0601 - NEBULISATION SYSTEMS	2
Z1203 - INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS	2
Z1208 - OBSTETRICS AND GYNAECOLOGY INSTRUMENTS	2

In total 63 product notifications; products were grouped on EMDN level 3

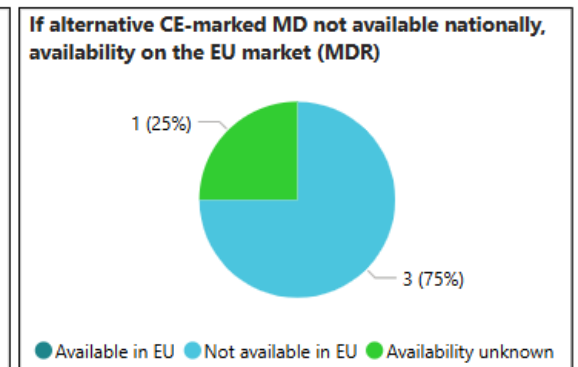
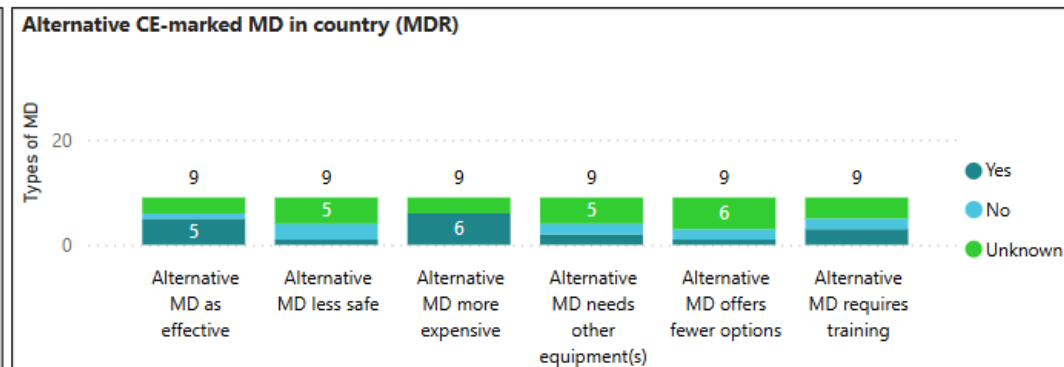
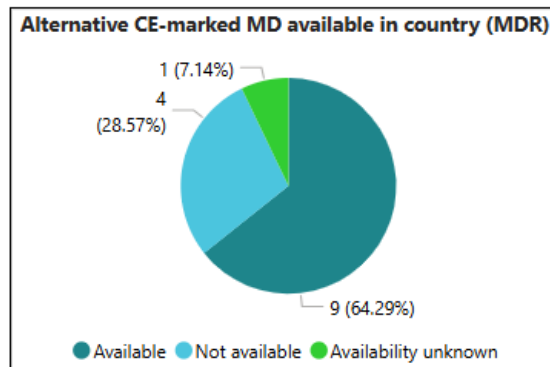
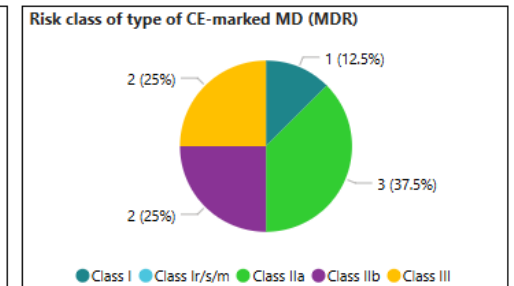
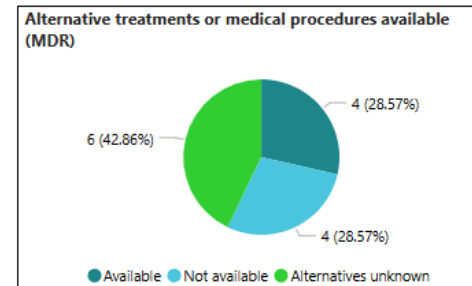
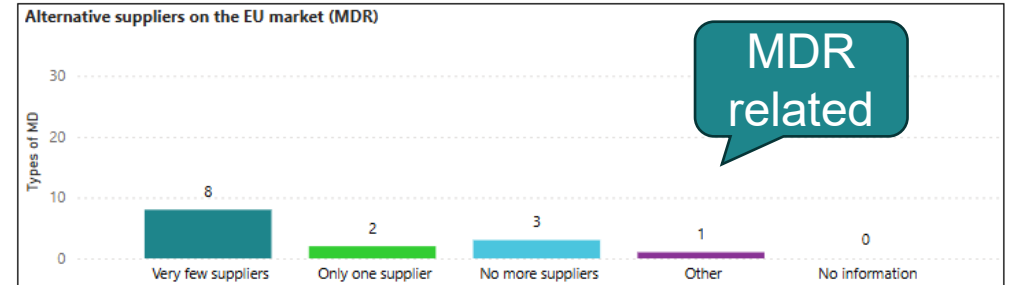
HSP survey – PAST: MDs reported – EMDN Group A

MD

Reported EMDN level (n=14)

A010101	HYPODERMIC NEEDLES
A010202	BONE MARROW BIOPSY NEEDLES AND KITS
A010202	BONE MARROW BIOPSY NEEDLES AND KITS
A01020202	BONE MARROW EXPLANT NEEDLES AND KITS
A01020402	VILLOCENTESIS NEEDLES AND KITS
A0201	SINGLE-USE SYRINGES
A020102	INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
A02010203	INFUSION AND IRRIGATION SYRINGES, CATHETER CONE, SINGLE-USE
A020105	BLOOD GAS ANALYSIS, SYRINGES WITH NEEDLES AND KITS
A020106	INSULIN SYRINGES, SINGLE-USE
A020108	ENTERAL FEEDING SYRINGES
A03010399	ENTERAL FEEDING CONTROLLERS - OTHER
A060204	THORACENTESIS AND PARACENTESIS DRAINAGES AND KITS
A11	SAMPLE COLLECTION SWABS

In red font = no more suppliers on the EU market



HSP survey – PAST: MDs reported – EMDN Group C

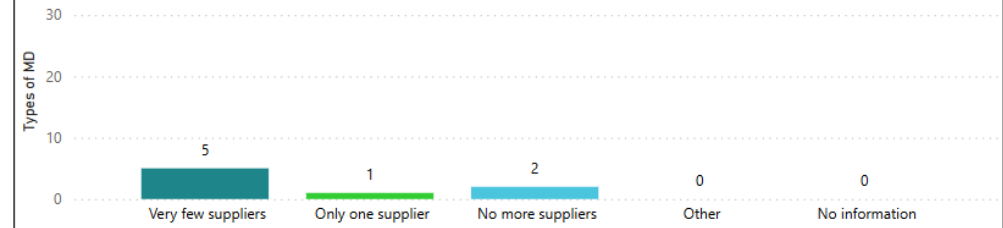
MD

Reported EMDN level (n=8)

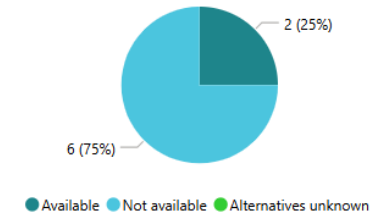
C0103 - ARTERIAL CANNULAS
C01040101 - CARDIAC ANGIOGRAPHY DIAGNOSTIC DEVICES
 C019014 - CARDIAC VALVULOPLASTY CATHETERS
C019015 - CARDIAC TRANSEPTAL PUNCTURE KITS
 C03 - CARDIAC SURGERY AND HEART TRANSPLANT DEVICES
 C030101 - EXTRACORPOREAL CIRCULATION KITS
 C03010301 - CARDIOPULMONARY SUPPORT KITS (C.P.S. AND ECMO)
 C0502 - CARDIOVASCULAR INTRODUCER SHEATHS, VALVED

In red font = no more suppliers on the EU market

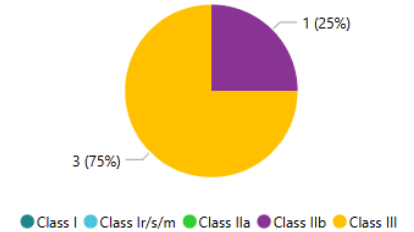
Alternative suppliers on the EU market (MDR)



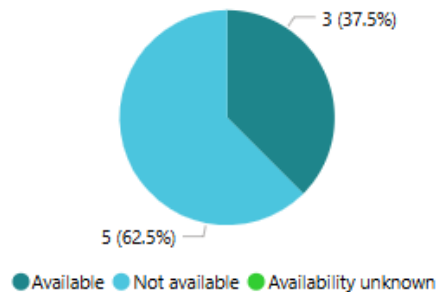
Alternative treatments or medical procedures available (MDR)



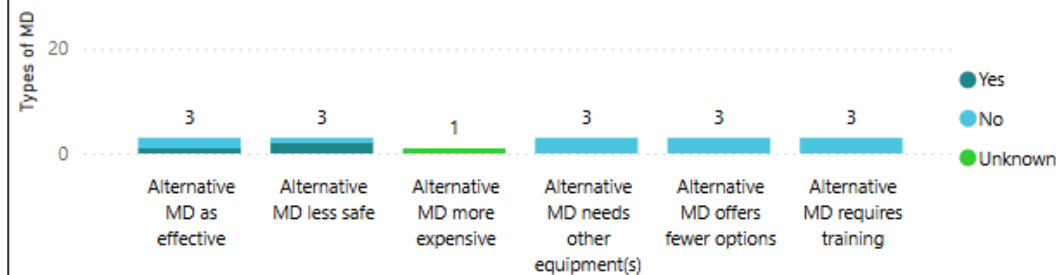
Risk class of type of CE-marked MD (MDR)



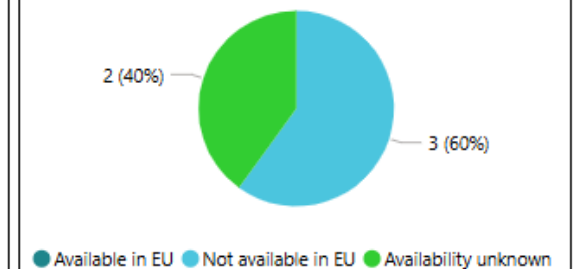
Alternative CE-marked MD available in country (MDR)



Alternative CE-marked MD in country (MDR)



If alternative CE-marked MD not available nationally, availability on the EU market (MDR)



HSP survey – PAST: MDs reported – EMDN Group D

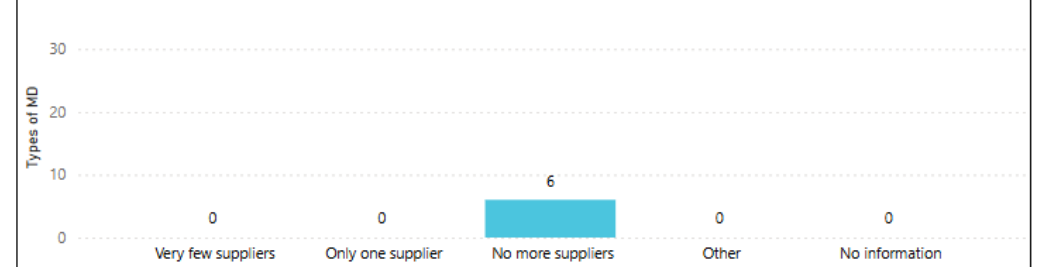
MD

Reported EMDN level (n=6)

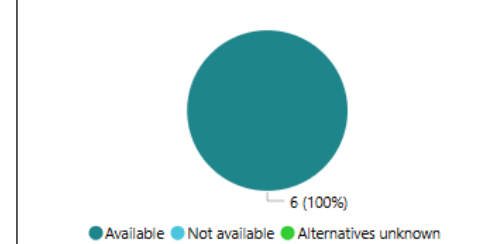
D030302 - SODIUM CHLORITE FOR THE DISINFECTION OF MEDICAL DEVICES
D0502 - HYDROGEN PEROXIDE FOR DISINFECTION OF MEDICAL DEVICES
D0701 - ETHANOL FOR THE DISINFECTION OF MEDICAL DEVICES
D0702 - ISOPROPYL ALCOHOL FOR THE DISINFECTION OF MEDICAL DEVICES
D0799 - ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
D0801 - ENZYMATIC DETERGENTS FOR MEDICAL DEVICES

In red font = no more suppliers on the EU market

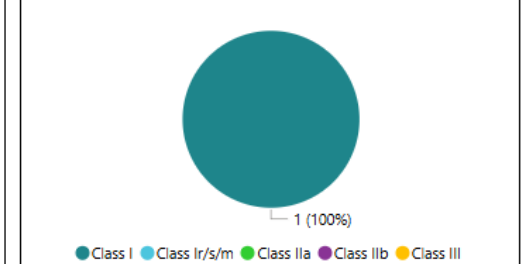
Alternative suppliers on the EU market (MDR)



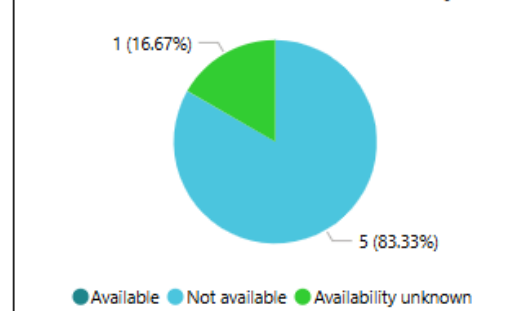
Alternative treatments or medical procedures available (MDR)



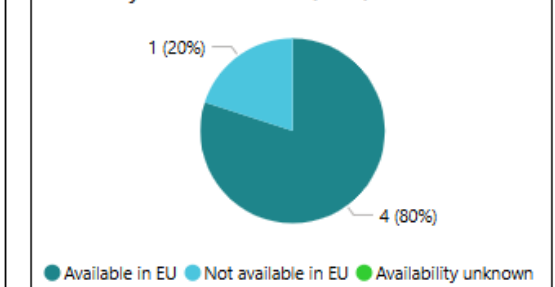
Risk class of type of CE-marked MD (MDR)



Alternative CE-marked MD available in country (MDR)



If alternative CE-marked MD not available nationally, availability on the EU market (MDR)

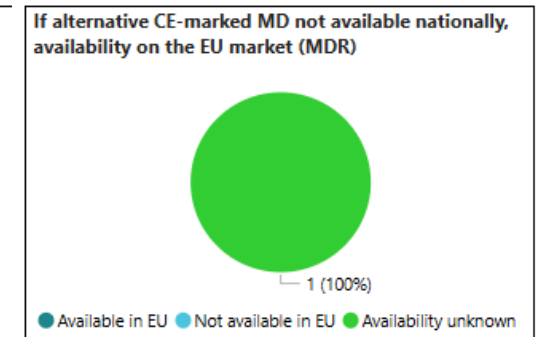
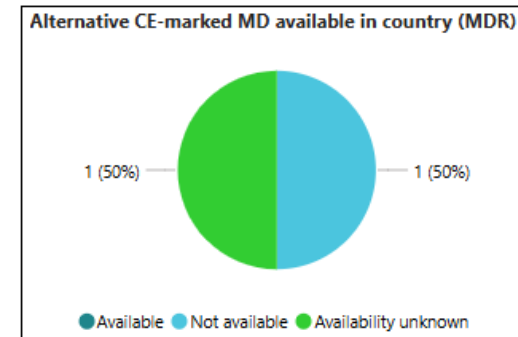
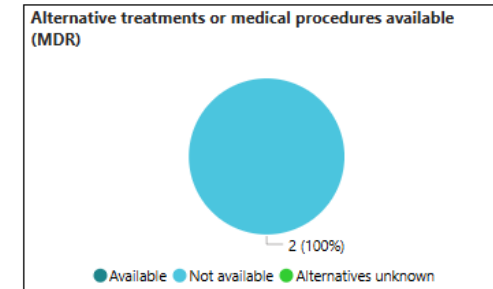
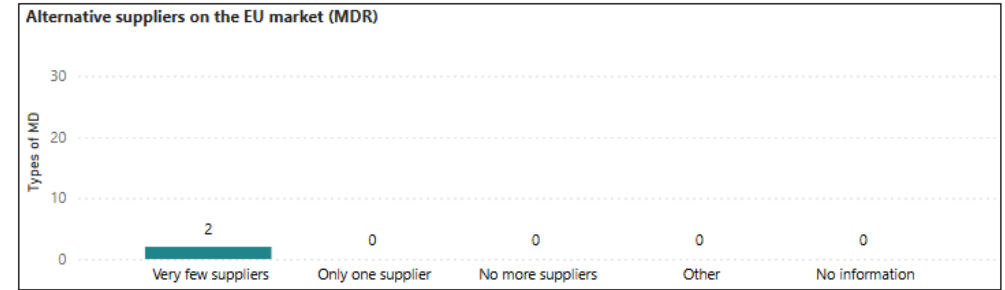


HSP survey – PAST: MDs reported – EMDN Group F

MD

Reported EMDN level (n=2)

F900101 - PERITONEAL DIALYSIS CATHETERS AND KITS
F900202 - PERMANENT HEMODIALYSIS CATHETERS AND KITS

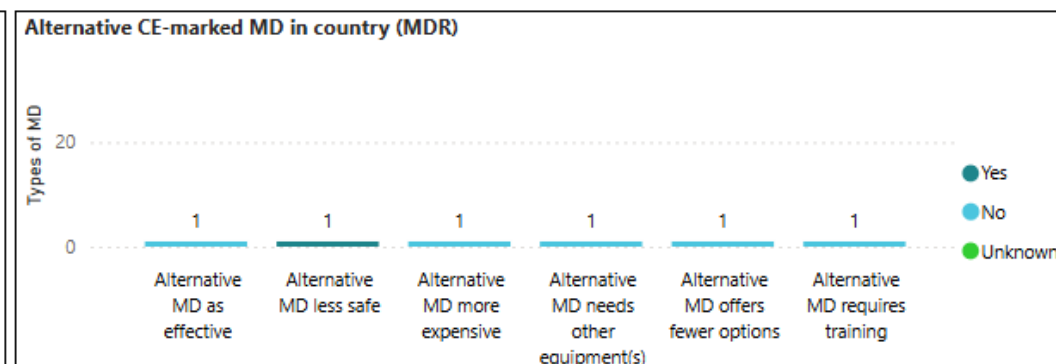
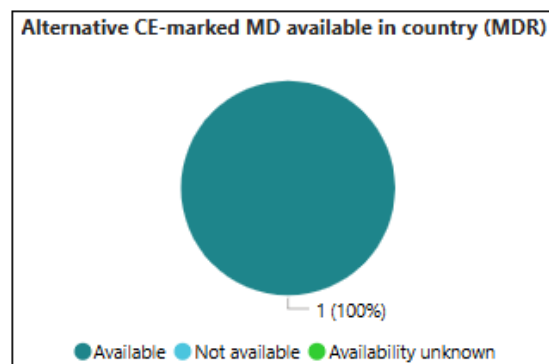
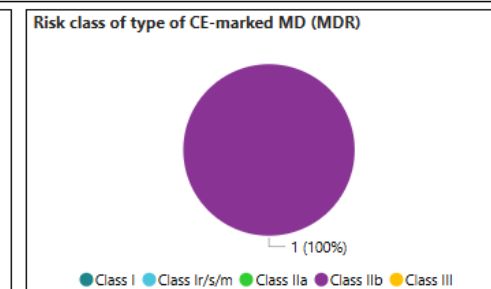
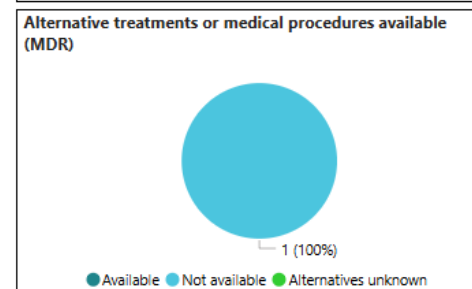
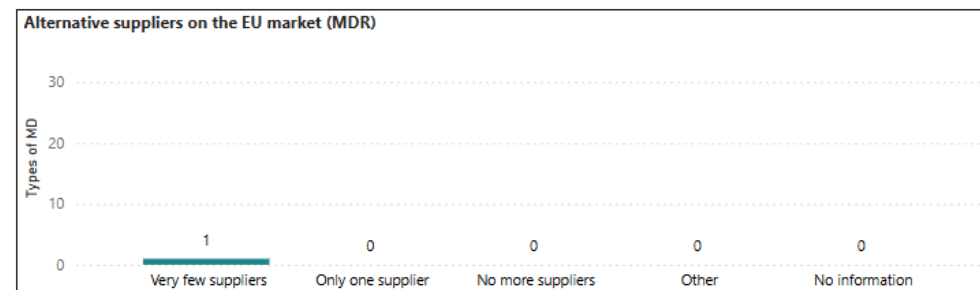


HSP survey – PAST: MDs reported – EMDN Group G

MD

Reported EMDN level (n=1)

G030603 - INTESTINAL COATING SYSTEMS FOR ABSORPTION REDUCTION

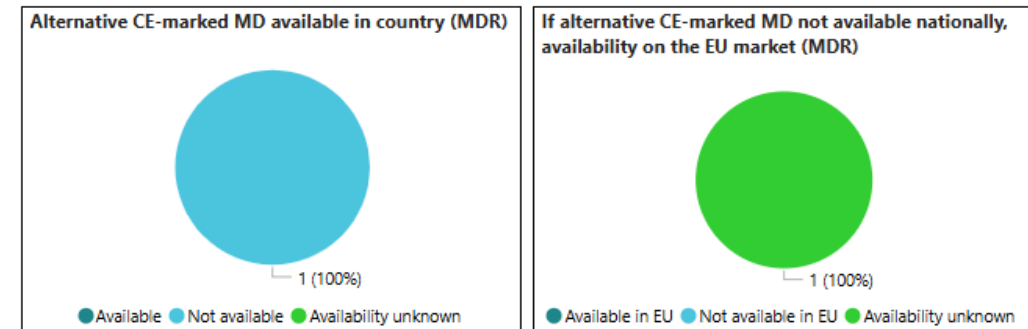
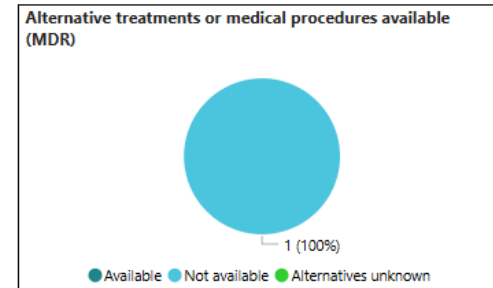
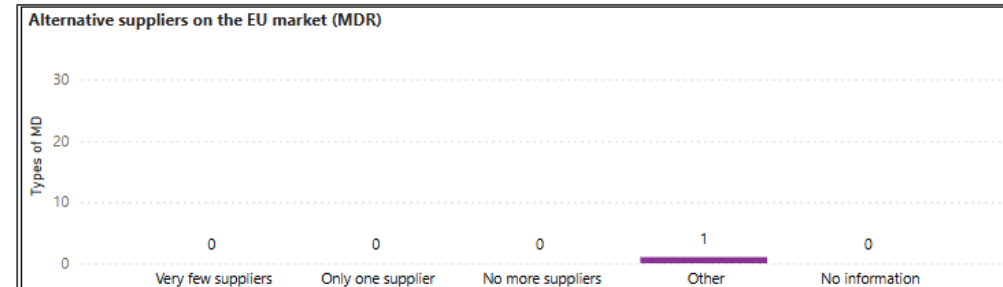


HSP survey – PAST: MDs reported – EMDN Group J

MD

Reported EMDN level (n=1)

J05 - BRACHYTHERAPY IMPLANTABLE DEVICES

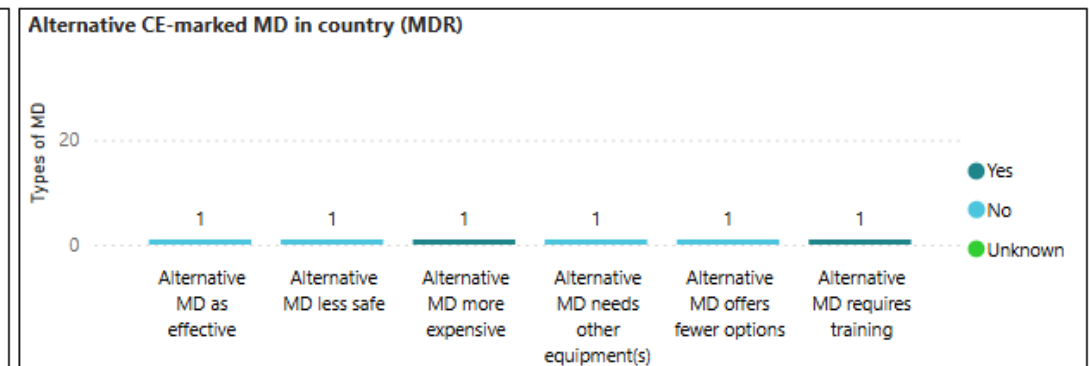
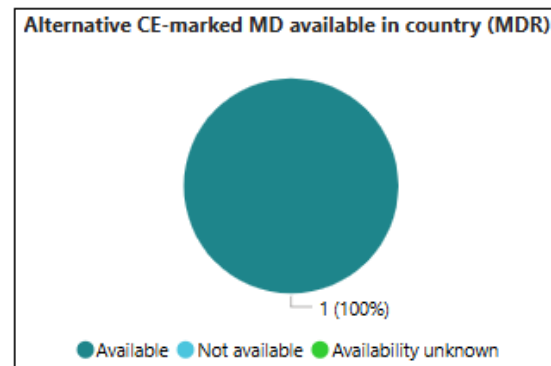
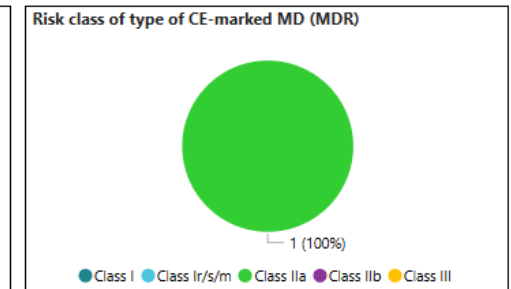
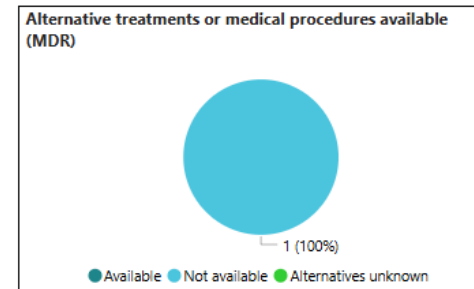
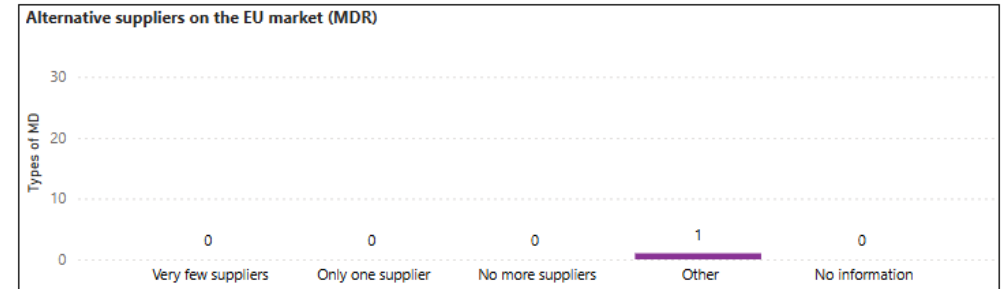


HSP survey – PAST: MDs reported – EMDN Group M

MD

Reported EMDN level (n=1)

M0501 - SURGICAL PLASTERS

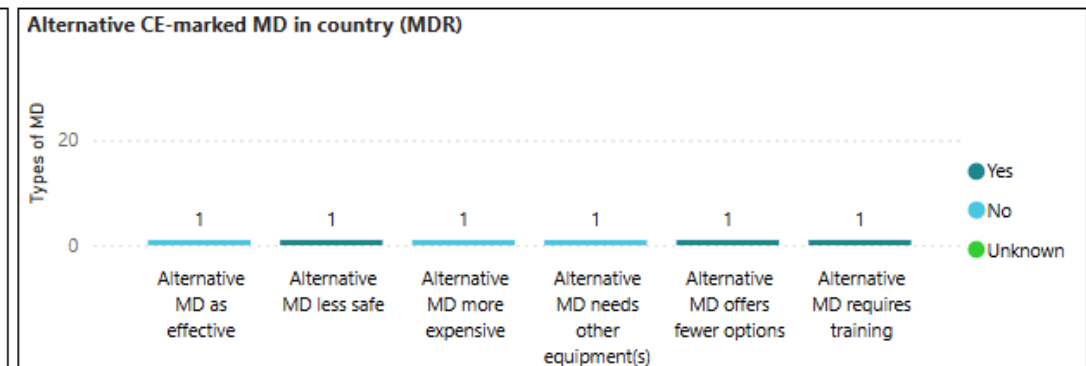
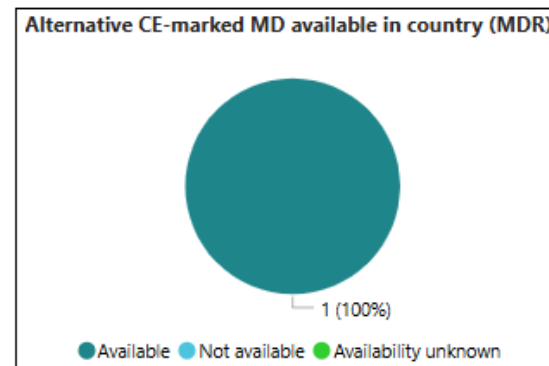
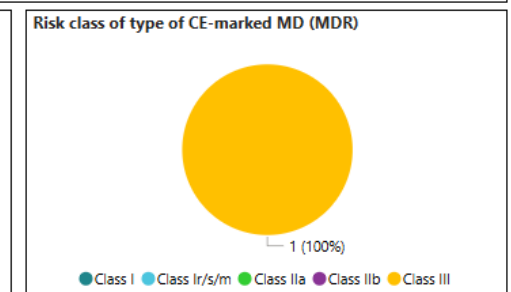
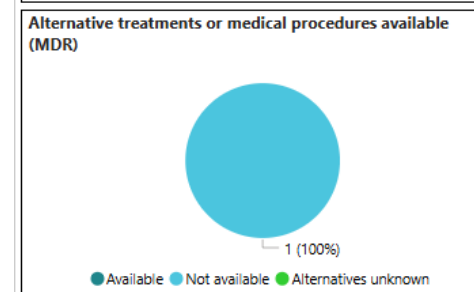
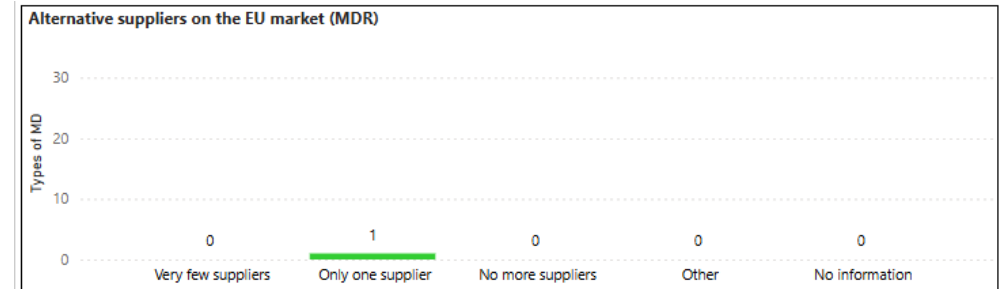


HSP survey – PAST: MDs reported – EMDN Group N

MD

Reported EMDN level (n=1)

N010380 - INTRACRANIAL DRAINAGE DEVICES AND KITS - ACCESSORIES



HSP survey – PAST: MDs reported – EMDN Group P

MD

Reported EMDN level (n=4)

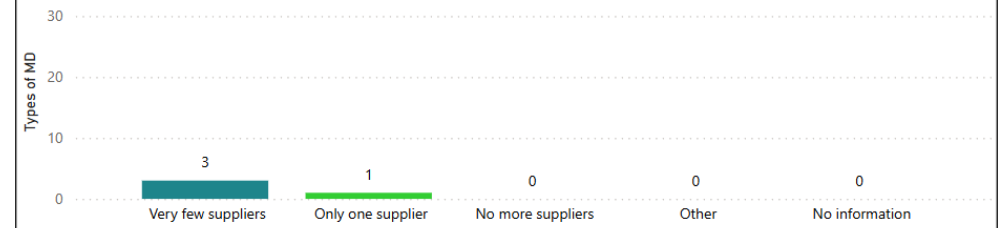
P0702 - VASCULAR PATCHES

P070402 - VASCULAR STENTS

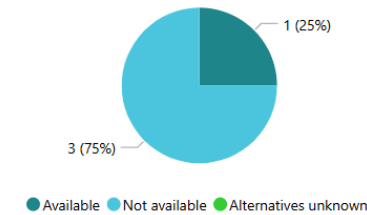
P090703 - IMPLANTABLE VERTEBRAL STABILISATION OR FIXATION SYSTEMS

P0909 - KNEE PROSTHESES

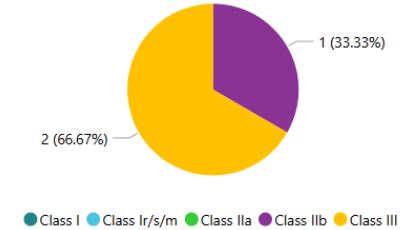
Alternative suppliers on the EU market (MDR)



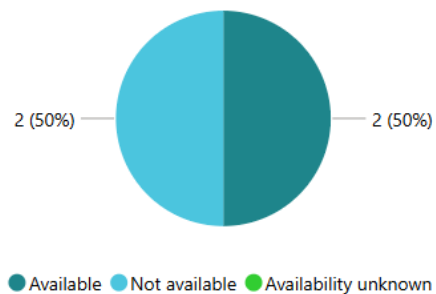
Alternative treatments or medical procedures available (MDR)



Risk class of type of CE-marked MD (MDR)

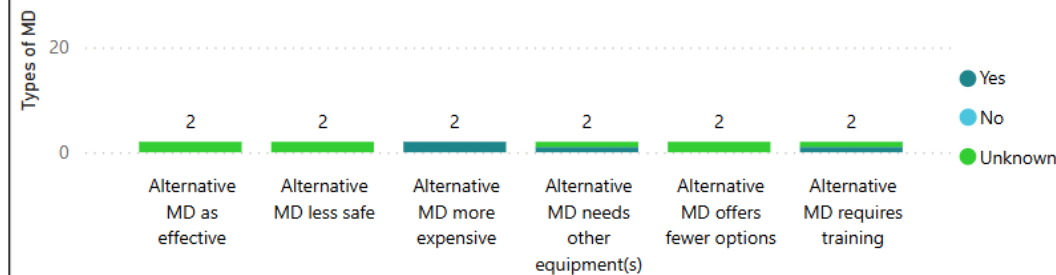


Alternative CE-marked MD available in country (MDR)

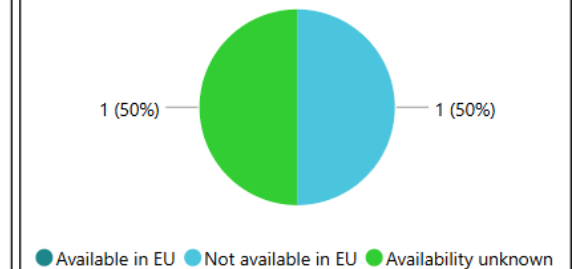


Alternative CE-marked MD in country (MDR)

Only in 2 cases alternative CE-marked MDs were available



If alternative CE-marked MD not available nationally, availability on the EU market (MDR)



HSP survey – PAST: MDs reported – EMDN Group Q

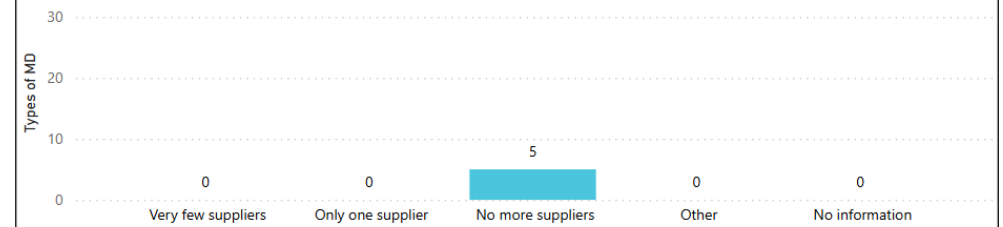
MD

Reported EMDN level (n=5)

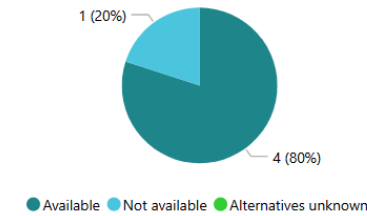
Q010101 - DENTAL RESTORATION DEVICES
Q01010102 - TEMPORARY AND PERMANENT DENTAL RESTORATION CEMENTS
Q01010106 - DENTAL RESTORATION GLASS IONOMERS
Q01010399 - DENTAL MEDICATION DEVICES - OTHER
Q019001 - SALIVA ASPIRATORS AND SALIVA ABSORBENTS

In red font = no more suppliers on the EU market

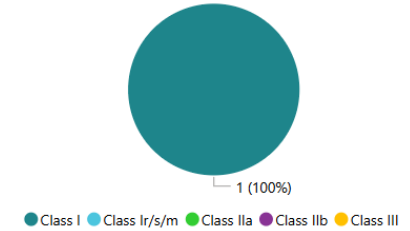
Alternative suppliers on the EU market (MDR)



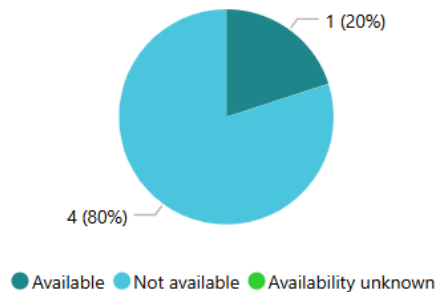
Alternative treatments or medical procedures available (MDR)



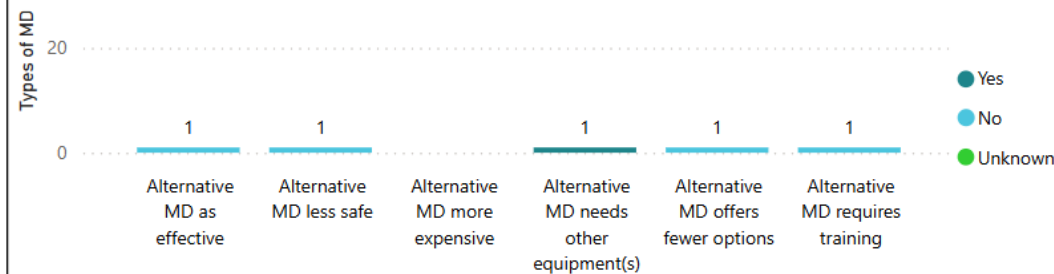
Risk class of type of CE-marked MD (MDR)



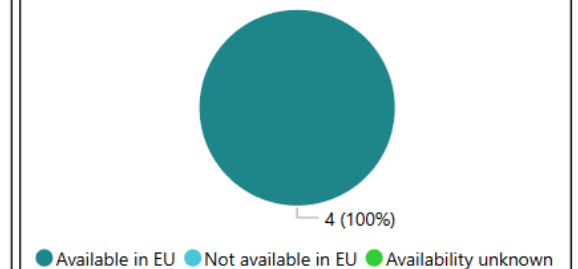
Alternative CE-marked MD available in country (MDR)



Alternative CE-marked MD in country (MDR)



If alternative CE-marked MD not available nationally, availability on the EU market (MDR)



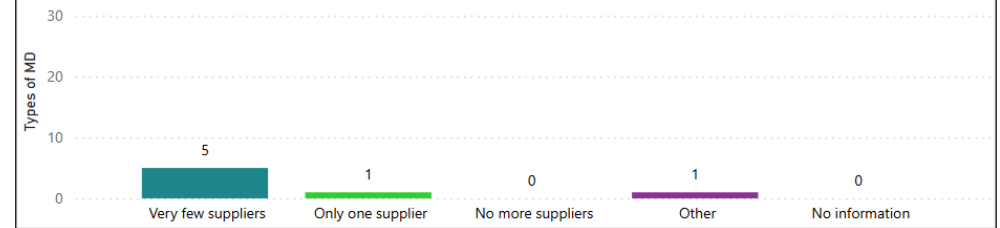
HSP survey – PAST: MDs reported – EMDN Group R

MD

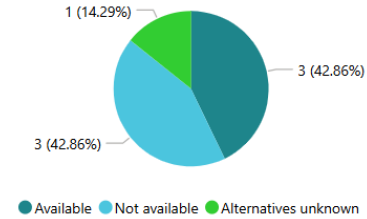
Reported EMDN level (n=7)

R010102 - GUEDEL AIRWAY TUBES
R0103 - ENDOTRACHEAL TUBES
R0105 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS
R02 - BREATHING CIRCUITS AND CATHETER MOUNTS
R0501 - RESPIRATORY SUCTION PROBES AND SYSTEMS
R0601 - NEBULISATION SYSTEMS
R0601 - NEBULISATION SYSTEMS

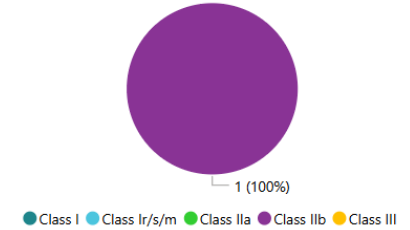
Alternative suppliers on the EU market (MDR)



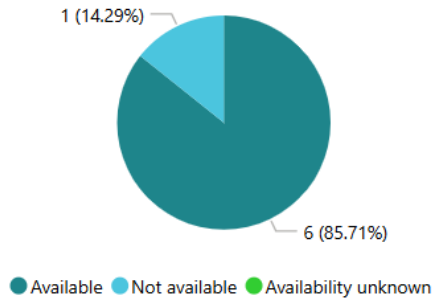
Alternative treatments or medical procedures available (MDR)



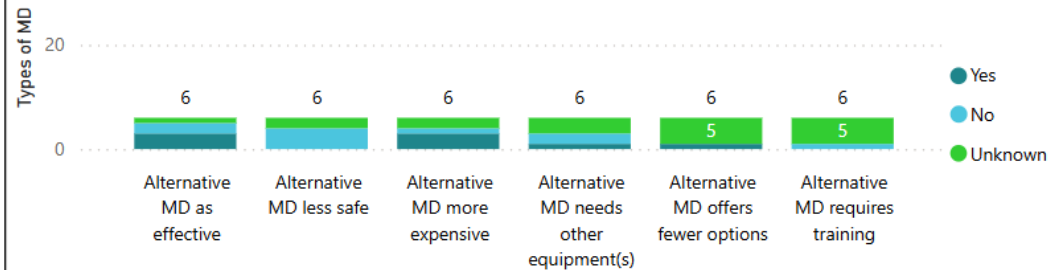
Risk class of type of CE-marked MD (MDR)



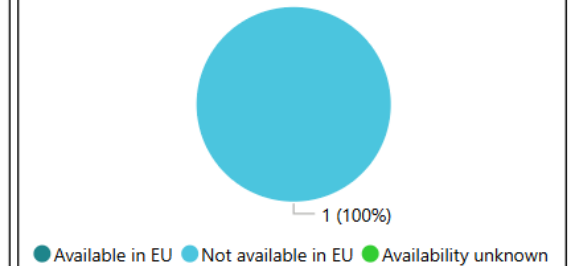
Alternative CE-marked MD available in country (MDR)



Alternative CE-marked MD in country (MDR)



If alternative CE-marked MD not available nationally, availability on the EU market (MDR)

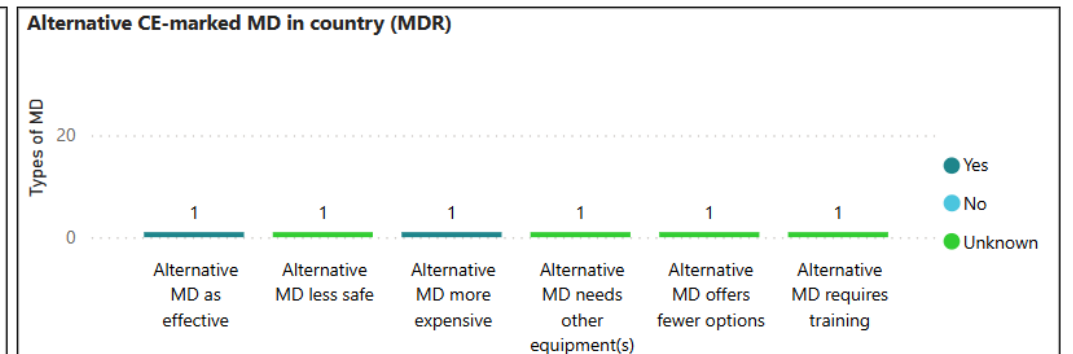
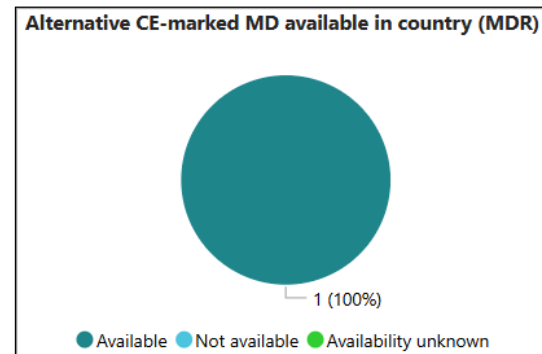
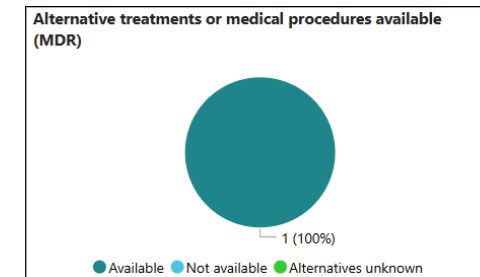
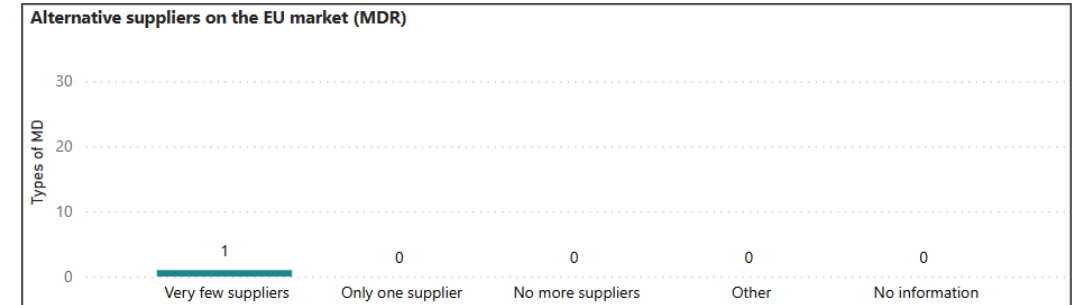


HSP survey – PAST: MDs reported – EMDN Group U

MD

Reported EMDN level (n=1)

U010105 - URETHRAL PROSTATIC AND BLADDER CATHETERS, NELATON



HSP survey – PAST: MDs reported – EMDN Group V

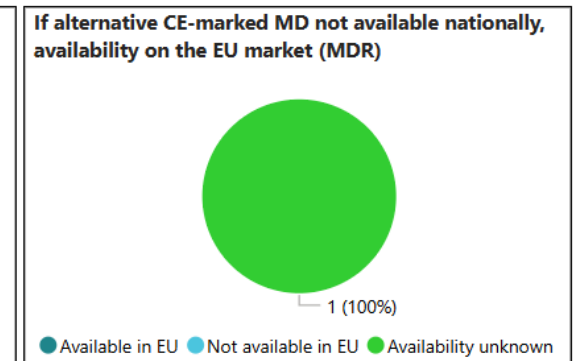
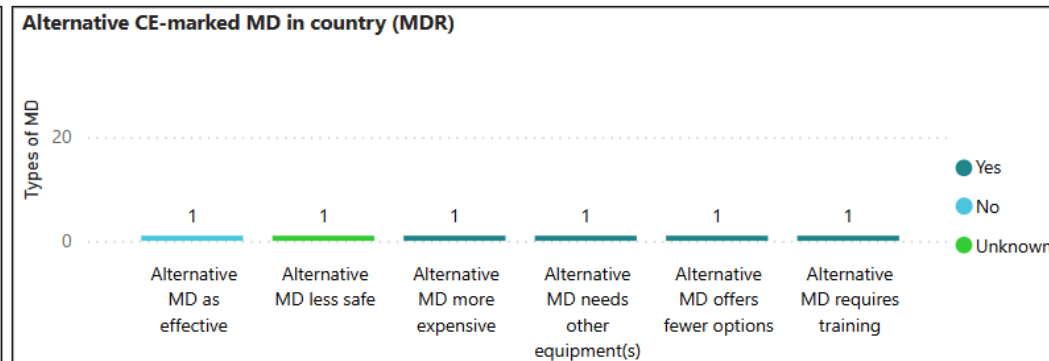
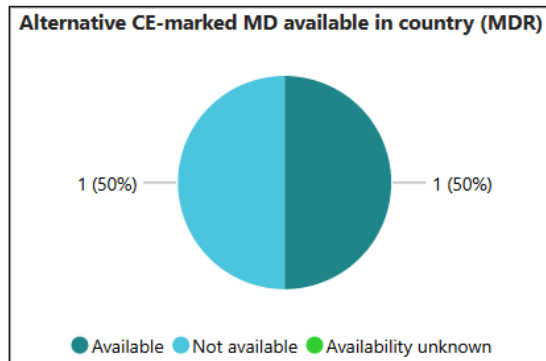
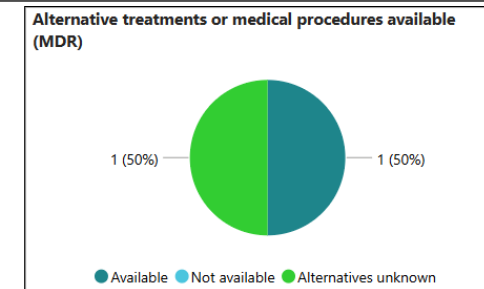
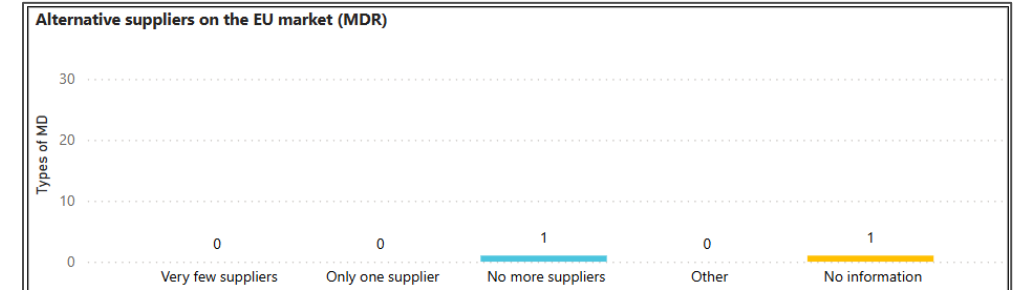
MD

Reported EMDN level (n=2)

V020380 - NEWBORN NUTRITION DEVICES - ACCESSORIES

V92 - MEDICAL DEVICE SOFTWARE - NOT INCLUDED IN OTHER CLASSES

In red font = no more suppliers on the EU market



HSP survey – PAST: MDs reported – EMDN Group Z

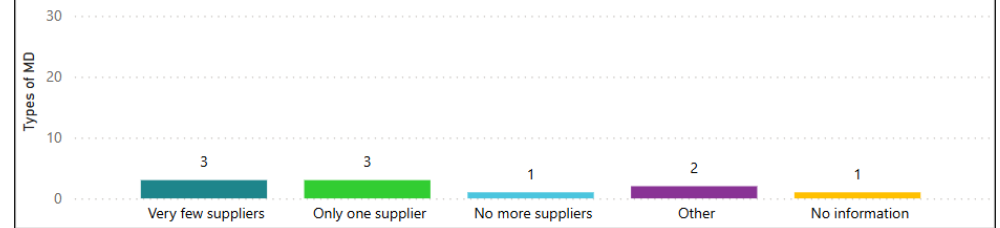
MD

Reported EMDN level (n=10)

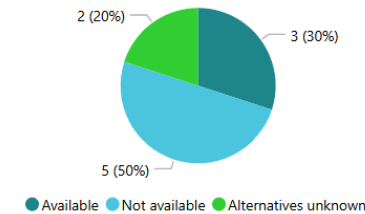
Z - MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES
 Z11010392 - BRACHYTHERAPY RADIATION SYSTEMS - MEDICAL DEVICE SOFTWARE
 Z11049099 - VARIOUS ULTRASOUND INSTRUMENTS - OTHER
Z119002 - DOSIMETERS
 Z12030105 - PULMONARY VENTILATORS FOR HOSPITAL USE
 Z12039002 - INTRA COMPARTMENTAL PRESSURE MONITOR SYSTEMS
 Z12059003 - CLOT ASPIRATORS
 Z120604 - IONTOPHORESIS EQUIPMENT
 Z12080408 - SWEAT TEST STIMULATORS
 Z12080408 - SWEAT TEST STIMULATORS

In red font = no more suppliers on the EU market

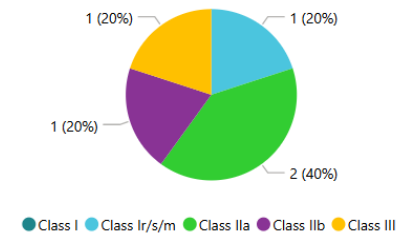
Alternative suppliers on the EU market (MDR)



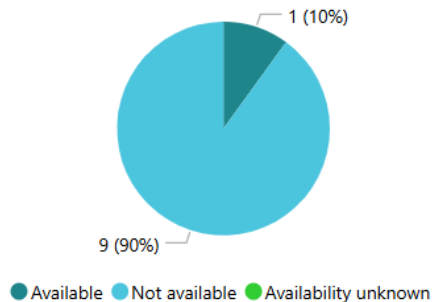
Alternative treatments or medical procedures available (MDR)



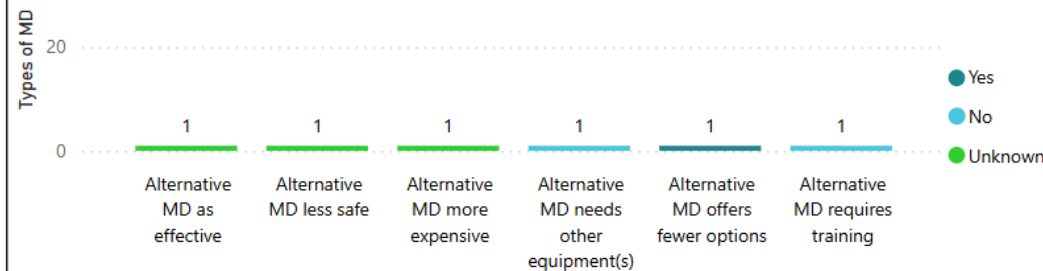
Risk class of type of CE-marked MD (MDR)



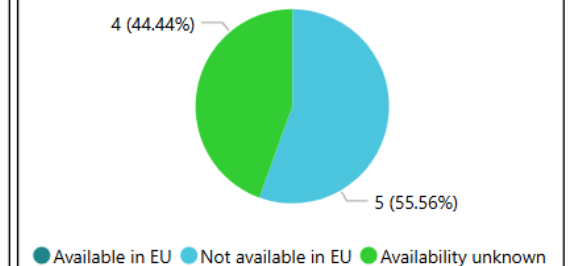
Alternative CE-marked MD available in country (MDR)



Alternative CE-marked MD in country (MDR)



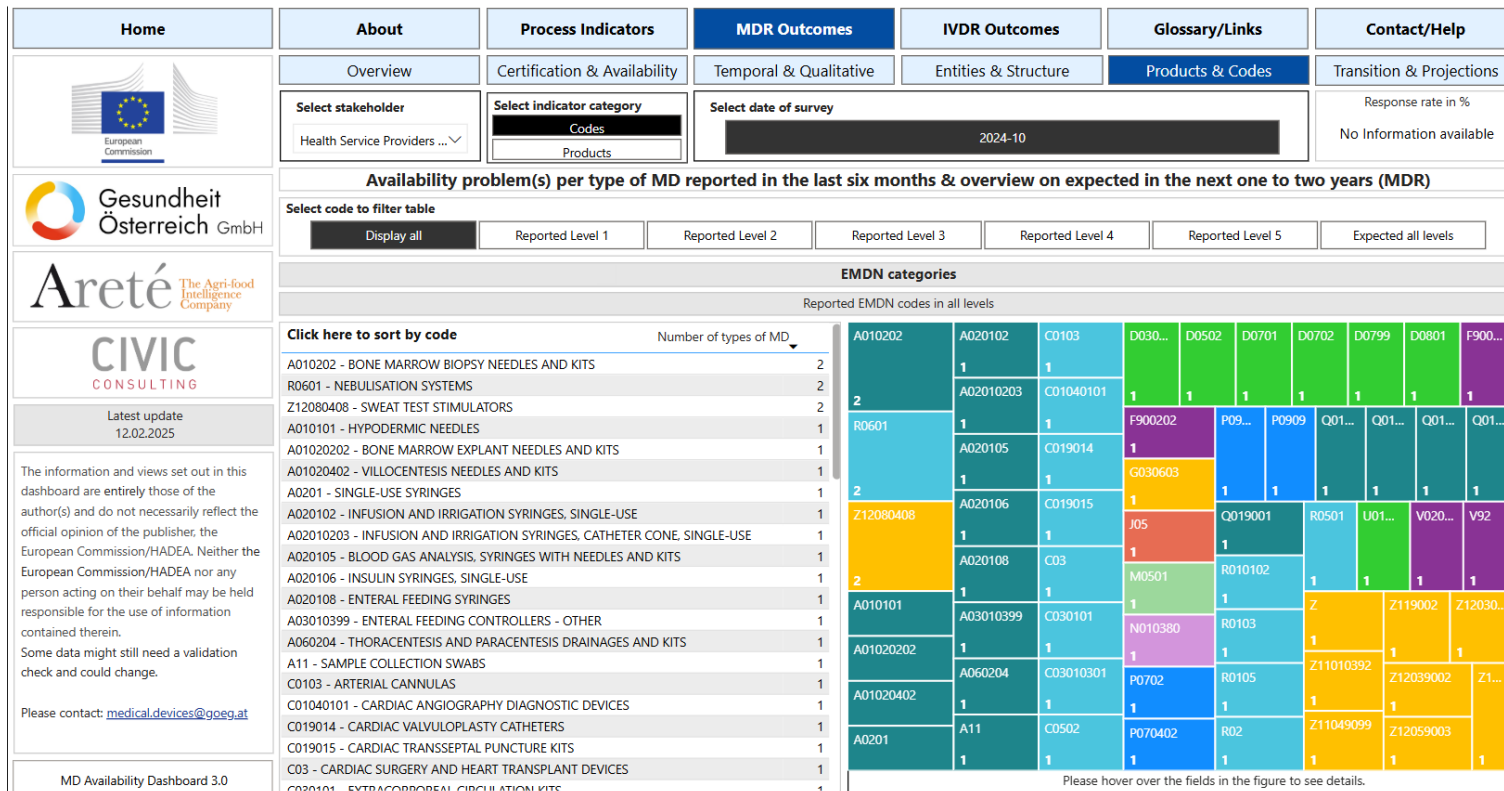
If alternative CE-marked MD not available nationally, availability on the EU market (MDR)



HSP survey – PAST: MDs reported – EMDN level 5

- More granular information is included in the dashboard on EMDN level 5

Monitoring the Availability of Medical Devices and In Vitro Diagnostic Medical Devices in the EU



FUTURE

HSP survey – Future: 22 product notifications

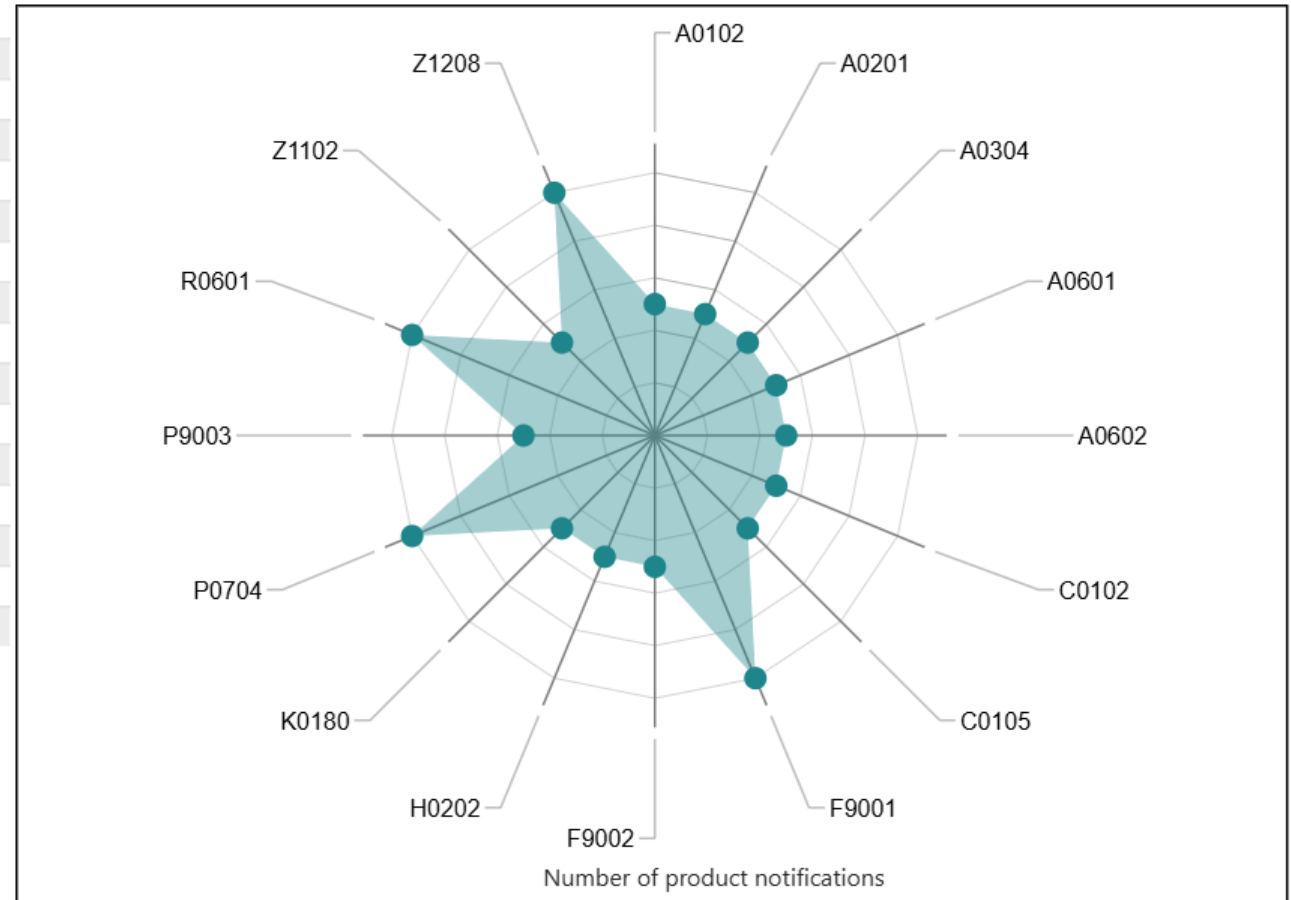
Product notifications based on the level of granularity received (different EMDN levels were reported by HSP)

F900101 - PERITONEAL DIALYSIS CATHETERS AND KITS	2
P070402 - VASCULAR STENTS	2
R0601 - NEBULISATION SYSTEMS	2
Z12080408 - SWEAT TEST STIMULATORS	2
A01020299 - NEEDLES AND KITS - BONE MARROW BIOPSY - OTHER	1
A020108 - ENTERAL FEEDING SYRINGES	1
A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE	1
A0601 - SURGICAL DRAINAGE SYSTEMS	1
A060203 - PLEURAL DRAINAGES WITH VALVE AND KITS	1
C010204 - SUBCUTANEOUS IMPLANTABLE VENOUS ACCESS PORT SYSTEMS	1
C010502 - INTRAVASCULAR EMOBILIC PROTECTION CATHETERS AND SYSTEMS	1
F900202 - PERMANENT HEMODIALYSIS CATHETERS AND KITS	1
H0202 - STAPLERS, OPEN SURGERY	1
J05 - BRACHYTHERAPY IMPLANTABLE DEVICES	1
K0180 - ENDOTHERAPY DEVICES - OTHER ACCESSORIES	1
P900301 - PTFE TISSUE PATCHES	1
Z - MEDICAL EQUIPMENT AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES	1
Z110201 - COMPUTERISED GAMMA CAMERAS	1

HSP survey – Future: EMDN codes Level 3

F9001 - PERITONAEAL DIALYSIS DEVICES (NOT INCLUDED IN OTHER GROUPS)	2
P0704 - VASCULAR AND CARDIAC ENDOPROSTHESES	2
R0601 - NEBULISATION SYSTEMS	2
Z1208 - OBSTETRICS AND GYNAECOLOGY INSTRUMENTS	2
A0102 - BIOPSY NEEDLES AND KITS	1
A0201 - SINGLE-USE SYRINGES	1
A0304 - ADMINISTRATION KITS	1
A0601 - SURGICAL DRAINAGE SYSTEMS	1
A0602 - PERCUTANEOUS DRAINAGE SYSTEMS	1
C0102 - CENTRAL I.V. CATHETERS	1
C0105 - INTRAVASCULAR PROTECTION DEVICES	1
F9002 - VASCULAR ACCESS DEVICES (ONLY FOR HAEMODIALYSIS)	1
H0202 - STAPLERS, OPEN SURGERY	1
K0180 - ENDOTHERAPY DEVICES - OTHER ACCESSORIES	1
P9003 - TISSUE PATCHES	1
Z1102 - NUCLEAR MEDICINE INSTRUMENTS	1

In total 63 product notifications; products were grouped on EMDN level 3



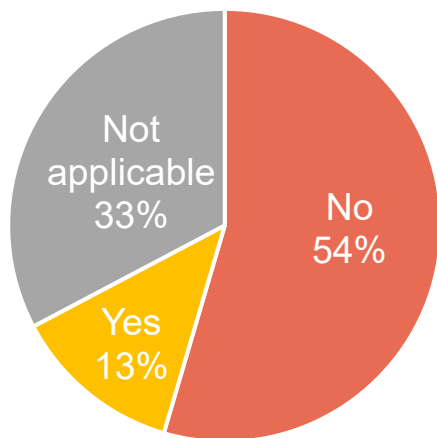
2.3. Survey results for in vitro diagnostic medical devices

Questionnaire part C including questions 7 to 8

HSP survey – results (n = 55)

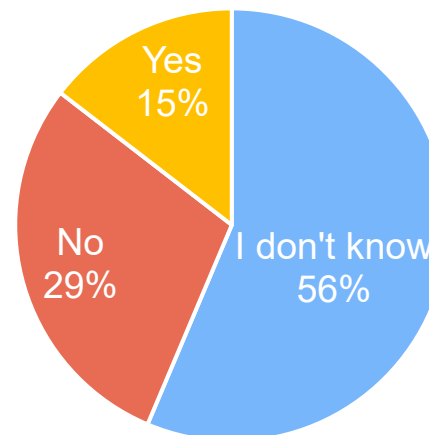
IVD PAST:

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?**



IVD FUTURE:

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?**



* Related to the availability of medical devices on the European market in the context of the implementation of IVDR; budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions were not the subject of this survey.

HSP survey – results (n = 55)

	PAST: Problems* related to the purchasing / being supplied with relevant IVDs in the last six months	FUTURE: Problems* related to the purchasing / being supplied with specific types of IVDs in the coming 1-2 years
In vitro diagnostic medical devices	13 product notifications	12 product notifications

* Related to the availability of medical devices on the European market in the context of the implementation of the IVDR; budget constraints within the purchasing department or health institution, any consequences of (national) purchasing practices or national reimbursement/coverage decisions were not the subject of this survey.

PAST

HSP survey – supplier situation

Alternative suppliers on the EU market for reported types of devices (IVDR)

Number of product notifications



- No other supplier can supply reagents suitable for the same high-throughput analyser.
- The machine on which the CE-IVD test will be run will be discontinued.
- Product was not available for a certain time, alternatives cannot be easily implemented without proper validation (2x).
- Production was stopped.

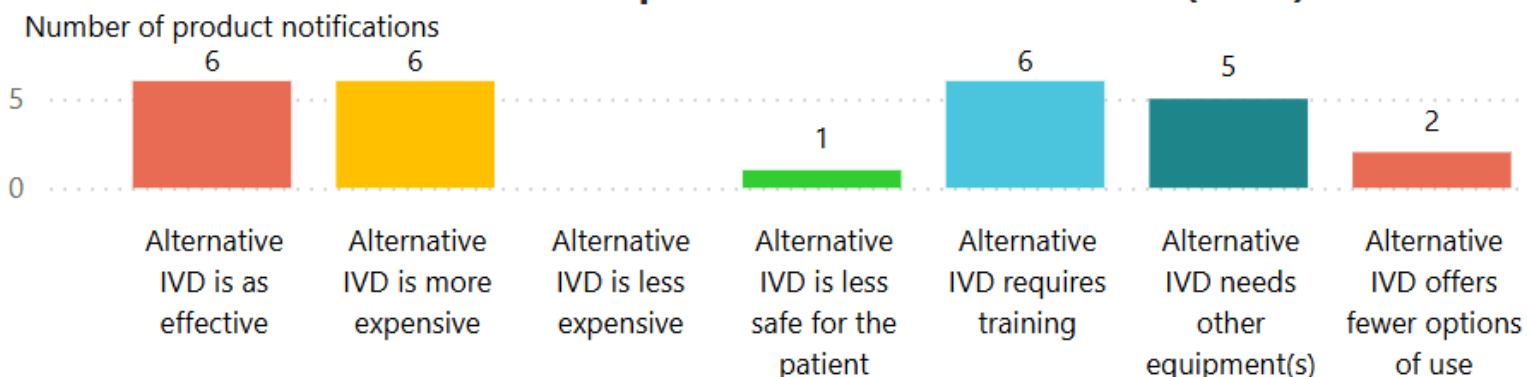
13 product notifications

HSP survey – alternatives available?

Alternative CE-marked IVD available for reported types of devices (IVDR)



Alternative CE-marked IVD in comparison to non available IVD (IVDR)



HSP survey – Past: Reported IVDs

Product notifications based on the level of granularity received (different EMDN levels were reported by HSP)

W010401 - BACTERIOLOGY - CULTURE MEDIA	2
W01029099 - IMMUNOCHEMISTRY REAGENTS - OTHER	1
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)	1
W01030607 - INTERLEUKINS RECEPTORS (IL-2R,IL6R ...)	1
W010307 - HISTOLOGY/CYTOLOGY REAGENTS	1
W01040102 - PREPARED MEDIA IN TUBES (BACTERIOLOGY)	1
W01050102 - GONOCOCCI (NEISSERIA GONORRHOEAE)	1
W01050103 - SYPHILIS (TREPONEMA PALLIDUM)	1
W01050118 - CLOSTRIDIUM DIFFICILE	1
W020205 - HISTOLOGY / CYTOLOGY	1
W0299 - IVD INSTRUMENTS - OTHER	1
W05030201 - PIPETTES	1

HSP survey – PAST: IVDs reported – EMDN Group W01

IVD

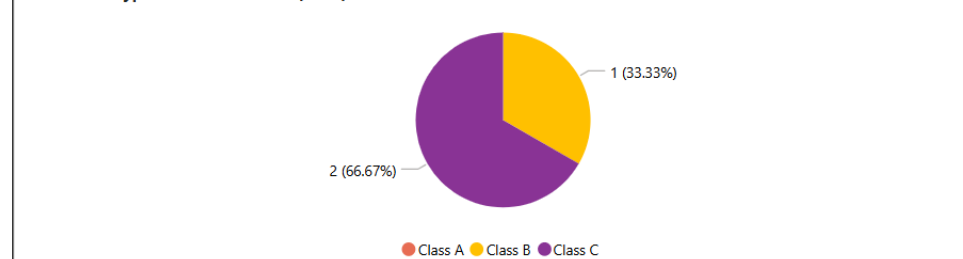
Reported EMDN level (n=10)

W01029099 - IMMUNOCHEMISTRY REAGENTS - OTHER
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)
W01030607 - INTERLEUKINS RECEPTORS (IL-2R,IL6R ...)
W010307 - HISTOLOGY/CYTOLOGY REAGENTS
W010401 - BACTERIOLOGY - CULTURE MEDIA
W010401 - BACTERIOLOGY - CULTURE MEDIA
W01040102 - PREPARED MEDIA IN TUBES (BACTERIOLOGY)
W01050102 - GONOCOCCI (NEISSERIA GONORRHOEAE)
W01050103 - SYPHILIS (TREPONEMA PALLIDUM)
W01050118 - CLOSTRIDIUM DIFFICILE

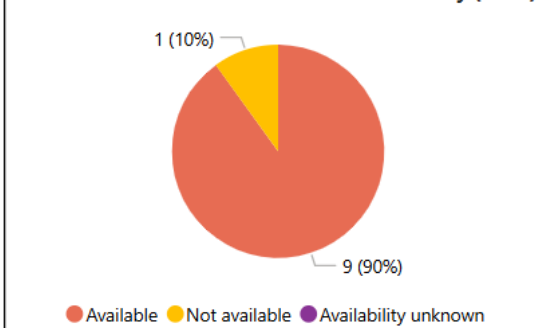
Alternative suppliers on the EU market (IVDR)



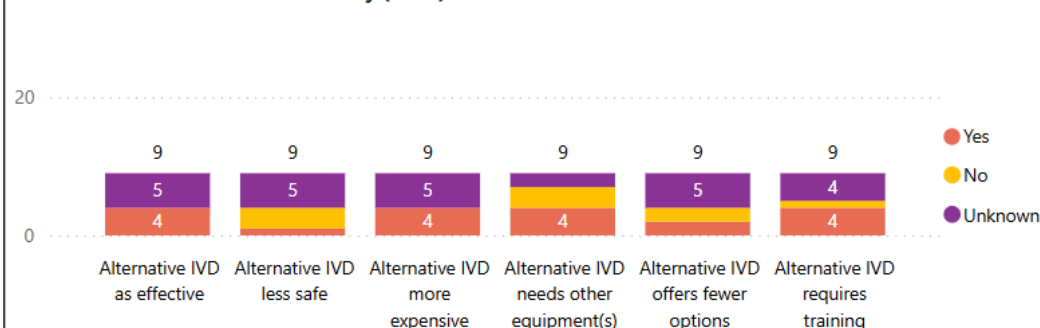
Risk class of type of CE-marked IVD (IVDR)



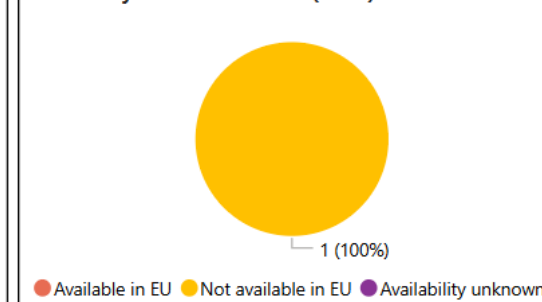
Alternative CE-marked IVD available in country (IVDR)



Alternative CE-marked IVD in country (IVDR)



If alternative CE-marked IVD not available nationally, availability on the EU market (IVDR)

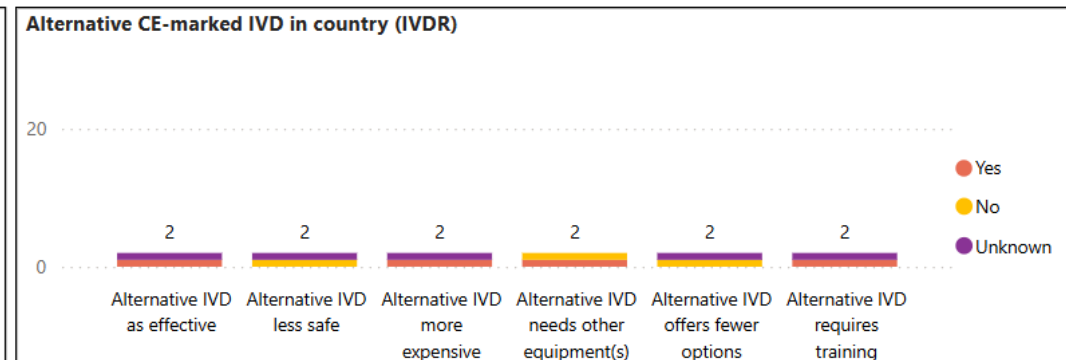
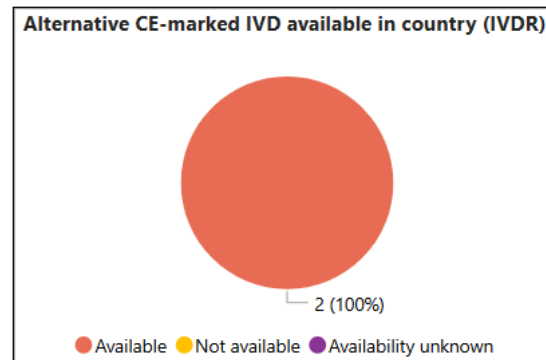
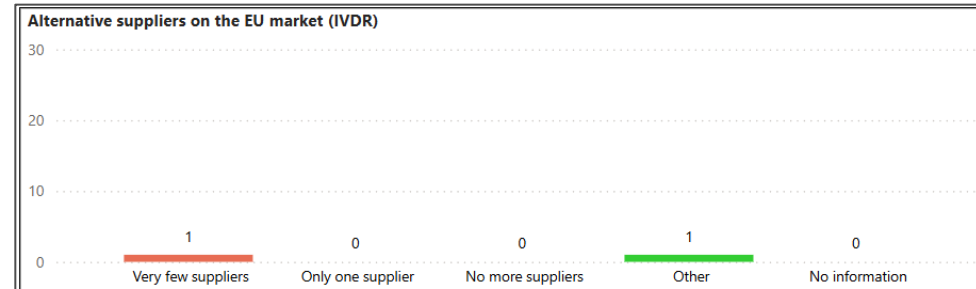


HSP survey – PAST: IVDs reported – EMDN Group W02

IVD

Reported EMDN level (n=2)

W020205 - HISTOLOGY / CYTOLOGY
W0299 - IVD INSTRUMENTS - OTHER

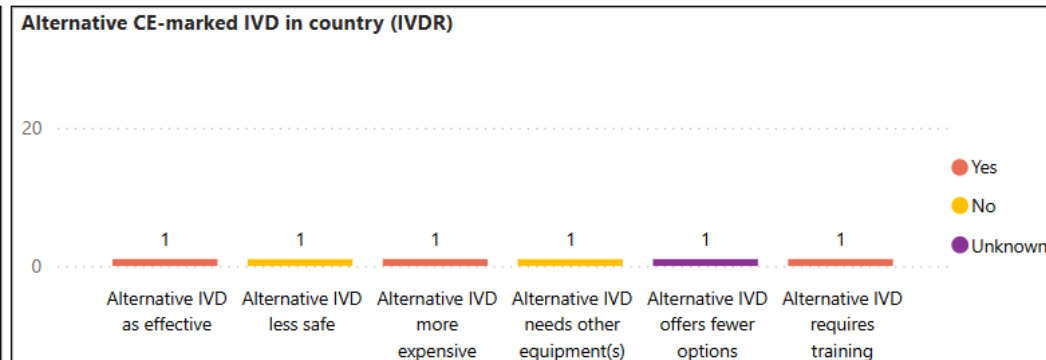
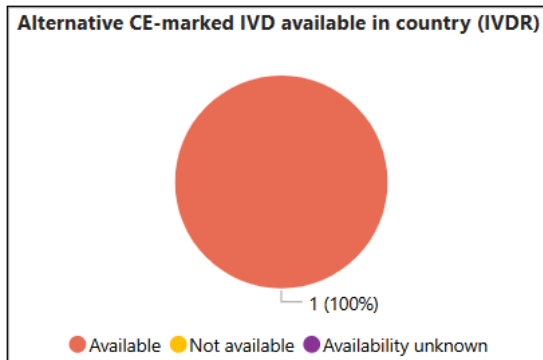
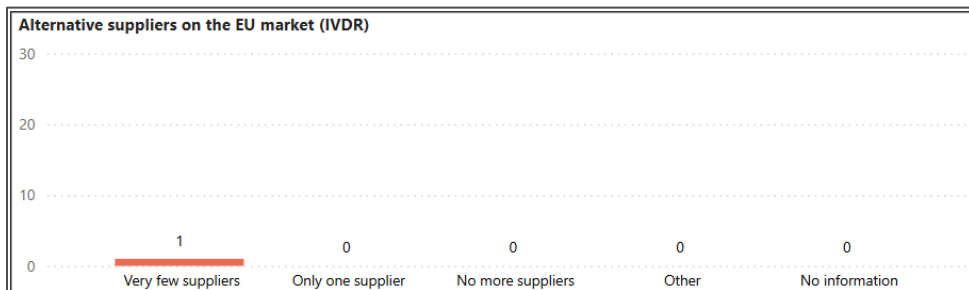


HSP survey – PAST: IVDs reported – EMDN Group W05

IVD

Reported EMDN level (n=1)

W05030201 – PIPETTES



FUTURE

HSP survey – Future: 12 product notifications

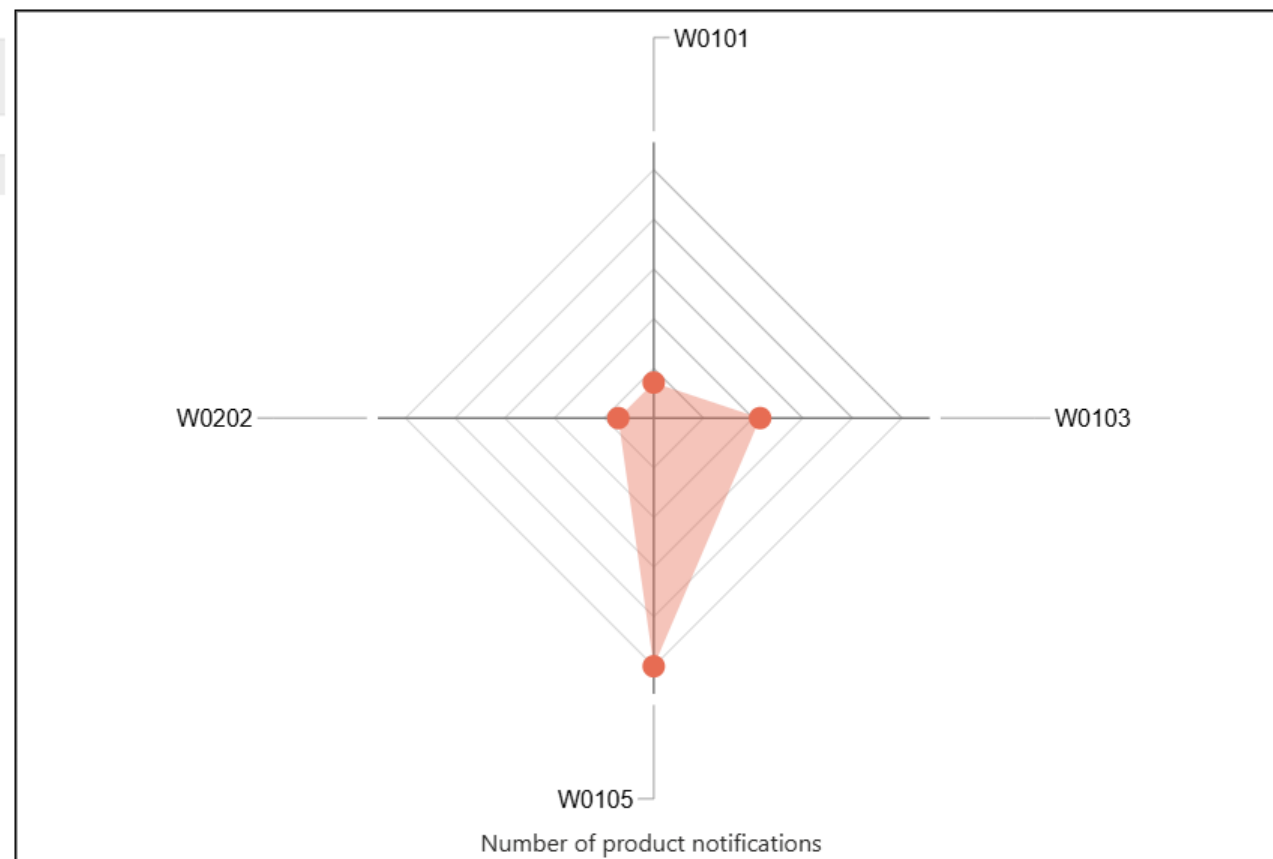
Product notifications based on the level of granularity received (different EMDN levels were reported by HSP)

W01010304 - CHLORIDE	1
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)	1
W010307 - HISTOLOGY/CYTOLOGY REAGENTS	1
W010308 - MONOCLONAL ANTIBODIES / FLOW CYTOMETRY	1
W010501 - BACTERIOLOGY (INFECT. IMMUNOLOGY/NAT)	1
W01050102 - GONOCOCCI (NEISSERIA GONORRHOEAE)	1
W01050203 - HEPATITIS C VIRUS	1
W010504 - OTHER VIROLOGY TESTS (INFECT. IMMUNOLOGY/NAT)	1
W01050501 - TOXOPLASMA	1
W01050603 - MYCOLOGY IMMUNOASSAYS	1
W01050604 - MYCOLOGY - NA REAGENTS	1
W020205 - HISTOLOGY / CYTOLOGY	1

HSP survey – Future: EMDN codes Level 3

W0105 - INFECTIOUS DISEASES	7
W0103 - HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY	3
W0101 - CLINICAL CHEMISTRY	1
W0202 - HEMATOLOGY / HISTOLOGY / CYTOLOGY INSTRUMENTS	1

In total 12 product notifications; products were grouped on EMDN level 3



Summary and additional information

Summary

- Few replies received to the HSP survey
- Shortages/withdrawals occur causing concerns for health service providers
 - But not a homogeneous problem in Europe
 - Shortages often occur at short notice
 - Lack of information from manufacturers to suppliers
- Examples of unavailable MDs / IVDs: e.g. bone marrow explant needles and kits, villocentesis needles and kits, enteral feeding controllers, devices for pediatric cardiac catheterization, MDs in the field of neonatology, infection serology etc.
- Different situation for MDs as for IVDs
- Some institutions in Europe (e.g. EuroPHARMAT in France, ZINN in The Netherlands) have their own databases to manage and mitigate shortages
- Further investigations on product level needed

Additional information

Zorg Inkoop Netwerk Nederland (ZINN)



About

Zorg Inkoop Netwerk Nederland operates a national reporting center for shortages of medical supplies. This institution helps ensure the continuity of care by coordinating responses to potential shortages.

Definition of a potential shortage:

- The medical device is unavailable for more than 14 days for healthcare use;
- The potential shortage is expected to occur within the next 6 months;
- The potential shortage has been verified with the supplier or with two or more healthcare institutions;
- The supplier has not offered a (suitable) alternative.

<https://zorginkoopnetwerknederland.nl/>

Potential shortages reported



Total number of medical devices for which a potential shortage was reported (3 July 2023 – 31 March 2025): **2.634**

Reason provided	In %
MDR – product will not be MDR certified	36,1%
End-of-life product	15,9%
Unknown	22,3%
MDR – certificate not in time	13,1%
Production issue	5,3%
Logistics issue	3,0%
Discontinued by this supplier	1,7%
Safety issue	1,4%
IVDR – product will not be IVDR certified	0,4%
Raw material issue	0,4%
Supplier bankrupt	0,2%
IVDR – not on time	0,1%
Withdrawn from the market in the Netherlands	0,1%

Source: <https://zorginkoopnetwerknederland.nl/>

Potential shortages reported



- Top 10 medical devices
(3 July 2023 – 31 March 2025):

Top 10		
1	65.16.77.30 - Vascular stent bare metal	187
2	65.05.95.02 - Biopsy needle general	132
3	65.04.77.06 - Blood collection system	52
4	65.79.03.25 - Instrument	52
5	65.02.10.02 - Feeding tube	51
6	65.02.10.12 - Enteral feeding accessories	45
7	65.02.05.04 - Intravenous needle, cannula	44
8	65.16.47.02 - Urinary tract stent	41
9	65.09.03.09 - Fixation material for MHM	40
10	65.04.47.40 - Percutaneous kidney drainage + accessories	39

- Solution to shortage

Solution	In %
One-to-one alternative available	42,9%
Unknown	26,6%
Alternative offered by supplier verified and deemed suitable	17,4%
Alternative with the same intended use available	8,9%
No shortage after verification	2,0%
No alternative available: recommendation to initiate process for alternative methods/resources	1,5%
Verification could not be completed	0,4%
Exemption granted by the Ministry of Health (VWS)	0,2%

N=2463

Thank you

Contact for questions: medical.devices@goeg.at



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