



# EURIPID

## Feasibility study for the integration of medical devices into EURIPID

Deliverable D 6.3

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State-of-Play Report for Grant Agreement #826652 "Euripid", Version 3.0



# EURIPID

## Feasibility study for the integration of medical devices into EURIPID

Deliverable D 6.3

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This report contributes to the implementation of the 2030 Agenda, in particular to Sustainable Development Goal (SDG) 3 "Good Health and Well-being" as well as to sub-goal 3.8 "Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all".

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## List of abbreviations

AB	Added Benefit (AB)
ACV	Added Clinical Value
CEPS	Comité Economique des Produits de Santé / Healthcare products pricing committee (France)
BoP	Euripid Board of Participants
DRG	Diagnosis-related groups
EUDAMED	European Database on Medical Devices
EURIPID	The European Integrated Price Information Database
GÖG	Gesundheit Österreich GmbH / Austrian National Public Health Institute
HaDEA	European Health and Digital Executive Agency
HTA	Health Technology Assessment
IVD(R)	In-vitro-diagnostic Medical Device(s) Regulation
LKF	Leistungsorientierte Krankenanstaltenfinanzierung / Diagnosis-related groups funding in Austria
MD	Medical Device(s)
MDR	Medical Devices Regulation
NEAK	National Institute of Health Insurance Fund Management (Hungary)
n. a.	Not applicable
PPRI	Pharmaceutical Pricing and Reimbursement Information Network
UDI	Unique Device Identifier
SUKL	Státní ústav pro kontrolu léčiv / State Institute for Drug Control (Czech Republic)

## List of country abbreviations

### Country abbreviations of EURIPID Collaboration partners (2021) plus Croatia

AT	Austria	IE	Ireland
BE	Belgium	IL	Israel
BG	Bulgaria	IT	Italy
CH	Switzerland	LT	Lithuania
CY	Cyprus	LV	Latvia
CZ	Czech Republic	NL	Netherlands
DK	Denmark	NO	Norway
EE	Estonia	PL	Poland
EL	Greece	PT	Portugal
ES	Spain	SE	Sweden
FI	Finland	SI	Slovenia
FR	France	SK	Slovakia
HR	Croatia	UK	United Kingdom
HU	Hungary		

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Austria	Gesundheit Österreich GmbH / Austrian National Public Health Institute
Belgium	Rijksinstituut voor ziekte- en invaliditeitsverzekering / Institut National d'Assurance Maladie-Invalidité / National Institute for Health and Disability Insurance
Bulgaria	Национален съвет по цени и реимбурсиране на лекарствените продукти / National Council on Prices and Reimbursement of Medicinal Products
Croatia	Hrvatski zavod za zdravstveno osiguranje / Croatian Health Insurance Fund
Czech Republic	Státní ústav pro kontrolu léčiv / State Institute for Drug Control
Denmark	Sundhedsdatastyrelsen / The Danish Health Data Authority
Estonia	Eesti Haigekassa / Estonian Health Insurance Fund
Finland	Läkemedelsprisnämnden / Pharmaceuticals Pricing Board
France	Caisse nationale de l'assurance maladie / National Health Insurance Fund
Hungary	Nemzeti Egészségbiztosítási Alapkezelő / National Institute of Health Insurance Fund Management
Israel	Ministry of Health
Latvia	Nacionālais veselības dienests / National Health Service
Lithuania	Valstybinė ligonių kasa / National Health Insurance Fund
Netherlands	Ministerie van Volksgezondheid, Welzijn en Sport / Ministry of Health, Welfare and Sport Zorginstituut Nederland / National Health Care Institute
Norway	Folkehelseinstituttet / Norwegian Institute of Health
Spain	Ministerio de Sanidad, Consumo y Bienestar Social / Ministry of Health, Consumers and Social Welfare
Sweden	Tandvårds- och läkemedelsförmånsverket / Dental and Pharmaceutical Benefits Agency



# 1 Introduction

## 1.1 Background and aim

The European Integrated Price Information Database (EURIPID) has been established as voluntary non-profit collaboration of national pricing and reimbursement authorities in European countries. Since its start in 2010, the core intention of the EURIPID Collaboration is to contribute to safeguarding access to affordable medicinal products for all patients and improve transparency in the field of pricing. A total of 26 countries are already members of EURIPID and in regular exchange on pharmaceutical prices (Euripid 2021).

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 conduct **a feasibility study for the integration of medical devices into EURIPID** (Deliverable D 6.3, internal Deliverable 15).

The **aim of this task** is to give a brief description of selected national pricing policy frameworks for medical devices and to outline potential next steps for an integration into the website (content, procedural, structural, topical, technical). First, existing information on medical devices already collected via this project was summarized and analysed. Secondly, a central component of this study was to conduct a survey of the price and reimbursement lists in the countries to be able to assess a possible integration of prices of medical devices into EURIPID.

Medical devices and in vitro diagnostics have been legally reorganized at European level. On 25 May 2017, **two new EU medical devices regulations** on medical devices (MDR 2017/745) and on in vitro diagnostic medical devices (IVDR 2017/746) came into force, with a transitional period of four years for medical devices and five years for in vitro diagnostic medical devices. The MDR has already become fully effective on 26 May 2021. (Regulation (EU) 2017/745 2017; Regulation (EU) 2017/746 2017). A key aspect of these two regulations is the establishment of a **new European database on medical devices (EUDAMED)**, which provides for a uniform nomenclature and identification of medical devices. (EUDAMED 2021) In general, medical devices have become more visible and important because of the Corona crisis.

The latest report from MedTech Europe<sup>1</sup> states that medical technology spending in European countries vary significantly from 5% to 12% of total healthcare spending. Per capita spending on medical technology in Europe is at around €265 (weighted average). On average, **7.6% of total healthcare expenditure is spent on medical technology: 6.9% on medical devices (incl. imaging) and 0.8% on in vitro diagnostics.** (MedTech Europe 2021)

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<sup>1</sup> MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure.

## 1.2 Previous work on medical devices within EURIPID

This study builds on earlier activities done within the framework of the project EURIPID. A call for sharing of prices of medical devices (MD) was done at the end of 2018. In June 2020, a general list of medical devices was approved to be considered for further analysis (Deliverable D 4.1). Furthermore, the GÖG team conducted a lime survey among the EURIPID collaboration partners to explore their interest in sharing of medical devices price information. The key findings of these activities are described below.

### 1.2.1 Call for sharing prices of medical devices (2018)

A first call for sharing the prices of medical devices by the Czech partner SUKL (Státní ústav pro kontrolu léčiv) to the EURIPID member countries at the end of 2018 did not lead to many responses. Only Austria (partly), Hungary, Poland, Sweden, and the Czech Republic provided requested information including price data.

### 1.2.2 Matching list of medical devices (2020)

In May 2020, a list of medical devices for further analysis has been collated (Deliverable D 4.1) which was approved in June 2020. The aim was to establish an initial comparability of medical devices and their prices. Although the task was to compare the prices from five countries, the differences and gaps in the available databases required the inclusion of nine countries in the project to find at least ten matching products. The comparison revealed that the medical devices selected were rarely included in the surveyed databases, only two matching blood sugar testing stripes could be identified. The most common medical devices across all the databases were covers (dressings) and stoma care products (mostly pouches), followed by infusion sets. Unfortunately, the differences in the national lists led to the inclusion of several products from the same producers. Ten medical devices could not be identified as originally requested in the Grant Agreement. This work showed how difficult it is to find a common denominator between countries regarding medical devices.

In early 2021, the study team asked the Executive Committee of the EURIPID collaboration whether or not the list of devices should be updated or complemented with Covid-19 related products, e.g. disinfectants or Rapid Antigen Tests. After thorough considerations, the Executive Committee decided to stick to the approved list.

### 1.2.3 Lime survey (2021)

Information on the enlargement of the EURIPID database were obtained through a Lime survey addressed to the 26 EURIPID Collaboration partners which the EURIPID Secretariat conducted between 30 December 2020 and 9 February 2021. Besides pharmaceutical topics (e.g. managed entry agreements, volume information, patent status), questions were also asked about medical devices.

Answers were received from 22 countries: Austria (AT), Belgium (BE), Bulgaria (BG), Cyprus (CY), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), Greece (EL), Hungary (HU), Israel (IL), Italy (IT), Lithuania (LT), Latvia (LV), Netherlands (NL), Norway (NO), Poland (PL), Portugal (PT), Slovenia (SI), Spain (ES), Switzerland (CH) and Sweden (SE). Four countries (France (FR), Ireland (IE), Slovakia (SK) and United Kingdom (UK)) did not respond to the survey.

The survey showed that no country ranked it as first priority and some countries as second or third priority to integrate price information of medical devices into EURIPID. It must be noted that many participating EURIPID partners are exclusively national competent authorities for pricing and reimbursement of pharmaceuticals and not in charge of the pricing and/or reimbursement of medical devices.

EURIPID Collaboration partners were also asked about data sharing on price data of medical devices. Poland and Ireland already submit some prices of medical devices to EURIPID, for the Czech Republic and Lithuania submission is possible. In most countries this topic has to be discussed and/or prices of medical devices cannot be supplied.

The Lime survey showed that interest in medical devices is very low.

### 1.3 Methodology

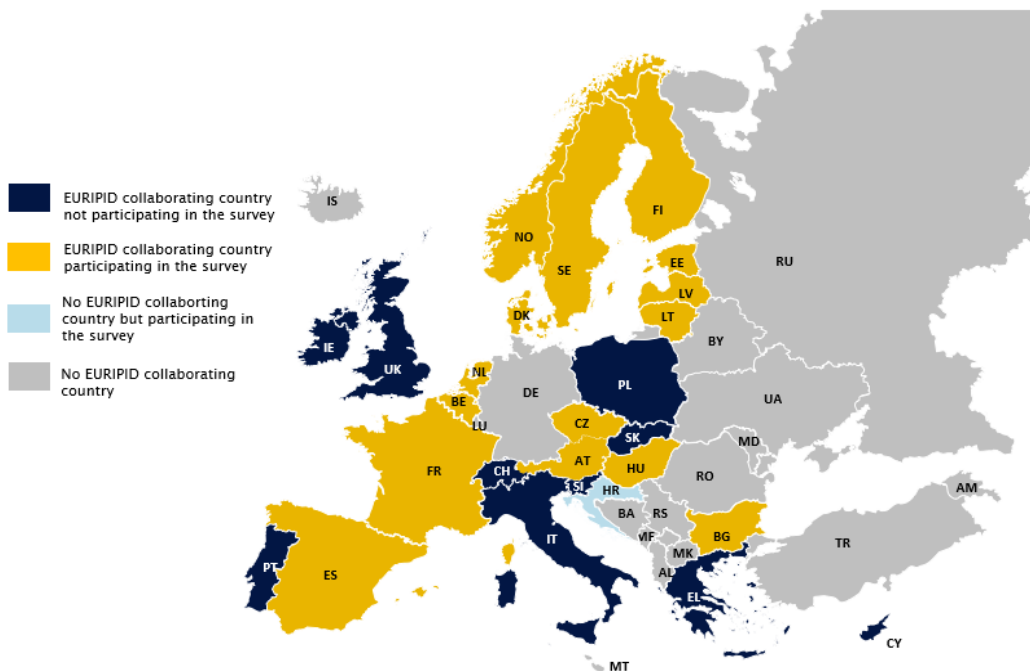
Building on previous work, this report aims to analyse the feasibility of integrating medical devices into the EURIPID database. For this purpose, another survey was conducted (see Annex 7.1 Survey on the integration of prices of MD in EURIPID) with the EURIPID collaborating partners to investigate whether or not reimbursement and price lists for medical devices exist in the countries and for which price types.

The questionnaire was sent to the 26 EURIPID collaboration partners including Croatia on 21 June 2021, followed by a friendly reminder on 1 July 2021.

Answers were received from 17 countries (see Figure 1): Austria (AT), Belgium (BE1 and BE2; two responses from two different organisations), Bulgaria (BG), Croatia (HR; not a collaboration partner but also responded to the questionnaire), Czech Republic (CZ), Denmark (DK), Estonia (EE), Finland (FI), France (FR), Hungary (HU), IL (Israel), LV (Latvia), Lithuania (LT), Netherlands (NL), Norway (NO), Spain (ES) and Sweden (SE).

The comprehensive set of results can be found in the appendix (see Annex 7.2. Survey results).

Figure 1: EURIPID collaborating countries participating in the survey, 2021



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

Source: EURIPID collaborating partners, data compilation by EURIPID Secretariat

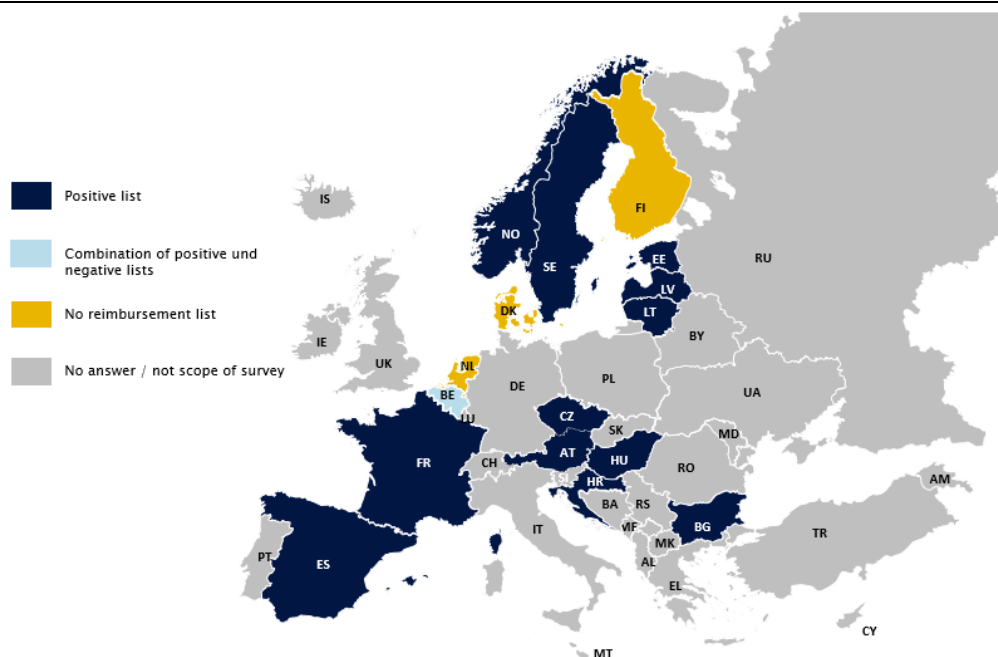
## 2 Reimbursement lists of medical devices

A reimbursement list contains medical devices with specific reimbursement status. Reimbursement is defined as coverage of the cost of reimbursable medical devices by a public payer (such as social health insurance / National Health Service). It may either include medical devices eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list). Reimbursement lists may target either the outpatient sector (usually positive lists or negative lists) or the in-patient sector or both. Part B of the survey (see Annex 7.2.2) collected details on the availability and management of reimbursement lists.

### 2.1 Availability of reimbursement lists

Except for Denmark, Finland and the Netherlands, all participants in the survey have a reimbursement list for medical devices in the form of a positive list (see Figure 2). In Belgium, there is a positive and negative list, with currently no products on the negative list. Israel has not a list of products but a list of medical procedures (treatments). In the Netherlands, reimbursement is regulated in an “open system” where health insurers check and decide whether or not a medical device will be reimbursed. This depends on the functionalities of the product. The National Health Care Institute only intervenes if the health insurers cannot decide or do not agree.

Figure 2: Availability of reimbursement lists, 2021



Not on map: Israel – Positive list

Source: EURIPID collaborating partners, data compilation by EURIPID Secretariat

## 2.2 Accessibility of reimbursement lists

In all participating countries (except for Denmark and Finland which do not have a reimbursement list) reimbursement lists are publicly available (see Table 1). In Austria, some reimbursement tariffs of Health Insurance Funds are published but a complete list is not public. In France, there are publicly and non-publicly accessible lists.

The responsibility for maintaining the reimbursement lists usually lies with Social insurances, National Health Services (NHS) and Ministries of Health are mainly responsible. In most of the participating countries, reimbursement lists are updated on a regular basis (mostly annually or monthly). In Belgium, some lists are adjusted when a distributor introduces a request for a new product. Croatia and Spain update their lists irregularly on an ad-hoc basis.

The lists include reimbursed medical devices of various risk classes (Class I, II a, II b, III), and in some countries also in vitro diagnostic devices (Austria, Bulgaria, Croatia, Czech Republic, Lithuania, Netherlands).

Table 1: Accessibility of reimbursement lists, 2021

Country	Reimbursement list publicly accessible	Responsible authorities for maintaining	Link to publicly available list(s)	Update interval
Austria	Yes <sup>1</sup>	Social insurances	<a href="https://www.gesundheitskasse.at/cdscontent/?contentid=10007.837669&amp;portal=oegkwportal">https://www.gesundheitskasse.at/cdscontent/?contentid=10007.837669&amp;portal=oegkwportal</a> <a href="https://www.bvaeb.at/cdscontent/?contentid=10007.840383&amp;portal=bvaebportal">https://www.bvaeb.at/cdscontent/?contentid=10007.840383&amp;portal=bvaebportal</a> <a href="https://www.svs.at/cdscontent/?contentid=10007.816812&amp;portal=svsportal">https://www.svs.at/cdscontent/?contentid=10007.816812&amp;portal=svsportal</a>	Regularly: annually
Belgium	Yes	Social insurances	<a href="https://ondpanon.riziv.fgov.be/IRREQPublic/fr">https://ondpanon.riziv.fgov.be/IRREQPublic/fr</a> <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Paginas/lijsten-producten-orthopedie.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Paginas/lijsten-producten-orthopedie.aspx</a> <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiciens/Paginas/Lijstenvan-hoortoestellen.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiciens/Paginas/Lijstenvan-hoortoestellen.aspx</a> <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx</a>	Regularly: monthly, bimonthly, quarterly  Irregularly: for new products
Bulgaria	Yes	National Health Insurance Fund	<a href="https://www.nhif.bg/page/1491">https://www.nhif.bg/page/1491</a>	Regularly: annually
Croatia	Yes	NHS	<a href="https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi">https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi</a>	Irregularly
Czech Republic	Yes <sup>2</sup>	Health insurance	<a href="https://www.sukl.cz/sukl/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz">https://www.sukl.cz/sukl/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz</a> <a href="https://www.vzpcz.cz/poskytovatele/ciselniky/zdravotnicke-prostredky">https://www.vzpcz.cz/poskytovatele/ciselniky/zdravotnicke-prostredky</a> <a href="https://www.szpcr.cz/zdravotnicke_prostredky">https://www.szpcr.cz/zdravotnicke_prostredky</a>	Regularly: monthly

Country	Reimbursement list publicly accessible	Responsible authorities for maintaining	Link to publicly available list(s)	Update interval
Denmark	No reimbursement list	n. appl.	n. appl.	n. appl.
Estonia	Yes	Social insurance NHS	<a href="https://www.riigiteataja.ee/akt/116122020016">https://www.riigiteataja.ee/akt/116122020016</a> <a href="https://www.riigiteataja.ee/akt/tilisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#">https://www.riigiteataja.ee/akt-tilisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#</a> <a href="https://www.riigiteataja.ee/akt/126062021006">https://www.riigiteataja.ee/akt/126062021006</a>	Regularly: annually
Finland	No reimbursement list	n. appl.	n. appl.	n. appl.
France	Yes <sup>1</sup>	Social insurance NHS MoH National Public Health Institute	<a href="http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI">http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI</a> <a href="https://base-donnees-publique.medicaments.gouv.fr/telechargement.php">https://base-donnees-publique.medicaments.gouv.fr/telechargement.php</a>	Regularly
Hungary	Yes	Health insurance	<a href="https://neak.gov.hu/felso_menu/szakmai_oldal/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html">https://neak.gov.hu/felso_menu/szakmai_oldal/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html</a>	Regularly: monthly
Israel	Yes	MoH	<a href="https://call.gov.il/infocenter/index?page=mail-page&amp;sendcontent=home&amp;id=null&amp;query=page=home&amp;purpose=share">https://call.gov.il/infocenter/index?page=mail-page&amp;sendcontent=home&amp;id=null&amp;query=page=home&amp;purpose=share</a>	Regularly: annually
Latvia	Yes	NHS	<a href="https://www.vmnvd.gov.lv/lv/kompensejamo-zalusaraksti">https://www.vmnvd.gov.lv/lv/kompensejamo-zalusaraksti</a>	Regularly: monthly
Lithuania	Yes	NHS	<a href="https://ligoniukasa.lrv.lt/lt/veiklos-sritys/gydymo-istaigoms-ir-partneriams/kompensuojamieji-vaistai-ir-medicinos-pagalbos-priemones-2/informacija-apie-kainynu-rengima">https://ligoniukasa.lrv.lt/lt/veiklos-sritys/gydymo-istaigoms-ir-partneriams/kompensuojamieji-vaistai-ir-medicinos-pagalbos-priemones-2/informacija-apie-kainynu-rengima</a>	Regularly: annually
Netherlands	No reimbursement list	n. appl.	n. appl.	n. appl.
Norway	Yes	n. appl.	<a href="https://www.helfo.no/produkt-og-prislister/produkt-og-prislister">https://www.helfo.no/produkt-og-prislister/produkt-og-prislister</a>	Regularly: quarterly
Spain	Yes	MoH	<a href="https://www.mscbs.gob.es/profesionales/nomenclator.do">https://www.mscbs.gob.es/profesionales/nomenclator.do</a>	Irregularly
Sweden	Yes	National agency	<a href="https://www.tlv.se/beslut/sok-i-data-basen.html?tab=2">https://www.tlv.se/beslut/sok-i-data-basen.html?tab=2</a>	Regularly: monthly

MoH = Ministry of Health, n. appl. = not applicable, NHS = National Health Service

<sup>1</sup> Publicly accessible and non-publicly accessible lists available.

<sup>2</sup> Around 90% of included products have a price.

Source: EURIPID collaborating partners, data compilation by EURIPID Secretariat

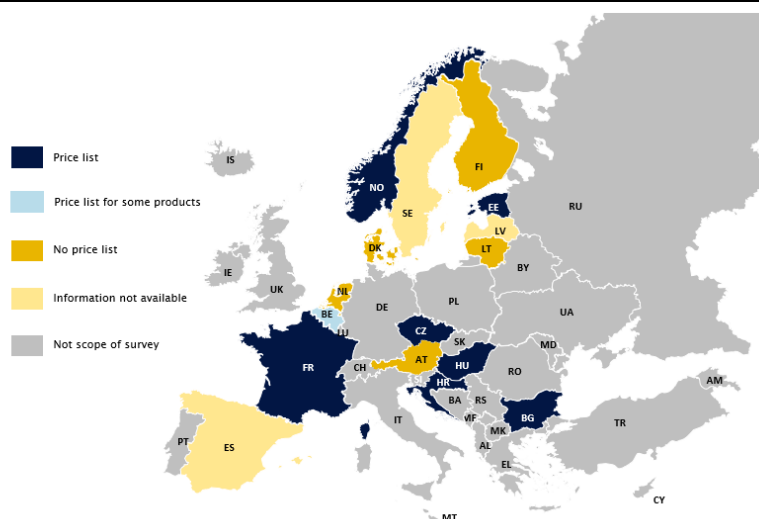
## 3 Price lists of medical devices

A price list indicates the prices of all or some medical devices (e. g. those subject to reimbursement). Part C of the survey (see Annex 7.2.3) collected details on the availability and management of price lists. Part D surveyed details with regard of inclusion of price types in the lists (see Annex 7.2.4).

### 3.1 Availability of price lists

Figure 3 shows that in Bulgaria, Croatia, the Czech Republic, Estonia, France, Hungary, and Norway price lists for medical devices are available. This survey does not capture how many products of a country's market are included in the price lists. But it is known from Belgium and the Czech Republic that the list only includes some medical devices (e.g. 90% of products in the Czech Republic). In Bulgaria, the price list includes some/several groups of medical devices and in-vitro-diagnostics. The list contains only devices and in vitro diagnostic medical devices which are subject to reimbursement. Austria, Denmark, Finland, Israel, Lithuania, and Netherlands have no such price list for medical devices. In the Netherlands, health insurers negotiate the prices for medical devices for the next year on an annual basis. For Latvia, Spain (procurement is normally carried out at hospital or regional level) and Sweden (each of the 21 Swedish regional councils have price lists available for the medical devices that they procure) no information on price lists is available. In contrast to the prices of pharmaceuticals (see Transparency Directive 89/105/EEC), there is no obligation to publish the prices of (reimbursed) medical devices.

Figure 3: Availability of price lists, 2021



Not on map: Israel - No price list

Source: EURIPID collaborating partners, data compilation by EURIPID Secretariat



## 3.2 Accessibility of price lists

Austria, Denmark, Finland, Israel, Lithuania, and the Netherlands have no official price list. The price lists of Croatia, Czech Republic, Estonia, Hungary, and Norway are publicly accessible (see Table 2 for links). In addition to publicly accessible lists, there are also non-accessible price lists for medical devices in Belgium and France. In Bulgaria and Sweden price lists are not public, and in Spain and Latvia no information is available.

Table 2: Accessibility of price lists, 2021

Country	Price list publicly accessible	Responsible authorities for maintaining	Link to publicly available list(s)	Update interval
Austria	No price list	n. appl.	n. appl.	n. appl.
Belgium	Yes <sup>1</sup>	National Public Health Institute	<a href="https://www.vas.ehealth.fgov.be/registers/sadm/web/search/public">https://www.vas.ehealth.fgov.be/registers/sadm/web/search/public</a>	Irregularly: on request
		Social insurance Ministry of Economics	<a href="https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/orthopedisten/Paginas/lijsten-producten-orthopedie.aspx">https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/orthopedisten/Paginas/lijsten-producten-orthopedie.aspx</a> <a href="https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/audiciens/Paginas/Lijsten-van-hoor-toestellen.aspx">https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/audiciens/Paginas/Lijsten-van-hoor-toestellen.aspx</a> <a href="https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx">https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx</a>	Regularly: yearly with indexation
Bulgaria	No	Bulgarian Drug Agency	n. appl.	n. appl.
Croatia	Yes	Social insurance	<a href="https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi">https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi</a>	Irregularly
Czech Republic <sup>2</sup>	Yes	State Institute for Drug Control	<a href="https://www.sukl.cz/sukl/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz">https://www.sukl.cz/sukl/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz</a>	Irregularly
Denmark	No price list	n. appl.	n. appl.	n. appl.
Estonia	Yes	Social insurance NHS	<a href="https://www.riigiteataja.ee/akt/116122020016">https://www.riigiteataja.ee/akt/116122020016</a> <a href="https://www.riigiteataja.ee/akti-lisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#">https://www.riigiteataja.ee/akti-lisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#</a> <a href="https://www.riigiteataja.ee/akt/126062021006">https://www.riigiteataja.ee/akt/126062021006</a>	Regularly: yearly
Finland	No price list	n. appl.	n. appl.	n. appl.
France	Yes <sup>1</sup>	MoH Social insurance	<a href="http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI">http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI</a>	Regularly

Country	Price list publicly accessible	Responsible authorities for maintaining	Link to publicly available list(s)	Update interval
Hungary	Yes	Health insurance	<a href="https://neak.gov.hu/felso_menu/szakmai_oldalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html">https://neak.gov.hu/felso_menu/szakmai_oldalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html</a>	Regularly: monthly
Israel	No price list	n. appl.	n. appl.	n. appl.
Latvia	No information available	n. appl.	n. appl.	n. appl.
Lithuania	No price list	n. appl.	n. appl.	n. appl.
Netherlands	No price list	n. appl.	n. appl.	n. appl.
Norway	Yes	n. appl.	<a href="https://www.helfo.no/produkt-og-prislister/produkt-og-prislister">https://www.helfo.no/produkt-og-prislister/produkt-og-prislister</a>	Irregularly
Spain <sup>3</sup>	No information available	n. appl.	n. appl.	Irregularly
Sweden	No <sup>4</sup>	n. appl.	n. appl.	Regularly: monthly

MoH = Ministry of Health, n. appl. = not applicable

<sup>1</sup> Public and not public lists available

<sup>2</sup> **Czech Republic:** As a prerequisite for reimbursement of medical devices prescribed on a voucher it is necessary to submit the current price list signed by the manufacturer of the medical device or a document certifying the price of the manufacturer of the medical device.

<sup>3</sup> **Spain:** Procurement is normally carried out at hospital or regional levels.

<sup>4</sup> **Sweden:** All 21 Swedish regional councils (responsible for the healthcare) have price lists available for the medical devices that they procure and most prices are available upon request (due to the Swedish Public Access to Information and Secrecy Act).

Source: EURIPID collaborating partners, data compilation by EURIPID Secretariat

### 3.3 Price specifications in price lists and VAT rate

None of the countries participating in the survey provide information for all price types. In Belgium there are three price types that can be found in different price lists. Croatia, Estonia, Hungary, and Spain have information on retail prices of medical devices. The Czech Republic, France, Latvia, Norway, and Sweden offer information on different price types. Austria, Bulgaria, Denmark, Finland, Israel, and the Netherlands have no price information at all.

The VAT rate varies between 27% (Hungary) and 5% (Croatia, Hungary – for selected medical devices, Lithuania).

Table 3: Price specifications, 2021

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 <sup>1</sup>	No	Yes	Yes <sup>2</sup>	Yes <sup>2</sup>	6 or 21 <sup>3</sup>
Bulgaria	n. a.	n. a.	n. a.	n. a.	20
Croatia	No	No	Yes	Yes	5
Czech Republic	Yes	Yes	No	Yes <sup>4</sup>	15 or 21
Denmark	n. a.	n. a.	n. a.	n. a.	n. a.
Estonia	No	No	No	Yes	9, 20 <sup>5</sup>
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 <sup>6</sup>	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 <sup>7</sup>
Sweden	No <sup>8</sup>	Yes <sup>9</sup>	Yes <sup>9</sup>	No <sup>10</sup>	25

MD = Medical device(s), MoH = Ministry of Health, n. a. = not applicable, VAT = Value added tax

<sup>1</sup> **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.

<sup>2</sup> **Belgium:** Depends on the respective price list.

<sup>3</sup> **Belgium:** Generally, 6% for implants and 21% for invasive MD but there are some exceptions.

<sup>4</sup> **Czech Republic:** Maximum trade margin according to the price regulation of the MoH.

<sup>5</sup> **Estonia:** Usually the VAT for medical devices is 9%, but there are some exceptions where 20% is applied.

<sup>6</sup> **Netherlands:** Health insurers and/or healthcare providers are responsible for purchasing the MD that are covered by the basic health insurance package. Therefore, the MoH has no insight in the purchasing prices.

<sup>7</sup> **Spain:** 21% for inhalers, inhalation chambers and vaginal showers

<sup>8</sup> **Sweden:** Not for reimbursed MD to outpatients and most likely not for MD procured by hospitals.

<sup>9</sup> **Sweden:** For reimbursed MD to outpatients. No information regarding MD procured by hospitals.

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

Source: EURIPID collaborating partners, data compilation by EURIPID Secretariat

## 4 Pricing and reimbursement policy frameworks

One aim of this report is also to describe pricing and reimbursement policy frameworks on medical devices. For this purpose, the countries Austria, Czech Republic, Hungary, and France were selected and the system (including the pricing of medical devices) is briefly outlined below.

### 4.1 Austria

Table 4: Pricing and reimbursement of medical devices in Austria, 2021

	Indicator	Outpatient sector	Inpatient sector
Competent Authorities	Authority responsible for setting the price of a MD	Free pricing; no competent authority	Free pricing; no competent authority. All inpatient institutions like individual hospitals or their centralised bodies, nursing homes, rehab hospitals or others.
	Authority responsible for reimbursement / coverage decision	Five Social Security Institutions in 2021	264 Individual hospitals (or their centralised bodies) are responsible for reimbursement/funding. (2019); nine regional governments (social welfare programs, programs for handicapped people); Federal Office for Social Affairs and Disability – Social Ministry Service
Price build up and procurement policies	Free pricing (manufacturer or importer sets price)	Yes, on manufacturer and/or retail price level	Yes, on manufacturer and/or retail price level
	Price regulated by law	No	No
	Bilateral price control policies (public procurement, price negotiations etc.)	Yes, public procurement and price negotiations on manufacturer and/or retail price level	Yes, public procurement in different intervals (depending on medical device) at manufacturer/retail price level. Price negotiations are done by purchasing departments or central buying of hospitals with manufacturer or trader at manufacturer/retail price level (=purchase price).
	Price referencing	Yes, Health Insurance Funds compare the price of a medical device with other medical devices of the same category (usually to the lowest priced in the cluster) before adding a new medical device into the benefit catalogue (“Leistungskatalog”).	Yes, hospitals compare the price of a medical device with other medical devices of the same category (usually to the lowest priced in the cluster) before adding a new medical device into the internal medical devices catalogue.
Coverage and funding policies	Process and criteria of coverage / funding	Several expert committees conduct economic and qualitative evaluations of applied devices and provide recommendations to sickness funds which are in charge of taking the reimbursement decisions.	Medical devices are included in the lump sums which can be generated for reimbursement of the procedure and diagnosis-orientated case groups (DRG) in hospitals (“Leistungsorientierte Krankenanstaltenfinanzierung – LKF”). Some, mostly highly innovative medical devices, are exceptions in the DRG lump sum system, since these medical devices are recorded in their own diagnosis-orientated case groups

LKF = Leistungsorientierte Krankenanstaltenfinanzierung / DRG = Diagnosis-related groups

Source: GÖG 2021

## 4.2 Czech Republic

Table 5: Pricing and reimbursement of medical devices in the Czech Republic, 2021

Indicator		Outpatient sector	Inpatient sector
Competent Authorities	Authority responsible for setting the price of a MD	Free pricing; price set by manufacturer or importer	Free pricing; price set by manufacturer or importer. Public procurement is organized by hospitals or their associations.
	Authority responsible for reimbursement / coverage decision	State Institute for Drug Control; Reimbursement is limited by law.	Free pricing; no competent authority. Public procurement is organized by hospitals or their associations.
Price build up and procurement policies	Free pricing (manufacturer or importer sets price)	Yes	Yes
	Price regulated by law (authority sets price based on a law)	No	No
	Bilateral price control policies (public procurement, price negotiations etc.)	The highest price agreement is crucial. Price competition	Public procurement is organized by hospitals or their associations.
	Price referencing	No	No
Coverage and funding policies	Process and criteria of coverage / funding	The Ministry of Health is the responsible authority for development of legal basis and strategic matters in the field of medical devices. The State Institute for Drug Control publishes the list of reimbursed medical devices prescribed on order.	Medical devices used in hospitals are not subject to an individual payment for each item, but to a flat rate.  The Commission for Medical Facilities of the Association of Health Insurance Companies of the Czech Republic will decide on the application for the classification of medical devices in the nomenclature based on the assessment of documents SZP ČR – ZP including reimbursement. However, the applicable legislation is always decisive. The decision-making considers the benefit to the patient and the economic demands.

SZP ČR = Svaz zdravotních pojišťoven ČR / General Health Insurance Company of the Czech Republic

Source: SUKL 2021

## 4.3 Hungary

Table 6: Pricing and reimbursement of medical devices in Hungary, 2021

Indicator		Outpatient sector	Inpatient sector
Competent Authorities	Authority responsible for setting the price of a MD	Nemzeti Egészségbiztosítási Alapkezelő (NEAK) / National Institute of Health Insurance Fund Management	Free pricing; no competent authority. Public procurements are organised by NEAK (for certain high-priced products), hospitals or their hospital associations.
	Authority responsible for reimbursement / coverage decision	Nemzeti Egészségbiztosítási Alapkezelő (NEAK) / National Institute of Health Insurance Fund Management	Nemzeti Egészségbiztosítási Alapkezelő (NEAK) / National Institute of Health Insurance Fund Management
Price build up and procurement policies	Free pricing (manufacturer or importer sets price)	No	Yes, on all price levels
	Price regulated by law (authority sets price based on a law)	No	No
	Bilateral price control policies (public procurement, price negotiations etc.)	No	Yes There are public procurements. Some high-priced medical devices are procured by NEAK, while other, especially medical devices/aids with high turnover are purchased centrally by ÁEEK / National Health Care Services Center; the rest of medical devices/aids are procured by the hospitals.
	Price referencing	Yes There is an internal reference pricing system within the functional groups. The applicants must submit the price in other countries, but there are no means to verify the information.	No
Coverage and funding policies	Process and criteria of coverage / funding	Reimbursement application procedure, similar to medicinal products. Criteria: efficacy, safety, ratio between cost and therapeutic value, budgetary impact analysis, health economist analysis, health technology analysis (if necessary)	Medical devices are included in the lump sums of the diagnosis-orientated case groups (DRG) in hospitals. Some, mostly highly innovative medical devices, are exceptions in the DRG lump sum system, since these medical devices are financed on a case-by-case basis, while three groups (cochlear implants, pacemaker, and artificial heart valves) are publicly procured. High priced medical devices which could not be financed via the DRG system must go through HTA.

DRG = Diagnosis-related groups, HTA = Health Technology Assessment

Source: NEAK 2021

## 4.4 France

Table 7: Pricing and reimbursement of medical devices in France, 2020

Indicator		Outpatient sector	Inpatient sector
Competent Authorities	Authority responsible for setting the price of a MD	Comité Economique des Produits de Santé (CEPS) / Healthcare products pricing committee	Comité Economique 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	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, MD 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.
	Price referencing	Yes, price setting for MD that can be integrated into a generic reimbursement line and for MD 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 and 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
Coverage and funding policies	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, morbidity, and quality of life. Reimbursement is granted for five 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 five years with a periodic reassessment.

AB = Added Benefit, ACV = Added Clinical Value, CEPS = Comité Economique des Produits de Santé, DRG = Diagnosis-related groups, EU4 = EU4Health Programme, HTA = Health Technology Assessment, MD = Medical Device(s)

Source: PPRI 2020

## 5 Conclusions

The aim of this report was to assess the feasibility of integrating medical devices into the European Integrated Price Information Database (Euripid). The study analysed previous work on medical devices within EURIPID, a survey was conducted with the EURIPID collaborating partners to investigate whether or not reimbursement and price lists for medical devices exist in the countries and for which price types. Data for the pricing and reimbursement policy framework of four countries were collected. In summary, the research team came to the following conclusions:

**Low interest:** Despite the Covid-19 crisis, EURIPID Collaborating partners' interest in medical devices has not increased. The Lime survey in 2021 showed that none of the countries surveyed deems adding medical devices prices to the EURIPID database as a top priority. This result had already been shown by an earlier query conducted in 2016. It must be added that the contact persons of the EURIPID Collaborating partners are mostly not responsible for medical devices and that this result might have been achieved for this reason.

**Difficult comparability:** The initial collection of data on comparable medical devices across the countries surveyed by the Czech medicines' agency SUKL demonstrated how difficult it is to find even ten devices that have been marketed in a similar way in the different countries. Due to the sheer size of each market, the study team faced additional challenges to collect comparable data. For example, in Austria, a relatively small country, around 500,000 different medical devices have been marketed in 2021 as compared to 9.287 pharmaceuticals for human use (BASG 2021).

Price comparisons of medical devices are currently difficult to conduct due to the different product names and nomenclatures used in the EU member states but the comparability should become easier in the future. The obligatory use of the new European Database for Medical Devices (EUDAMED) is accompanied by using the European Medical Device Nomenclature (EMDN) (European Commission 2020). The new EUDAMED database will also include an UDI<sup>2</sup> module where each medical device becomes individually traceable. However, EUDAMED will not become mandatory until all six modules are fully available. According to the European Commission, this will be accomplished after 2023. (European Commission 2021)

**Good availability of reimbursement prices:** The Survey on the integration of prices of MD in EURIPID showed that except of Denmark, Finland and the Netherlands, all participants have at least a sort of reimbursement list or criteria for medical devices in the form of a positive list. Reimbursement pricing could be built into EURIPID relatively easily.

**Narrow common denominator on price types:** Price lists (with information on the various price types) are only publicly available in six of the 16 participating countries (Belgium, Croatia, Czech Republic, France, Hungary, Norway). Another challenge is that the price types used are quite

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<sup>2</sup> UDI is a worldwide system for uniform product labelling of medical devices and will also simplify the comparability of medical device prices in the future.



divers, e.g. the add-ons for distribution or handling are not regulated in contrary to medicines. This is a major limitation for any comparison and makes an integration of prices in EURIPID very difficult and technically challenging at this point in time.

**Technical assessment:** Besides the very complex task to compare medical devices across countries, there is a lack of mandatory or statutory pricing regulations which would make the technical implementation into EURIPID extremely challenging. The original work plan proposed a pilot to integrate ten selected devices, however, this was not feasible due to the limited resources available for this task.

### Outlook and next steps

The feasibility study was presented at the 9<sup>th</sup> EURIPID Board of Participants (BoP) Meeting on 21 September 2021 and further steps were discussed in the context of current developments. EURIPID participants had the opportunity to provide feedback on the report and findings after the meeting until 15 October 2021, which was integrated into this final report.

In view of the conclusions and current developments, the Board of Participants took the final decision to postpone the integration of medical devices into EURIPID until a later date (October 2023 at the earliest). The European Medical Devices Database (EUDAMED) is expected to be fully operational after 2023. By then, the new European Medical Device Nomenclature (EMDN) will also be operational as well as the Unique Device Identifier (UDI) of the European Union and the (already existing) price lists of the countries will presumably be adapted. EURIPID recommends including the UDI in national systems. Once this nomenclature is implemented, the exercise could be repeated based on the current learnings and work and should include a concrete pilot with selected products.

The study team would like to thank all EURIPID participants for their cooperation, contributions, and fruitful discussion on this important topic.

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- Transparency Directive 89/105/EEC (1988): Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems

## 7 Annex

### 7.1 Survey on the integration of prices of MD in EURIPID



Gesundheit Österreich  
GmbH



## Survey on the integration of prices of **medical devices** in the European Integrated Price Information Database (EURIPID)

<https://euripid.eu/>

### General information

**Aim of survey:** The aim of this survey is to assess the feasibility of integrating prices of medical devices into the European Integrated Price Information Database (EURIPID).

**Duration of survey:** 21 – 30 June

**Deadline:** Please send your answer **by 30 June 2021** to [euripid\\_intern@goeg.at](mailto:euripid_intern@goeg.at).

Please contact [euripid\\_intern@goeg.at](mailto:euripid_intern@goeg.at) for questions or feedback to the survey.

### A. Administrative part

**Section A:** Please fill in country and contact details.

#### A.1. Country details

- Country: Please choose your country.

#### A.2. Contact details of person completing the questionnaire:

- Name:
- Institution:
- Function:
- Address:
- Phone:
- Official e-mail:

## B. Reimbursement lists on medical devices (MD)

**Section B:** Please enter information on the availability and data content of reimbursement lists.

*Reimbursement list: A list that contains medical devices regarding to their reimbursement status. They may either include medical devices eligible for reimbursement (positive list) or those explicitly excluded from reimbursement (negative list). Reimbursement lists may target either the out-patient sector (usually positive lists or negative lists) or the in-patient sector or both.*

### B.1. Are reimbursement lists of medical devices available in your country?

- Yes
  - No *[If no, please continue with section C.]*
  - Don't know *[If unknown, who has this information for your country? Please specify:            )]*
- Comments:

### B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?

- Positive list (= list including all medical devices eligible for reimbursement)
  - Negative list (= list including all medical devices explicitly excluded from reimbursement)
  - Both (positive list and negative list)
  - Don't know
- Comments:

### B.3. If reimbursement lists of medical devices are available, are they public?

- Publicly available
  - Not publicly available
  - Both (public and not public lists available)
  - Don't know
- Comments:

### B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?

- Social insurance
  - National Health Service (NHS)
  - Ministry of Health
  - National Public Health Institute
  - Regions
  - Other (please specify):
  - Don't know
- Comments:

**B.5. If reimbursement lists are publicly available, could you please add link(s):**

https://
https://
https://

**B.6. If reimbursement lists are not publicly available, who has access to the lists?**

- Social insurance
- National Health Service (NHS)
- Ministry of Health
- Public Health Institute
- Regions
- Other (please specify):
- Don't know

Comments:

**B.7. If reimbursement lists of medical devices are available, which medical devices are included?**

- Medical devices
  - Class I (low risk) – devices that pose almost no risk to patient safety
  - Class II a (medium risk) – requires regular assessment by a notified body
  - Class IIb (medium/high risk) – regular conformity assessments are mandated with notified bodies
  - Class III (high risk) – includes machinery that is important to patient health or to sustaining the life of a patient
- In vitro diagnostics
- Other (please specify):
- Don't know

Comments:

**B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?**

- Reimbursed medical devices
- Hospital only medical devices (e.g. pacemaker)
- Special reimbursement categories (i.e.: patient named reimbursement, individually decided reimbursement etc.) (Please indicate: )
- Non-reimbursed medical devices
- Other (please specify):
- Don't know

Comments:

**B.9. How often are the reimbursement lists adjusted?**

- Regularly (on a daily/weekly/monthly/quarterly etc. basis):
  - Irregularly:
  - Don't know:
- Comments:

**C. Price lists on medical devices for procurement**

**Section C:** Please enter information on the availability and data content of price lists.

*Price list: A list giving the prices of medical devices for sale or procurement.*

**C.1. Are price lists of medical devices available in your country?**

- Yes
  - No *[If no, the questionnaire is closed.]*
  - Don't know *[If unknown, who has this information for your country? Please indicate:            )]*
- Comments:

**C.2. If price lists of medical devices are available, are they public?**

- Publicly available
  - Not publicly available
  - Both (public and not public lists available)
  - Don't know
- Comments:

**C.3. If price lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?**

- Ministry of Health
  - Social insurance
  - National Health Service (NHS)
  - National Public Health Institute
  - Other (please specify):
  - Don't know
- Comments:

**C.4. If price lists are publicly available, could you please add link(s):**

https://
https://
https://

**C.5. If price lists of medical devices are available, which medical devices are included?**

- Medical devices
    - Class I (low risk) – devices that pose almost no risk to patient safety
    - Class II a (medium risk) – requires regular assessment by a notified body
    - Class IIb (medium/high risk) – regular conformity assessments are mandated with notified bodies
    - Class III (high risk) – includes machinery that is important to patient health or to sustaining the life of a patient
  - In-vitro-diagnostics
  - Other (please specify):
  - Don't know
- Comments:

## D. Price specifications in price lists

Section D: Please enter information on the price specifications of price lists.

### D.1. Manufacturer price: Is the manufacturer price included in the price lists?

*Manufacturer price (ex-factory price, wholesale purchasing price): Price paid to the manufacturer by wholesalers.*

- Yes
  - No
  - Don't know
- Comments:

### D.2. Wholesale price: Is the wholesale price included in the price lists?

*Wholesale selling price, pharmacy purchasing price: Price charged by wholesalers to retailers (pharmacies, drugstores, specialist shops etc.). Price paid by retailer to wholesalers including wholesale add-on (mark up, margin, service charge, etc.).*

- Yes
  - No
  - Don't know
- Comments:

### D.3. Net retail price: Is the net retail price included in the price lists?

*Net pharmacy retail price, net public price, net pharmacy selling price: Price charged by retailer (pharmacies, drugstores, specialist shops etc.) to the general public. It includes the retailer add-on (remuneration of the retailer for the service of dispensing a medical device, e.g. mark up, margin, service charge, etc.) and does not include value added tax (VAT) or other taxes.*

- Yes
  - No
  - Don't know
- Comments:

**D.4. Gross retail price: Is the gross retail price included in the price lists?**

*Gross pharmacy retail price, gross public price, gross pharmacy selling price: Price charged by retailer (pharmacies, drugstores, specialist shops etc.) to the general public. It includes the retailer add-on (remuneration of the retailer for the service of dispensing a medical device, e.g. mark up, margin, service charge, etc.), the value added tax (VAT) and eventual other taxes.*

- Yes
  - No
  - Don't know
- Comments:

**D.5. How high is the VAT rate (added to net retail price) on medical devices?**

- Vat rate:
- Exemptions of VAT rate:
- Other forms and rates of taxes:
- Comments:

**D.6. Is another price type also relevant / common in your country?**

- Preferential price / price achieved via (open) tenders
  - NHS price / trade price:
  - Other (please specify):
- Comments:

**D.7. How often are the price lists adjusted?**

- Regularly (on a daily/weekly/monthly/quarterly etc. basis):
  - Irregularly:
  - Don't know:
- Comments:

**Thank you very much for participation!**

Please send the completed survey to [euripid\\_intern@goeq.at](mailto:euripid_intern@goeq.at).



## 7.2 Survey results

### 7.2.1 Part A: Administrative part

A1. Country	A2. Contact details of person completing the questionnaire
Austria	<b>Name:</b> Friederike Windisch <b>Institution:</b> Austrian National Public Health Institute (GÖG) <b>Function:</b> Deputy Head of Pharmacoeconomics Department <b>Address:</b> Stubenring 6, 1010 Vienna <b>Phone:</b> +43 1 51 561-254 <b>Official e-mail:</b> friederike.windisch@goeg.at
Belgium	<b>Response 1:</b> <b>Name:</b> Valérie Noblesse <b>Institution:</b> INAMI-RIZIV <b>Function:</b> Conseiller- évaluateur scientifique <b>Address:</b> avenue Galilée 5/01, 1210 Bruxelles <b>Phone:</b> +32 27393851 <b>Official e-mail:</b> valerie.noblesse@riziv-inami.fgov.be  <b>Response 2:</b> <b>Name:</b> Glenn Van Biesen <b>Institution:</b> National Institute of Health and Disability Imbursement (NIHDI - RIZIV - INAMI) <b>Function:</b> policy officer medical devices <b>Address:</b> Galilleelaan 5/01 Brussels <b>Phone:</b> +32 2 739 73 89 <b>Official e-mail:</b> glenn.vanbiesen@riziv-inami.fgov.be
Bulgaria	<b>Name:</b> Mariya Vasileva <b>Institution:</b> National Council on Prices and Reimbursement of Medicinal Products <b>Function:</b> Member of the NCPRMP <b>Address:</b> 15 Acad. Ivan Ev. Geshov Blv. <b>Phone:</b> +359 2 8953 105 <b>Official e-mail:</b> office@ncpr.bg
Croatia	<b>Name:</b> Gordana Fiolic <b>Institution:</b> Croatian Health Insurance Fund (HZZO) <b>Function:</b> Medical doctor <b>Address:</b> Margaretska 3, 10000 Zagreb, Croatia <b>Phone:</b> +36 91 2550724 <b>Official e-mail:</b> Gordana.Fiolic@hzzo.hr
Czech Republic	<b>Name:</b> MUDr. Darek Foit, MBA <b>Institution:</b> State Institute for Drug Control <b>Function:</b> Director, Medical Devices Section <b>Address:</b> Šrobárova 48, 100 41 Prague 10 <b>Phone:</b> +420 272 185 914 <b>Official e-mail:</b> darek.foit@sukl.cz
Denmark	<b>Name:</b> Jonas Schneider <b>Institution:</b> The Danish Health Data Authority <b>Function:</b> Special advisor <b>Address:</b> Ørestads Boulevard 5, 2300 Copenhagen S <b>Phone:</b> +46 32683535 <b>Official e-mail:</b> josc@sundhedsdata.dk
Estonia	<b>Name:</b> Katrin Pudersell <b>Institution:</b> Estonian Health Insurance Fund <b>Function:</b> Chief specialist <b>Address:</b> Lastekodu 48 10113 Tallinn <b>Phone:</b> +372 6696 625 <b>Official e-mail:</b> katrin.pudersell@gmail.com

A1. Country	A2. Contact details of person completing the questionnaire
Finland	<b>Name:</b> Ulla Kurkijärvi <b>Institution:</b> Pharmaceuticals Pricing Board <b>Function:</b> Principal pharmaceutical officer <b>Address:</b> P.O. Box 33, FI-00023 Government, Finland <b>Phone:</b> +358 295 163 436 <b>Official e-mail:</b> ulla.kurkijarvi@stm.fi
France	<b>Name:</b> Raicha Da Silva <b>Institution:</b> CNAM <b>Function:</b> Statistician <b>Address:</b> 50 avenue du Professeur André Lemierre 75986 Paris 20 Cedex 20 <b>Phone:</b> + 33 01 72 60 24 11 <b>Official e-mail:</b> raicha.da-silva@assurance-maladie.fr
Hungary	<b>Name:</b> Gergely Németh <b>Institution:</b> NEAK <b>Function:</b> Pharmacist <b>Address:</b> Váci út 73/A. Budapest 1139 <b>Phone:</b> +36 30 429 1847 <b>Official e-mail:</b> nemeth.ger@neak.gov.hu
Israel	<b>Name:</b> Claude Hagege <b>Institution:</b> Ministry of Health <b>Function:</b> Deputy director of pricing <b>Phone:</b> +972 2 5080817 <b>Address:</b> P.O.B 1176 Jerusalem, Israel <b>Official e-mail:</b> claude.hagege@moh.gov.il
Latvia	<b>Name:</b> Zane Kivleniece <b>Institution:</b> National Health Service <b>Function:</b> not applicable <b>Address:</b> Cēsu street 31 k-3, Riga, <b>Phone:</b> +371 26364160 <b>Official e-mail:</b> zane.kivleniece@vmnvd.gov.lv
Lithuania	<b>Name:</b> Evelina Macinskiene <b>Institution:</b> National Health Insurance Fund <b>Function:</b> Specialist of Medicines reimbursement department <b>Address:</b> Europos aikste 1a, Vilnius <b>Phone:</b> +370 5 2364 184 <b>Official e-mail:</b> evelina.macinskiene@vlk.lt
Netherlands	<b>Name:</b> RR Bronsgeest <b>Institution:</b> Ministry of Health, Welfare and Sport <b>Function:</b> Policy officer <b>Address:</b> P.O. Box 20350, 2500 EJ The Hague <b>Phone:</b> +31 70 340 79 11 <b>Official e-mail:</b> rr.bronsgeest@minvws.nl
Norway	<b>Name:</b> Ajsela Imamovic <b>Institution:</b> Norwegian Institute of Health <b>Function:</b> Senior advisor <b>Address:</b> not applicable <b>Phone:</b> not applicable <b>Official e-mail:</b> ajima@helsedir.no
Spain	<b>Name:</b> Estíbaliz Espinosa <b>Institution:</b> Ministry of Health <b>Function:</b> Pharmacist <b>Address:</b> Paseo del Prado, 18. 28014 Madrid <b>Phone:</b> +34 915964420 <b>Official e-mail:</b> meespinosa@mscbs.es
Sweden	<b>Name:</b> Peter Skiöld <b>Institution:</b> The Dental and Pharmaceutical Benefits Agency, TLV <b>Function:</b> Analyst <b>Address:</b> Box 225 20 [Fleminggatan 18], 104 22 Stockholm <b>Phone:</b> +46 856842711 <b>Official e-mail:</b> peter.skiold@tlv.se

## 7.2.2 Part B: Reimbursement lists of medical devices

A1. Country	B.1. Are reimbursement lists of medical devices available in your country?	B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?	B.3. If reimbursement lists of medical devices are available, are they public?	B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	B.5. If reimbursement lists are publicly available, could you please add link(s):	B.6. If reimbursement lists are not publicly available, who has access to the lists?	B.7. If reimbursement lists of medical devices are available, which medical devices are included?	B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?	B.9. How often are the reimbursement lists adjusted?
Austria	Yes	Positive list	Both (public and not public lists available)  Comments: Some reimbursement tariffs of Health Insurance Funds are published	Social insurance	<a href="https://www.gesundheitskasse.at/cdscontent/?contentid=10007.837669&amp;portal=oegkwportal">https://www.gesundheitskasse.at/cdscontent/?contentid=10007.837669&amp;portal=oegkwportal</a>  <a href="https://www.bvaeb.at/cdscontent/?contentid=10007.840383&amp;portal=bvaebportal">https://www.bvaeb.at/cdscontent/?contentid=10007.840383&amp;portal=bvaebportal</a>  <a href="https://www.svs.at/cdscontent/?contentid=10007.816812&amp;portal=svsportal">https://www.svs.at/cdscontent/?contentid=10007.816812&amp;portal=svsportal</a>	Social insurance	Medical devices In vitro diagnostics	Reimbursed medical devices Special reimbursement categories: Custom made devices	Regularly
Belgium 1	Yes Comments: not always product per product, can be more generic	Both (positive list and negative list) Comments: but there is no product on the negative list	Publicly available	Social insurance (INAMI-RIZIV)	<a href="https://ond-panon.riziv.fgov.be/IRREQPublic/fr">https://ond-panon.riziv.fgov.be/IRREQPublic/fr</a>	Not applicable	Medical Devices Implants Invasive medical devices	Reimbursed medical devices Comment: the list of reimbursed implants and invasive medical device is for inpatient but also day-hospitalisation and in some cases, outpatient is also included.	Regularly: monthly for new references if the product needs to be on a list of products to be reimbursed.  For new technologies: a few times per year

A1. Country	B.1. Are reimbursement lists of medical devices available in your country?	B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?	B.3. If reimbursement lists of medical devices are available, are they public?	B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	B.5. If reimbursement lists are publicly available, could you please add link(s):	B.6. If reimbursement lists are not publicly available, who has access to the lists?	B.7. If reimbursement lists of medical devices are available, which medical devices are included?	B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?	B.9. How often are the reimbursement lists adjusted?
Belgium 2	Yes Comments: for some type of products yes, others not but it is the intention of the NIHDI to create lists for most types of medical devices in orthotics.	Positive list	Publicly available	Social insurance National Health Service (NHS) Other (please specify): federal agency of medications and health products	<a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Paginas/Lijsten-producten-orthopedie.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Paginas/Lijsten-producten-orthopedie.aspx</a>  <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiociens/Paginas/Lijsten-van-hoortoestellen.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiociens/Paginas/Lijsten-van-hoortoestellen.aspx</a>  <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx</a>	Not applicable	Medical Devices Class I Class II a	Reimbursed medical devices	Regularly: some bi-monthly, some quarterly  Irregularly: some lists are adjusted when a distributor introduces a request for a new product
Bulgaria	Yes	Positive list	Publicly available	National Health Insurance Fund	<a href="https://www.nhif.bg/page/1491">https://www.nhif.bg/page/1491</a>	Not applicable	Medical Devices In vitro diagnostics	Reimbursed medical devices	Regularly: on annual basis
Croatia	Yes	Positive list	Publicly available	Social insurance	<a href="https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi">https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi</a>	Not applicable	Medical devices (Class I, II a, II b, III) In vitro diagnostics Other: batteries, accumulators	Reimbursed medical devices	Irregularly

A1. Country	B.1. Are reimbursement lists of medical devices available in your country?	B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?	B.3. If reimbursement lists of medical devices are available, are they public?	B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	B.5. If reimbursement lists are publicly available, could you please add link(s):	B.6. If reimbursement lists are not publicly available, who has access to the lists?	B.7. If reimbursement lists of medical devices are available, which medical devices are included?	B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?	B.9. How often are the reimbursement lists adjusted?
Czech Republic	Yes	Positive list	Publicly available	National Health Service (NHS): Hospital only medical devices  Other (please specify): State Institute for Drug Control: For medical devices prescribed for a voucher	<a href="https://www.sukl.cz/sukl/s-eznam-zdravotnickych-prostredku-hrazenych-na-poukaz">https://www.sukl.cz/sukl/s-eznam-zdravotnickych-prostredku-hrazenych-na-poukaz</a>  <a href="https://www.vzp.cz/poskytovatele/ciselniky/zdravotnicke-prostredky">https://www.vzp.cz/poskytovatele/ciselniky/zdravotnicke-prostredky</a>  <a href="https://www.szpcr.cz/zdravotnicke_prostredky">https://www.szpcr.cz/zdravotnicke_prostredky</a>	Not applicable	Medical Devices In vitro diagnostics Other: Hospital only medical devices	Reimbursed medical devices	Regularly: monthly
Denmark	No	-	-	-	-	-	-	-	-
Estonia	Yes	Positive list	Publicly available	Social insurance National Health Service (NHS) Comments: depending on the MD it is either one of the two organizations.	<a href="https://www.riigiteataja.ee/akt/116122020016">https://www.riigiteataja.ee/akt/116122020016</a>  <a href="https://www.riigiteataja.ee/akt/tilisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#">https://www.riigiteataja.ee/akt/tilisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#</a>  <a href="https://www.riigiteataja.ee/akt/126062021006">https://www.riigiteataja.ee/akt/126062021006</a>	-	Medical Devices Class I Class II a Class II b Class III	Reimbursed medical devices Hospital only medical devices (e.g. pacemaker)	Regularly: yearly

A1. Country	B.1. Are reimbursement lists of medical devices available in your country?	B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?	B.3. If reimbursement lists of medical devices are available, are they public?	B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	B.5. If reimbursement lists are publicly available, could you please add link(s):	B.6. If reimbursement lists are not publicly available, who has access to the lists?	B.7. If reimbursement lists of medical devices are available, which medical devices are included?	B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?	B.9. How often are the reimbursement lists adjusted?
Finland	No	-	-	-	-	-	-	-	-
France	Yes	Positive list Comments: Some positive lists can include some medical devices excluded from reimbursement often because the devices were eligible in the past	Both (public and not public lists available)	Social insurance National Health Service (NHS) Ministry of Health National Public Health Institute	<a href="http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI">http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI</a>  <a href="https://base-donnees-publique.medicaments.gouv.fr/telechargement.php">https://base-donnees-publique.medicaments.gouv.fr/telechargement.php</a>	Social insurance National Health Service (NHS) Ministry of Health Public Health Institute Regions	Medical Devices (Class I, II a, II b, III)	Reimbursed medical devices	Regularly Comments: The lists are often adjusted for the reimbursement sake. But having access to those modifications could be difficult.
Hungary	Yes	Positive list	Publicly available	Social insurance	<a href="https://neak.gov.hu/felso_menu/szakmai_oldal/gyogy-szer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html">https://neak.gov.hu/felso_menu/szakmai_oldal/gyogy-szer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html</a>	Not applicable	Medical Devices (Class I) Don't know Comments: I do not know which devices fall under the given categories	Reimbursed medical devices	Regularly: monthly

A1. Country	B.1. Are reimbursement lists of medical devices available in your country?	B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?	B.3. If reimbursement lists of medical devices are available, are they public?	B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	B.5. If reimbursement lists are publicly available, could you please add link(s):	B.6. If reimbursement lists are not publicly available, who has access to the lists?	B.7. If reimbursement lists of medical devices are available, which medical devices are included?	B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?	B.9. How often are the reimbursement lists adjusted?
Israel	Yes Comments: There is not a list of products but a list of medical procedure (treatment). If several medical devices are available, the HMO/hospitals decide which they want to use.	Positive list	Publicly available	Ministry of Health	<a href="https://call.gov.il/infocenter/index?page=mailpage&amp;sendcontent=home&amp;id=null&amp;query=page=home&amp;purpose=share">https://call.gov.il/infocenter/index?page=mailpage&amp;sendcontent=home&amp;id=null&amp;query=page=home&amp;purpose=share</a>	Not applicable	-	Reimbursed medical devices	Regularly: annually
Latvia	Yes	Positive list	Publicly available	National Health Service (NHS)	<a href="https://www.vmnvd.gov.lv/lv/kompensejamo-zalu-saraksti">https://www.vmnvd.gov.lv/lv/kompensejamo-zalu-saraksti</a>	Not applicable	Medical devices (Class I)	Reimbursed medical devices Comments: Only four groups of devices are reimbursed: test strips for diabetes, stoma care products, incontinence products and storages for medicines inhalation	Regularly: monthly
Lithuania	Yes	Positive list	Publicly available	National Health Service (NHS)	<a href="https://ligoniukasa.lrv.lt/lt/veiklosritys/gydymo-istaigoms-ir-partneriams/kompensuojamieji-vaistai-ir-medicinos-pagalbos-priemones-2/informacija-apie-kainynu-rengima">https://ligoniukasa.lrv.lt/lt/veiklosritys/gydymo-istaigoms-ir-partneriams/kompensuojamieji-vaistai-ir-medicinos-pagalbos-priemones-2/informacija-apie-kainynu-rengima</a>	Not applicable	Medical Devices (Class I, II a) In vitro diagnostics	Reimbursed medical devices	Regularly: Once a year
Netherlands	No	-	-	-	-	-	-	-	-
Norway	Yes	Positive list	Publicly available	-	<a href="https://www.helfo.no/produkt-og-prislister/produkt-og-prislister">https://www.helfo.no/produkt-og-prislister/produkt-og-prislister</a>	Not applicable	Medical devices (Class I)	Reimbursed medical devices	Regularly: quarterly

A1. Country	B.1. Are reimbursement lists of medical devices available in your country?	B.2. If reimbursement lists of medical devices are available, are they positive or negative lists?	B.3. If reimbursement lists of medical devices are available, are they public?	B.4. If reimbursement lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	B.5. If reimbursement lists are publicly available, could you please add link(s):	B.6. If reimbursement lists are not publicly available, who has access to the lists?	B.7. If reimbursement lists of medical devices are available, which medical devices are included?	B.8. If reimbursement lists of medical devices are available, which types of medical devices are included?	B.9. How often are the reimbursement lists adjusted?
Spain	Yes	Positive list	Publicly available	Ministry of Health	<a href="https://www.mscbs.gob.es/profesionales/nomenclador.do">https://www.mscbs.gob.es/profesionales/nomenclador.do</a>	Not applicable	Medical Devices (Class I, II a) Comments: There are just a reduced number of reimbursable medical devices with a maximum price set. They are mainly class I products for dispensing in pharmacies in the outpatient sector against an NHS prescription.	Reimbursed medical devices	Irregularly
Sweden	Yes	Positive list	Publicly available	Other (please specify): TLV, Tandvårds och läkemedelsförmånsverket  Comments: National agency	<a href="https://www.tlv.se/beslut/sok-i-databasen.html?tab=2">https://www.tlv.se/beslut/sok-i-databasen.html?tab=2</a> <a href="https://www.tlv.se/beslut/sok-i-databasen.html?tab=2">https://www.tlv.se/beslut/sok-i-databasen.html?tab=2</a>	Not applicable	Comments: Medical device consumables	Reimbursed medical devices	Comments: As products are included or excluded in the national system for reimbursement, prices are (potentially) adjusted monthly.



## 7.2.3 Part C: Price lists of medical devices for procurement

A1. Country	C.1. Are price lists of medical devices available in your country?	C.2. If price lists of medical devices are available, are they public?	C.3. If price lists of medical devices are (publicly or not publicly) available, who is responsible for the maintaining of the lists?	C.4. If price lists are publicly available, could you please add link(s):	C.5. If price lists of medical devices are available, which medical devices are included?
Austria	No	-	-	-	-
Belgium 1	Yes (but not for every medical device)	Publicly available	National Public Health Institute (is complementary at the list of the reimbursed medical devices)	<a href="https://www.vas.ehealth.fgov.be/registers/sadm/web/search/public">https://www.vas.ehealth.fgov.be/registers/sadm/web/search/public</a>	Medical devices (mobile application also)
Belgium 2	Yes (for some products)	Both (public and not public lists available)	Social insurance Other (please specify): ministry of economics	<a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Paginas/lijsten-producten-orthopedie.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/orthopedisten/Paginas/lijsten-producten-orthopedie.aspx</a>  <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiociens/Paginas/Lijstenvan-hoortoestellen.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/audiociens/Paginas/Lijstenvan-hoortoestellen.aspx</a>  <a href="https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx">https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/bandagisten/Paginas/lijsten-producten-artikel-27-nomenclatuur-geneeskundige-verstrekkingen.aspx</a>	Medical devices Class II a
Bulgaria	Yes	Not publicly available	Other (please specify): Bulgarian Drug Agency	-	Medical devices In-vitro-diagnostics
Croatia	Yes	Publicly available	Social insurance	<a href="https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi">https://hzzo.hr/zdravstvena-zastita/medicinski-proizvodi</a>	Medical Devices (Class I, II a, II b, III) In vitro diagnostics Other: batteries, accumulators
Czech Republic	For notification of reimbursement of medical devices prescribed on a voucher it is necessary to submit the current price list signed by the manufacturer of the medical device or a document certifying the price of the manufacturer of the medical device.	Publicly available	Other: State Institute for Drug Control (For the categorization and reimbursement regulation of medical devices prescribed for a voucher)	<a href="https://www.suki.cz/suki/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz">https://www.suki.cz/suki/seznam-zdravotnickych-prostredku-hrazenych-na-poukaz</a>	Medical devices In-vitro-diagnostics
Denmark	No	-	-	-	-
Estonia	Yes	Publicly available	Social insurance National Health Service (NHS)	<a href="https://www.riigiteataja.ee/akt/116122020016">https://www.riigiteataja.ee/akt/116122020016</a>  <a href="https://www.riigiteataja.ee/akt/tilisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#">https://www.riigiteataja.ee/akt/tilisa/1250/9202/0004/SOM_23092020_m44lisa.pdf#</a>  <a href="https://www.riigiteataja.ee/akt/126062021006">https://www.riigiteataja.ee/akt/126062021006</a>	Medical Devices (Class I, II a, II b, III)

Finland	No	-	-	-	-
France	Yes	Both (public and not public lists available)	Ministry of Health Social insurance	<a href="http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI">http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI</a>	Medical Devices (Class I, II a, II b, III)
Hungary	Yes	Publicly available	Social insurance	<a href="https://neak.gov.hu/felso_menu/szakmai_oldal/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html">https://neak.gov.hu/felso_menu/szakmai_oldal/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/puphag/Vegleges_PUPHAG.html</a>	Medical Devices (Class I) Don't know Comments: I do not know which devices fall under the given categories.
Israel	No	-	-	-	-
Latvia	Don't know	Don't know	Don't know	-	Don't know
Lithuania	No	-	-	-	-
Netherlands	No				
Norway	Yes	Publicly available	-	<a href="https://www.helfo.no/produkt-og-pris-lister/produkt-og-pris-lister">https://www.helfo.no/produkt-og-pris-lister/produkt-og-pris-lister</a>	Medical devices Class I
Spain	Don't know Comments: Procurement is normally carried out at hospital or regional level.	Don't know	Don't know		Medical Devices Class I Don't know
Sweden	Don't know Probably each of the 21 Swedish regional councils (responsible for the healthcare) have price lists available for the medical devices that they procure.	Don't know Comments: Probably most of the prices are public upon request (due to the Swedish Public Access to Information and Secrecy Act).	Comments: Probably most of the prices are public upon request (due to the Swedish Public Access to Information and Secrecy Act).	-	Other (please specify): Probably, prices of publicly procured medical devices.

## 7.2.4 Part D: Price specifications in price lists

A1. Country	D.1. Manufacturer price: Is the manufacturer price included in the price lists?	D.2. Wholesale price: Is the wholesale price included in the price lists?	D.3. Net retail price: Is the net retail price included in the price lists?	D.4. Gross retail price: Is the gross retail price included in the price lists?	D.5. How high is the VAT rate (added to net retail price) on medical devices?	D.6. Is another price type also relevant / common in your country?	D.7. How often are the price lists adjusted?
Austria	-	-	-	-	20%	-	-
Belgium 1	No	Yes (implants and invasive medical devices are mainly purchase by the pharmacy. There is no extra charge by the pharmacist on the price of implants and invasive MD.)	n.a.	n.a.	6 or 21% (generally 6% for implants, 21% for invasive MD but there are some exceptions)	reimbursement price	Irregularly: depending of the introduced request
Belgium 2	Don't know	Yes (some lists have wholesale price only)	No (some lists have both wholesale price and net retail price, and some have only net retail price visible for the general public)	Yes (some lists have both wholesale price and gross retail price, and some have only gross retail price visible for the general public)	6%	NHS price / trade price: reimbursement price is sometimes mentioned.	Regularly: yearly with indexation

A1. Country	D.1. Manufacturer price: Is the manufacturer price included in the price lists?	D.2. Wholesale price: Is the wholesale price included in the price lists?	D.3. Net retail price: Is the net retail price included in the price lists?	D.4. Gross retail price: Is the gross retail price included in the price lists?	D.5. How high is the VAT rate (added to net retail price) on medical devices?	D.6. Is another price type also relevant / common in your country?	D.7. How often are the price lists adjusted?
Bulgaria	Don't know	Don't know	Don't know	Don't know	20%	NHS price / trade price: The cost which is paid by NHIF	Don't know
Croatia	No	No	Yes	Yes	5%	-	Irregularly
Czech Republic	For notification of reimbursement of medical devices prescribed on a voucher it is necessary to submit the current price list signed by the manufacturer of the medical device or a document certifying the price of the manufacturer of the medical device.	Yes Comment: The maximum final price (MFC = the manufacturer's price with the maximum trade margin according to the price regulation of the Ministry of Health and VAT) a medical device can be traded. It is the value that is listed in the List of Medical devices in the MFC field and it is valid for the entire market in the Czech Republic. This value cannot be exceeded but a medical device can be traded at a lower price.	No	No	15% or 21% Comment: Maximum trade margin - according to the price regulation of the Ministry of Health	Comments: Agreement on the highest price according to § 39v of Act No. 48/1997 Coll.	Irregularly
Denmark	-	-	-	-	-	-	-
Estonia	No	No	No	Yes	9% Comments: Usually the VAT for medical devices is 9%, but there are some exceptions where 20% is applied.	-	Regularly: yearly
Finland	-	-	-	-	-	-	-
France	Yes	No Comments: Even if not included the wholesale price can sometimes be calculated.	No	Yes	Comments: There are different VAT: 2,1%, 5,5%, 10% or 20% it depends of the device.	-	Regularly Comments: The lists are often adjusted for the reimbursement sake. But having access to those modifications could be difficult.
Hungary	No	No	Yes	Yes	5 or 27%	-	Regularly: monthly
Israel	-	-	-	-	-	-	-
Latvia	No	Yes	No	Yes	12%	-	Regularly
Lithuania	No	No	No	No	5%	NHS price / trade price: reimbursement price	Regularly: Once a year
Netherlands	Don't know Comments: In the Netherlands, the health insurers and/or healthcare providers are responsible for purchasing the medical devices that are provided by the basic health insurance package. Therefore, the Ministry has no insight in the purchasing prices.	Don't know Comments: In the Netherlands, the health insurers and/or healthcare providers are responsible for purchasing the medical devices that are provided by the basic health insurance package. Therefore, the Ministry has no insight in the purchasing prices.	Don't know Comments: In the Netherlands, the health insurers and/or healthcare providers are responsible for purchasing the medical devices that are provided by the basic health insurance package. Therefore, the Ministry has no insight in the purchasing prices.	Don't know Comments: In the Netherlands, the health insurers and/or healthcare providers are responsible for purchasing the medical devices that are provided by the basic health insurance package. Therefore, the Ministry has no insight in the purchasing prices.	In the Netherlands, the VAT rate differs among the type of medical devices (between 9% and 21%).	-	Regularly: Health insurers negotiate the prices for medical devices for the next year on an annual basis.
Norway	No	Yes	Yes	No	25%	-	Irregularly
Spain	No	No	No	Yes	10% Exemptions of VAT rate: 21% for inhalers, inhalation chambers and vaginal showers.	-	Irregularly
Sweden	No Don't know Comments: No, not for reimbursed medical devices to outpatients. Don't know, but most likely not for medical devices procured by hospitals.	Yes Don't know Comments: Yes, for reimbursed medical devices to outpatients. No information regarding medical devices procured by hospitals.	Yes Don't know Comments: Yes, for reimbursed medical devices to outpatients. No information regarding medical devices procured by hospitals.	No Don't know Comments: Not for reimbursed products to outpatients (the pharmacy adds 25% VAT). No information regarding medical devices procured by hospitals.	25%	Preferential price / price achieved via (open) tenders	Regularly: Don't know Comments: Prices of reimbursed medical devices to outpatients are adjusted monthly. No information regarding medical devices procured by hospitals.

