

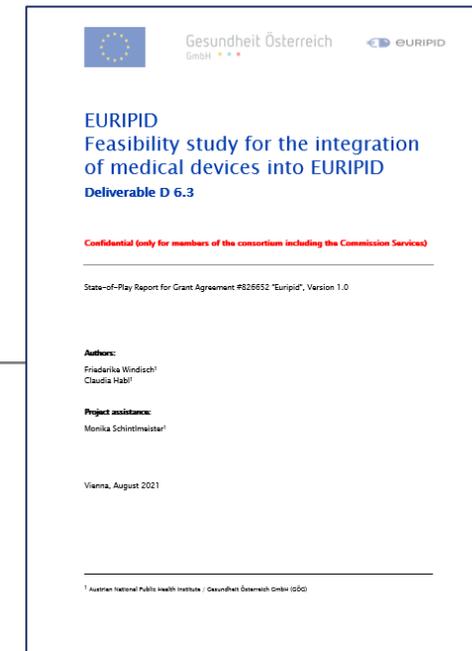


Feasibility study on the potential integration of Medical Devices

Presentation of results

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9th BoP Meeting on 21st September 2021



Agenda

1. Background

2. Results of the survey on the integration of prices of Medical Devices (MD) in EURIPID

3. Pricing models on MD

4. Conclusions & recommendations



1. Background

Starting point, aim & preliminary work

Starting point & aim

Starting Point

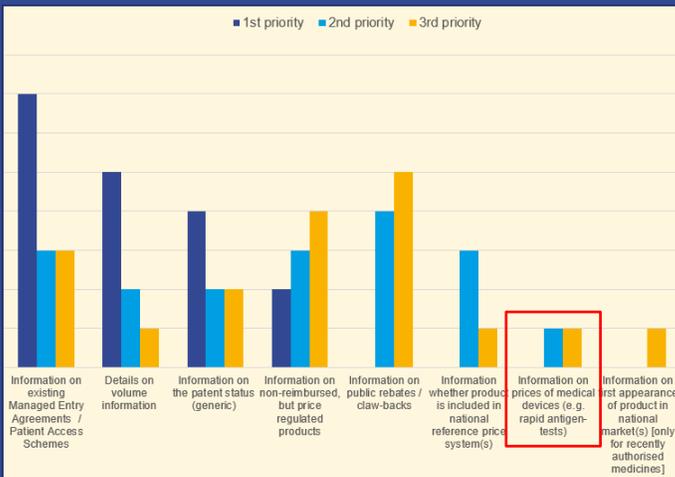
The EURIPID Collaboration has also **considered including medical devices into the database** and, as part of the current grant agreement #826652 Euripid which is co-funded by the European Union's Health Programme (2014-2020), agreed to make a **feasibility study for the integration of medical devices into EURIPID** (Deliverable D6.3).

Aim

The **aim of this task** is to give a brief description of selected national pricing models for MD and to outline potential next steps for an integration into the website.

For this purpose, all **information on MD** already collected via EURIPID was **summarized and analyzed** and a **survey on the integration of prices of MD in EURIPID** among the EURIPID collaborating partners was conducted.

Preliminary work on MD



2018: Call for sharing prices of MD

- First preliminary call for sharing the prices of MD by the Czech partner SUKL within the EURIPID collaboration partners.
- Only Hungary, Poland, Sweden and the Czech Republic provided information on lists and some price information.

2020: Matching list of medical devices

- In May 2020, a list of MD for further analysis has been drawn up.
- Although the task was to compare the prices from five countries, the differences and scarcities in the available databases forced the inclusion of nine countries in the project to find at least ten matching products. This work has shown how difficult it is to find a common denominator between countries regarding MD.

2021: Lime-survey on data extension

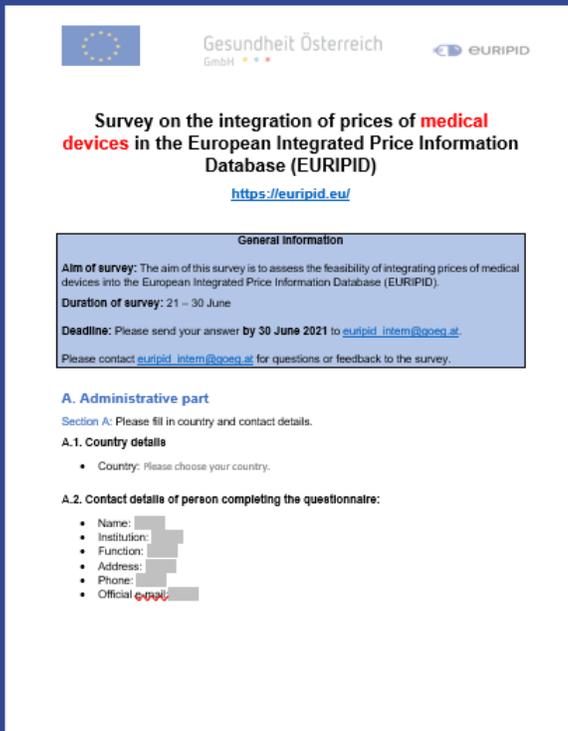
- Lime-survey among the 26 EURIPID Collaboration partners by the EURIPID Secretariat between December 2020 and February 2021.
- Results on prioritization: Information on prices of MD is second or third priority. No country has ranked it as first priority.
- Results on ability to deliver data: In most countries this topic has to be discussed and/or prices of MD are not deliverable.



2. Survey on the integration of prices of MD

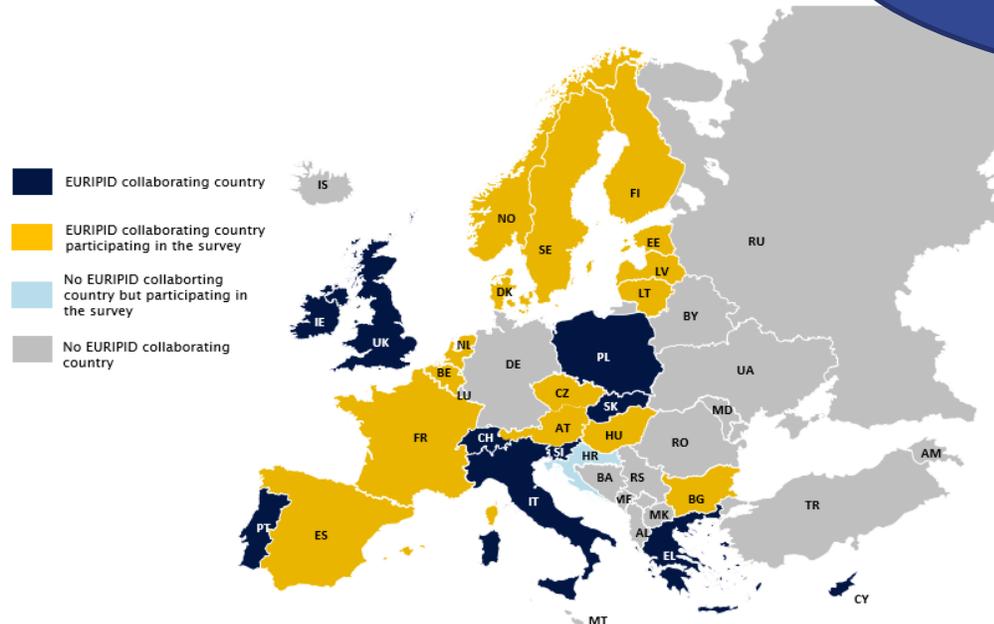
Methodology & Results

Methodology



- **Survey:** prepared by GÖG
 - A: Administrative part
 - B: Reimbursement lists on medical devices
 - C: Price lists on medical devices for procurement
 - D: Price specifications in price lists
- **Aim:** to assess the feasibility of integrating prices of MD into EURIPID
- **Target group:** 26 EURIPID collaboration partners and Croatia
- **Time frame:** E-mail on 21 June 2021, friendly reminder on 1 July 2021
- **Responding countries:** 17 out of 27 (AT, BE¹, BG, HR², CZ, DK, EE, FI, FR, HU, IL, LV, LT, NL, NO, ES, SE)
 - 1 BE: two responses from two different organizations
 - 2 HR: not a collaboration partner but also completed the questionnaire

Thank you for participation!

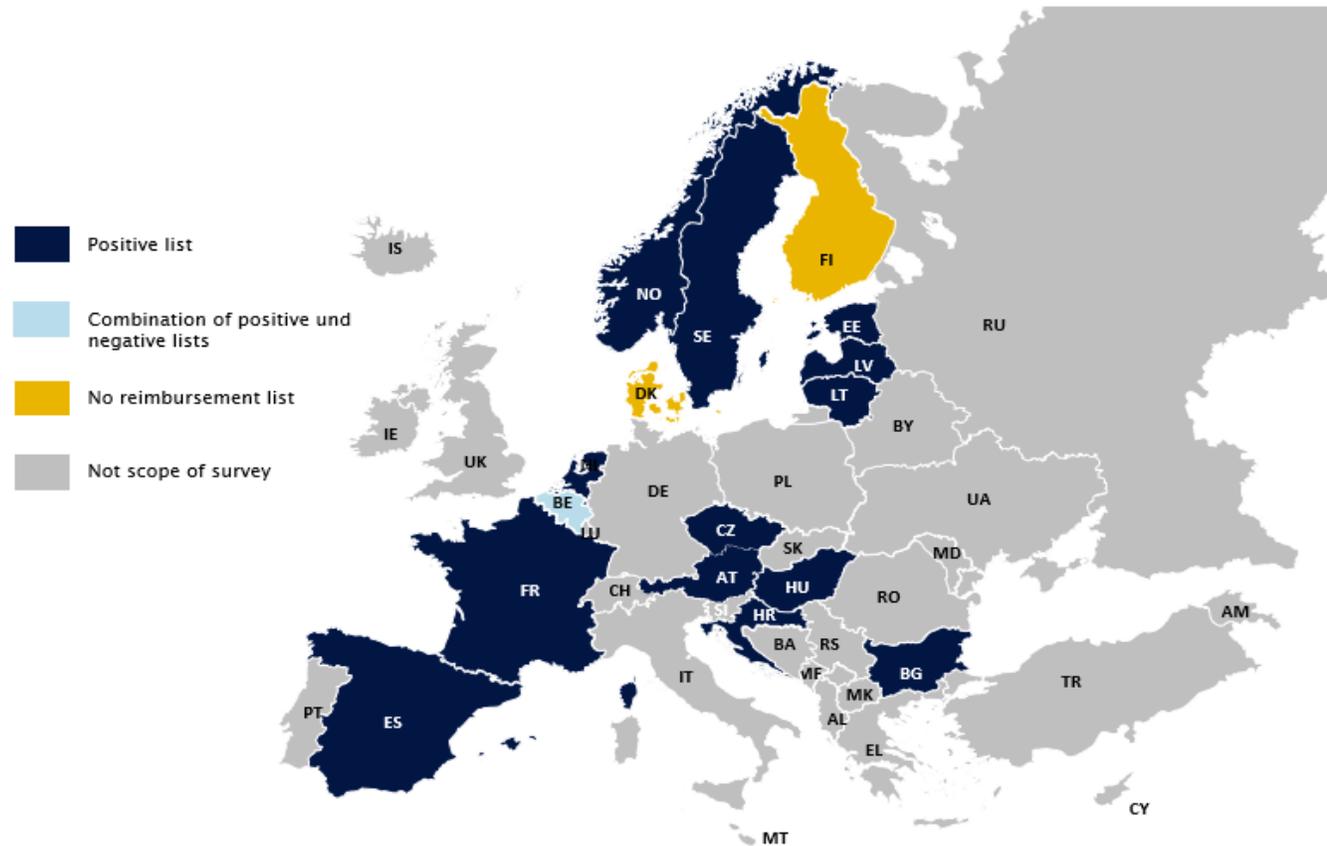


Not on map: Israel – EURIPID collaborating country participating in the survey

Results

Availability of reimbursement lists of MD

- **Positive list:** AT, BG, HR, CZ, EE, FR, HU, IL, LV, LT, NL, NO, ES, SE
- **Combination of positive and negative lists:** BE
- **No reimbursement list:** DK, FI



Not on map: Israel - Positive list

Results

Access to reimbursement lists of MD

- No reimbursement list: DK, FI
- Reimbursement list publicly available: AT, BE, BG, HR, CZ, EE, FR, HU, IL, LT, LV, NL, NO, ES, SE
- Responsible authorities for maintaining the reimbursement lists: mainly Social insurances, National Health Services (NHS) and Ministries of Health
- Update interval: in most countries on a regular basis (mostly annually or monthly)

Link to publicly available list(s) can be found in the report.



Country	Reimbursement list publicly available	Responsible authorities for maintaining	Link to publicly available list(s)	Update interval
Austria	Yes ¹	Social insurance	https://www.gesundheitskasse.at/cdscontent/?contentid=10007.837669&portal=oeqkwportal https://www.bvaeb.at/cdscontent/?contentid=10007.840383&portal=bvaebportal https://www.svs.at/cdscontent/?contentid=10007.816812&portal=svsportal	Regularly; annually
Belgium	Yes	Social insurance	https://ondpanon.riziv.fgov.be/IRREQPublic/fr https://www.riziv.fgov.be/nl/professionals/individual-eleazorverleners/orthopedisten/Paginas/liisten-producten-orthopedie.aspx https://www.riziv.fgov.be/nl/professionals/individual-eleazorverleners/audiiciens/Paginas/liisten-van-hoortoestellen.aspx https://www.riziv.fgov.be/nl/professionals/individual-eleazorverleners/bandaqisten/Paginas/liisten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx	Regularly; monthly, bimonthly, quarterly Irregularly; for new products
Bulgaria	Yes	Social insurance NHS Federal Agency of Medications and Health Products	https://www.nhif.bg/page/1491	Regularly; annually
Croatia	Yes	NHS	https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi	Irregularly

Results

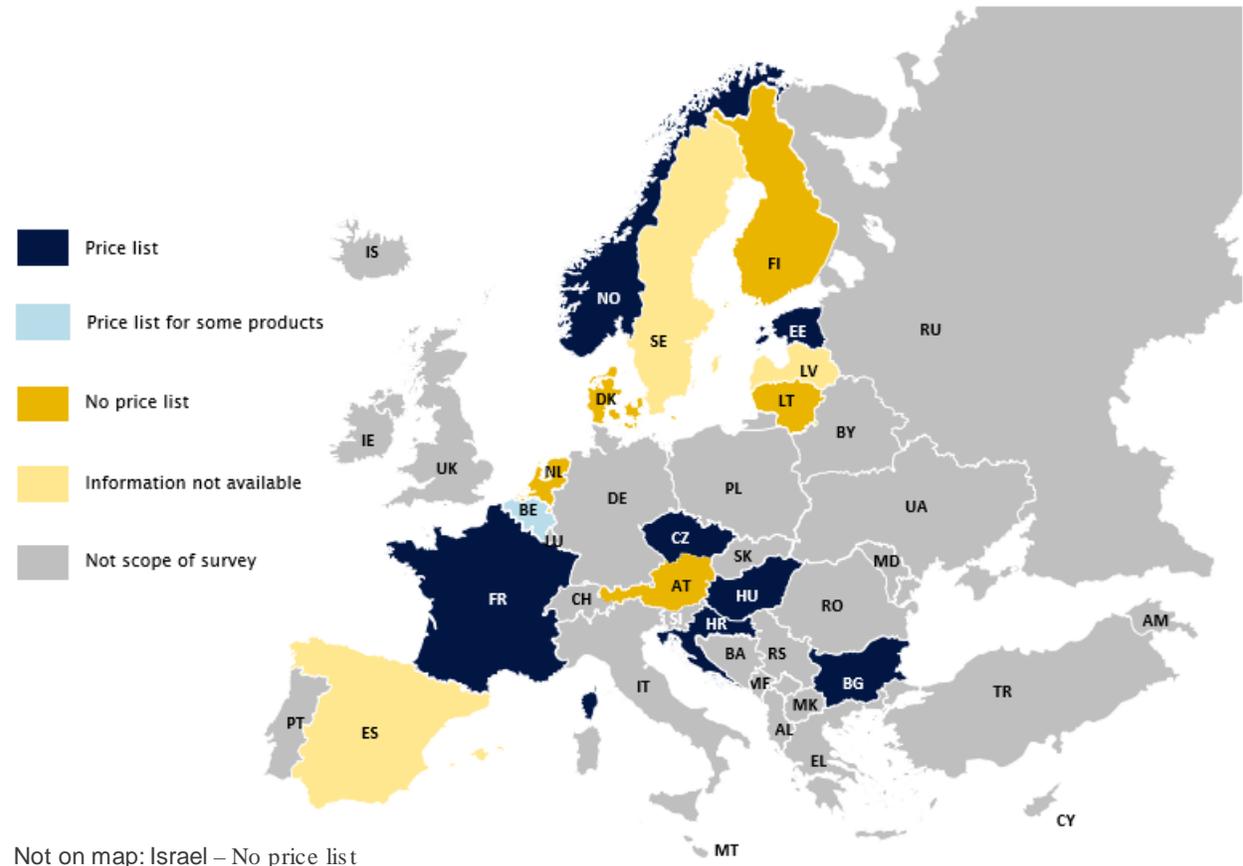
Availability of price lists of MD

- Price lists available: BG, HR, CZ¹, EE, FR, HU, NO
- Price lists for some products: BE
- No price list: AT, DK, FI, IL, LT, NL
- Information not available: LV, ES², SE³

1 for around 90% of products

2 procurement is normally carried out at hospital or regional level

3 probably each of the 21 Swedish regional councils have price lists available for the medical devices that they procure



Results

Access to price lists of MD

- Price list publicly available: HR, CZ, EE, HU, NO
- Price list not publicly available: BG
- Publicly and not publicly available lists: BE, FR
- No official price list: AT, DK, FI, IL, LT, NL
- No information available: LV, ES¹, SE²

1 Procurement is normally carried out at hospital or regional level.

2 Probably each of the 21 Swedish regional councils (responsible for the healthcare) have price lists available for the medical devices that they procure and most of the prices are public upon request (due to the Swedish Public Access to Information and Secrecy Act).

Link to publicly available list(s) can be found in the report.



Country	Price list publicly available	Responsible authorities for maintaining	Link to publicly available list(s)	Update interval
Austria	No price list	n. a.	n. a.	n. a.
Belgium	Yes ¹	National Public Health Institute	https://www.vas.ehealth.fgov.be/regions/sadm/web/search/public	Irregularly; depending of the introduced request
		Social insurance Ministry of Economics	https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Pagina/Lijst-producten-orthopedie.aspx https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiiciens/Pagina/Lijst-van-hoortoestellen.aspx https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/handdoelsten/Pagina/Lijst-producten-artikel-27-nomenclatuur-geneseskundige-verstrekingen.aspx	Regularly; yearly with indexation
Bulgaria	No	Bulgarian Drug Agency	n. a.	n. a.
Croatia	Yes	Social insurance	https://hzzo.hr/zdravstvena-zastita/medicinski-projodi	Irregularly
Czech Republic	Yes	State Institute for Drug Control	https://www.suki.cz/suki/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz	Irregularly
Denmark	No price list	n. a.	n. a.	n. a.
Estonia	Yes	Social insurance NHS	https://www.riiqiteataia.ee/akt/116121020016 https://www.riiqiteataia.ee/akt/1155125012002_0004/SOM_23092020_m44lisa.pdf# https://www.riiqiteataia.ee/akt/126062021006	Regularly; yearly
Finland	No price list	n. a.	n. a.	n. a.
France	Yes ¹	Moh Social insurance	http://www.codage.ext.cnamts.fr/codif/bdm-it/index_presentation.php?c_sie=AMEU	Regularly
Hungary	Yes	Health insurance	https://http://neak.gov.hu/felso_menu/szakmai_oldalak/gyogyyszer_szeszeskoz_ayogy_furdo_tamogatasi_egeszseguvyl_vallalkozasoknak_pu_phaa/Vegleoes_PUPHAG.html	Regularly; monthly
Israel	No price list	n. a.	n. a.	n. a.
Latvia	No information available	n. a.	n. a.	n. a.
Lithuania	No price list	n. a.	n. a.	n. a.

Results

Price specifications in price lists and VAT rate

- No country has all price levels available.
- The VAT rate varies between 27% and 5%.

Country	Manufacturer price	Wholesale price	Net retail price	Gross retail price	VAT rate on medical devices in %
Austria	n. a.	n. a.	n. a.	n. a.	20
Belgium ¹	No	Yes	Yes ²	Yes ²	6 or 21 ³
Bulgaria	n. a.	n. a.	n. a.	n. a.	20
Croatia	No	No	Yes	Yes	5
Czech Republic	Yes	Yes	No	Yes ⁴	15 or 21
Denmark	n. a.	n. a.	n. a.	n. a.	n. a.
Estonia	No	No	No	Yes	9, 20 ⁵
Finland	n. a.	n. a.	n. a.	n. a.	n. a.
France	Yes	No	No	Yes	2.1, 5.5, 10 or 20
Hungary	No	No	Yes	Yes	5 or 27
Israel	n. a.	n. a.	n. a.	n. a.	n. a.
Latvia	No	Yes	No	Yes	12
Lithuania	No	No	No	No	5
Netherlands ⁶	n. a.	n. a.	n. a.	n. a.	between 9 and 21
Norway	No	Yes	Yes	No	25
Spain	No	No	No	Yes	10 or 21 ⁶
Sweden	No ⁸	Yes ⁹	Yes ⁹	No ¹⁰	25

MoH = Ministry of Health, MD = Medical Device(s), n. a. = not applicable

1 Belgium: Implants and invasive MD are mainly purchased by the pharmacy. There is no extra charge by the pharmacist on the price of implants and invasive MD.

2 Belgium: Depending on price list.

3 Belgium: Generally, 6% for implants and 21% for invasive MD but there are some exceptions.

4 Czech Republic: Maximum trade margin according to the price regulation of the Ministry of Health.

5 Estonia: Usually the VAT for medical devices is 9%, but there are some exceptions where 20% is applied

6 Netherlands: Health insurers and/or healthcare providers are responsible for purchasing the medical devices that are provided by the basic health insurance package. Therefore, the MoH has no insight in the purchasing prices.

6 Spain: 21% for inhalers, inhalation chambers and vaginal showers

8 Sweden: Not for reimbursed MD to outpatients and most likely not for MD procured by hospitals.

9 Sweden: For reimbursed MD to outpatients. No information regarding MD procured by hospitals

10 Sweden: Not for reimbursed MD to outpatients (the pharmacy adds 25% VAT). No information regarding MD procured by hospitals.



3. Pricing models on MD



Pricing models

- Available countries: Austria, Czech Republic, Hungary, France
- Data collected (for the outpatient and inpatient sector):
 - Competent Authorities
 - Authority responsible for setting the price of a MD
 - Authority responsible for reimbursement / coverage decision
 - Price build up and procurement policies
 - Free pricing
 - Price regulated by law
 - Bilateral price control policies (public procurement, price negotiations etc.)
 - Price referencing
 - Coverage and funding policies
 - Process and criteria of coverage / funding

Indicator		Outpatient sector	Inpatient sector
 Competent Authorities	Authority responsible for setting the price of a MD	Comité Économique des Produits de Santé (CEPS) / Healthcare products pricing committee	Comité Économique des Produits de Santé (CEPS) / Healthcare products pricing committee
	Authority responsible for reimbursement / coverage decision	Ministère des Solidarités et de la Santé / French Ministry of Health	Ministère des Solidarités et de la Santé / French Ministry of Health
 Price build up and procurement Policies	Free pricing (manufacturer or importer sets price)	No	Yes; Medical devices are aimed to be included into DRGs and free pricing applies in this case.
	Price regulated by law (authority sets price per unit of a lot)	No	No
	Bilateral price control policies (public procurement, price negotiations etc.)	Yes Price negotiations: In general, there are negotiations between CEPS and manufacturers (price level: ex-factory price and/or retail level). Retail margins are also negotiated.	Yes Price negotiations: If certain criteria are met, MDs won't be included into DRGs and national price will be negotiated with CEPS (ex-factory price and retail level) based on French HTA and other criteria (see outpatient pricing). Retail margins are also negotiated. The price negotiated with CEPS is the maximum national price. Other negotiations can be done after, directly between the economic operator and hospitals.
 Coverage and Funding Policies	Price referencing	Yes Price setting: - for MDs that can be integrated into a generic reimbursement line - for MDs that cannot be integrated into a generic reimbursement line: price depends on: comparators' price, added clinical value (ACV) from French HTA, expected or reported sales volumes, Health Economic Models (if assessed by CEPS), International benchmarking (EU4)	Yes Price setting: - for MDs that can be integrated into a generic reimbursement line - for MDs that cannot be integrated into a generic reimbursement line: price depends on: comparators' price, added clinical value (ACV) from French HTA, expected or reported sales volumes, Health Economic Models (if assessed by CEPS), International benchmarking (EU4), hospital prices.
	Process and criteria of coverage / funding	Ministry of Health makes reimbursement decision. Reimbursement can be automatic (after CE mark) when a MD can be integrated into a generic reimbursement line (same characteristics as other devices already reimbursed). For others, a sufficient Added Benefit (AB) is needed from the HAS assessment to appear on the reimbursed list. The AB is mainly driven by the clinical value of the MD and improvement on death rate, quality and quality of life. Reimbursement is granted for 5 years with a periodic reassessment.	Medical devices are included in the lump sums which can be generated for reimbursement by DRGs in hospitals. The Ministry of Health makes the reimbursement decision. Reimbursement can be automatic (after CE mark) when a MD can be added into a generic reimbursement line (same characteristics as other devices already reimbursed) or into DRGs. For others, a sufficient Added Benefit (AB) is needed from the HAS assessment to appear on the reimbursed list. Reimbursement is granted for 5 years with a periodic reassessment.

Detailed information can be found in the report.





4. Conclusions & Recommendations

Conclusions

- **Low interest** to add MD prices to the EURIPID database
- **Difficult comparability:** different product names and nomenclatures used in the EU member states
- **Good availability** of reimbursement prices
- **Little common denominator** on price levels

Recommendations

- **Postponement of the integration of MD prices into EURIPID to a later date**
- EUDAMED (European Medical Devices Database) is expected to be fully operational by the end of 2022
 - Unique Device Identifier (UDI) included
 - European Medical Device Nomenclature (EMDN) included
- Afterwards a new attempt for the integration of MD could be started (based on the current learnings and work) with a concrete pilot and selected products.
 - earliest starting point: summer 2023



THANK YOU
FOR YOUR
ATTENTION!

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