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HTA, Reimbursement and Pricing of Diagnostic Tests for CA-ARTI

An international overview of policies (Task 5.5)

FINAL (LIVING DOCUMENT)

VALUE-Dx

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Abbreviations

ADL	Affections de longue durée (Long-term conditions), France
AMR	Antimicrobial resistance
ASO	Antistreptolysin O
CA-ARTI	Community acquired acute respiratory tract infection
CE	Conformité Européenne
CEPS	Comité Economique des Produits de Santé (Health Products Pricing Committee), France
CHIF	Croatian Health Insurance Fund
CRP	C-reactive protein
DRG	Diagnosis-related group
Dx	Diagnostic(s)
EAP	External Advisory Panel
EBM	Einheitlicher Bewertungsmaßstab (name of reimbursement formulary for technologies in Germany)
EHIF	Eesti Haigekassa (Estonian Health Insurance Fund)
EOPYY	ΕΥΡΩΠΑΪΚΗ ΚΑΡΤΑ ΑΣΦΑΛΙΣΗΣ (National Organisation for the Provision of Health Services), Greece
EPR	External price referencing
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
FFS	Fee-for-service
FinCCHTA	Kansallinen HTA-koordinaatioyksikkö (Coordinating Center for Health Technology Assessment), Finland
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee),Germany
GKV	Gesetzliche Krankenversicherung (Statutory Health Insurance Funds), Germany
GÖG	Gesundheit Österreich GmbH (Austrian National Public Health Institute)
GP	General Practitioner
H2020	Horizon 2020
HTA	Health Technology Assessment(s)
IMI	Innovative Medicines Initiative
IPR	Internal price referencing
LPPR	Liste des prestations et produits remboursable (list of reimbursable services and products), France
MD	Medical device(s)
n/a	No information available

NEAK	Nemzeti Egészségbiztosítási Alapkezelő (National Institute of Health Insurance Fund Management), Hungary
NHS	National Health Service
ÖGK	Österreichische Gesundheitskasse (Austrian Social Health Insurance Fund)
OOP	Out-of-pocket
P4P	Pay-for-performance
PCR	Polymerase chain reaction
PCT	Procalcitonin
POCT	Point-of-care testing
PPP	Pharmacy purchasing price (wholesale price)
PPRI MD	Pharmaceutical Pricing and Reimbursement Information Sub-group on Medical Devices
PPRI	Pharmaceutical Pricing and Reimbursement Information (network of competent authorities responsible for pricing and reimbursement of medicines)
PRP	Pharmacy retail price
R&D	Research and development
RIZIV / NIHDI	Institut national d'assurance maladie-invalidité (National Institute of health and disability insurance), Belgium
RTI	Respiratory tract infection
SHI	Social Health Insurance
SVS	Sozialversicherungsanstalt der Selbständigen (Social insurance institution for the self-employed), Austria
TLV	Tandvårds- och läkemedelsförmånsverket (Dental and Pharmaceutical Benefits Agency), Sweden
UNCAM	Union nationale des caisses d'assurance maladie (National Union of Health Insurance Funds), France
USA	United States of America
VAT	Value-added tax
VBP	Value-based pricing
VODI	Value of diagnostic information
VŠZP	Všeobecná zdravotná poisťovňa (Public Health Insurance Company), Slovakia
WHO	World Health Organization
WP	Work Package

List of country abbreviations

AL	Albania
AM	Armenia
AT	Austria
BE	Belgium
BG	Bulgaria
BY	Belarus
CH	Switzerland
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IL	Israel
IS	Iceland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
MD	Moldova
MK	North Macedonia
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
RS	Republic of Serbia
SE	Sweden
SI	Slovenia
SK	Slovakia
TR	Turkey
UA	Ukraine
UK	United Kingdom
XK	Kosovo

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- Belgium
  - Institut national d'assurance maladie-invalidité / RIZIV (National Institute of health and disability insurance / NIHDI)
- Estonia
  - Eesti Haigekassa (Estonian Health Insurance Fund / EHIF)
- Finland
  - Kansallinen HTA-koordinaatioyksikkö (Finnish Coordinating Center for Health Technology Assessment / FinCCHTA)[1]
- France
  - Comité Economique des Produits de Santé (Health Products Pricing Committee / CEPS)
- Germany
  - GKV-Spitzenverband (National Association of Statutory Health Insurance Funds)
- Greece
  - ΕΥΡΩΠΑΪΚΗ ΚΑΡΤΑ ΑΣΦΑΛΙΣΗΣ (National Organisation for the Provision of Health Services / EOPYY)
- Hungary
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- United Kingdom
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[1] Thanks to the contacts at the Ministry of Social Affairs and Health who coordinated the contact to FinCCHTA.

2. Executive Summary

Background and objective

The present report was produced in the frame of the VALUE-Dx project that intends to tackle AMR. The IMI project VALUE-Dx aims to demonstrate the value of diagnostics that help guide decisions on whether, or not, antibiotic prescribing is needed. VALUE-Dx is focused on Community-Acquired Acute Respiratory Tract Infections (CA-ARTI) in community care (outpatient sector).

The objective of this study is to survey Health Technology Assessment (HTA), pricing and reimbursement (funding) policies that are applied for diagnostics (Dx) for CA-ARTI in European countries. In particular, it is aimed to compare identified policies applied for CA-ARTI Dx to those used for medical devices (MD) in general in the same country and to explore differences across countries.

Methods

Information and data was gathered through a literature review and a primary data collection with competent authorities responsible for pricing and reimbursement. The review rather identified background information included in grey literature that was found in the hand search. The survey was conducted in the second half of 2020 with the aim to obtain country specific information on HTA, pricing and reimbursement policies for CA-ARTI Dx as well as on MD. Experts of pricing and reimbursement authorities who work on MD were addressed; most of them were members of the sub-group on MD of the PPRI network (PPRI MD) which is coordinated by the authors' Department. To ease the workload for the respondents, the questionnaires were pre-filled as far as possible. In total, information is available from 16 countries, thereof 15 Member States of the European Union and United Kingdom. Data relate to the policy situation of 2020.

Results

There is variation in the use of Dx for CA-ARTI between the countries. In most study countries, it is up to the general practitioner to decide on the application for a diagnostic test. The test for c-reactive protein (CRP) was reported to be used in the majority of study countries.

In none of the study countries, Dx were reported to be assessed systematically as part of the national pricing and reimbursement decision. This slightly differs from HTA implementation for other MD since in at least four study countries, HTA for some MD is embedded in the reimbursement or pricing decision process. If HTA for Dx for CA-ARTI are carried out, their methodology does not differ from those of other MD.

In six of the 15 study countries with information available on this matter, use of Dx for CA-ARTI in the outpatient setting (e.g. point-of-care testing at practitioners' offices) is reimbursed, and in two further countries laboratories are remunerated for the application of the tests. In seven further study countries, Dx for CA-ARTI are not included in a national reimbursement list (formulary) but the application of the Dx is provided free of charge to the patients. In the study countries, patients were reported to not have to pay for the use of Dx. Health care providers (e.g. general practitioners) are usually remunerated for the service of performing a diagnostic test as part of their fee-for-service payment.

In the 16 study countries, the reimbursement decision process does not differ for Dx compared to the one for other MD. The entity responsible for the reimbursement decision (e.g. a SHI) takes the decision of including a MD into reimbursement if it meets the defined criteria, usually based on an evaluation and

advice by an expert committee. In Germany, in the post-launch phase, Dx are treated differently since their prescribing is not controlled by SHI compared to the other MD that are subject to volume limits.

In the study countries, there is free pricing for most or all MD, so the supplier can determine the price. In five countries (France, Greece, Hungary, Slovakia and Spain), prices of defined MD are set by the authority. In doing so, usually the policy of internal price referencing is applied in which the prices of comparable MD are related to as a benchmark. In addition, France and Slovakia also consider prices of the respective MD in other countries (external price referencing). Pricing policies as part of price regulation in the above-mentioned five countries are applied for those MD which are included in the outpatient reimbursement lists (usually a rather small portion of MD). Dx are not among these MD and are thus not price-regulated.

However, there may be indirect price control in those cases when public purchasers (e.g. a national health service or regions) procure MD, including Dx.

In the supply chain, mark-ups on MD prices for distribution actors (wholesalers and/or community pharmacies) are regulated in Hungary, Slovakia and Sweden. Except for UK, a VAT is charged on MD, including Dx. VAT rates on MD range from 5% to 30% across the study countries where applicable, and in Belgium, Greece, Slovakia and Spain different VAT rates apply for different types of MD.

Discussion and Conclusions

The current study is the first to survey and comparatively analyse HTA, pricing and reimbursement policies applied to Dx for RTI and CA-ARTI in European countries. It thus sheds a light on the yet under-researched area of pricing and reimbursement policies for MD.

It shows that there is little direct price regulation (through specific pricing policies) for MD and de facto none for Dx but there may be indirect price control through procurement of public purchasers. In the study countries, patients tend to have access to Dx without any out-of-pocket payments as a result of the organisation of the health care system, including the remuneration schemes for health care providers. Overall, specific pricing and reimbursement policies that relate to single Dx have yet not been implemented for Dx for CA-ARTI. HTA are commonly carried out for MD, mostly at regional levels, but an alignment of HTA appraisal processes to national pricing and reimbursement processes is missing.

Following up on the descriptive mapping done for this report, more insight is needed to understand possible barriers and incentives of the current policies for Dx for CA-ARTI and thus to identify components for a fit for purpose policy framework that encourages the uptake of CA-ARTI Dx. The authors will conduct these activities in the further course of the VALUE-Dx project.

In addition, the survey confirmed the need to further develop the terminology and taxonomy of HTA, pricing and reimbursement policies adapted to Dx. The novelty of this research area, including limited clarity of some concepts, might have biased some responses in the survey. Thus, new perspectives and updated pieces of information on HTA, pricing and reimbursement policies for CA-ARTI Dx may be captured in an updated version at a later stage, since this report is intended to be a "living document".

3. Background

3.1. This report in the framework of VALUE-Dx

VALUE-Dx

The VALUE-Dx project is focused on understanding the value of diagnostics for combatting antimicrobial resistance (AMR). Diagnostics contribute to optimised antibiotic use since diagnostic tests ensure prescribing of antibiotics only when they are clinically needed.[2]

VALUE-Dx focuses its research on community care (outpatient sector), which is defined as the first point of contact with health services. Innovative and cost-effective diagnostics could transform clinical care - especially in community care settings where the majority of antibiotics are prescribed - by reducing uncertainty about potential benefit antibiotics may offer to individuals. Through a thorough understanding of value indicators and barriers to the adoption of diagnostics, VALUE-Dx will develop and improve health economic models and policy recommendations with the objective of reducing AMR in Community-Acquired Acute Respiratory Tract Infections (CA-ARTI).[3]

The overall aim of VALUE-Dx is to facilitate point of care diagnostic testing in order to transform medical practice and achieve more personalised, evidence-based antibiotic prescription and usage in the community care settings to combat AMR.[4]

VALUE-Dx is an IMI2-funded project. IMI stands for "Innovative Medicines Initiative" which is an EU public-private partnership funding health research and innovation.

Work Package 5 in the framework of VALUE-Dx

Overall, VALUE-Dx consists of seven Work Packages (WP) that are interacting with each other (see also Figure 1 on the following page)[5]:

1| Technological and Clinical Value Factors
2| Laboratory Analyses and Biobanking
3| Data Management & Analytics
4| Platform Randomised controlled trial of point of care Diagnostics for Enhancing the quality of aNtibiotic prescribing for CA-ARTI in ambulatory care in Europe (PRUDENCE) & Advanced Diagnostics for Enhanced QUality of Antibiotic prescription in respiratory Tract infections in Emergency rooms (ADEQUATE)
5| Economic Value, Policies and Innovative Funding Models
6| Education and Advocacy
7| Project Management and Sustainability

[2] VALUE-Dx (2019b)
[3] VALUE-Dx (2020); VALUE-Dx (2019b)
[4] Penta (2019); VALUE-Dx (2020)
[5] VALUE-Dx (2019a)

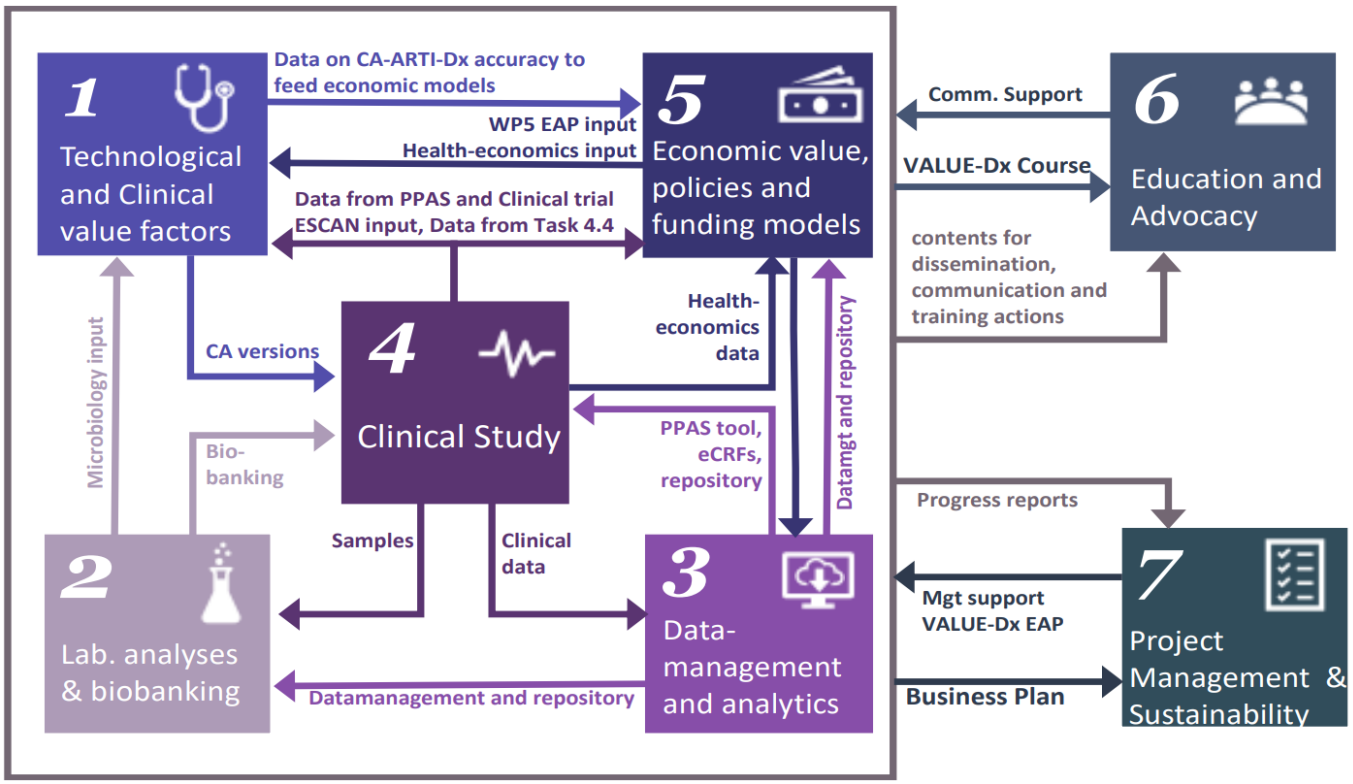

Figure 1: Interaction between the Work Packages

Reference: VALUE-Dx (2019a)

The present report is part of Task 5.5 under WP 5. WP 5 investigates the economic value, policies and innovative funding models. It is structured in seven different tasks:

1| Establishment, maintenance and management of a WP5 regulatory-health technology assessment (HTA)-payer External Advisory Panel (EAP)
2| Review of the current HTA environment and methodologies, inclusive health-economic frameworks, and models, used for valuing diagnostics and analysing antibiotic resistance
3| Trial based health economic analysis of (rapid, localised) diagnostics strategies in close collaboration with WP4
4| Development of a health-economic model for cost-effectiveness of diagnostics beyond the trial-based setting
5| Analysis of existing and potentially innovative policies applied to include new diagnostics (Dx) in the care systems with a view of identifying good practice and a proposal for enhancing fit-for-purpose policy frameworks related to HTA, pricing and funding mechanisms
6| Transferability of health-economic approaches and results of such transfers between countries, notably to H2020 Associated Countries
7| Interviewing stakeholders on policy and regulatory factors

Task 5.5 in the framework of Work Package 5

The successful implementation and long-term viability of rapid diagnostic testing does not solely depend on developing, selling, and marketing of these kind of medical devices.[6] It may also be beneficial to demonstrate the economic value - especially from a long-term societal perspective - and to incentivise

[6] Okeke et al. (2011); Johnson et al. (2018); Lee et al. (2010)

the uptake of rapid diagnostic tests through appropriate policies with regard to pricing, reimbursement (funding) and HTA.

While it can be hypothesised that HTA, reimbursement and pricing policies have, among others, an impact on the development, market entry and uptake of diagnostics, there is limited knowledge if and how these policies have been implemented for medical devices in general and for rapid diagnostic tests in particular in European countries.[7]

Against this backdrop, Task 5.5 aims to review and analyse the current policy environment in Europe and identify good practices for the assessment of diagnostics and decisions on funding and their price (objective 4 of WP 5), as a basis for the development of proposals for fit-for-purpose policies (objective 7).

3.2. The scope of this report

3.2.1. The aim of this report

The present report aims to map policies related to HTA (value assessment), pricing and reimbursement (funding) of diagnostics for CA-ARTI in the EU Member States and a few H2020 Associated countries.

In particular, it is aimed to set identified HTA practices and pricing and reimbursement for diagnostics for CA-ARTI in comparison to the policies as in use for medical devices in general.

As such, the findings of this study will be used for the next step of Task 5.5: the description of the key facilitators and barriers and the recommendations for an innovative fit for purpose pricing and funding model for diagnostics for CA-ARTI. Furthermore, Task 5.7 will explore facilitators and barriers of adapting or implementing novel diagnostics in community care, by interviewing policy and decision makers. The hypothesis is that pricing and reimbursement policies may play a role in ensuring appropriate uptake.

In the following, different dimensions of the scope of this study are outlined (and visualised in Figure 2).

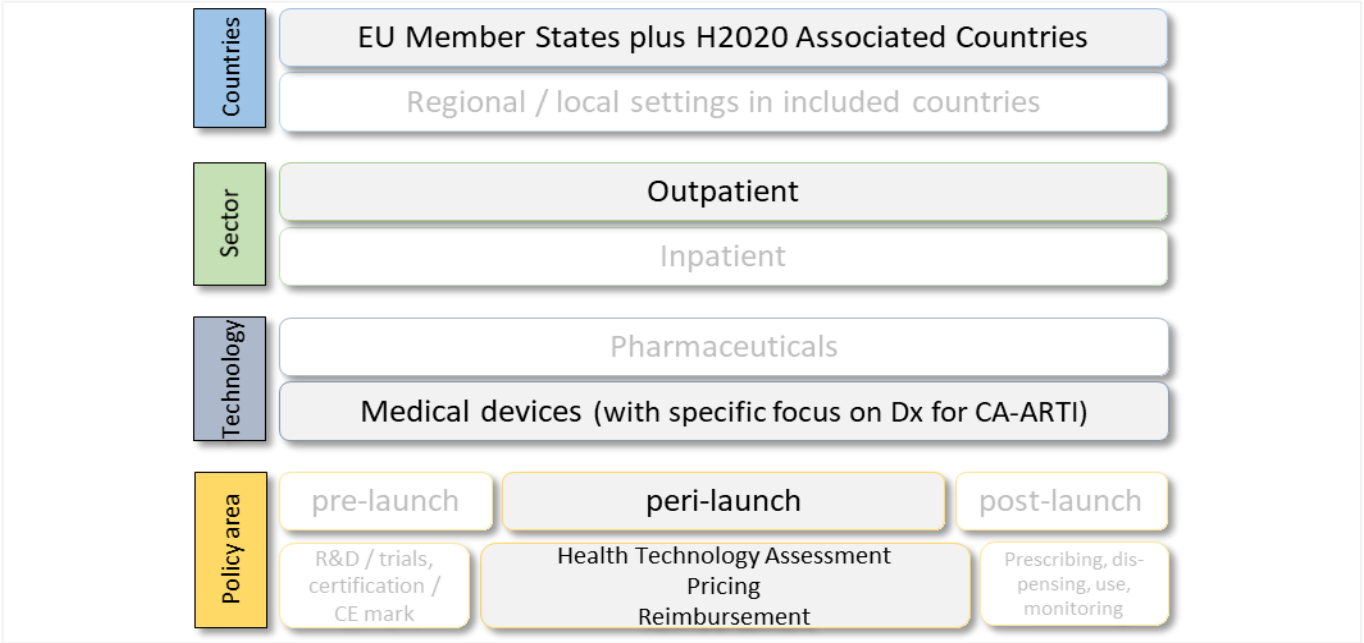

Figure 2: Scope of the report

Reference: GÖG

[7] Innovative Medicines Initiative (2017); Hays et al. (2019)

3.2.2. The disease in question: community-acquired acute respiratory tract infections (CA-ARTI)

Community-acquired acute respiratory tract infections (CA-ARTI) are among the most frequent infectious diseases worldwide. Respiratory infections can be caused by viruses and bacteria. In reality, around 90 % of respiratory infections are caused by viruses, for which antibiotics are ineffective.[8]

Uncomplicated ARTI is the most frequent cause of inappropriate antibiotic use, and there is a need of more judicious antibiotic prescribing to prevent exposure to drug-related adverse events, selection of antibiotic resistance and emergence of opportunistic pathogens that substitute the indigenous microbiota. Antibiotic resistance rates are related to antibiotic use in any setting, but opportunities to decrease unnecessary treatments are probably most prevalent in primary care and emergency departments.[9]

3.2.3. The technology and setting in question: (rapid) diagnostic tests for CA-ARTI in the outpatient sector

Diagnostic tests

Optimal clinical management of CA-ARTI is impaired by the difficulty for physicians to clearly diagnose if a patient's infection is caused by a bacteria or a virus. Rapid, accurate, specific point-of-care diagnostic tests that generate results within minutes can support the decision-making of physicians.[10]

These rapid diagnostic tests (Dx) might overcome the major drawback in the clinical management of respiratory tract infections: the absence of a standardised approach to screening for major pathogen groups, to enable identification of the causative organisms, and to ascertain antimicrobial susceptibilities.[11]

Thus, there is a need to assess the impact of rapid syndromic diagnostic testing in patients with CA-ARTI presenting to physicians on clinical decision making related to antibiotic prescribing. At the same time it is vital to ensure that the decisions guided by the rapid syndromic diagnostic testing results do not compromise patient safety.[12]

The value of Dx as a critical component of antimicrobial stewardship programmes is apparently not fully established throughout Europe. This may delay the adoption and use of currently available diagnostic tests by health professionals as well as the development of advanced or innovative diagnostic tools.[13]

Outpatient sector

The present report relates to the outpatient sector. In contrast to "hospital" (inpatient sector), "outpatient" relates to the type of health care sector in which ambulatory / community (outpatient) care and services are provided. This includes any first point of contact for patients with an infectious disease, especially of the respiratory tract. First points of contact in the community include the general practitioner (GP), a specialist and any primary care facility (including e.g. laboratories). In addition, the

[8] Okeke et al. (2011); Zumla et al. (2014)
[9] VALUE-Dx (2020)
[10] Caliendo et al. (2013); Lee et al. (2010); Okeke et al. (2011)
[11] Hays et al. (2019); Innovative Medicines Initiative (2017); Innovative Medicines Initiative (2019)
[12] O'Brien et al. (2019)
[13] Innovative Medicines Initiative (2017); O'Brien et al. (2019); Zumla et al. (2014)

outpatient hospital department or emergency department of a hospital (without overnight stay) is also subsumed under this definition.[14]

3.2.4. The policies in question: HTA, pricing and reimbursement

The study maps three policies that are allocated in the so-called peri-launch phases. It is key to understand that policies (policy measures) are instruments, tools and approaches that allow policy-makers to achieve defined objectives.[15] The responsibility to implement, appropriately design, monitor and eventually adapt policies is with public authorities (i.e. government officials). Thus, any actions undertaken by the private sector are not covered under the term "policies" and are not scope of this study.

Peri-launch activities

In a comprehensive value chain approach that has increasingly been applied in the area of pharmaceuticals[16], three phases for the life-cycle of health products are distinguished (see also the policy areas in Figure 2).

- Pre-launch activities:
  They relate to policies before the launch of a health product in the market and also before the formal authorisation (i.e. before the peri-launch phase). They include policies with regard to planning and preparedness (e.g. horizon scanning, forecasting) and incentives for research and development (R&D).

- Peri-launch activities:
  They relate to policies in the period between the formal authorisation for bringing a product in the market (e.g. the marketing authorisation for medicines, the CE mark for medical devices, where needed, or the notification to the regulatory body) and the actual launch of the health product by the supplier. In principle, if no peri-launch policies have been implemented, this period can be very short and even non-existing, since the product is immediately launched as soon as it is possible.
  Policies with regard to the decision on the price (pricing) and coverage (funding) of the health product, in combination with a value assessment (HTA) are the key peri-launch activities, and they are the focus of this study.

- Post-launch activities:
  They relate to policies undertaken after the launch of a health product in the market. As such, they include activities to incentivise (or limit) the uptake of defined products, through ensuring rational prescribing, dispensing and use. Any monitoring and evaluation activities are further examples.

[14] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2020)
[15] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2020)
[16] World Health Organization (2015); Vogler et al. (2018a); Vogler et al. (2018b)

What is HTA?

HTA comprises the systematic evaluation of properties, effects, and/or impacts of health technologies. HTA is a multidisciplinary process to evaluate the efficacy, effectiveness, safety, plus the social, economic, organizational and ethical issues of a health intervention or health technology.[17]

The World Health Organization defines a health technology as the "[...] application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of lives."[18]

The aim of HTA is to support the decision-making on whether, or not, a health technology, such as a diagnostic, is to be included into reimbursement (e.g. public funding, see below), and under which conditions. As such, HTA can give recommendations to support reimbursement and/or pricing decisions and can provide evidence-based suggestions for which patients and for how long should a technology be provided.[19] HTA is a supportive tool for (political) decisions, but it is not a (pricing or reimbursement) policy per se (a policy means a course or principle of action in this context).

What is reimbursement?

Reimbursement policies relate to the decision on whether, or not, a health technology (e.g. a medical device) will be funded by a third party / public payer, and to which extent and under which conditions. An overview of major reimbursement terms can be found in Table 1 below.

- **Third party payer:** Depending on the organisation of the health care system, the third party payer can be the National Health Service (NHS) or a social insurance institution. Complementary health insurance (e.g. provided by non-profit mutual association such as the "mutualités" in Belgium and France or commercial providers) is also possible.[20]
- **Extent of reimbursement**: A health technology considered reimbursable may be fully or partially funded by the respective third party payer. In the case of partial funding, co-payments are charged on patients. If a health technology is not reimbursed at all, then the patient has to cover all out-of-pocket costs (it might happen in certain health systems that the medical provider, such as the practitioner or the hospital, bears the costs).
- **Conditions of reimbursement:** Third party payers may decide and/or agree with the provider of the health technology (mainly the supplier / manufacturer) to reimburse only defined specific indications or conditions. This may target the decision on the reimbursement status, as well as the extent of reimbursement. Furthermore, decisions on the reimbursement status and reimbursement extent may vary across socio-economic groups (e.g. full reimbursement and exemptions from any co-payments for vulnerable groups) and across sectors (e.g. co-payments in the outpatient sector but full funding of a health technology for inpatient use).

The use of certain medical devices (MD), including some Dx, requires a health professional. Thus, for the analysis of the reimbursement situation for MD itself, an analysis of the remuneration for the service is essential.

[17] Australian Government (2019); INAHTA (2020); O'Rourke et al. (2020)
[18] World Health Organization (No Year)
[19] INAHTA (2020); O'Rourke et al. (2020)
[20] Mossialos et al. (2004)

Table 1: Major terms and their definitions related to reimbursement policies

TERMS	DEFINITION
Remuneration (of service)	The payment of a health care provider (individual or organisation) for the services provided. The services may be paid directly by the patient or by a third party payer. In the case of distribution of a MD in the supply chain, wholesalers and pharmacies might be remunerated; Synonym: Distribution remuneration
Reimbursement (funding)	Coverage of the cost of reimbursable health technologies by a public payer (such as social health insurance/national health service, NHS).
Reimbursement status	Classification to whether a health technology is eligible for reimbursement (reimbursable medical devices) or not (non-reimbursable medical devices).
Reimbursement price	The maximum amount of a health technology paid for by a third party payer.
Reimbursement list	A list that contains health technologies with regard to their reimbursement status. They may either include medicines or medical devices eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list).
Positive list (formulary)	List of medical devices that may be prescribed, dispensed and used at the expense of a third-party payer
Out-of-pocket (OOP) payments	The expenses of a person for health technologies that are not reimbursed by a third party payer – often for a defined period (e.g. a year). They include: • Expenses for non-reimbursable health technologies • Any form of co-payment; e.g. prescription fee, percentage co-payment, deductible
Co-payments	Patient's contribution towards the cost of a health technology covered by the insurer. Can be expressed as a percentage of the total cost of the health technology (percentage co-payment), as a fixed amount (e.g. prescription fee) or a deductible (=initial expense up to a fixed amount which must be paid out-of-pocket for a health technology or over a defined period of time by an insured person; then all or a percentage of the rest of the cost is covered by a third party payer)

Reference: Definitions based on the Glossary of Pharmaceutical Terms[21], adjusted to meet requirements for MD

What is pricing?

Pricing relates to the action of a government authority to set the price of a health technology and/or indirectly influence it. Indirect price control can be exercised through procurement activities (e.g. tendering). For definitions of major terms in the context of pricing see Table 2.

In principle, there are two possibilities: The public authorities may apply full price control (i.e. regulate the price of a health technology), or they may allow the supplier to freely set the price (free pricing). Furthermore, prices can also be negotiated between the suppliers and government entities (NHS, regional health service or insurance funds).

[21] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2020)

Table 2: Major terms and their definitions related to pricing/procurement policies

TERMS	DEFINITION
Pricing (price control, price regulation)	Action by a government authority to set the price of a health technology and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it.
Statutory pricing	Pricing procedure, where prices of a health technology are set on a regulatory basis (e.g. law, enactment, decree).
Free pricing	Pricing policy where suppliers /manufacturer can determine the price of the health technology they launch.
Price negotiation	A pricing procedure, in which prices are discussed and agreed (e.g. between supplier and third party payer).
Price type	The level (i.e. stage in the supply chain) at which the price of a health technology is set. Common price types include the ex-factory price, the purchasing price (wholesale price) and the (pharmacy) retail price.
External price referencing (EPR)	The practice of using the price(s) of a health technology in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.
Internal price referencing (IPR)	The practice of using the price(s) of identical or similar health technologies in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.
Value-based pricing (VBP)	Through this policy authorities set the prices of a new health technology and/or decide on reimbursement based on the therapeutic value that a technology offers, usually assessed through health technology assessment (HTA) or economic evaluation. In a full-fledged VBP, the pricing and reimbursement systems are integrated, and the price and reimbursement decision is taken jointly, based on a value assessment.
Cost-plus pricing	A pricing policy that takes into account production costs, promotional expenses, research & development, administration costs, overheads and a profit to determine a price.
Mark-up	The percentage of the purchasing price added on to get the selling price (e.g. a wholesale mark-up on the ex-factory price, or a pharmacy mark-up on the wholesale price).
Margin	The percentage of the selling price that is profit (e.g. a wholesale margin as a percentage of the wholesale price and a pharmacy margin as a percentage of the pharmacy retail price).
Procurement	A process to purchase goods and services (e.g. MD) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
Procurement methods	Purchasing, hiring or obtaining by any other contractual means goods, works or services or any mixture thereof.
Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender/offer is the most advantageous.

Reference: Definitions based on the Glossary of Pharmaceutical Terms[22], adjusted to meet requirements for MD

[22] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (2020)

4. Methods

4.1. Research questions

Against the backdrop of limited knowledge on policies for diagnostics in the peri-launch phase, the present study aims to answer the following research questions:

- Which are the key policies with regard to HTA, pricing and reimbursement that are applied for (CA-ARTI) diagnostics in the countries of the study?
- How do policy frameworks differ across the countries?
- Do HTA, pricing and reimbursement policies for CA-ARTI Dx differ from those applied for other diagnostics and medical devices?

4.2. Methodological approach

To answer the research question, an initial literature search was conducted (step 1). Based on its findings, a questionnaire was created and pre-filled (step 2). The questionnaire was sent to several country experts to gain information about HTA, pricing and reimbursement policies in EU Member States and some Horizon 2020 associated countries.

4.2.1. Step 1: Literature search

A systematic literature search, supplemented by targeted hand search, was used to identify relevant literature to answer the above mentioned research questions. Generally, the search terms were kept broad (e.g. the search was not exclusively restricted to diagnostics of CA-ARTI).

The systematic literature search was conducted on the 8th of October 2019 in PubMed. Before de-duplication, 1,465 citations were identified from the database search. The specific search strategy employed can be found in paragraph 9.1 in the Annex.

Two review authors (SF, SV) included and excluded the literature independently from each other. It was planned to involve a third researcher in case of disagreement, but no differences occurred.

Furthermore, an additional hand search, especially for grey literature via Google was conducted and 26 additional publications were identified. The selection process is displayed in Figure 3.

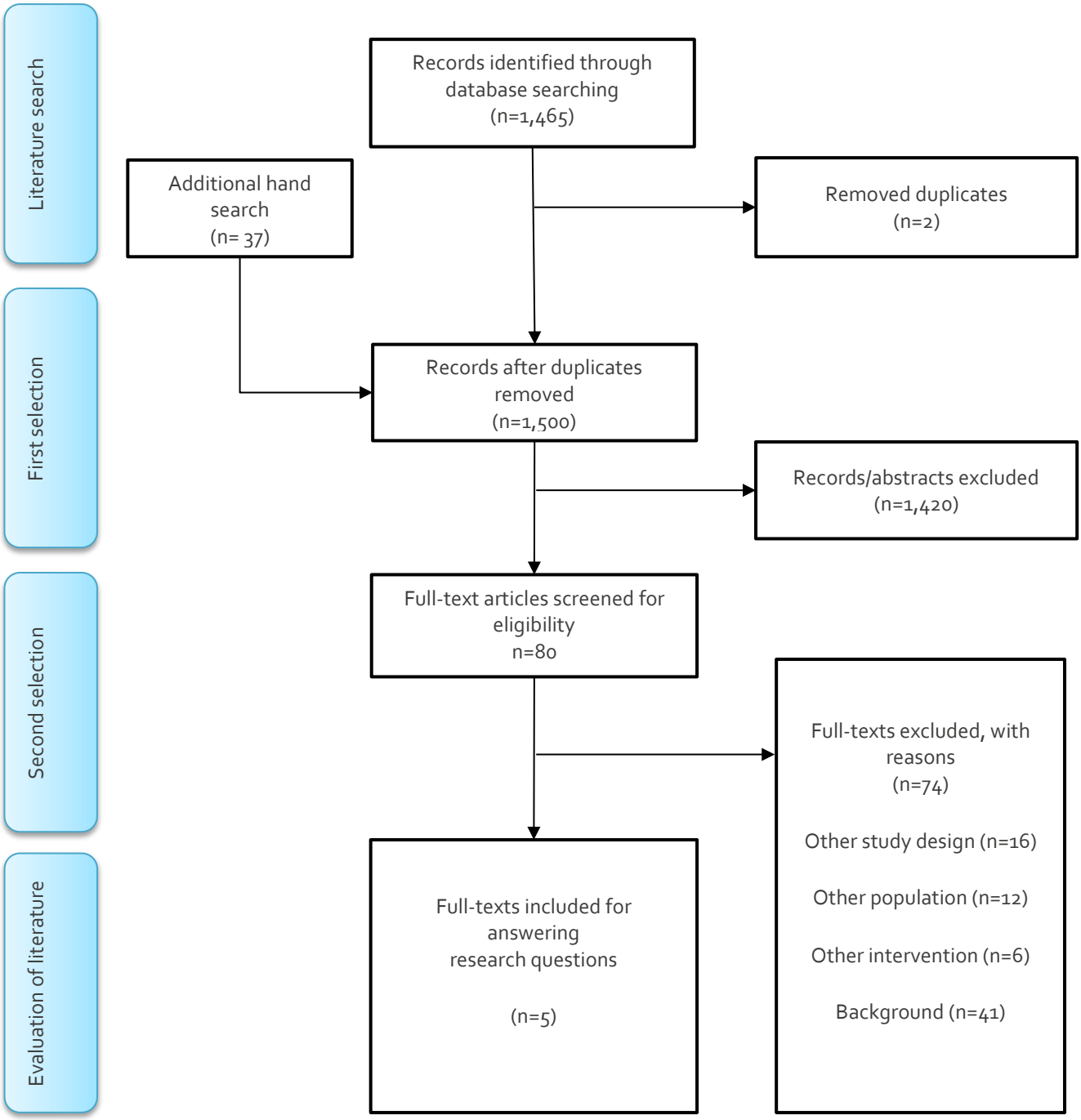

Figure 3: PRISMA Flow Diagram

A total of 1,420 records were excluded, based on the screening of the respective abstracts. The exclusion of these records was due to obvious reasons, for instance when studies were from countries that were not in the scope of the report (such as USA, Asian countries, etc.; see also section 3.2.1) or when articles did not consider diagnostics for infectious diseases (e.g. diagnostics like magnetic resonance imaging).

The specific reasons for exclusion, based on full-texts, were as follows:

- Other study design: 16 studies were excluded because there was no or no up-to-date[23] information on HTA, reimbursement, or pricing policies available,
- Other population: 12 studies were excluded because the analysed interventions were not focussing on diagnosing infectious diseases (e.g. studies were focussing on diagnosing cancer),
- Other intervention: 6 studies were excluded since they did not analyse MD or the diagnostic tests in question (e.g. companion tests or study was not on MD at all).
- Background: A total of 30 studies were excluded due to various reasons, but were used as background literature.

All the grey literature (e.g. governmental documents or websites) that was used to pre-fill the survey (see following section) is not considered.

In the end, a total of 5 sources were considered to answer the research question and therefore are cited in the Results in chapter 5.

4.2.2. Step 2: Survey

Information and data of pricing and reimbursement policies for medical devices (including price information) were obtained through a survey of competent authorities, mainly members of the Pharmaceutical Pricing and Reimbursement Information (PPRI) sub-group on Medical Devices.

The PPRI network is a collaboration of pricing and reimbursement authorities for medicines of 52, mainly European countries as well as international and European institutions. The aim of the network is to facilitate information exchange between public officials (including personal networking meetings), supported by scientific evidence and a common understanding of policy issues. While PPRI has been in existence since 2005, the Sub-group on Medical Devices (PPRI MD) was established in 2018 at the request of the members, to ensure a more focused discussion on policies in this field.[24]

The main objectives of the subgroup are:

- to exchange information on pricing and reimbursement policies of medical devices,
- to promote networking and exchange between competent authorities and
- to improve transparency in this field.

The questionnaire developed by the study authors was revised upon feedback of the WP5-partners of VALUE-Dx. In addition, the questionnaire was sent to two countries for piloting (Austria and Greece).

The questionnaire, including an informed consent, and a maximum of two reminders were sent to contacts in 31 countries in the time between 26th of June and 5th November 2020. Figure 4 visualises the process how country information was collected.

[23] There was no certain cut-off for consideration.

[24] Gesundheit Österreich GmbH - Pharmacoeconomics Department (2020); Vogler et al. (2014); Vogler et al. (2015)

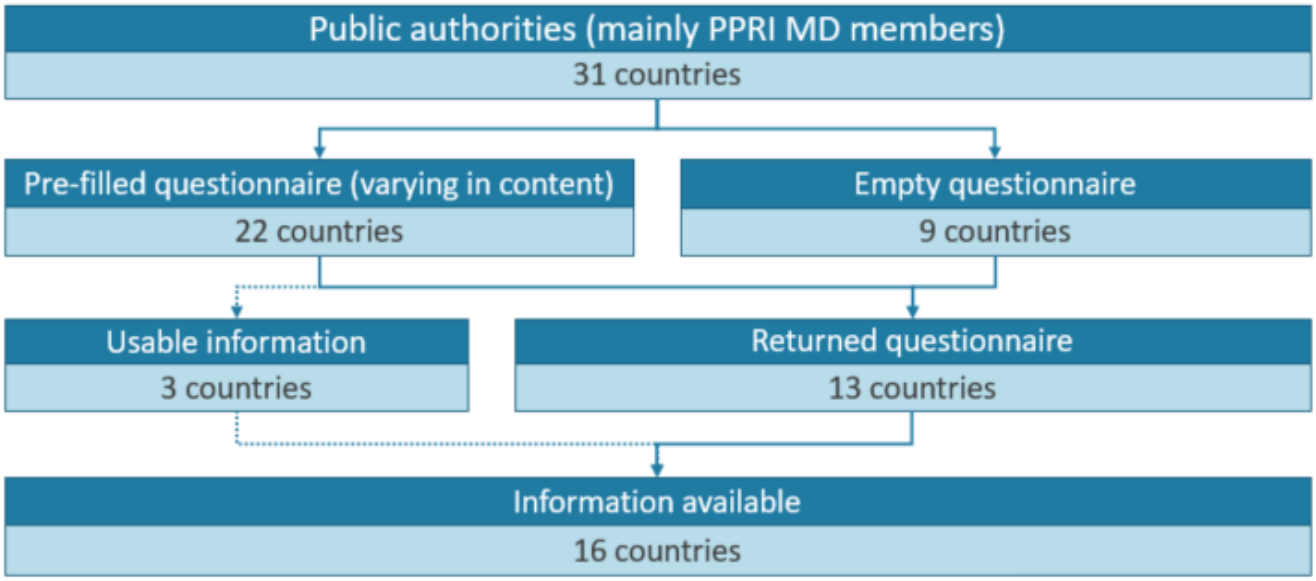

Figure 4: Visualisation of country information gain

Abbreviation: PPRI MD = Pharmaceutical Pricing and Reimbursement Information Sub-group on Medical Devices
Reference: GÖG

Depending on the existing literature and on information available from previous work of the PPRI MD, the questionnaire was pre-filled for 22 of the 31 countries, to a various extent (for some countries only some basic general information was available). This was done to ease the workload for the respondents, thus to increase the number of responses. The country experts are invited to confirm or revise the pre-filled information and to add missing data.

Moreover, the questionnaire was also sent to authorities in countries that are not (yet) members of the PPRI MD: HTA agencies, pricing authorities and third party payers.

All contacts are experts who are or were involved in pricing and/or reimbursement decisions for diagnostics in general and particularly in CA-ARTI Dx.

Responses were received from 13 countries. The information of three countries (Croatia, Italy and Slovakia) was pre-filled by the study authors based on answers from previous surveys but could not be validated or were only validated in parts by the country experts. Collected policy information relates to the year 2020.

In the end, information from 16 of the 31 considered countries was available (13 validated, 3 not fully validated) to answer the research questions appropriately (see Figure 5). The blank questionnaire is displayed in Annex 9.2.

Respondents of seven countries as well as members of WP 5 of the VALUE-Dx project commented on a draft version of this report shared on 23 December 2020.

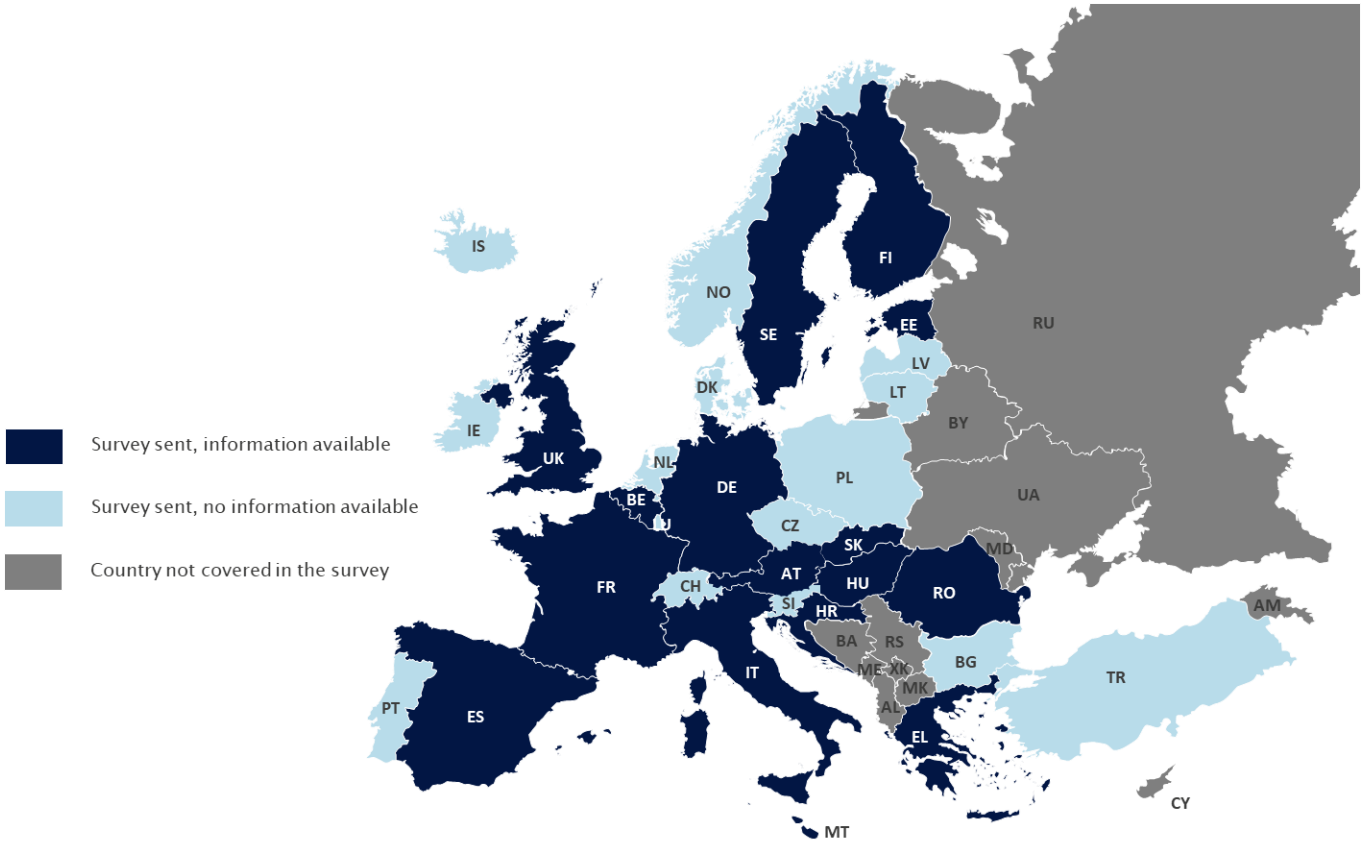

Figure 5: Overview of country information available (2020)

Reference: GÖG survey with competent authorities for medical devices

5. Results

5.1. Rapid diagnostic tests for RTI or CA-ARTI used in the outpatient sector in the study countries

This section describes the kind of diagnostics (Dx) that are in use for respiratory tract infections (RTI) or community-acquired acute respiratory tract infections (CA-ARTI) and the decision-making process on whether a Dx is applied or not.

5.1.1. Country overview on types of rapid diagnostic tests for RTI or CA-ARTI in use

The opening question in the questionnaire was whether fast diagnostic tests for (community-acquired acute) respiratory tract infections (RTI or CA-ARTI) are **used** in the outpatient sector in the respective country. This question was supplemented by the question what type of test is used (see also the questionnaire in the Annex 9.2).

Overall, the test for c-reactive protein (CRP) was indicated to be used in the majority of countries (see Table 3). Fields with a "☑" mean that the test is definitely used in the outpatient sector, including laboratories (mainly due to an explicit funding), fields with a "?" mean that since these tests are potentially available in all countries.

Table 3: Country overview of use of rapid diagnostic tests (2020)

COUNTRY	ASO	CRP	PCR	PCT	OTHERS*
Austria	☑	☑	?	?	☑
Belgium	☑	☑	☑	?	?
Croatia	?	☑	?	?	?
Estonia	?	☑	?	?	☑
Finland	?	☑	?	?	?
France	?	☑	☑	?	☑
Germany	?	☑	?	☑	☑
Greece	?	☑	?	?	?
Hungary	?	☑	?	?	?
Italy	?	?	?	?	?
Malta	?	?	?	?	?
Romania	?	☑	☑	?	☑
Slovakia	?	☑	?	?	☑
Spain	?	?	?	?	☑
Sweden	?	☑	?	?	?
United Kingdom	?	?	?	?	?

Abbreviations: ASO = antistreptolysin O; CRP = c-reactive protein; PCR = polymerase chain reaction; PCT = procalcitonin; X = test is definetly used; ? = test is probably used; * = other tests could be used e.g. test for A streptococci

Reference: GÖG survey with competent authorities for medical devices and EUnetHTA-reports[25]

[25] O'Brien et al. (2019), EUnetHTA (2017)

5.1.2. Guidance for the use of rapid diagnostic tests for RTI or CA-ARTI

In most study countries (e.g. Estonia, Finland, Romania, Sweden), it is the responsibility of the general practitioner to decide whether or not a Dx is applied. Sometimes the decision might be supported by available guidelines (see Table 4).

This section has to be seen in the context of the individual health care systems and the remuneration methods of practitioners in the countries (see also section 5.3.2). Especially in those countries in which practitioners are paid by salary and Dx are not reimbursed by a special fee, the doctor might use Dx, even though he or she will not receive any funding.

Table 4: Country overview of decision-making to apply a rapid diagnostic test (2020)

COUNTRY	DECISION-MAKING
Austria	Practitioner (individually, not guideline based)
Belgium	Prescription made by medical doctor, clinical biologist decides which tests are used
Croatia	n/a
Estonia	Practitioner (based on guidelines)
Finland	Practitioner (based on guidelines)
France	Practitioner (individually, not guideline based)
Germany	Prescription made by medical doctor, clinical biologist decides which tests are used
Greece	n/a
Hungary	n/a
Italy	n/a
Malta	Practitioner (individually)*
Romania	Practitioner (based on guidelines and considering the terms from framework-agreement with National Social Insurance House)
Slovakia	n/a
Spain	Health System provides protocols for application*
Sweden	Practitioner (based on guidelines and potentially other restrictions (e.g. financial))*
United Kingdom	Practitioner (based on expertise and/or guidelines)*

Abbreviations: * = Dx not reimbursed on national level; n/a = (information) not available

Reference: GÖG survey with competent authorities for medical devices and EUnetHTA-report[26]

[26] O'Brien et al. (2019)

5.2. HTA for rapid diagnostic tests for RTI or CA-ARTI in the study countries

5.2.1. Overview of HTA for medical devices and diagnostic tests

In four of the 16 study countries, health technology assessment (HTA) for MD is embedded in the reimbursement (or pricing) policy process, i.e. to inform the reimbursement and pricing decisions. In five out of 16 countries, no HTA for MD (at least at national level) is conducted. In the remaining seven countries, HTA for MD is not embedded in a systematic way and might be conducted under certain circumstances (e.g. for high-risk and/or costly MD).

Overall, every country has its own criteria to decide on which topics an HTA is conducted and whether, or not, a "full HTA" (i.e. including a health economic analysis) or a "crude" assessment is undertaken (i.e. assessing solely safety).

Figure 6 provides the overview in which countries HTA is conducted at national level. Table 5 provides further details on HTA (if an HTA is embedded in decision-making, e.g. for reimbursement decision, the scope of MD for which HTA are performed and possible differences for HTA for Dx from those for MD).

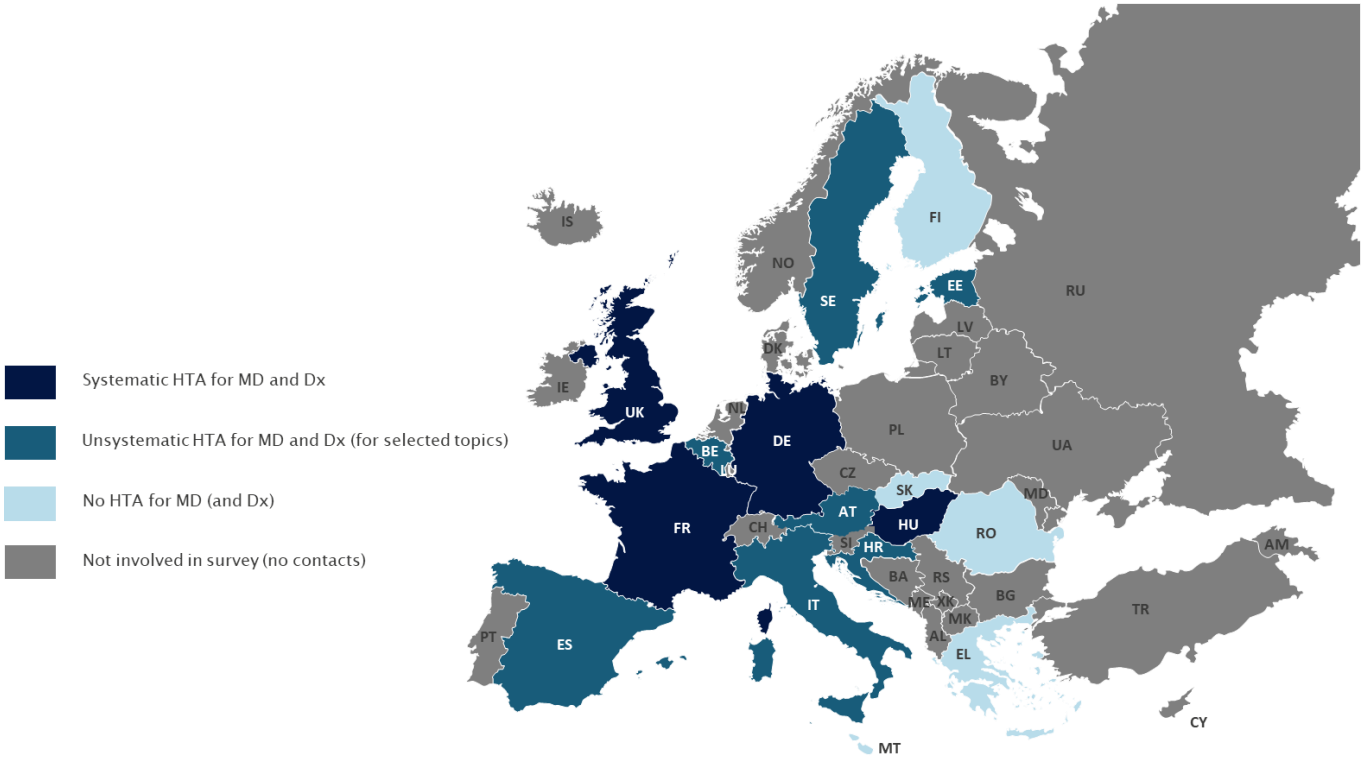

Figure 6: Country overview of HTA on national level (2020)

Reference: GÖG survey with competent authorities for medical devices

In none of the countries the implementation into decision-making of HTA for Dx differs from other MD. The answers of the survey point to a situation that there is no explicit assessment of Dx in a systematic way in any of the study countries.

Table 5: Country overview of implementation of HTA into decision-making (2020)

COUNTRY	HTA EMBEDDED IN DECISION-MAKING PROCESS	HTA FOR TYPE OF MD	HTA FOR DX FOR RTI/CA-ARTI DIFFERENT FROM OTHER MD
Austria	Not systematically	HTA may be conducted for selected topics (mostly high risk products (IIb and III))	No
Belgium	Not systematically	(Limited) HTA may be conducted for selected topics	No
Croatia	Not systematically	HTA may be conducted for selected topics	No
Estonia	Not systematically	HTA may be conducted for selected topics	No
Finland	No	No HTA for MD	Not appl.
France	Yes	New MD with different characteristics than MD already reimbursed; HTA is more for methods/procedures	No**
Germany	Yes	HTA is for methods/procedures, not for MD	No
Greece	No	No HTA for MD	Not appl.
Hungary	Yes	HTA for MD that meet an unmet medical need	No
Italy	Not systematically	HTA may be conducted for selected topics*	Not appl.
Malta	No	No HTA for MD	Not appl.
Romania	No	No HTA for MD	Not appl.
Slovakia	No	No HTA for MD	Not appl.
Spain	Not systematically	HTA may be conducted for selected topics*	No
Sweden	Not systematically	HTA may be conducted for selected topics*	No
United Kingdom	Not systematically	New MD with different characteristics to other MD already reimbursed*	No

Abbreviations: HTA = health technology assessment; MD = medical device; Not appl. = not applicable; * = HTA for MD and Dx for reimbursement is not an national level and is up to regions/municipalities; ** = HTA for Dx does not differ systematically

Reference: GÖG survey with competent authorities for medical devices

5.2.2. HTA processes for medical devices and rapid diagnostic tests for RTI or CA-ARTI

Figure 7 shows the number of institutions (at national level) and the scope of MD assessed. As stated in the previous section 5.2.1, Dx (for RTI or CA-ARTI) are not systematically assessed by an HTA in any of the countries. Thus, the HTA process for MD cannot be compared with the HTA process for Dx.

In three of the study countries, HTA for MD takes place on regional level (Italy, Spain, Sweden); in further three countries (Austria, Croatia and UK) more than three agencies perform assessments of MD. Therefore, the HTA processes for MD and the dimensions/criteria used might vary in these countries.

In the remaining countries, HTA is either done for certain categories of MD (such as costly MD) or for new MD that are assessed for reimbursement. In most of the countries, efficacy and safety is assessed (based on existing literature).

Further information on HTA processes for MD and the criteria that are used for the assessment can be found in Annex 9.4.

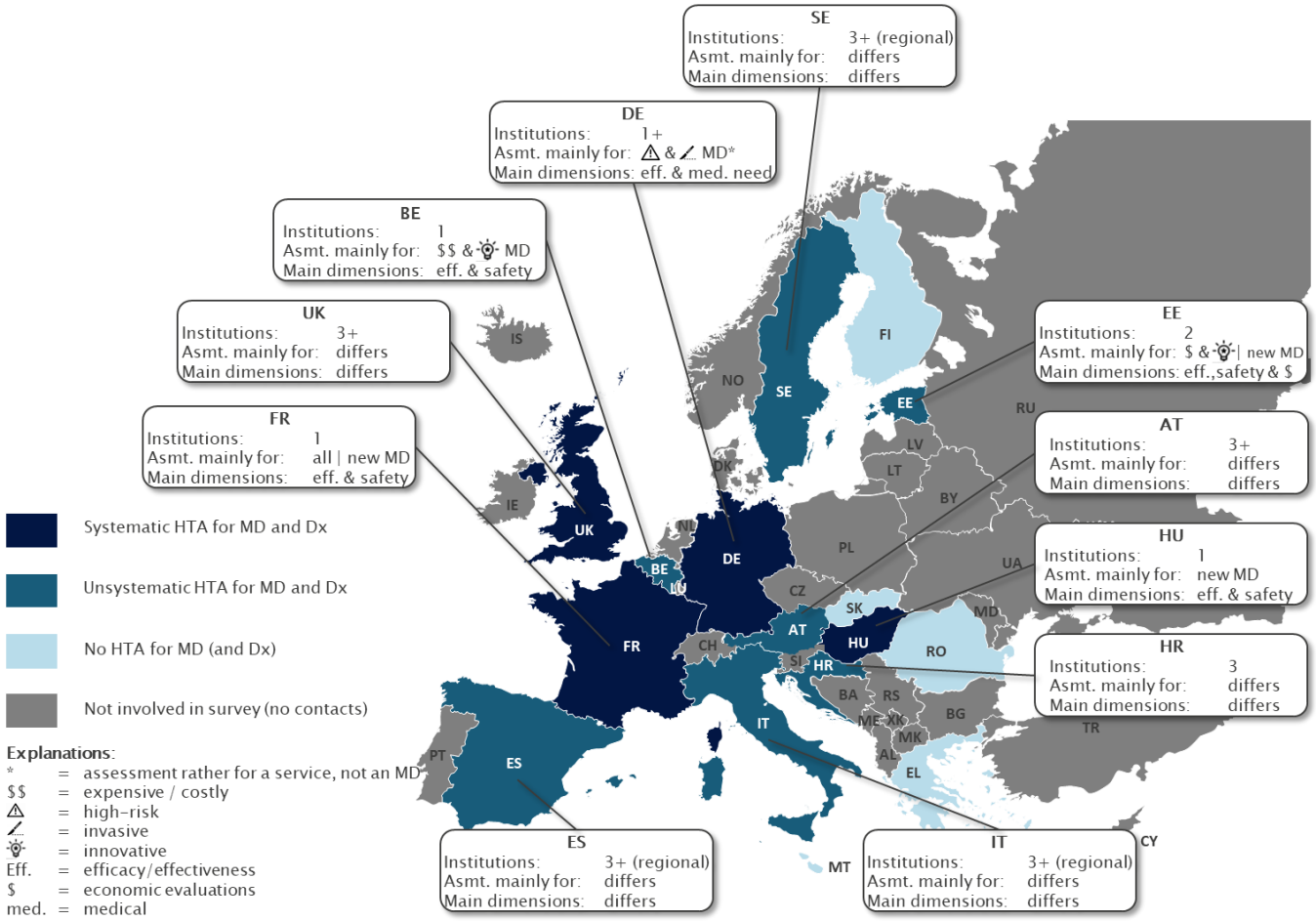

Figure 7: Country overview of HTA process for MD and Dx (2020)

Reference: GÖG survey with competent authorities for medical devices

5.3. Reimbursement of rapid diagnostic tests for RTI or CA-ARTI in the study countries

5.3.1. Reimbursement status of rapid diagnostic tests for RTI or CA-ARTI

In eight of the study countries, Dx for RTI or CA-ARTI used in the outpatient setting are reimbursed or at least reimbursed in certain settings. In the latter case Dx are exclusively reimbursed in laboratories in Belgium and Germany, but there is no reimbursement of POCT at national level (e.g. at practitioners' offices). Furthermore, the kind of reimbursement differs between countries (e.g. fee for testing in general or fee for the material costs for testing).

In seven of the study countries, Dx for RTI or CA-ARTI are not explicitly reimbursed, i.e. not included in a positive list (formulary) – at least at national level. However, it is possible that Dx are reimbursed on regional level in Sweden.

It should be noted that the health care system in these seven countries is organised as a National Health Service (NHS) or a mixture of an NHS and SHI, as in Greece[27] (see also Annex 9.3), and payment of outpatient services is mainly done by capitation fee or salaries (see next section 5.3.2).

An overview of the reimbursement status (at national level) of Dx in the study countries is provided in Figure 8. No information was available for Croatia.

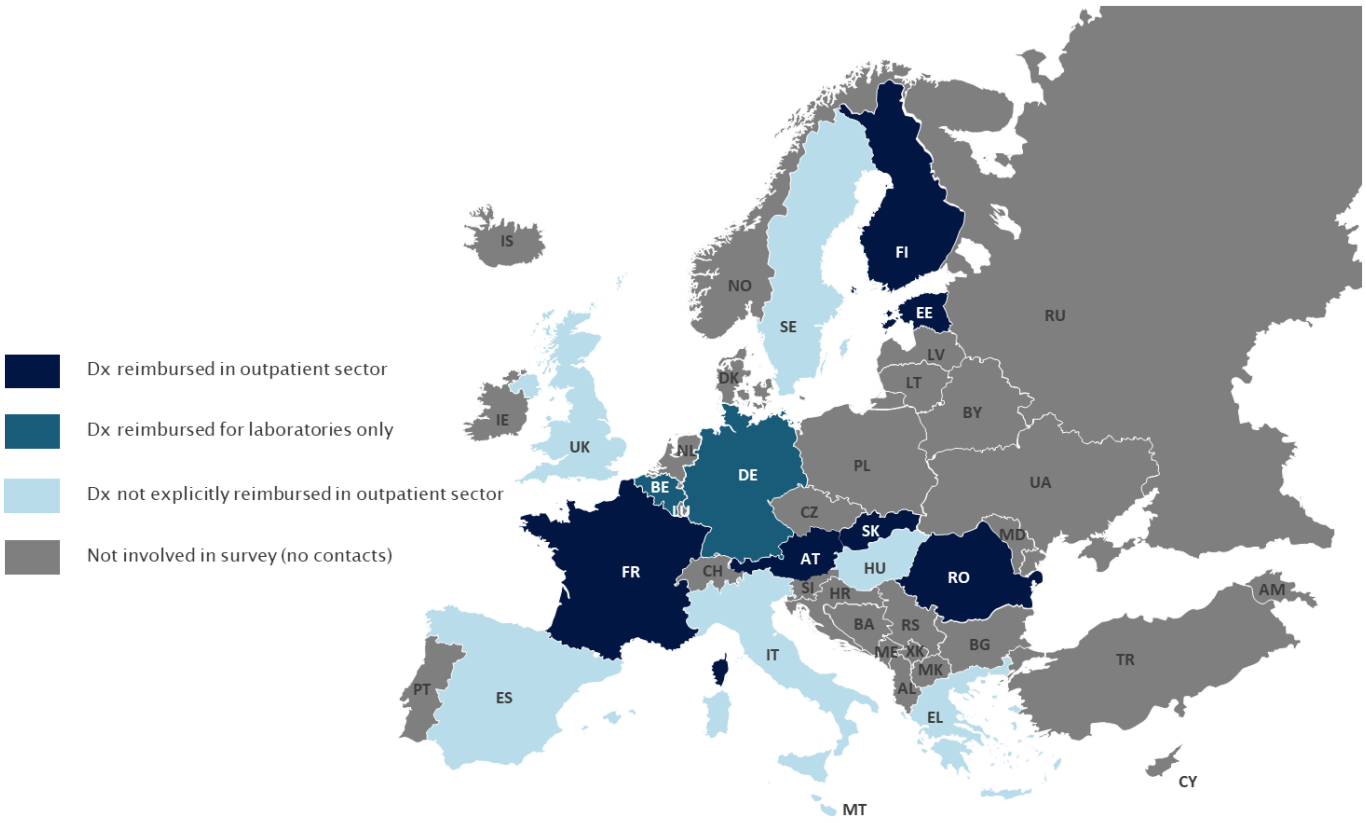

Figure 8: Reimbursement status of Dx (2020)

Reference: GÖG survey with competent authorities for medical devices

The definitions of the reimbursement policies can be found in section 3.2.4.

[27] Vogler et al. (2019)

5.3.2. Reimbursement mechanisms and remuneration methods in general, for medical devices and for rapid diagnostic tests for RTI or CA-ARTI

In addition to the reimbursement status of the Dx per se, it is also of importance whether, or not, its application by a health professional is remunerated (i.e. reimbursement of the service for the patient). The organisation of the health care system (an NHS, an SHI, or a mixture of both, see previous section 5.3.1) and the remuneration of (outpatient) services in general (e.g. how practitioners are paid, see Table 6) determine how health care providers are remunerated for the service in which a MD or Dx is applied.

Table 6: Remuneration systems for (outpatient) services

PAYMENT METHOD	EXPLANATION
Fee-for-service (FFS)	Payment per item of service provided
Capitation	Payment per patient per time period
Salary	Fixed payment "per period of time"
Pay-for-performance (P4P)	Remuneration and measuring physician performance based on achieving certain clinical targets
Combination	Combination of elements of the four methods

Reference: GÖG, based on Rudmik et al. (2014)

Whereas a FFS remunerates defined treatments or services performed by a health care provider, capitation, salary and P4P are remuneration methods that pay the practitioners and other providers for the services, independent from the extent of treatment or service. Moreover, remuneration by FFS provides remuneration for:

- a service (e.g. diagnosis of CA-ARTI in general),
- a device in general (e.g. use of a Dx) or
- a certain device (e.g. use of a certain Dx, such as PCR testing).

The following Table 7 summarises the outpatient remuneration schemes in the study countries and compares remuneration for MD to those for Dx (for RTI and CA-ARTI).

The findings suggest that in cases in which Dx are funded by a third party payer, this is rather done as part of a FFS funding than as explicit funding of the single device.

Table 7: Country overview of outpatient remuneration for services in which MD are applied in comparison to remuneration for services that apply for Dx for RTI or CA-ARTI (2020)

COUNTRY	REMUNERATION IN GENERAL*	REMUNERATION OF SERVICES APPLYING MD	REMUNERATION OF SERVICES APPLYING DX (FOR RTI/CA-ARTI)
Austria	Capitation + FFS	Fee for a service (generic) or for a MD (if there is a fee)	Fees for Dx, to remunerate a test in general or a certain type of test (e.g. CRP) Note: Laboratories may receive a lower fee than practitioners (depending on the SHI fund, practitioner might get material costs reimbursed).
Belgium	FFS	Fee for a service (mostly), not for a MD	No defined fee for Dx for practitioners Laboratories receive a defined amount of money per test
Croatia	Capitation + FFS (+ P4P)	n/a	n/a
Estonia	FFS + capitation (+ P4P)	Fee for a service (generic) or for a MD	Fees for Dx to remunerate a test/service in general No difference between rapid Dx and laboratory Dx
Finland	Capitation Note: FFS (based on DRG pricing) in public hospitals outpatient care	n/a	n/a
France	FFS (+P4P) Note: mainly patients pay doctors and claim for reimbursement (share) at SHI	Fee for a service (generic) or for a MD	Fees for Dx, to remunerate a test in general or a certain type of test (the latter case is rare)
Germany	FFS (+capitation) Note: capitation is based on funding that consists of morbidity-adjusted payment and separate-budgetary services	Fee for a service (generic), not for a MD	No defined fee to remunerate practitioners for Dx use Laboratories receive a defined amount of money per test Note: PCT in laboratories are financed for three years extra budget without quantity limit
Greece	FFS (+salary)	Fee for a service (generic) or a MD	Dx are not explicitly remunerated
Hungary	FFS	Mostly fee for a service, not for a MD	Dx are not explicitly remunerated
Italy	Capitation	n/a	Dx are not explicitly remunerated
Malta	Salary	n/a	Dx are not explicitly remunerated
Romania	FFS	Mostly fee for a service, not for a MD	No defined fee to remunerate practitioners for Dx use
Slovakia	Capitation (GPs) + FFS (specialists)	Fee for a service (generic), not for a MD	No defined fee to remunerate practitioners for Dx use
Spain	Salary	n/a	Dx are not explicitly remunerated Note: There might be some rapid Dx for RTI / CA-ARTI reimbursed in the outpatient setting if included in some strategy approved by the health system

COUNTRY	REMUNERATION IN GENERAL*	REMUNERATION OF SERVICES APPLYING MD	REMUNERATION OF SERVICES APPLYING DX (FOR RTI/CA-ARTI)
Sweden	Capitation + FFS (+ combination)	Differs between regions Note: Remuneration of MD (and Dx) can be by a (certain) fee or capitation, or combination of both	Differs between regions Note: Health care providers can charge patient fees for laboratory tests, but this practice may differ between regions
United Kingdom	P4P + capitation	n/a	Dx are not explicitly remunerated Note: There is no (separate) remuneration of Dx, unless Dx are subject to local agreements

Abbreviations: * = main remuneration not in brackets; additional remuneration in brackets; ASO = antistreptolysin; CRP = c-reactive protein; DRG = diagnosis-related group; Dx = diagnostic; FFS = fee-for-service; GP = general practitioner; n/a = not available; P4P = pay-for-performance; PCT = procalcitonin; SHI = Social Health Insurance

Reference: GÖG survey with competent authorities for medical devices

5.3.3. Reimbursement decision process for medical devices and rapid diagnostic tests for RTI or CA-ARTI

The reimbursement decision process for MD in the outpatient sector varies among the study countries (see Table 8).

However, in the majority of the study countries the process to reach a reimbursement decision for Dx does not differ from that for MD in general.

However, there is an important difference between Dx and MD in general regarding the reimbursement decision in Germany (see Figure 9), which can impact post-launch use. In Germany, practitioners' and laboratory services are monitored by SHI funds (e.g. the number of defined procedures are benchmarked between practitioners). However, prescriptions of laboratory Dx are exempt from volume limits (i.e. practitioners can prescribe them without any control of the SHI).

Moreover, there is no national decision procedure regarding the reimbursement of Dx in Sweden. However, decisions are taken by the Swedish regions and their facilities individually and reimbursement may vary across the country.

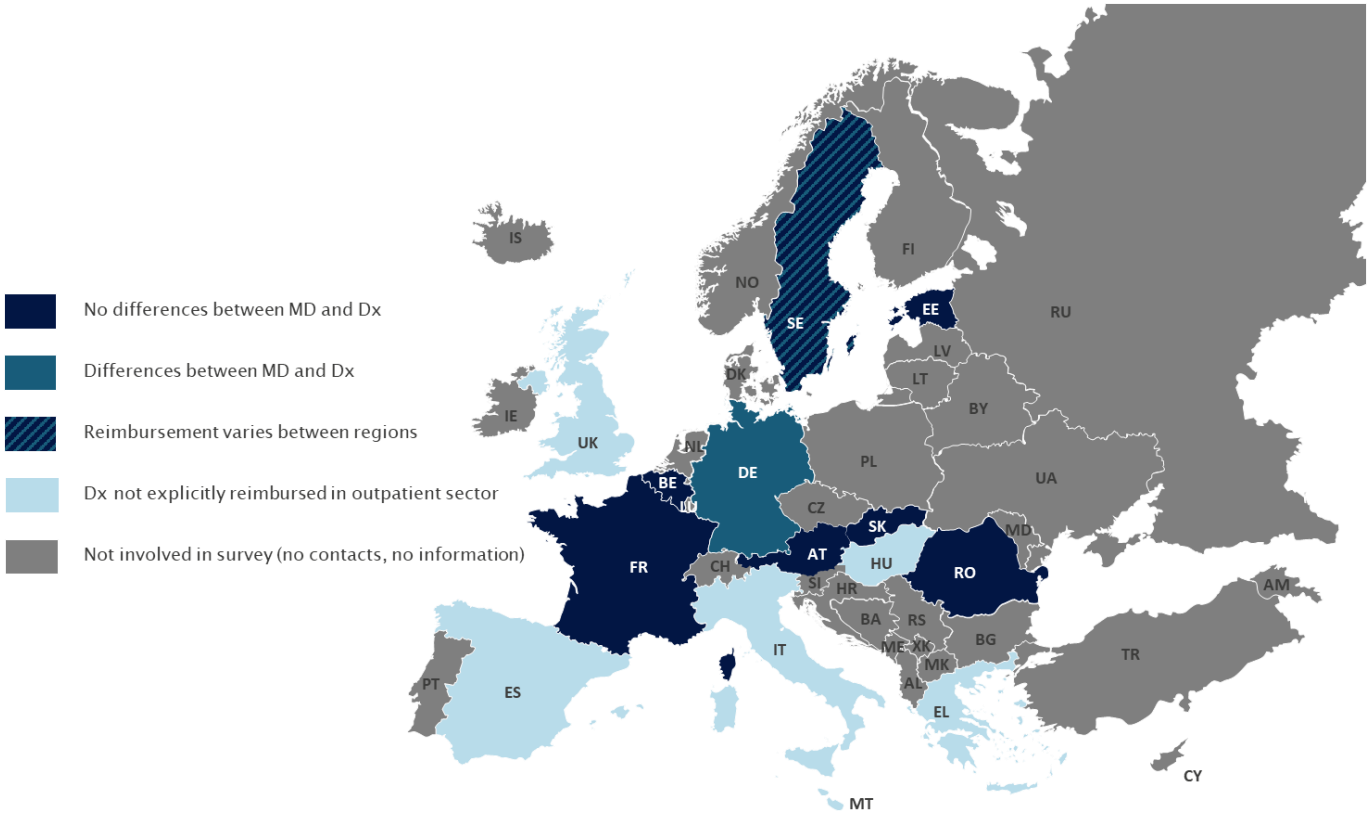

Figure 9: Country overview of reimbursement process for MD in comparison to Dx for RTI or CA-ARTI (2020)

Reference: GÖG survey with competent authorities for medical devices

Table 8: Country overview of reimbursement process for MD in comparison to Dx for RTI or CA-ARTI (2020)

COUNTRY	AUTHORITY/COMMITTEE ON REIMBURSEMENT	CRITERIA TAKEN INTO CONSIDERTATION FOR REIMBURSEMENT DECISION	FURTHER INFORMATION
Austria	The evaluation committees provide recommendations to SHI funds, which are in charge of the reimbursement decisions.	If a new medical device meets the criteria of an existing MD in the reimbursement list, it can be reimbursed as such.	For new medical devices, the supplier can request for reimbursement.
Belgium	Different expert committees (and commissions) within the NIHDI (National Institute of health and disability insurance) provide recommendations on reimbursement (and co-payments) to the Minister for Social Affairs.	If a new medical device meets the criteria of an existing MD in the reimbursement list, it can be reimbursed as such. Reimbursement decision is based on scientific (economic as well as qualitative) evaluation reports	In some cases, a file to ask for inclusion in the reimbursement list is a prerequisite (in case that additional information, e.g. scientific publications are needed).
Croatia	Committee for general medical devices provides recommendations to CHIF Management Board, which is in charge of reimbursement decisions.	Official criteria for a MD to get reimbursed are determined by the "Ordinance on the criteria for placing medical devices on the basic and additional list of medical devices" of the Croatian Health Insurance Fund (CHIF) and the criteria for determining the prices of medical devices: (MD of same kind = 95% of current price; new generation MD = 100 % of current price; new MD = economic analysis needed)	None
Estonia	The specific sections of the EHIF list are updated by EHIF in cooperation with medical associations.	Reimbursement decisions are based on clinical and economic evaluations (criteria: existence of medically justified indications for the use of the MD/service by the general public and existence of alternative medical devices/services or treatment methods; the optimal quantity of MD needed for treatment; amount of resources needed to offer the service, correspondence to the funds of health insurance, cost effectiveness of the medical device/service; conformity of the medical device with the Medical Devices Act)	EHIF and medical associations propose the structure of the service list, including which specific services are introduced with individual fees. For instance, updating the section that includes diagnostic tests that is currently underway is done in cooperation with the Estonian Society for Laboratory Medicine, who provide a recommendation for which services should be included in the list. For any new service proposed, at least a rapid HTA is necessary to make sure the proposed service meets the criteria for reimbursement.
Finland	No information available	No information available	No information available

COUNTRY	AUTHORITY/COMMITTEE ON REIMBURSEMENT	CRITERIA TAKEN INTO CONSIDERTATION FOR REIMBURSEMENT DECISION	FURTHER INFORMATION
France	Ministry of Health, follow-up decision on reimbursement rate for outpatient MD by National Union of Health Insurance Funds (UNCAM)	• If a medical device meets the criteria of an existing MD in the reimbursement list, it can be reimbursed as such. • For others, a value assessment (HTA, with sufficient added benefit needed) is performed by HAS, and an SA/SR and an ASA I to V assessment is granted (see section 5.2)	Diagnostic tests are reimbursed at 60% (e.g. hepatitis C and HIV test are reimbursed at 100%)
Germany	Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA)	New diagnostic and therapeutic procedures can only be reimbursed by SHI funds if they are considered "necessary, appropriate, and economic" by the G-BA	New technologies to be used in the outpatient setting also need to be listed in the "Einheitlicher Bewertungsmaßstab" (EBM). Evaluation Committee (Bewertungsausschuss): defines and maintains the EBM catalogue, which is the basis for the fee for service remuneration of providers. No volume limits for Dx for laboratories Note: for new Dx for laboratories, manufacturers can apply for admission into EBM under certain conditions
Greece	n/a	n/a	The standard reimbursement decision process of medical devices is to set by law.
Hungary	National Institute of Health Insurance Fund Management (Nemzeti Egészségbiztosítási Alapkezelő, NEAK)	Reimbursement decisions are based on efficacy, safety, ratio between cost and therapeutic value, budgetary impact analysis, health economist analysis, health technology analysis (if necessary)	None
Italy	n/a	n/a Note: There is no explicit decision on inclusion of MD into reimbursement (MD are funded if they are purchased by the NHS and regions	None
Malta	n/a	n/a	None

COUNTRY	AUTHORITY/COMMITTEE ON REIMBURSEMENT	CRITERIA TAKEN INTO CONSIDERTATION FOR REIMBURSEMENT DECISION	FURTHER INFORMATION
		Note: There is no explicit decision on inclusion of MD into reimbursement. A Cost-Benefit Analysis is carried out for high cost medical devices	
Romania	National Social Insurance House (Casa Națională de Asigurări de Sănătate)	The National Social Insurance House establishes a standard fee for service taking into consideration different factors (e.g. the prices of MD in the market).	The provisions that a MD has to fulfil are laid down in the framework-agreement with National Social Insurance House that every provider has to sign.
Slovakia	Public Health Insurance Company (Všeobecná zdravotná poisťovňa, VŠZP)	Before inclusion into reimbursement of medical devices, the following shall be taken into account: • Efficacy (from clinical trials) • Amount of reimbursement for similar MD • Comparing MD with other available treatment options (e.g. indications, therapeutic benefit, work ability recovery, cost-effectiveness)	None
Spain	n/a	n/a Note: There is no explicit decision on inclusion of MD into reimbursement	n/a
Sweden	Decisions are taken by the Swedish regions and their facilities individually and reimbursement can vary across the country.	By law, the cost-benefit ratio must be reasonable	There are no national decision procedures regarding the reimbursement of Dx.
United Kingdom	n/a	No dedicated reimbursement decision for certain MD Note: Providers and Commissioners of care are able to decide what meets the needs of their local population, supported by national policy and guidance. They commission services appropriate to the needs of their population.	None

Abbreviations: CHIF = Croatian Health Insurance Fund; Dx = diagnostics; EHIF = Estonian Health Insurance Fund; n/a = information not available; SHI = Social Health Insurance

Reference: GÖG survey with competent authorities for medical devices, and Olberg et al. (2014)

5.3.4. Co-payments for medical devices and rapid diagnostic tests for RTI or CA-ARTI

In the majority of the study countries, no co-payments or out-of-pocket payments (in case of no reimbursement) are charged for Dx (for RTI or CA-ARTI) in the outpatient sector.

Table 9: Country overview of co-payments for MD in comparison to Dx for RTI or CA-ARTI in the outpatient sector (2020)

COUNTRY	CO-PAYMENTS IN GENERAL	CO-PAYMENT SPECIFITIES	EXCEPTIONS FOR CO-PAYMENTS	CO-PAYMENTS OF MD VS.
Austria	For some MD (e.g. medical aids), depending on SHI fund	Application of co-payment depends on SHI fund	No co-payments for certain vulnerable groups	No difference (no co-payments for patients in largest SHI fund)
Belgium	For some MD (e.g. hearing aids), depending on SHI fund	• Co-payments are not mandatory for medical devices and professionals that sell these medical devices can decide not to charge co-payments. • Co-payments can be either a fixed amount or a percentage of the price in reimbursement list	No co-payments for certain vulnerable groups	No difference
Croatia	For reimbursable MD (i.e. those in reimbursement list)	Co-payments can be either fixed or a percentage of the of the price in reimbursement list	No co-payments for certain vulnerable groups and persons with compulsory and supplementary health insurance	Unclear
Estonia	For reimbursable MD (i.e. in reimbursement list)	• No co-payment for services at practitioner • Co-payment for MD purchased by patient: usually 10%, but for some cases also 50%, when there is an alternative cheaper method of treatment available in Estonia (e.g. wound dressings)	No co-payments for certain vulnerable groups (applies for EHIF list)	• No co-payments apply to diagnostic tests that are reimbursed by EHIF • As rapid diagnostic tests for RTI or CA-ARTI are only reimbursed when performed by a medical professional (GP or in a lab) through the health service list (and not through medical devices), they do not include a co-payment.
Finland	No co-payments	None	None	No difference

COUNTRY	CO-PAYMENTS IN GENERAL	CO-PAYMENT SPECIFITIES	EXCEPTIONS FOR CO-PAYMENTS	CO-PAYMENTS OF MD VS.
France	For reimbursable MD (i.e. those in reimbursement list) Note: In practice, co-payment is covered by complementary health insurance ("mutuelle"), which is mandatory and majority of French population has.	A co-payment of 40% of the retail price is, in principle, applicable	Exemption from co-payment for patients with defined severe and chronic diseases (affections de longue durée / ALD) in cases of the use of MD related to these diseases.	No difference Note: Dx is either covered or co-payments or OOP apply (depends on "mutuelle"). ALD exemption from co-payments is not applicable for rapid diagnostic tests for RTI or CA-ARTI
Germany	For some MD (e.g. hearing aids) Note: every SHI offer certain MD without co-payment, for more expensive MD co-payments apply	Fixed co-payments for certain MD (e.g. hearing aids or orthopaedic aids, distributed by pharmacies or orthopaedic/medical supply stores)	Reductions and exemptions for co-payments are applicable	No difference to most MD
Greece	For reimbursable MD (i.e. those in reimbursement list)	Co-payment varies between 0 and 25% of retail price, according the health status of each patient.	Exemption from co-payment: People with certified disabilities	Full OOP for Dx Note: Dx are not explicitly reimbursed
Hungary	For reimbursable MD (i.e. those in reimbursement list)	Percentage co-payments (50, 70, 80, 90, 98%) of retail price	Excluded from co-payment are persons in socioeconomically disadvantageous situations or with certain chronic diseases.	Full OOP for Dx Note: Dx are not explicitly reimbursed
Italy	No co-payments	None	None	Unclear
Malta	No co-payments	None	None	OOP Note: Dx are not explicitly reimbursed, practitioner can decide to charge patient
Romania	No co-payments	None	None	No co-payments
Slovakia	For reimbursable MD (i.e. those in reimbursement list)	• Co-payment ratio is set individually for every group of MD of retail price • Fixed co-payment: Prescription fee is 0,17 EURO	Exemptions from co-payment: vulnerable population, disabled patients, deductible limits of co-payment for certain groups	No difference to most MD

COUNTRY	CO-PAYMENTS IN GENERAL	CO-PAYMENT SPECIFITIES	EXCEPTIONS FOR CO-PAYMENTS	CO-PAYMENTS OF MD VS.
Spain	No co-payments for reimbursable MD (i.e. those in reimbursement list)	Exemption from OOP payments for MD, including Dx, if the MD is considered to be eligible for reimbursement	None	Full OOP for Dx Note: Dx are not explicitly reimbursed, practitioner can decide to charge patient
Sweden	Regulations and amount of co-payments vary between regions	Many regions have high-cost protection for medical aids	Patients up to the age of 18 are exempted from co-payments	Patient co-payments for Dx are rather common
United Kingdom	No co-payments Note: In the NHS, practitioners are not allowed to charge patients	None	None	No difference Note: Dx are not explicitly reimbursed, practitioner has to bear costs for Dx

Abbreviations: Dx = diagnostics; EHIF = Estonian Health Insurance Fund; MD = medical device; n/a = not available; OOP = out-of-pocket payments; SHI = Social Health Insurance

Reference: GÖG survey with competent authorities for medical devices

5.3.5. Development and discussions on possible changes related to reimbursement of MD, including rapid diagnostic tests for RTI or CA-ARTI

Table 10 summarises ongoing discussions and exceptional pathways for reimbursement for defined MD as well as Dx. However, the survey revealed information for only four countries.

Table 10: Incentives to extend reimbursement of Dx for RTI or CA-ARTI (2020)

COUNTRY	INCENTIVES
Austria	n/a
Belgium	n/a
Croatia	n/a
Estonia	There is a discussion about the reimbursement of rapid Dx more generally. Currently, the discussion has not focused on Dx being incentivised, but rather if rapid tests should be listed as separate services on the health service list and therefore acquire separate reimbursement rates. For the review process, the discussion has mainly been between EHIF, the Estonian Society for Laboratory Medicine and the Family Physicians Association of Estonia.
Finland	n/a
France	Innovative medical devices or procedures (including Dx) can be temporarily funded through a dedicated exceptional pathway. The funding covers partial or total related to the innovation: patient stay, medical device and/or procedure as well as the costs of additional data collection.
Germany	Laboratory diagnostics for antibiotic therapy were removed from the so-called "profitability control" by practitioners (that means practitioners can use Dx without any limits) For new innovative medical devices, no evaluation of the added benefit is needed, laboratory diagnostics for antibiotic therapy were removed from the profitability control

COUNTRY	INCENTIVES
	Reimbursement of PCT with extra-budget and without quantity limitations. There is an ongoing discussion and several (past) pilot projects on antibiotic stewardships, etc. Several stakeholders are involved.
Greece	n/a
Hungary	n/a
Italy	n/a
Malta	n/a
Romania	n/a
Slovakia	n/a
Spain	n/a
Sweden	n/a
United Kingdom	Many discussions are underfoot to transform the services for patients and improve care and patient health outcomes. None surrounding the specifics of incentives for rapid diagnostics for RTI or CA-ARTI are currently underway. For all discussions, as many related stakeholders as possible are invited to contribute, support and critique proposals.

Abbreviations: CA-ARTI = community acquired acute respiratory tract infection; Dx= diagnostics; EHIF = Estonian Health Insurance Fund; n/a = no information available; PCT = procalcitonin. RTI= respiratory tract infection

Reference: GÖG survey with competent authorities for medical devices

5.4. Pricing of rapid diagnostic tests for RTI or CA-ARTI in the study countries

This section explores:

- whether, or not, price control (price regulation) is applied for (defined) MD, including Dx, and
- whether, or not, there is also price control for (defined) MD, including Dx, in the supply chain.

In cases where there is price control for (defined) MD including Dx, we investigated which pricing policies are applied (e.g. external price referencing (EPR), internal price referencing (IPR), value based pricing (VBP), tendering, cost-plus pricing, for the definitions of the pricing policies can be found in section 3.2.4).

In case of price regulation in the supply chain for (defined) MD including Dx, we studied whether, or not, wholesale and pharmacy retail price were subject to price regulation, and if remuneration regulation for distribution actors (wholesale and pharmacy) applies, and how it is designed. Price-impacting taxes (e.g. value-added tax) were also studied.

Again, this chapter on pricing policies explores possible differences for rapid diagnostic tests for RTI or CA-ARTI compared to Dx in general and other groups of MD.

5.4.1. Price regulations for medical devices and rapid diagnostic tests for RTI or CA-ARTI

There is free pricing for medical devices in the majority of the countries, due to the absence of price regulation.

In five countries (France, Greece, Hungary, Slovakia and Spain), prices of defined medical devices are set by the authority, based on different pricing policies (see section 5.4.2). However, this price regulation usually only addresses MD which have been classified to be eligible for reimbursement (reimbursable MD), and this is usually a rather small list. In principle, there is no distinction between the application of price control for rapid diagnostics for RTI and CA-ARTI but in the above-mentioned cases of price regulation for outpatient reimbursable MD, it should be noted that Dx are usually not reimbursable and thus also not reimbursed. In addition, medical devices may be procured by the national or regional health services which is an indirect price control.

Procurement can be done by national / regional and local health services, insurance institutions, states, municipalities, laboratories or practitioners.

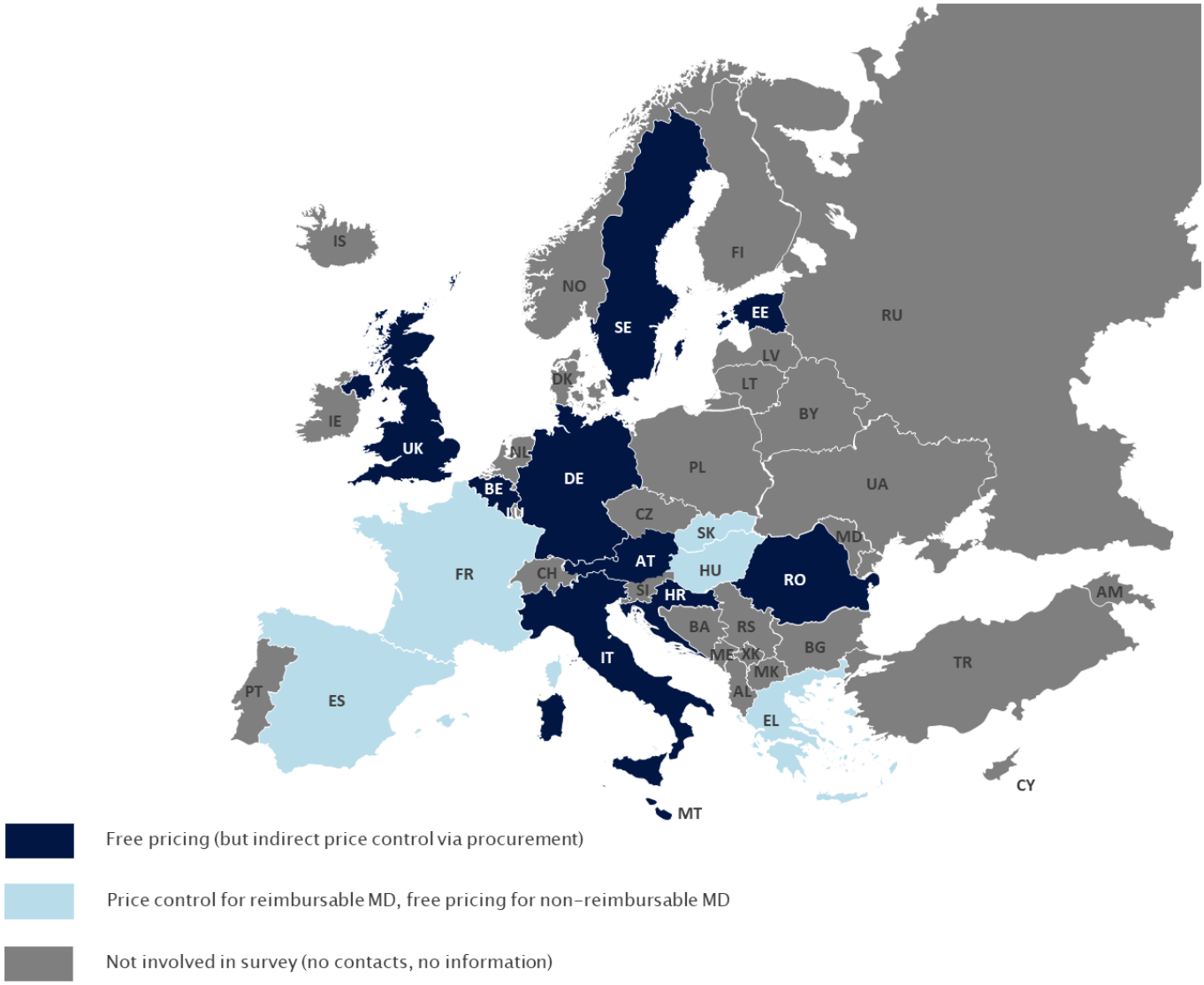

Figure 10: Country overview of price regulations for MD (2020)

Reference: GÖG survey with competent authorities for medical devices

Thus, there is (mostly) free pricing for MD and Dx in: Austria, Belgium, Croatia, Estonia, Germany, Italy, Malta, Romania, Sweden, and UK. Price regulations for MD, but free pricing for Dx are in: France, Greece, Hungary, Slovakia, and Spain. Slovakia is the only study country with regulated prices for MD and Dx.

Further information can be found in Table 11 below.

Table 11: Price regulations for MD in comparison to Dx for RTI or CA-ARTI (2020)

COUNTRY	PRICE REGULATION FOR MD IN GENERAL	REGULATED PRICE TYPE FOR MD	DIFFERENCES MD VS. DX (FOR RTI/CA-ARTI)
Austria	Free pricing Note: indirect price control via procurement	Not applicable Note: procurement price in case of procurement	None
Belgium	Free pricing Note: maximum price for certain categories of MD;indirect price control via procurement	Not applicable Note: procurement price in case of procurement	None
Croatia	Free pricing (mostly) Note: indirect price control via procurement	Not applicable Note: procurement price in case of procurement	None
Estonia	Free pricing Note: indirect price control via procurement	Not applicable Note: procurement price in case of procurement	None
Finland	n/a	n/a	n/a
France	Set in price negotiation for reimbursable MD Note: for MD on LPPR-list; free pricing for all other MD	Ex-factory price + PRP Note: for MD on LPPR-list; no information on retail margins	Free-pricing for Dx due to reimbursement status Note: Dx are not on LPPR-list (price for Dx should be inferior to tariff paid)
Germany	Free pricing Note: indirect price control via procurement	Not applicable Note: procurement price in case of procurement	None
Greece	Regulated by law Note: for MD on EOPYY-list; free pricing for all other MD	Ex-factory price Note: for MD on EOPYY-list; no information on retail margins	Free-pricing for Dx due to reimbursement status Note: Dx are not explicitly reimbursed
Hungary	Regulated by law Note: for MD on reimbursement list	PRP	Free-pricing for Dx due to reimbursement status Note: Dx are not explicitly reimbursed
Italy	Free pricing Note: There is no explicit decision on inclusion of MD into reimbursement	Not applicable Note: procurement price in case of procurement	None Note: Dx are not explicitly reimbursed
Malta	Free pricing Note: There is no explicit decision on inclusion of MD into reimbursement; indirect price control via procurement	Not applicable Note: procurement price in case of procurement	Free-pricing Note: Dx are not explicitly reimbursed
Romania	Free pricing Note: indirect price control via procurement	Not applicable Note: procurement price in case of procurement	None

COUNTRY	PRICE REGULATION FOR MD IN GENERAL	REGULATED PRICE TYPE FOR MD	DIFFERENCES MD VS. DX (FOR RTI/CA-ARTI)
Slovakia	Regulated by law Note: for MD on reimbursement list; free pricing for non-prescription MD Price must be lower than the average of the three lowest EU prices; wholesale margin: 8.5 %; pharmacy margin: 11.5 %	Ex-factory price + PRP	None
Spain	Regulated by law Note: for MD on reimbursement list; free pricing for all other MD	Ex-factory price + PRP Note: for MD on reimbursement list; no information on retail margins	Free-pricing Note: Dx are not explicitly reimbursed
Sweden	Free pricing (mostly) unless reimbursable MD Note: prices regulated by law for MD on TLV list; MD and Dx are usually procured by the regions by public tender, thus indirect regulation via procurement	Not applicable Note: procurement price in case of procurement Note: indirect regulation via procurement for all other MD; Ex-factory price + PRP for MD on TLV-list	None Note: Decisions are taken by the Swedish regions and their facilities individually
United Kingdom	Free pricing (mostly) Note: MD and Dx are usually procured by Providers and Commissioners of care, MD and Dx are usually procured by the regions by public tender, thus indirect regulation via procurement. They commission services appropriate to the needs of their population.	Not applicable Note: procurement price in case of procurement	None

Abbreviations: Dx = diagnostics; EOPYY = Greek National Health Insurance body; LPPR = Liste des prestations et produits remboursables; MD = medical device, n/a = no information available; PPP = pharmacy purchasing price (wholesale price); PRP = pharmacy retail price; TLV = Tandvårds- och läkemedelsförmånsverket / Dental and Pharmaceutical Benefits Agency
Note: with regard to the price type regulated

Reference: GÖG survey with competent authorities for medical devices

5.4.2. Pricing policies and criteria for medical devices and rapid diagnostic tests for RTI or CA-ARTI

As stated in the previous section, prices are only regulated in a few countries.

The most frequently applied pricing policy for MD is internal price referencing (IPR) in which the price of a MD to be included in the country's reimbursement list is set in relation of the price of an similar MD already in the list. However, it is only used in the context of reimbursable MD which tend to be few MD. Since in none of the study countries (except Slovakia), Dx have been included in reimbursement lists, internal price referencing does not play a role (see Table 12:).

France and Slovakia also consider the prices in other countries (EPR) in setting the prices of reimbursable MD (which may include Dx in Slovakia). For reimbursable MD (not for Dx), France also does price negotiations which may contain a value-based pricing elements.

Countries reported not to use tendering as an outpatient pricing / procurement policy for MD; however in some cases tendering or tendering-like procedures can be expected to play a role in procurement processes.

Table 12: Pricing policies for MD and difference to those for Dx for RTI or CA-ARTI (2020)

COUNTRY	EPR	IPR	VBP	TENDERING	COST-PLUS PRICING	OTHER	DIFFERENCES MD AND DX (FOR RTI OR CA-ARTI)
Austria	No	No	No	No	No	No	No
Belgium	No	No	No	No	No	No	No
Croatia	No	No	No	No	No	No	No
Estonia	No	No	No	No	No	No	No
Finland	n/a	n/a	n/a	n/a	n/a	n/a	n/a
France	Yes Note: for MD on LPPR	Yes Note: for MD on LPPR	Yes Note: for MD on LPPR	Yes	No	No	No Note: no price control for Dx
Germany	No	No	No	No	No	No	No
Greece	No	Yes Note: for MD on EOPYY list	No	No	No	No	No Note: no price control for Dx
Hungary	No	Yes Note: for MD on reimb. list	No	No	No	No	No Note: no price control for Dx
Italy	No	No	No	No	No	No	No
Malta	No	No	No	No	No	No	No
Romania	No	No	No	No	No	No	No

COUNTRY	EPR	IPR	VBP	TENDERING	COST-PLUS PRICING	OTHER	DIFFERENCES MD AND DX (FOR RTI OR CA-ARTI)
Slovakia	Yes Note: price ≤ three lowest prices in EU	No	No	No	No	No	No
Spain	No	Yes Note: for MD on reimb. list	No	No	No	No	No Note: no price control for Dx
Sweden	No	Partly Note: not mandatory	No	Yes	No	No	No
United Kingdom	No Note: Depends on local policies	Likely Note: Depends on local policies	Likely Note: Depends on local policies	No Note: Depends on local policies	Likely Note: Depends on local policies	No	No

Abbreviations: Dx = diagnostics; EOPYY = Greek National Health Insurance body; EPR = external price referencing; IPR = internal price referencing; LPPR = Liste des prestations et produits remboursables / List of reimbursable services and products; MD = medical device; n/a = no information available, reimb. = reimbursement; VBP = value-based pricing

* The reimbursement status of the MD determines whether, or not, price control is in place (and in such case, IPR is applied). Dx are not included in the reimbursement list, so that there is no difference between Dx and other MD not included in the reimbursement list.

Reference: GÖG survey with competent authorities for medical devices

5.4.3. Mark-ups and tax rates for medical devices and rapid diagnostic tests for RTI or CA-ARTI

Information on mark-ups and value-added tax (VAT) for MD in comparison to Dx (for RTI or CA-ARTI) in the study countries is summarised in Table 13.

In none of the study countries, different VAT rates for Dx compared to those for MD are applied. However, in four countries (see Figure 11) different VAT rates are charged on different types of MD[28]. Overall, there is variation in the VAT for MD across countries (from 0% in UK to 30% in Estonia).

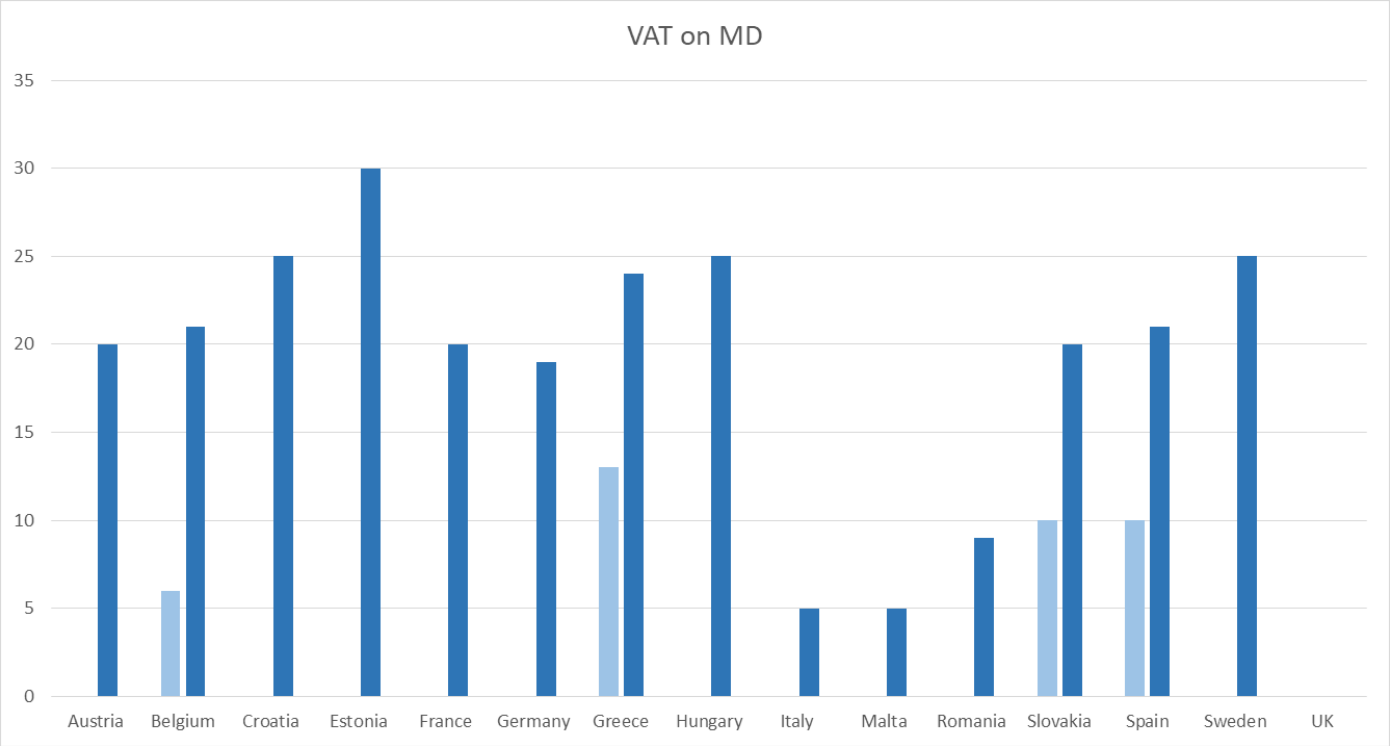

Figure 11: Country overview of value-added tax rates for MD (2020)

Reference: GÖG survey with competent authorities for medical devices

Mark-ups for MD are exclusively regulated in three countries: Hungary, Slovakia and Sweden. In these cases, mark-ups for Dx do not differ from those of other MD.

Table 13: Mark-ups and value-added taxes for MD in general and for Dx for RTI or CA-ARTI (2020)

COUNTRY	MARK-UPS FOR MD	VAT FOR MD	DIFFERENCES MD AND DX (FOR RTI OR CA-ARTI)
Austria	Not regulated	20%	No
Belgium	Not regulated	6% or 21% (depending on the device)	No
Croatia	Not regulated	25%	No

[28] In Sweden, there is no VAT when MD are purchased via public procurement.

COUNTRY	MARK-UPS FOR MD	VAT FOR MD	DIFFERENCES MD AND DX (FOR RTI OR CA-ARTI)
Estonia	Not regulated	30% (9% for MD used by people with disabilities)	No
Finland	n/a	n/a	n/a
France	Not regulated (subject to negotiation)	20%	No
Germany	Not regulated	19%	No
Greece	Not regulated	13 or 24% (depending on the device)	No
Hungary	Regulated (for MD on reimb. list; pharmacy margin with fix and a variable component, dependents on price & type of product)	25%	No (no margins for Dx due to their reimbursement status)
Italy	Not regulated	5%	No
Malta	Not regulated	5%	No
Romania	Not regulated	9%	No
Slovakia	Regulated (for MD on reimb. list: wholesale: 8.5%; pharmacy; 11.5%)	10% or 20% (depending on the device)	No
Spain	Not regulated (subject to negotiation)	10% or 21% (21% for e.g. medical equipment such as Dx)	No
Sweden	Regulated (for MD on reimb. list; pharmacy: unknown margin)	25 % (no VAT for public procured MD)	No (no margins for Dx due to their reimbursement status)
United Kingdom	Not regulated (subject to negotiation)	0% (no VAT for outpatient services)	No

Abbreviations: Dx = diagnostics; MD = medical device; n/a = no information available, reimb. = reimbursement; VAT = value-added tax

Reference: GÖG survey with competent authorities for medical devices

5.4.4. Steps undertaken to grant premium prices for rapid diagnostic tests for RTI or CA-ARTI

The survey did not reveal any ongoing discussion on premium or special pricing for Dx in any of the study countries.

In the UK, though, discussions are underfoot to transform the services for patients and improve care and patient health outcomes. None surrounding the specifics of incentives for rapid diagnostics for RTI or CA-ARTI are currently underway.

6. Discussion

Findings of the mapping in the light of existing evidence

The current study investigated major policies related to HTA, pricing and reimbursement applied for diagnostics (Dx) for CA-ARTI in the European countries generally and in particular with regard to differences across countries as well as between the policies for CA-ARTI Dx and other Dx and medical devices in general. The findings of the present study can be summarised as follows:

1| HTA

- In the majority of study countries HTA are not systematically performed at national levels to inform pricing and reimbursement decisions for MD.
- In case that HTA are carried out for medical devices (MD), Dx are not assessed through a different methodology than other MD.

2| Reimbursement

- Reimbursement of MD appears to be linked to the organisation of the health system and the remuneration system for health care providers in the outpatient sector (e.g. if practitioners are remunerated by salary, the use of a MD is mostly not separately funded).
- In case of fee-for-service remuneration for health care providers in the outpatient sector, only a few countries have separate fees for Dx in place.
- Dx are funded by third party payers at national level in eight of the study countries (in two countries remuneration is only for laboratories).
- No differences in the reimbursement decision process between Dx and MD were reported.
- Due to different funding mechanisms (reimbursement list, procurement by NHS), patients usually do not have to co-pay for use of Dx in the outpatient setting.

3| Pricing

- In the majority of the study countries there is free pricing of MD (that means the supplier sets the price).
- In the rare cases of price control (mainly for reimbursable MD) internal price referencing of comparable MD is the most commonly applied pricing policy.
- However, there may indirect price control through public procurement.
- In case that there are pricing policies in place, no differences between Dx and MD were identified. However, in some countries, the reimbursement status determines whether, or not, a MD is subject to price regulation.

These findings offer new evidence (and serve as a starting point for further research and policy development), since pricing and reimbursement policies applied for Dx for CA-ARTI have not been researched before. Overall, there is limited evidence on pricing and reimbursement policies for MD in general. To the knowledge of the authors, informed by a review done in the course of this study, a few studies describe peri-launch policies for MD in general (a study as of 2009 on four European

countries[29] and for diagnostic tests[30] (a yet unpublished study as of 2021 on ten G10 countries)). Despite its limitations due to the novelty of the topic (see below limitations), this study fills a major information gap. It responds to the need to get an overview of pricing and reimbursement policies for Dx and further MD, as it was requested by other authors.[31]

There may be different reasons for this limited evidence on policies for Dx and for MD in general: Overall, the level of regulation for MD (also in terms of market approval) is lower for MD than for medicines, and thus there are fewer policies to be captured in literature. Furthermore, the MD market is heterogeneous given the variety of products: so any description of policies for MD in general is somewhat simplified, and a comprehensive picture of the policy framework for MD would require a compilation of the set of these policies for different groups of MD. HTA and procurement for Dx and other MD are conducted at regional levels in some countries (e.g. Spain, Italy), while national policies are not in place. Lastly, it may also be assumed that in the last decades the focus of policy-makers has rather been on medicines, which resulted in more research on policies for pharmaceuticals compared to diagnostics and other MD.

Implications for policy-making and research

To address AMR, multi-faceted approaches are required. Research, policy discussion and implementation have focused on important areas of antimicrobial stewardship programs and on the development of novel antibiotics (e.g. incentives for R&D) that have a lower probability to produce AMR. Another key avenue is an increased use of Dx to determine whether, or not, an antibiotic needs to be prescribed. However, the level of use of Dx is still low, and it was asked for policies that incentivise the uptake of Dx for CA-ARTI.[32]

The yet low use of Dx may be attributable to a number of causes. First of all, the uptake of Dx might be conflicting: antibiotics tend to be low-priced, whereas diagnostics add an expense to health systems and might be more expensive, which decreases the motivation for third party payers to reimburse Dx. In addition, the positive impact of Dx is not seen immediately and occurs only later in time (due to lower antimicrobial resistance).[33]

As for medicines, policy measures to contribute to the development, production, launch and uptake of Dx can be taken at different stages of the value chain (see section 3.2.4). Overall, successful uptake of Dx requires a complex "mix-and-match" implementation package.[34] This includes appropriate peri-launch activities, thus pricing and reimbursement policies. While researchers aimed to identify possible barriers to patient access to MD as well to efficient use of resources, they also stressed the importance of creating an overview of existing policies first.[35] The present study attempted to close this missing link.

As next steps, it is important to understand the impact of the pricing and reimbursement policies on possible uptake of Dx. By now, very few impact evaluations of pricing and reimbursement

[29] Schreyögg et al. (2009)
[30] Vogler S. et al. (2021)
[31] Beck et al. (2019)
[32] Bundesministerium für Gesundheit (2019)
[33] O'Neill (2016)
[34] Hays et al. (2019)
[35] Beck et al. (2019); Simoens (2009)

policies for MD are available (e.g. one of a reimbursement policy called "reference pricing" in the USA[36] and another on centralised regional procurement in Italy.[37] However, it has to be acknowledged that even for medicines the number of evaluation studies on pricing policies that meet strong quality criteria is limited.[38] But through policy implementation over the years, experience has been gained on possible supportive and hindering factors of specific pricing and reimbursement policies and it has been documented in (frequently grey) literature. Thus, identifying barriers and incentives in pricing and reimbursement policies for the uptake of Dx for CA-ARTI may build on the knowledge base generated for medicines.

In pricing and reimbursement there is not "the" policy but policies can be implemented in different designs. As shown for pharmaceutical policies[39], the design can considerably impact the ability to achieve the intended policy objective. This learning is to be taken into consideration in the investigation of barriers and incentives of pricing and reimbursement policies.

With regard to HTA for MD in general and Dx in particular, major progress in terms of the methodology development (including health economic evaluations) have been made in recent years, and further work is ongoing.[40] For instance, the "value of diagnostic information" (VODI) concept was developed to allow considering different dimensions and perspectives in an assessment.[41]

While further methodology development on HTA related to the specificities of Dx for CA-ARTI is appreciated, the policy perspective appears to require further development. The study showed that currently HTA for Dx for CA-ARTI is rather conducted at regional or local levels. National appraisal processes appear to be missing, and the HTA outcomes are not embedded in the national pricing and reimbursement processes.

While research on identifying incentivising and hindering aspects in the pharmaceutical pricing and reimbursement policy frameworks for Dx for CA-ARTI in the study countries will follow as a next step in this project, more in-depth insight in country-specific particularities of the policy design might be needed. New information and different perspectives may be brought in at a later stage. Thus, the present report should be seen as a living document.

Learning of this project can be used to further develop the conceptual basis of policy framework for MD which has been a rather unstudied research and policy area.

Limitations

A systematic literature search was conducted but due to the absence of (recent) peer-reviewed articles, mainly grey literature identified in hand search had to be considered.

A general issue is the chosen method of conducting a survey, which contains the risk of several biases, such as an interpretation bias. While the authors are confident to have been able to present more information due to their approach to present pre-filled questionnaires to country experts and

[36] Robinson et al. (2016)
[37] Callea et al. (2017)
[38] World Health Organization (2020)
[39] KenneallyWalshe (2012); Vogler S. et al. (2020); Moreno-Torres et al. (2011)
[40] Schnell-Inderst et al. (2015); Soares et al. (2018); Price et al. (2018)
[41] Wurcel et al. (2019)

asking for their confirmation, a potential confirmation bias cannot be excluded. Furthermore, the questionnaire could not be pre-filled for some countries.

An example for a potential bias is information generated based on the first question (see section 5.1.1): the questionnaire asked for the use of rapid diagnostic tests in the individual countries. Due to existing market approval for all mentioned tests, it is likely that these tests are in use. However, the respondents only have data on use of the tests if they are reimbursed. For instance, the CRP test is available in the UK, but not reimbursed and therefore it may, or may not, be used.

Overall, probably due to the lower level and heterogeneity of regulation and policy implementation for medical devices and Dx, a low number of policies were identified for these health technologies, and it was a challenge to identify country experts. In this context it also needs to be mentioned that Dx and also MD are mostly used by practitioners or laboratories in the outpatient sector (and not e.g. by patients). Therefore, public funding of Dx is mostly included in the remuneration of the service of the practitioner (or laboratory).

Another limitation of the present research results the focus on the outpatient sector (in line with the original VALUE-Dx project design), since point-of-care testing can also done in the inpatient sector. However, for instance in Germany, general practitioners account for more than two thirds of all antibiotic prescriptions.[42]

In addition, potential language barriers between GÖG and the country experts may have decreased the number of responses to the survey. Furthermore, the language barriers and the lack of a clear taxonomy and framework in the research field of policies for MD and Dx could have led to different interpretations of certain elements of the questionnaire.

Ultimately, due to the Covid-19 pandemic, delays in written responses were encountered in some cases.

As this is a new and yet unstudied research and policy area, some findings might be preliminary. As part of the "living document" concept, they may be updated at a later stage when new evidence will be available.

[42] Infozentrum für Prävention und Früherkennung (2017)

7. Conclusion

The current study has shed some light on the areas of HTA, pricing and reimbursement policies for Dx for CA-ARTI that have, to the authors' knowledge, not been yet studied. By mapping these policies for Dx for CA-ARTI in several European countries, it was shown that the overall level of policy implementation in pricing and reimbursement for Dx, including Dx for CA-ARTI, is rather low and that HTA as a supportive tool to inform pricing and reimbursement decisions at national levels is rarely used in the study countries.

Dx for CA-ARTI constitute a valuable instrument to ensure rational antibiotic prescribing and thus to tackle AMR. Together with further policy actions, including those in the pre-launch and post launch phases, pricing and reimbursement policies, supported by HTA, can contribute to patient access to and uptake of health products, such as Dx for CA-ARTI.

For the development of a well-designed package of HTA, pricing and reimbursement policies, more knowledge on their impact is needed. Thus, further research will be conducted in the course of the VALUE-Dx project: Based on the findings of this descriptive mapping exercise, the authors address the following research questions (outcomes available by 2022):

- How do existing HTA, pricing and reimbursement policies incentivize or hinder uptake of CA-ARTI Dx?
- What improvements are required to ensure implementation of fit-for-purpose policy frameworks to incentivise uptake of CA-ARTI Dx?

Further research of the authors at a more granular level will also allow continuing to review the existing findings. This research has also documented the need to (further) develop a taxonomy related to pricing and reimbursement policies for Dx and to disseminate terms and concepts with policy-makers, technical experts in authorities and researchers. This may also contribute to identifying existing national policies, and implementation aspects of surveyed policies, that had not been sufficiently captured in the survey conducted for this study. Thus, this report is intended to be a starting point for further research on policy implementation impacts and as a "living document" to refine the description of the surveyed measures.

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9. Annex

9.1. Literature Search

1| For the systematic literature search, the following search strategy in PubMed was applied:

((((reimburse*[Title/Abstract] OR pricing[Title/Abstract] OR funding[Title/Abstract] OR HTA[Title/Abstract] OR health technology assessment[Title/Abstract])) AND (((policy[Title/Abstract] OR policies[Title/Abstract])) OR (health policy[MeSH Terms])))) AND ((((diagnostics[Title/Abstract] OR diagnosis[Title/Abstract] OR diagno*[Title/Abstract] OR test[Title/Abstract] OR tests[Title/Abstract] OR testing[Title/Abstract])) OR ("diagnosis/diagnosis"[MeSH Terms])) OR ("diagnosis/therapy"[MeSH Terms])) AND ((Lecture[ptyp] OR pubmed books[filter] OR Journal Article[ptyp] OR Government Document[ptyp] OR Review[ptyp]) AND "last 10 years"[PDat])

2| When screening the abstracts (and full-texts) the following criteria for population, intervention, publications type, geographic scope and languages had to be met:

- Population:
  - Patients with infectious diseases
    - Patients with respiratory tract infection
    - Patients with respiratory infections
    - Patients with community acquired respiratory tract infections (CA-ARTI)
- Intervention:
  - Diagnostics (for CA-ARTI); e.g.:
    - Serological tests (e.g. C-Reactive Protein (CRP), Procalcitonin (PCT))
    - Real-time/nested multiplex RT-PCR,
    - Urine antigen test
    - Mass Spectromy (e.g. Matrix Assisted Laser Desorption Ionization Time-of-Flight)
    - Multiplex microarray competitive DNA hybridization,
    - Isothermal RT-helicase-dependent amplification (I),
    - Loop-mediated isothermal DNA amplification (LAMP),
    - (Isothermal) nucleic acid amplification /polymerase chain reaction
- Publication type: any publication on pricing or reimbursement policies of diagnostics (for CA-ARTI)
- Geographic scope: all EU Member States, H2020 Associated countries
- Languages: no restrictions, national languages to be included

9.2. Survey

Gesundheit Österreich
Forschungs- und Planungs GmbH

VALUE-Dx

Survey for COUNTRY

We would highly appreciate if you could validate the prefilled information and respond to the questions.

Kindly use track change or mark your changes in colour. We also marked some passages (where we are unsure and/or have some questions).

The survey was responded by:

Name: Enter your name here

Institution: Enter the name of your institution here

Email of respondent: Enter your email here

Telephone no.: Enter your phone number here

Kindly respond to the following declaration by ticking, if applicable:

☐ I feel appropriately informed about the purpose of this survey, its methodology and my contribution (informed consent).

☐ I agree to have my name listed in the acknowledgements of the survey (acknowledgements)

☐ I would like to receive a compilation of the findings of this survey when finalising (sharing of compilation).

Scope of survey – Products	
Are fast diagnostic tests for (community-acquired acute) respiratory tract infections (RTI or CA-ARTI) used in the outpatient sector in Germany? (e.g. CRP test)? Note: Besides "normal" diagnostic tests for RTI or CA-ARTI, this question addresses also new tests that generate results within minutes. E.g.: • Serological tests (e.g. C-Reactive Protein (CRP), Procalcitonin (PCT)) • Real-time/nested multiplex RT-PCR, • Urine antigen test • Mass spectrometry • Multiplex microarray competitive DNA hybridization, • Isothermal RT-helicase-dependent amplification (), • Loop-mediated isothermal DNA amplification (LAMP), • (Isothermal) nucleic acid amplification /polymerase chain reaction	
If yes, which of these specific diagnostic tests are already in use in the outpatient sector? Note: see examples of products of different suppliers which also exemplifies the different types (e.g. CRP, PCR, etc.) in Annex 1	
If yes, how is the decision made to use these specific tests (e.g. practitioner, guidelines, etc.)?	

Health Technology Assessment (HTA)	
What is your national HTA institution / department in charge of assessing medical devices (MD) and diagnostics (IVD)?	
Are funding (reimbursement) and/or pricing decisions for fast diagnostic tests for RTI or CA-ARTI based on prior HTA? If yes, which under which conditions?	
Briefly describe the HTA process for fast diagnostic tests for RTI or CA-ARTI? *Kindly elaborate:* • Which dimensions (effectiveness, safety, cost-effectiveness) are covered? • Which criteria / indicators are applied?	
Do HTA processes for fast diagnostic tests for RTI or CA-ARTI differ from those for other MD, incl. diagnostic tests in general? What are the differences? Note: To assess patient-relevant outcomes, consequences (sensitivity, specificity, safety, etc.) of the test and also any subsequent therapies can be taken into account. This can be done through direct comparison of the therapeutic consequences of the new test with those of the reference test or by "linked evidence" (linking studies on diagnostic accuracy to studies on therapeutic effectiveness).	
Reimbursement (includes funding and/or coverage)	
Are fast diagnostic tests for RTI or CA-ARTI (e.g. CRP) reimbursed by public payers in the outpatient sector in Germany? If yes, could you provide an estimate of the number of reimbursed fast diagnostic tests for RTI or CA-ARTI (or the share of fast vs. "normal" diagnostic tests for RTI or CA-ARTI)? Note: The focus lies on point-of-care-testing and tests that generate results within minutes.	

How are fast diagnostic tests for RTI or CA-ARTI reimbursed in the outpatient setting? Note: possible mechanisms include: fee-for-service, pay-for-performance, lump sum or product-based funding Are there specific incentives regarding the reimbursement of fast diagnostic tests for RTI or CA-ARTI used in the outpatient setting?	
Are the reimbursement mechanisms for fast diagnostic tests for RTI or CA-ARTI different from those for other MD, including diagnostic tests in general? If yes, how do the mechanisms differ?	
Kindly explain the (decision) procedures regarding the inclusion of fast diagnostic tests for RTI or CA-ARTI into reimbursement?	
Are the reimbursement decision procedures for fast diagnostic tests for RTI or CA-ARTI different from those for other MD, including diagnostic tests in general? If yes, how do the reimbursement decisions differ?	
Are there patient co-payments charged for fast diagnostic tests for RTI or CA-ARTI? If yes, which are these co-payments?	
Do patient co-payments charged for fast diagnostic tests for RTI or CA-ARTI differ from those charged for other MD, including diagnostic tests in general? If yes, how do the co-payments differ?	
Is there a discussion ongoing that reimbursement of fast diagnostic tests for RTI or CA-ARTI should be (further) incentivised? Note: e.g. higher reimbursement rate/amount, alternative reimbursement schemes to incentivise the uptake of diagnostic tests (which are faster, have a higher sensitivity/ specificity, test for a high number of viruses/bacteria) If yes, what is the content of this discussion?	
If yes, who are the involved stakeholders? Please provide some references, e.g. from media, websites (in national language is fine)	

Survey for COUNTRY

3

Pricing	
Are prices of fast diagnostic tests for RTI or CA-ARTI used in the outpatient sector regulated by law? If yes, how are the prices regulated and for which types of fast diagnostic tests for RTI or CA-ARTI?	
Does price regulation for fast diagnostic tests for RTI or CA-ARTI differ from price control diagnostic tests or other MD in general? If yes, how does price regulation differ?	
Which price type of fast diagnostic tests for RTI or CA-ARTI used in the outpatient sector is price-regulated? Note: price types are ex-factory price, wholesale price (pharmacy purchasing price), pharmacy retail price? Are there differences to other MD, incl. diagnostic tests in general?	
Which additional pricing policies are applied for fast diagnostic tests for RTI or CA-ARTI used in the outpatient sector?	
None (there is free pricing for medical devices)	
Do pricing policies and applied criteria differ for fast diagnostic tests for RTI or CA-ARTI from those applied for other MD, including diagnostic tests in general? If yes, how? Are higher prices granted? Any (price) incentives?	
Kindly inform whether, or not, the following pricing policies are applied for fast diagnostic tests for RTI or CA-ARTI used in the outpatient sector: external price referencing, internal price referencing, value-based pricing, tendering and cost-plus pricing Note: for definitions see the glossary at the end of the survey	
Are there any differences related to these pricing policies between their application for fast diagnostic tests for RTI or CA-ARTI and for other MD, including diagnostic tests in general?	
Are wholesale and pharmacy mark-ups regulated for fast diagnostic tests for RTI or CA-ARTI? (How) are community pharmacies remunerated for supplying fast diagnostic tests for RTI or CA-ARTI?	
If yes, how does wholesale and pharmacy mark-up regulation for fast diagnostic tests for RTI or CA-ARTI differ from those applied for other MD, including diagnostic tests in general?	

4

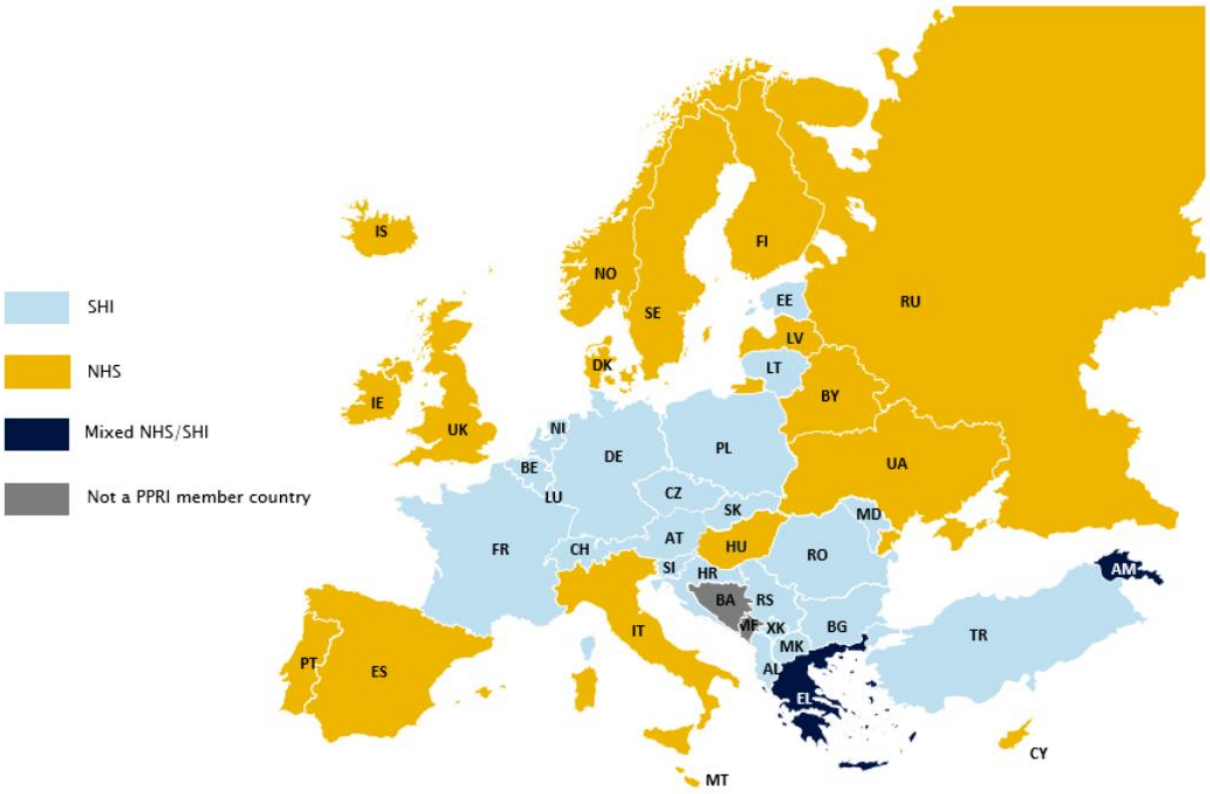
Are sales taxes (e.g. VAT) applied on fast diagnostic tests for RTI or CA-ARTI, and if yes, at which price type?	
If yes, how sales taxes for fast diagnostic tests for RTI or CA-ARTI differ from those applied for other MD, including diagnostic tests in general?	
Is there a discussion ongoing on incentivizing pricing/prices of fast diagnostic tests for RTI or CA-ARTI? Note: e.g. higher prices for defined diagnostic tests (which are faster, have a higher sensitivity/ specificity, test for a high number of viruses/bacteria) If yes, what is the content of this discussion?	
If yes, who are the involved stakeholders? If possible, please provide some references, e.g. from media, websites (in national language is fine)	
Anything to add	
Any literature / documents/ evaluation studies that we should consult?	
Feel free to add any further comments reg. HTA, reimbursement or pricing for fast diagnostic tests for RTI or CA-ARTI.	

THANK YOU VERY MUCH FOR YOUR SUPPORT!

Survey for COUNTRY

5

9.3. Organisation of health care systems



NHS = National Health Service, SHI = Social Health Insurance
NHS: Canada, Kazakhstan, South Africa; SHI: Israel, Republic of Korea; mixed NHS/SHI: Kyrgyzstan
Countries were classified according to the predominant features of health care system organisation and funding

Reference: Vogler S, Zimmermann S, Haasis MA. PPRI Report 2018 - Pharmaceutical pricing and reimbursement policies in 47 PPRI network member countries. Vienna: WHO Collaborating Centre for Pricing and Reimbursement Policies, Gesundheit Österreich GmbH (GÖG / Austrian National Public Health Institute); 2019.

9.4. Detailed information of selected results

Table 14: Detailed country overview of HTA process for MD and criteria (2020)

COUNTRY	HTA PROCESS FOR MD	DIMENSIONS AND CRITERIA USED
Austria	HTA process differs between the several institutions and committees that conduct evaluations of MD and provide recommendations	• Dimensions: e.g. effectiveness and safety, in some cases budget-impact and/or cost-effectiveness (other dimensions, like social, legal or ethical domains plays a minor role) • Criteria: e.g. (strength of) evidence
Belgium	Belgian Health Care Knowledge Centre / Federaal Kenniscentrum (KCE) analyses technologies. Assessments are mostly conducted for "innovative" and high-priced products, for which industry negotiates prices with the public authorities	• Dimensions: mainly efficacy and safety, often in combination with an economic analysis (e.g. cost-effectiveness). Other dimensions, like social, legal or ethical domains play a minor role. • Criteria: (strength of) evidence
Croatia	HTA process differs between the three institutions that conduct HTA: • Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ) / Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi • Croatian Health Insurance Fund (CHIF) / Hrvatskog zavoda za zdravstveno osiguranj • Croatian Institute of Public Health (CIPH) / Hrvatski zavod za javno zdravstvo	• Dimensions: e.g. effectiveness and safety, additional economic evaluation • Criteria: e.g. quality of evidence
Estonia	The topics for HTA reports are chosen by the Ministry of Social Affairs and the Eesti Haigekassa/Estonian Health Insurance Fund (EHIF). There are full assessments (mostly conducted for "innovative" and high-priced products, done by Centre for HTA) and there are small-scale rapid HTA for each new intervention before these become eligible for reimbursement (done by EHIF)	• Dimensions: effectiveness and safety, economic analysis is an integral part of each evaluation done by EHIF (applies for the list of medical devices and the list of health services). There is no official willingness-to-pay threshold, often cost minimization analysis (other dimensions, like social, legal or ethical domains play a minor role) • Criteria: e.g. (strength of) evidence
Finland	No HTA for MD	not appl.
France	The National Commission for the Evaluation of Medical Devices and Technologies / Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS) and Commission d'Évaluation Économique et de Santé Publique (CEESP) of High Authority for Health / Haute Autorité de Santé (HAS) perform a medical-technical assessment and economic evaluation and give a consultancy advice on the added value of an MD and whether, or not, it should be reimbursed.	• Dimensions: Key indicators are the expected value (Service attendu/SA) or, if sufficient, the improvement in the expected value (Amélioration du service attendu (ASA) in the case of the first application for inclusion in reimbursement; for renewals it is the rendered value (Service rendu/SR) and the improvement in the rendered value (Amélioration du service rendu/ASR). The SA / SR is the relevant indicator for the decision whether, or not, a MD will be reimbursed. It is based on the following dimensions: therapeutic / diagnostic effects, adverse effects and its placement in the area of public health.

COUNTRY	HTA PROCESS FOR MD	DIMENSIONS AND CRITERIA USED
		• Criteria: The ASA / ASR impacts the price of an MD that will be negotiated between the supplier and the Pricing Committee CEPS. There are five different ASA /ASR rates: major (I), important (II), modest (III), minor (IV) and absence of value (V).
Germany	Assessments by G-BA (Federal Joint Committee / Gemeinsamer Bundesausschuss) were introduced for invasive and high-risk devices and are based on systematic literature searches; these HTAs can also be conducted by IQWiG (German Institute for Quality and Efficiency in Health Care / Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)	• Dimensions: main assessment dimensions are effectiveness, medical need (no economic evaluations) • Criteria: possible outcomes are the acceptance of method (clinical benefit sufficiently demonstrated), coverage with evidence development demonstrated (clinical benefit not yet sufficiently, clinical trial support), rejection of method (no reason to assume potential for clinical benefit or even harmful for patients)
Greece	No HTA for MD	not appl.
Hungary	National Institute of Pharmacy and Nutrition/ Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI) evaluates the therapeutic role in healthcare delivery (for new services considered for reimbursement), conducts assessments if an MD meets an unmet medical need, and OGYÉI considers the added value compared to current alternatives. There is also an evaluation whether the MD justifies the proposed price, and the budgetary impacts	• Dimensions: clinical efficacy and safety, valid real-life effectiveness data, accompanied by analyses of cost-effectiveness and budgetary impact • Criteria: (strength of) evidence
Italy	There is no national HTA institution in charge of assessing MD but HTA reports are performed at national, regional and local levels.	There is no systematic structured process on national level for HTA. The taskforce (Cabina di Regia) brought together all relevant actors (Ministry of Health, Agencies such as AGENAS / National Agency for Regional Health Services and AIFA) and works on a national program for HTA, including the development of methodological frameworks.
Malta	No HTA for MD	not appl.
Romania	No HTA for MD	not appl.
Slovakia	No HTA for MD	not appl.
Spain	There is no national HTA institution in charge of assessing MD. HTA is rather done by regional HTA institutions, however coordinated by the Ministry of Health for some MD.	There is no systematic structured process on national level for HTA as a prerequisite to include MD in the system since funding is mainly done at regional level.

COUNTRY	HTA PROCESS FOR MD	DIMENSIONS AND CRITERIA USED
Sweden	Dental and Pharmaceutical Benefits Agency / Tandvårds- och läkemedelsförmånsverket (TLV) performs national HTA of MD. However, HTA is commonly done ad-hoc by regions or municipalities, possibly with the support of TLV	There is no systematic structured process on national level for HTA as a prerequisite to include MD in the system.
United Kingdom	Different agencies hold responsibilities across UK with different policies/processes. HTA Medicines and Healthcare Products Regulatory Agency (MHRA) is in charge of assessing MD on regulatory level. Clinical evidence and best practice is used to support all policy decision making. The Role of MHRA after Brexit will change.	There is no systematic structured process on national level for HTA For MHRA: • Dimensions: clinical, safety, effectiveness, and value for money standards • Criteria: Consideration or the range of risks and beneficial outcomes that might occur throughout the population to reduce and avoid healthcare inequalities arising from policy decisions, approvals, incentives, and recommendations.

Abbreviations: HTA = health technology assessment; MD = medical device; not appl. = not applicable

Reference: GÖG survey with competent authorities for medical devices

Table 15: Detailed country overview of reimbursement process for MD in comparison to Dx for RTI or CA-ARTI (2020)

COUNTRY	REIMBURSEMENT DECISION IN GENERAL FOR MD	DIFFERENCE MD VS. DX (FOR RTI/CA-ARTI)
Austria	• If a new medical device meets the criteria of an existing MD in the reimbursement list, it can be reimbursed as such. • For new medical devices, the supplier can request for reimbursement. The evaluation committees give recommendations to SHI funds, which are in charge of the reimbursement decisions.	No differences
Belgium	• If a new medical device meets the criteria of an existing MD in the reimbursement list, it can be reimbursed as such. • Different expert committees (and commissions) within the NIHDI (National Institute of health and disability insurance) provide recommendations to the Minister for social affairs on reimbursement (and co-payments) based on scientific (economic as well as qualitative) evaluation reports • In some cases, a file to ask for inclusion in the reimbursement list is a prerequisite (in case that additional information, e.g. scientific publications are needed).	No differences
Croatia	• Official criteria for a MD to get reimbursed are determined by the „Ordinance on the criteria for placing medical devices on the basic and additional list of medical devices of the Croatian Health Insurance Fund (CHIF) and the criteria for determining the prices of medical devices: (MD of same kind = 95% of current price; new generation MD = 100 % of current price; new MD = economic analysis needed) • Committee for general medical devices provides recommendations to CHIF Management Board, which is in charge of reimbursement decisions.	No differences Note: it is unclear whether Dx are reimbursed)
Estonia	• Reimbursement decisions are based on clinical and economic evaluations (criteria: existence of medically justified indications for the use of the MD/service by the general public and existence of alternative medical devices/services or treatment methods; the optimal quantity of MD needed for treatment; amount of resources needed to offer the service, correspondence to the funds of health insurance, cost effectiveness of the medical device/service; conformity of the medical device with the Medical Devices Act) • For any new service proposed, at least a rapid HTA is necessary to make sure the proposed service meets the criteria for reimbursement.	None (for diagnostic tests that are on the EHIF list) Note: The specific sections of the EHIF list are updated in cooperation with medical associations, who also propose the structure of the service list, including which specific services are introduced with individual fees. For instance, updating the section that includes diagnostic tests that is currently underway is done in cooperation with the Estonian Society for Laboratory Medicine, who provide a recommendation for which services should be included in the list.

COUNTRY	REIMBURSEMENT DECISION IN GENERAL FOR MD	DIFFERENCE MD VS. DX (FOR RTI/CA-ARTI)
Finland	No information available	No information available
France	• If a medical device meets the criteria of an existing MD in the reimbursement list, it can be reimbursed as such. • For others, a value assessment (HTA, with sufficient added benefit needed) is performed by HAS, and an SA/SR and an ASA I to V assessment is granted (see section 5.2)	No differences Note: Diagnostic tests are reimbursed at 60% (e.g. hepatitis C and HIV test are reimbursed at 100%)
Germany	• New diagnostic and therapeutic procedures can only be reimbursed by SHI funds if they are considered "necessary, appropriate, and economic" by the G-BA. • New technologies to be used in the outpatient setting also need to be listed in the "Einheitlicher Bewertungsmaßstab" (EBM).	No quantity limits for Dx for practitioners
Greece	n/a Note: The standard reimbursement decision process of medical devices is to set by law.	n/a Note: Dx are not explicitly reimbursed
Hungary	Reimbursement decisions are based on efficacy, safety, ratio between cost and therapeutic value, budgetary impact analysis, health economist analysis, health technology analysis (if necessary)	No differences Note: Dx are not explicitly reimbursed
Italy	n/a Note: There is no explicit decision on inclusion of MD into reimbursement (MD are funded if they are purchased by the SSN and regions (SSR / servizi sanitari regionali)	n/a Note: Dx are not explicitly reimbursed
Malta	n/a Note: There is no explicit decision on inclusion of MD into reimbursement. A Cost-Benefit Analysis is carried out for high cost medical devices	n/a Note: Dx are not explicitly reimbursed
Romania	The National Social Insurance House establishes a standard fee for service taking into consideration different factors (e.g. the prices of MD in the market). The provisions that a MD has to fulfil are laid down in the framework-agreement with National Social Insurance House that every provider has to sign.	No differences
Slovakia	Before inclusion into reimbursement of medical devices, the following shall be taken into account: • Efficacy (from clinical trials) • Amount of reimbursement for similar MD • Comparing MD with other available treatment options (e.g. indications, therapeutic benefit, work ability recovery, cost-effectiveness)	No differences
Spain	n/a Note: There is no explicit decision on inclusion of MD into reimbursement	n/a Note: Dx are not explicitly reimbursed
Sweden	By law, the cost-benefit must be reasonable	There are no national decision procedures regarding the reimbursement of Dx.

COUNTRY	REIMBURSEMENT DECISION IN GENERAL FOR MD	DIFFERENCE MD VS. DX (FOR RTI/CA-ARTI)
		Note: Decisions are taken by the Swedish regions and their facilities individually and reimbursement can vary across the country.
United Kingdom	No dedicated reimbursement decision for certain MD Note: Providers and Commissioners of care are able to decide what meets the needs of their local population, supported by national policy and guidance. They commission services appropriate to the needs of their population.	No differences

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