PPRI Medical Devices Brief: France 2022

PPRI Medical Devices Briefs Series

Commissioned by the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich GmbH

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This report contributes to the implementation of the 2030 Agenda for Sustainable Development, in particular to Sustainable Development Goal (SDG) 3 "good health and well-being" and its target 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.

About PPRI Medical Devices Briefs

This Brief presents the pricing and reimbursement policy framework for medical devices in France in 2022. It was produced as part of the activities of the PPRI Subgroup on Medical Devices. The PPRI Medical Devices Briefs Series complements the medicines-related series of the PPRI Pharma Briefs launched in 2019 and PPRI Posters on medicines and medical devices.

PPRI network

The Pharmaceutical Pricing and Reimbursement Information (PPRI) network is a collaboration of pharmaceutical pricing and reimbursement authorities of approximately 50 – mostly European – countries as well as international and European institutions (e.g. European Commission, OECD, World Health Organization). The aim of PPRI is to support the participating public institutions by facilitating exchange between their experts, providing scientific evidence, and developing a common understanding of health and pharmaceutical policy issues. The network is coordinated by the PPRI Secretariat which is hosted at the Pharmacoeconomics Department of the Austrian National Public Health Institute (Gesundheit Österreich / GÖG).

PPRI contributes to the international scientific evidence base in the areas of (comparative) health systems research and policy analysis related to medicines and further health products, by providing country information that is usually not published in the literature. This information supports policy-makers who want to benchmark their own work and learn about policies and experiences in other countries, and is used by researchers who perform policy analyses and require contextual information on national policy frameworks for pricing and reimbursement of health products.

PPRI Subgroup on Medical Devices

At request of PPRI network members, a Subgroup on Medical Devices (PPRI MD) was established in 2017. PPRI MD is focused on exchanging information on pricing and reimbursement policies for medical devices with a view to increasing transparency in the field.

Over the last 20 years, PPRI has developed a range of tools, including a glossary, a set of indicators for pharmaceutical system comparison, and templates for reporting country policy information. In PPRI MD, these tools are being gradually adapted to the specificities of medical devices, such as the high heterogeneity of products.

The PPRI MD Brief on France is the first of the PPRI MD Briefs series.

For requests and comments, please contact ppri@goeg.at.

Key data at a glance

General and economic data

Population (1 January 2021)	67.4 million inhabitants
Country size (1 January 2018)	632,734 km² (including oversea areas)
Gross domestic product / GDP (2020)	GDP per capita: € 33,960 / USD PPP 46,691 (provisional data)
Health expenditure / HE (2020)	HE per capita: USD PPP 5,564 (estimated data) HE in % of GDP: 11.1% Public HE as % of total HE: 83.7% (2019)
Expenditure on medical devices (2020)	Social Health Insurance (SHI) MD expenditure per capita: approx. € 208 Shares of the SHI MD expenditure per capita: approx. € 30 per procedure (incl. MD and IVD), approx. € 149 per MD on the reimbursement list (outpatient and inpatient) and approx. € 30 in the DRG system

DRG = diagnosis-related groups, GDP = gross domestic product, HE = health expenditure, IVD = in vitro diagnostic medical device(s), MD = medical device(s), PPP = Purchasing Power Parities, SHI = Social Health Insurance, USD = United States dollars

Sources: population – Eurostat [1], country size – INSEE [2], GDP – Eurostat [3], GDP in USD PPP and health expenditure: OECD [4], MD expenditure – CEPS presentation [5]

Medical devices market

MD market in value (2019)	Approx. € 30 billion sales
Suppliers of medical devices (2019)	1,502 MD companies (incl. 80 IVD MD companies)

Note: Number of medical devices on the market is unknown
IVD = in vitro diagnostic, IVD MD = in vitro diagnostic medical devices, MD = medical devices

Sources: SNITEM [6]

Pricing policies for medical devices (2022)

Price regulation	Price regulation depends on the reimbursement status of the MD: Product-specific price regulation (through price negotiation) for MD included in the reimbursement list (called Liste des prestations et produits remboursables / LPPR), if the value of the MD was demonstrated in an Health Technology Assessment (HTA) No product-specific price regulation for MD, including IVD MD, that are part of medical procedures but their reimbursement tariff for the health professional has been determined through negotiations Free pricing for all other MD (DRG, MD in medical procedures)
Pricing authorities	**Outpatient**: Economic Committee for Health Products (Comité économique des produits de santé / CEPS): inter-ministerial committee (affiliated to the Minister of Health, Minister of Economy and Minister of Social Security) **Inpatient**: same as for outpatient sector: CEPS
Key pricing policies	**External price referencing**: supplementary policy (four reference countries: Germany, Italy, Spain and United Kingdom) to inform the CEPS in the price negotiations with the supplier on eligible MD (reimbursable MD) **Internal price referencing**: supplementary policy (reference to a comparable MD or medicine in France, where applicable) to inform the CEPS in the price negotiations with the supplier on eligible MD (reimbursable MD) **Value-based pricing (VBP)**: no VBP as the sole policy, but value elements play a role (only MD with a demonstrated value are eligible for the price negotiation, added value of the MD is one criterion in the price negotiations)

	Price and tariffs negotiations: - Key pricing policy for outpatient MD and a policy for inpatient MD that are eligible for product-specific reimbursement; price and tariff negotiations between CEPS and the supplier; - National Union of Health Insurance Funds (Union nationale des caisses d'assurance maladie / UNCAM) and associations of health professionals negotiate the reimbursement tariff of medical procedures, in which outpatient MD and IVD are used; - Ministry of Health sets the tariffs for DRG in which inpatient MD are used. **Tendering and further procurement policies**: MD for hospital use that are not included in product-specific reimbursement (positive list) are procured by the hospitals or hospital groups **Managed-entry agreements**: CEPS (as part of the price negotiations) and hospitals or hospitals groups (as part of their procurement process) may conclude a managed-entry agreement for some MD
Pricing in the supply chain	**Wholesale / further distributors**: no regulation of the remuneration of wholesalers and further distributors, their margin is commercially negotiated between the manufacturer and pharmacist / retailer (free pricing) **Pharmacy / retailer**: for MD with price regulation the retail margin is determined in the price negotiation with CEPS, as a result of the setting of the reimbursement price and retail price **Value-added tax**: 20% for MD in general, reduced VAT: 5.5% for reimbursed MD to treat handicaps (inpatient MD and some outpatient MD); standard VAT: 20%

Source: information and data collated by the PPRI Secretariat

Reimbursement for medical devices (2022)

Reimbursement authorities	**Outpatient:** National Union of Health Insurance Funds (Union nationale des caisses d'assurance maladie / UNCAM) to negotiate the reimbursement tariffs of medical procedures that may include MD and IVD **Inpatient:** not applicable (inclusion into DRG upon procurement decision; statutory basis for product-specific inclusion of eligible implants and other invasive MD into reimbursement). Ministry of Health includes the MD in the positive list LPPR, if eligible, at a price negotiated by the CEPS **HTA body:** High Authority of Health (Haute Autorité de Santé / HAS)
Reimbursement lists	**Outpatient:** positive list (Liste des prestations et produits remboursables / LPPR) **Inpatient:** parts of the LPPR also apply to implants and other invasive MD for hospital use
HTA and reimbursement criteria	HAS assesses products prior to registration on LPPR or at the request of the Minister of Health **Outpatient**: positive outcome of HTA (demonstrated value in a medical-technical evaluation and additionally a medical-economic evaluation for MD with high value and budget impact) and successful price negotiation by CEPS lead to inclusion of eligible MD into the product-specific reimbursement list (LPPR) **Inpatient:** for implants and other invasive MD same as for outpatient; inclusion into DRG system (Groupe Homogène de Séjour / GHS), plus inclusion of high-risk MD of nine defined therapeutic groups in an intra-DRG positive list upon positive medical-technical evaluation of their risks by HAS
Co-payments for reimbursable medical devices	**Outpatient:** for MD included in the positive list LPPR and in medical procedures a co-payment of around 40% of the price of the MD applies, usually covered by the complementary health insurance ("mutuelle") which most French have; the out-of-pocket payment depends on the coverage taken by the patient; exemptions from co-payments exist for patients with defined severe and chronic diseases for use of MD in these diseases **Inpatient:** no co-payment applies

Source: information and data collated by the PPRI Secretariat

Key technical terms are defined in the glossary in the Annex.

Summary

With regard to safety and performance of medical devices (MD), France applies the respective EU legislation (Medical Device Regulation / MDR and In Vitro Diagnostic Medical Device Regulation / IVDR) which have been incorporated in national law. The competent authority for MD is the French Agency for Medicines and Health Products (Agence nationale de sécurité du médicament et des produits de santé / ANSM). Key public institutions are the High Authority of Health (Haute Autorité de Santé / HAS) as Health Technology Assessment (HTA) body, the Ministry of Solidarity and Health (Ministère des Solidarités et de la Santé) and its affiliated Economic Committee for Health Products (Comité économique des produits de santé / CEPS) as well as the National Union of Health Insurance Funds (Union nationale des caisses d'assurance maladie / UNCAM).

HAS is responsible for HTA of MD to be included into the reimbursement list (Liste des prestations et produits remboursables / LPPR). It can also evaluate entire classes of products after inclusion into the list. Only MD whose expected value ("service attendu" / SA) is considered sufficient are included in the LPPR list. This decision is taken by the Ministry of Solidarity based on the medical-technical evaluation performed by the HAS committee "Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé" (CNEDiMTS). Additionally, for MD with an expected major, important or modest added value and expected high budget impact a medical-economic evaluation of the HAS committee "Commission évaluation économique et de santé publique" (CEESP) is conducted. While the LPPR relates, in general, to outpatient MD, two of its sections (III: implantable MD, implants and tissue grafts of human origin and V: invasive MD used by a doctor) are for hospital use. For certain types of MD, registration is done by assigning them to a group of similar medical devices (so-called "generic line") and all MD which have the same characteristics of these generic lines are automatically eligible for the inclusion into the LPPR. When a product cannot be assigned to a generic line, it must go through an evaluation. In addition, public funding may also result from the remuneration for medical procedures that a health professional undertakes for the purposes of diagnosis, prevention, treatment or rehabilitation (e.g. in the pathways of the so-called Classification Commune des Actes Médicaux (CCAM), Codage des Actes Biologiques (NABM) or Nomenclature générale des actes professionnels (NGAP). If the procedure involves the application of MD or IVD, HAS conducts only upon request an assessment of both the procedure and the MD or IVD. Furthermore, to facilitate innovation, MD and procedures that are considered innovative are temporarily funded through a special procedure ("forfait innovation").

In the inpatient sector, MD are usually funded through the DRG system (Groupe Homogène de Séjour / GHS), with two exceptions of device-specific funding. Within the DRG system, high-risk MD of nine defined therapeutic groups are included in an intra-DRG positive list upon a positive medical-technical evaluation by HAS. Furthermore, a supplementary "liste en sus" includes defined expensive and innovative MD for inpatient use (implants and other invasive MD) in the LPPR, upon a positive HTA conducted by HAS. MD on the "listee n sus" are funded outside the DRG system on an individual product basis by the Social Health Insurance.

MD for outpatient use included in the LPPR are usually 60% covered; the 40% co-payment on the price of a MD is usually covered by a complementary health insurance. MD used in hospitals are always 100% reimbursed.

MD for outpatient use that are to be included in the reimbursement list (LPPR) are subject to price regulation through a price negotiation between the Economic Committee for Health Products CEPS and the supplier. External price referencing based on four reference countries (Germany, Italy, Spain and United Kingdom) and internal price referencing (reference to a comparable MD or medicine in France) are used as supplementary policies to inform the price negotiations. Further information considered in the negotiations include the budget impact, forecasts on volumes, sales and target population and possible medical-economic evaluation. In the price negotiations, the reimbursement price and the maximum retail price are fixed. In some cases, CEPS attaches conditionalities in the form of a managed-entry agreements, thus requesting discounts from the suppliers.

For all other MD used in the outpatient sector and in hospitals there is free pricing by the suppliers or negotiation between the supplier and the procuring hospitals. The standard value-added tax rate of 20% is applied for most MD (reduced VAT rate of 5.5% for few exceptions). In hospital procurement, health care facilities have been collaborating on the purchase for medicines, MD and further goods.

Keywords

Pricing, reimbursement, policies for medical devices and in vitro diagnostic medical devices, France

Resumé

Le marché des dispositifs médicaux (DM) en France s'appuie sur le cadre réglementaire européen, régi par deux nouveaux règlements distincts, l'un pour les DM, l'autre pour les dispositifs médicaux de diagnostic in vitro (DMDIV). L'autorité compétente pour les DM est l'Agence nationale de sécurité du médicament et des produits de santé (ANSM). D'autres institutions publiques clés sont la Haute Autorité de Santé (HAS) en tant qu'organisme d'évaluation des technologies de santé (ETS), le Ministère des Solidarités et de la Santé et le Comité économique des produits de santé (CEPS), ainsi que l'Union nationale des caisses d'assurance maladie (UNCAM).

La HAS est responsable de l'ETS pour les DM devant être inscrits sur la liste des prestations et produits remboursables (LPPR) et peut évaluer des classes entières de DM après leur inscription sur cette liste. Seuls les DM dont le « service attendu » (SA) est jugé suffisant sont inscrits sur la LPPR. Cette décision est prise par le Ministère de la Solidarité sur la base de l'évaluation médico-technique réalisée par la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (CNEDiMTS) de la HAS. De plus, pour les DM dont l'amélioration du service attendu (ASA) est majeure, important ou modeste (niveaux I à III) et dont l'impact attendu sur les dépenses publiques est élevé, une évaluation médico-économique doit être réalisé par l'entreprise et validée par la « Commission évaluation économique et de santé publique » (CEESP) de la HAS. Même si la LPPR concerne, en général, les DM utilisés par les patients en ville, deux de ses cinq parties sont destinées à l'hôpital (titre III : DM implantables, implants et greffons tissulaires d'origine humaine et titre V : DM invasifs non éligibles au titre III de la LPPR). Pour les DM qui ne sont pas les premiers dans leur catégorie, l'inscription sur la LPPR se fait par assimilation à une spécification (« ligne générique ») et tous les DM qui sont conformes au libellé et spécifications techniques minimales de l'une des descriptions génériques de la LPPR déjà existante sont automatiquement éligibles à l'inclusion dans le LPPR. Lorsqu'un DM n'est pas conforme à une ligne générique, notamment s'il est le premier dans sa catégorie, il doit passer par une évaluation. En outre, les DM liés à un acte réalisé par un professionnel de santé ne font pas l'objet d'une tarification individualisée mais sont intégrés dans le tarif de l'acte médical qu'un professionnel de la santé effectue à des fins de diagnostic, de prévention, de traitement ou de réadaptation. Ces actes sont inscrits dans des nomenclatures, telles que la Classification Commune des Actes Médicaux (CCAM), Codage des Actes Biologiques (NABM) ou la Nomenclature générale des actes professionnels (NGAP). Si la procédure implique l'utilisation d'un DM ou d'un DIV, la HAS réalise uniquement sur demande une évaluation à la fois de la procédure et du DM ou du DIV. Par ailleurs, la prise en charge forfaitaire ou « forfait innovation » est une prise en charge dérogatoire et transitoire ayant pour objectif de faciliter l'accès aux technologies innovantes.

Dans le secteur hospitalier, les DM sont principalement financés par les établissements, leur coût étant pris en compte dans la définition des tarifs par (Groupe Homogène de Séjour / GHS). Ils ne sont pas évalués par la HAS. La HAS évalue cependant deux types de DM utilisés à l'hôpital : neuf catégories de DM financés par les tarifs GHS mais présentant des risques particuliers (« liste intra-GHS ») et certains DM qui sont financés séparément « en sus » des tarifs GHS et sont inscrits sur une liste spéciale, communément appelée « liste en sus ».

Les DM à usage ambulatoire inclus dans la LPPR sont généralement pris en charge à 60% de leur tarif de responsabilité (qui peut être inférieur au prix pratiqué); la partie non prise en charge par l'assurance maladie obligatoire est généralement -au moins partiellement- couverte par une assurance maladie complémentaire. Les DM utilisés dans les hôpitaux sont totalement remboursés.

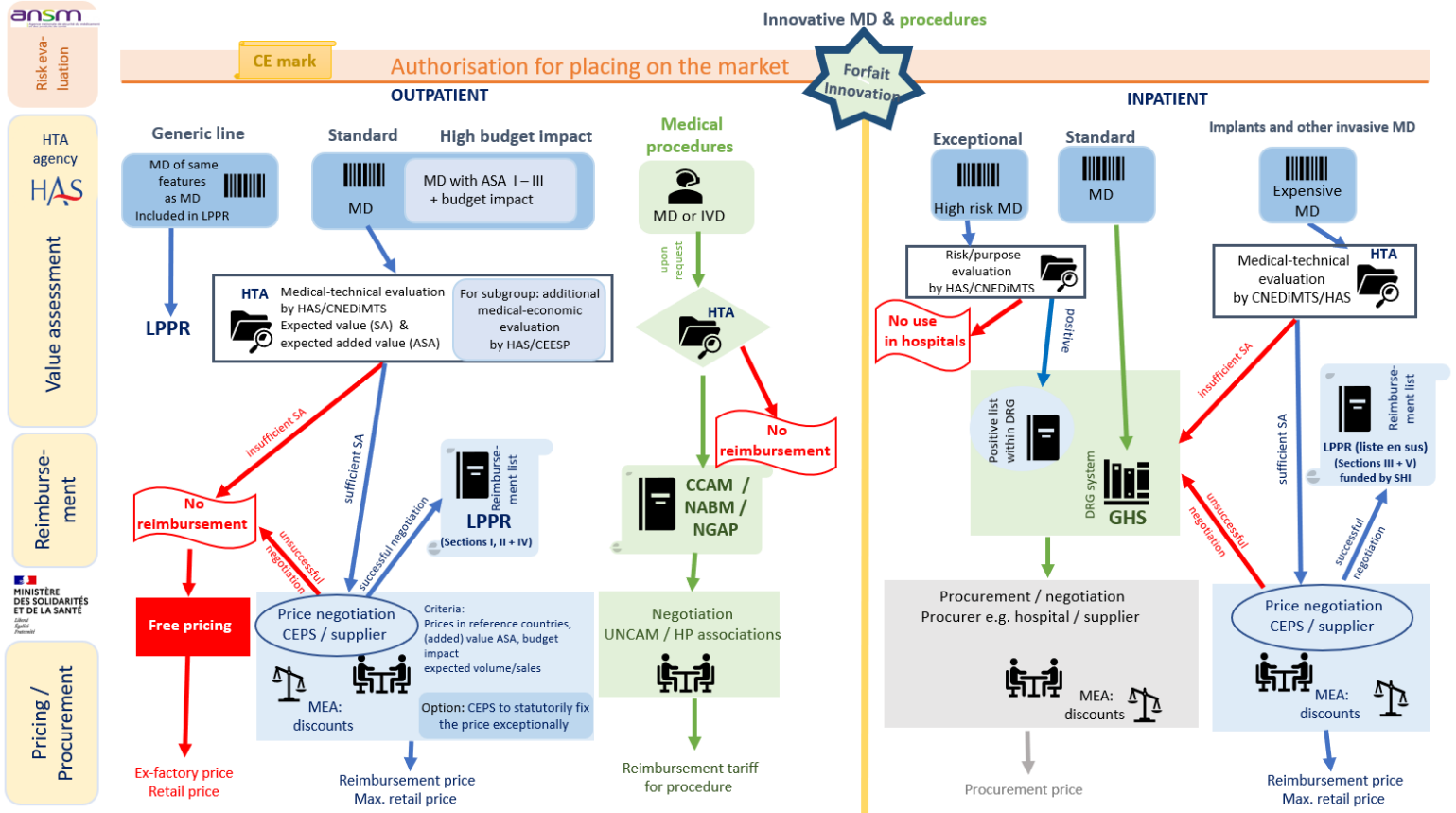
Le prix des DM inscrits dans la liste de remboursement (LPPR) est administré. La régulation des prix s'effectue par négociation entre le Comité économique des produits de santé (CEPS) et le fabricant. Le référencement externe des prix basé sur quatre pays de référence (Allemagne, Italie, Espagne et Royaume-Uni) et le référencement interne des prix (référence à un DM comparable en France) sont utilisés pour informer les négociations de prix. Parmi les autres informations prises en compte dans les négociations figurent l'impact budgétaire, les prévisions concernant les volumes, les ventes et la population cible, ainsi qu'une éventuelle évaluation médico-économique. Lors des négociations de prix, le prix de remboursement et le prix de vente maximum sont fixés. Dans certains cas, le CEPS peut décider d'un accord (« clause ») aboutissant à une remise.

Pour tous les autres DM utilisés dans le secteur ambulatoire et dans les hôpitaux, les prix sont fixés librement par les fabricants ou négociés entre le fabricant et les hôpitaux acheteurs. Le taux normal de la taxe sur la valeur ajoutée de 20 % est appliqué pour la plupart des DM (taux de TVA réduit de 5,5 % pour quelques exceptions). Dans le cadre des achats hospitaliers, les établissements de soins de santé collaborent pour l'achat de médicaments, de DM et d'autres biens.

Mots clés

Fixation des prix, remboursement, la politique pour les dispositifs médicaux, France

Graphical summary



Colour code: blue – product-specific reimbursement and pricing as well as positive assessments and positive conclusion of negotiations, green – procedures and procedure-specific reimbursement, red – negative assessments and unsuccessful negotiations

Abbreviations: ANSM = Agence nationale de sécurité du médicament et des produits de santé / National Agency for Medicines and Health Products, ASA = Amélioration du service attendu / expected added benefit, CCAM = Classification Commune des Actes Médicaux, CEPS = Comité économique des produits de santé / Economic Committee for Health Products, CEESP = Commission évaluation économique et de santé publique / Economic and Public Health Evaluation Commission (affiliated to HAS), CNEDiMTS = Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé / Commission for the Evaluation of Medical Devices and Technologies (affiliated to HAS), DRG = diagnosis-related groups, GHS = Groupe Homogène de Séjour (French DRG system), HAS = Haute Autorité de Santé /Health Technology Assessment body, HP = health professional, HTA = health technology assessment, IVD = in vitro diagnostic(s), LPPR = Liste des prestations et produits remboursables / reimbursement list, max. = maximum, MD = medical device(s), MEA = managed-entry agreement, NABM = Codage des Actes Biologiques, NGAP = Nomenclature générale des actes professionnels, SA = Service attendu / expected value, SHI = social health insurance, UNCAM = Union nationale des caisses d'assurance maladie / National Union of Health Insurance Funds

Source: graphical summary produced by the PPRI Secretariat

1 Framework

France is a Member State of the European Union (EU), and as such, two key EU Regulations are of relevance with regard to the definition of medical devices (MD): Regulation 2017/745 2017 (Medical Device Regulation, MDR [7]), which entered into force on 26 May 2021, and Regulation 2017/746 (In Vitro Diagnostic Medical Devices Regulation, IVD Regulation), which is currently rolled out, with the aim to apply as from 26 May 2022 on [8].

As in other EU Member States, medical devices (excluding IVD), are classified into different four classes (class I, IIa, IIb and III). The categorisation takes into account the intended purpose of the MD and their inherent risk (the higher the risk, the higher class). It is the responsibility of the manufacturer to undertake the classification of the MD.

As a prerequisite for being placed on the French market, a MD has to carry a CE mark following a conformity assessment. In case of a MD of low risk (i.e. a MD of class I, unless it is sterile or a measuring MD), the manufacturer self-certificates; for all other MD, a Notified Body has to be addressed to assess conformity of the MD with legal requirements. France has one notified body which is allowed to do conformity assessments in line with the MDR and IVDR: the Groupement pour l'évaluation des dispositifs médicaux (GMED) with the notified body number 0459 [9, 10].

In France, the competent authority for the market surveillance of medical devices is the National Agency for Medicines and Health Products (Agence nationale de sécurité du médicament et des produits de santé / ANSM). It is also involved in the designation and control of Notified Bodies [11, 12] as well as in charge of granting exceptional access to MD with a CE mark and for authorising clinical trials [13, 14].

With regard to pricing and reimbursement for MD, relevant public institutions are the High Authority of Health (Haute Autorité de Santé / HAS) which conducts Health Technology Assessments (HTA) for some MD, the Ministry of Solidarity and Health (Ministère des Solidarités et de la Santé) which decides on the reimbursement status of a MD and the Economic Committee for Health Products (Comité économique des produits de santé / CEPS), affiliated to the Ministry of Solidarity and Health), that negotiates the reimbursement and retail price for MD that are eligible for the reimbursement list (Liste des prestations et produits remboursables / LPPR). The National Union of Health Insurance Funds (Union nationale des caisses d'assurance maladie, UNCAM) negotiates the tariffs for medical procedures that include MD and IVD, and the sickness funds as third-party payers pay for reimbursable MD and medical procedures, supplemented by complementary health insurances (so-called "mutuelles") [15, 16].

Relevant national legislation in this context comprises the Social Security Code (Code de la sécurité sociale / CSS), which defines the responsibilities of CEPS, and the Public Health Code (Code de la santé publique / CSP) that incorporated relevant European legislation.

2 Reimbursement

Reimbursement for medical devices in outpatient use

If a MD has a CE mark and is to be included in the reimbursement system, the next steps include the value assessment, the subsequent price negotiation and reimbursement decision. For MD to be used in the outpatient sector, two major device-specific pathways are, in principle, applied, depending on the characteristics of the device:

» Reimbursement list (Liste des prestations et produits remboursables / LPPR):

  - "Generic" MD: If according to the company's declaration a MD offers the same characteristics as an existing MD part of a "generic MD line", then it can be assigned to the same "generic line". No health technology assessment (HTA) or of individual MD is performed. The National Commission for the Evaluation of Medical Devices and Technologies (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé / CNEDiMTS) of HAS defines the technical and clinical specifications for these groups and performs regular reassessments of the generic groups. This funding option is interesting for products that should enter the market within short time. The suppliers can include their products in the generic line by self-registration ("auto-inscription"), without having to submit a dossier to the CNEDiMTS. However, suppliers need to inform ANSM when they launch the product on the French market (décret n°2010-247) [17, 18]. Generic lines are subject to regular price negotiations by the CEPS, and the Minister of Health may ask the HAS to evaluate the devices. Many generic lines include a product and an associated service. The CEPS can then negotiate the price of the device or the service separately or propose a global package leaving it to the actors (manufacturer and distributor) to do their own negotiation.
  - If no generic line exists or if the supplier claims a clinical improvement, HAS conducts an HTA which consists of a medical-technical evaluation – and in case of high-cost MD – of an additional medical-economic evaluation. The outcome of the HTA serves as a basis for the price negotiation by the Pricing Committee CEPS and for the decision of the Ministry of Solidarity and Health on the inclusion into reimbursement.

» Medical procedures: If not eligible to LPPR, MD are reimbursed through medical procedures. Tariffs are negotiated between the UNCAM and the representatives of the health professionals. Manufacturers and distributors can freely set the price of these MD.

In addition, France has performance-based funding mechanisms to remunerate activities of health professionals ("health procedures"), which may include an application of a MD or IVD.

Health Technology Assessment: Evaluations by HAS

When the MD is subject to an assessment, the National Commission for the Evaluation of Medical Devices and Technologies (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé / CNEDiMTS) of HAS investigates the added value of the MD upon application of the supplier. The internal HAS Service for the Evaluation of MD (Service d'évaluation des

dispositifs / SED) performs a medical-technical evaluation for CNEDiMTS. Based on the findings, the CNEDiMTS communicates the assessment of the expected value (Service attendu / SA) and, if sufficient, the added value (Amélioration du service attendu (ASA) in case of the first application for inclusion in reimbursement. For renewals the assessment is expressed as the rendered value (Service rendu / SR) and the added rendered value (Amélioration du service rendu / ASR). The SA / SR is based on therapeutic and diagnostic effects of the MD, adverse effects and the MD placement in the area of public health, and it impacts the decision whether, or not, a MD will be reimbursed. The ASA / ASR rating is more specific and impacts the price of MD that will be negotiated between the supplier and the Pricing Committee CEPS (see "Pricing"). There are different ASA /ASR rates: major (I), important (II), modest (III), minor (IV) and absence of value (V) [19].

The medical-technical evaluation of CNEDiMTS is only relevant for MD that are assessed for inclusion in the outpatient and inpatient reimbursement list LPPR (see below), or in the intra-DRG positive list in the hospital sector. For the latter, however, the evaluation of the value (SA/SR) is sufficient, and the added value (ASA/ ASR) is not investigated [19].

For MD whose inclusion in the reimbursement list is requested, an additional medical-economic evaluation will be conducted by the Economic and Public Health Evaluation Commission (Commission évaluation économique et de santé publique / CEESP) if the MD has been attributed an ASA I to III and is likely to considerably impact the Social Health Insurance expenditure (e.g. exceeding 20 million euro in the second year) [20]. The medical-economic evaluation of CEESP is intended to be conducted in parallel to the finalisation of the medical-technical evaluation of CNEDiMTS, usually after six months. However, the additional medical-economic evaluation is not very common; on average, two MD (normally ones used in the inpatient sector) are assessed per year. The results are publicly available (for an example of a transcatheter mitral valve repair device see HAS 2015 [21]).

The HAS evaluations, which provide information on the expected value, added value and – in case of economic evaluations – the Incremental Cost-Effectiveness Ratio (ICER), are intended to inform the price negotiations of CEPS (cf. chapter "Pricing") with the supplier. If the expected value is considered sufficient (independent from the ASA rating), the supplier of the device is eligible to negotiate the price with CEPS, and a successful conclusion of the negotiation will lead to the inclusion of the MD into the reimbursement list.

In case of unsuccessful negotiations with CEPS, the supplier may seek reimbursement in another way – e.g. the company may switch to a generic line (if exists) or participate in a tender procedure directly with hospitals.

Reimbursement list LPPR

The decision on the inclusion of a MD into the reimbursement list (Liste des prestations et produits remboursables / LPPR) is taken by the Ministry of Solidarity and Health (unless for the "generic lines" with self-registration by suppliers). With the exception of generic lines the decision is based on the assessment of the CNEDiMTS which must demonstrate sufficient "expected value" (SA) or

"rendered value" (SR, in case of renewal) and the positive conclusion of the price negotiation between the Economic Committee of Health Products CEPS and the supplier. The HAS conducts a posteriori evaluation of generic lines

The LPPR is divided into five sections:

» Section I: MD for home treatment, life aids, food and dressings,
» Section II: Orthoses and prostheses,
» Section III: Implantable MD, implants and tissue grafts of human origin (inpatient sector)
» Section IV: Vehicles for physically handicapped people and
» Section V: Invasive MD used by a medical doctor that do not fall under section III – a newly added category in 2015 (inpatient sector).

MD that are included in Sections I, II and IV are used in the outpatient sector, whereas Sections III and V relate to the hospital sector. For Section V, eligible MD are included in the "liste en sus" (see below the information on MD in the hospital sector). In 2020, the expenditure for MD covered by Social Health Insurance amounted to 9.24 billion euro, which corresponded to a decrease of 2.13% compared to 2019. The reduction in expenditure was largely attributable to the COVID-19 pandemic. From 2016 till 2019, however, Social Health Insurance expenditure for listed MD had an average annual growth of 4%. The majority of Social Insurance expenditure for devices concerned MD used in the outpatient sector (7.37 billion euro, 80%); the respective funding shares for MD included in the LPPR remained rather stable among the sectors (outpatient and inpatient) since 2015 [22].

The pdf of the LPPR contains more than 1,000 pages; a searchable version is available at the website of the Social Health Insurance: http://www.codage.ext.cnamts.fr/codif/tips/index_presentation.php?p_site=AMELI. In 2020, four therapeutic areas were responsible for 56% of the Social Health Insurance expenditure for MD listed in the LPPR: pneumology and otolaryngology, orthopaedics, diabetes and cardio-vascular system [23].

The LPPR indicates the reimbursement tariff and the maximum retail price for the listed MD. MD are included in the LPPR for a maximum period of five years; renewals can be requested [19]. Generic lines must be re-evaluated every ten years. The LPPR also indicates the services associated with the products (e.g. a follow-up visit after the implantation of an insulin pump, a 7-day technical call for sleep apnea machines, etc.). The proposed tariff takes such services into account and therefore remunerates the health care professional who carries them out.

Remuneration of medical procedures

As another route of public funding, a health professional is remunerated for performing procedures in which a MD or, more frequently, an IVD is used for the purposes of diagnosis, prevention, treatment or rehabilitation. There are three relevant schemes:

» Classification Commune des Actes Médicaux (CCAM): list of medical procedures that a doctor undertakes for the purposes of diagnosis, prevention, treatment or rehabilitation,
» Codage des Actes Biologiques (NABM): list of procedures in which biologicals are involved,

» Nomenclature générale des actes professionnels (NGAP): list of clinical procedures for different health professionals (e.g. nursing, kinesiotherapists, etc.).

A procedure may relate to the use of a MD or an IVD on a single patient or more patients. Some procedures are funded by the Social Health Insurance; for instance, some diagnostic tests are linked to medical procedures performed by a health professional.

HAS only becomes active at request of UNCAM, the Ministry of Solidarity and Health, health professional associations or patient associations. Since the supplier does not submit a dossier, the medical-technical evaluation of the procedure, which includes the MD or IVD), rather starts from the scratch, based on a few data provided in a template (according to the PICO scheme).

In case of a positive assessment by HAS, UNCAM negotiates with the respective associations of health professionals to set the remuneration tariff. The suppliers of MD or IVD are not involved in these negotiations. The price of the MD or IVD is included in the reimbursement tariff of the procedure in a generic way, since no assessments of the single product (e.g. test kit) are conducted. Depending on the target population (e.g. for screening approaches) and the type of MD, the legal framework provides for different routes of procurement of MD or IVD used in medical procedures (e.g. on GP level, via social health insurance, pharmacy, etc.). A key legal provision is a decree of the Ministry of Solidarity and Health that defines which tests can be performed outside of medical biological laboratory and by whom.

In cases when no remuneration scheme has been defined for a medical procedure that involves the application of a MD or IVD, CNEDiMTS becomes active and starts an assessment of both the procedure and the MD [19].

Patient co-payments

MD included in the LPPR are reimbursed by the Social Health Insurance on a product basis. In general, 60% of the tariff of reimbursable MD is covered, resulting in a co-payment of around 40%. In practice, the co-payment is covered by the complementary health insurance ("mutuelle") that most French people have. Should the price charged exceed the reimbursement price, then the increased co-payment is usually also covered by the "mutuelle" but this depends on the coverage paid by the patient.

Patients suffering from defined severe and chronic diseases (affections de longue durée / ALD) are exempt from co-payments when they use a MD related to these diseases [24].

For publicly funded medical procedures, the same co-payment rules apply as for MD (i.e. 60% of the tariff is covered by the Social Health Insurance, 40% by the "mutuelle", possibly higher co-payments in cases of higher prices than the tariff depending on the patient's coverage).

Innovation incentive: "Forfait innovation"

As a kind of an early access scheme, MD or procedures which are considered innovative can be temporarily funded by the Social Health Insurance through a dedicated exceptional pathway, which is called "forfait innovation" (innovation fee / innovation package). This additional procedure aims to facilitate access to innovation and also to encourage the performance of a clinical study to provide missing data, in line with the principle of "pay to see" (in contrast to "see to pay" [19]). The funding covers partial or total cost of the MD or procedure as well as the costs of additional data collection and is made conditional on the finalisation of the study. Suppliers can submit an application for the "forfait innovation" to HAS that will evaluate the dossier with regard to eligibility of the MD or procedure for the "forfait innovation".

In addition, HAS also offers Early Scientific Advice [19, 25, 26].

Reimbursement for medical devices in inpatient use

DRG-based funding: GHS

Most MD used in hospitals are integrated in the performance-based costing system (Tarification à l'activité / T2A): this means that MD are included in the lump sums for hospital services which are generated for reimbursement as part of the Diagnosis Related Groups (DRG, called Groups Homogènes de Séjours /GHS).

An HTA is performed for only few MD used in inpatient health care facilities. It is up to the Pharmaceutical Therapeutic Committee of the individual hospitals or groups of hospitals to decide which MD to use and procure.

For expensive MD the GHS remuneration may not be sufficient to cover the costs of the MD; therefore, an additional funding scheme was implemented, the so-called "liste en sus". It offers product-specific reimbursement. Furthermore, the "intra-DRG" positive list applies for high-risk MD.

Supplementary list: "liste en sus"

As for medicines, a "supplementary list" ("liste en sus") applies for defined MD that are funded by the Social Health Insurance outside the DRG system on an individual product basis. The rationale for the "liste en sus" is to support innovation, while acknowledging that some MD used in hospitals are rather expensive. As the "liste en sus" is aimed at innovative MD, it mainly concerns MD with an ASA I to III; in some cases MD awarded an ASA of IV might be eligible (it depends on the product used as a comparator). In practice, most MD have awarded an ASA V, but compared to products initially with ASA I to III they may still be eligible for funding.

To be included in the "liste en sus", eligible MD must also be included in Sections III or V of the reimbursement list LPPR (which correspond to the "liste en sus"; so eligible MD must be included in both lists – LPPR and "liste en sus". The decision of the Ministry of Solidarity and Health on whether to accept or reject inclusion of the MD into the "liste of sus" is based on an assessment

of CNEDiMTS, taking into account, among others, the SA and ASA as well as cost estimates of the respective MD and on a successful price negotiations with CEPS.

Positive list within the DRG system: "liste positive intra-GHS"

Given their high-risk profiles, some defined MD groups are subject to a medical-technical evaluation by the HAS Commission CNEDiMTS. Based on an enabling law of 2012, two decrees of 2016 defined nine groups for which suppliers can apply for the inclusion into an intra-DRG positive list upon a positive medical-technical evaluation of HAS (with a SA/SR considered to be sufficient). The nine categories are:

» intracranial stents used in angioplasty of atheromatous stenosis,
» conventional implantable cardiac defibrillators with endocavity leads (single, dual and triple chamber)
» implantable cardiac defibrillators without endocavity leads (single, dual and triple chamber)
» biological surgical heart valves
» implantable devices for the vaginal treatment of pelvic organ prolapse
» implantable devices for the vaginal treatment of urinary incontinence
» MD for the upper treatment of pelvic organ prolapse
» intracranial flow diverter stents
» thrombectomy devices [19].

In order to be included into the intra-DRG positive list and to be used in hospitals, the MD must meet at least one of three following requirements: proof of clinical efficacy, definition of particular technical specifications or demonstration of effectiveness compared to available therapeutic alternatives. The inclusion in this positive list is granted for a defined period and can be renewed. It may be subject to prescription and use rules or the performance of additional studies [19]. Included MD are funded via DRG, and the list rather serves safety considerations, as the list of categories includes MD with high risk. The assessment of HAS may result in limited use (e.g. definition of specific health professionals to apply the MD, or in specific settings). If the outcome of the HAS assessment is negative, use in hospitals is not allowed, and hospitals must not purchase them.

No patient co-payments

No patient co-payments are applied for MD used in hospitals.

3 Pricing

Pricing for medical devices in outpatient use

The reimbursement price and the maximum retail price of reimbursable MD (i.e. those included in the reimbursement list LPPR) are regulated. Free pricing applies for non-reimbursed MD; i.e. the supplier can set the price as its discretion. In addition, free pricing also applies for products used in medical procedures and those assigned to DRG.

MD whose expected value (SA) or rendered value (SR, in cases of renewals) HAS assessed to be sufficient are eligible for price negotiations between the Economic Committee for Health Care Products (CEPS) and the supplier. As described in chapter "Reimbursement", the HAS Commission CNEDiMTS conducts a medical-technical assessment and determines the expected (or rendered) value (SA / SR) and the expected (or rendered) added value (ASA / ASR). Additionally, CEESP, another HAS Commission, conducts a medical-economic evaluation of MD with high or moderate ASA / ASR rating and expected major impact on public funding.

In the price negotiations, CEPS considers various data: the added expected / rendered value (ASA / ASR), the prices of MD in other countries (external price referencing / EPR), budget impact, volume and sales forecasts as well as predictable target population. Since beginning of 2022, security of supply is also taken into consideration [5]. MD with an ASA / ASR of I – III may be granted a higher price than a comparator which may be a MD or a medicine (internal price referencing). Germany, Italy, Spain and United Kingdom are the four countries that are considered in the EPR which is applied as a supplementary pricing policy to inform the price negotiation. Prices in British pound are converted at the exchange rate at the time of the application of the EPR policy; price data are neither weighted by volume nor by economic data (such as purchasing power parities). Updates are possible at any time.

After successful price negotiations, the reimbursement price (Tarif de responsabilité / TR) covered by the Social Health Insurance as well as the maximum retail price are fixed [19], and the MD will be included in the reimbursement list LPPR. In practice, the reimbursement and price decisions are taken rather simultaneously (a product that is included in the reimbursement list needs to have a price) [16].

In case of unsuccessful conclusion of the price negotiation, the MD will not be included in the reimbursement list, and the supplier can freely set the price.

The reimbursement price and the maximum retail price of MD included through "generic description" into the reimbursement list are set for each MD category. These prices are applied for the respective MD in the LPPR without further price negotiations [19]. CEPS has been regularly lowering the price of "generic descriptions".

CEPS is also mandated to request discounts that the supplier has to grant to the Social Health Insurance to allow for inclusion of a MD in the LPPR. The discounts, determined in a managed-entry agreement, can be defined for an individual MD or for a group of MD in a therapeutic area [22]. Price-volume agreements are most frequently used; further common MEA are "discounts for the first unit" with a lower confidential net price compared to the list price (which is published and referred to by other countries) and "mutualised clauses", which activate payment of the discount if sales of a group of similar MD in a cluster exceed a defined threshold. In 2020, CEPS had MEA for 117 MD or MD lines (compared to 86 and 103 MD in 2018 and 2019), with 41 suppliers (27 and 34 in 2018 and 2019, respectively), resulting in a total of discounts worth 87.9 million euro (80.2 million euro and 76.7 million euro in 2018 and 2019) [22, 23]. In terms of value, in 2020, around one third of the MEA was obtained from "discounts for the first unit", amounting to

28.7 million euro in 2020, followed by the "mutualised clauses" (22.2 million euro) and price-volume agreements (22 million euro) [22].

For MD, the value-added tax (VAT) amounts to 20%, which equals the standard VAT rate. For some reimbursed MD that are used to treat handicaps a reduced VAT of 5.5% is applied [27].

The retail margin is determined as an outcome of the price negotiation which sets the reimbursement price and retail price. Any further distribution margins are freely set by the suppliers and distributors [5].

As explained in the chapter on "Reimbursement", the remuneration tariffs for the medical procedures (e.g. CCAM) are negotiated between the National Union of Health Insurance Funds (UNCAM) and the respective associations of health professionals. The negotiations are informed by an evaluation conducted by HAS at request of the Ministry of Solidarity and Health, the national health insurance (CNAMTS), professional organisations or patient associations [28].

Pricing for medical devices in inpatient use

Free pricing is, in principle, applied for medical devices in the hospital sector. Indirect price control applies due to procurement activities of hospitals and hospital groups. Some hospitals collaborate in the purchase of goods and services, including MD. For instance, an important pooled procurement initiative is the hospital group procurer "Réseau des Acheteurs Hospitaliers" (Resah), which involves more than 700 health care facilities in the public and non-for-profit sectors. Resah procures any goods and services for their hospitals, including MD [29].

Prices for MD included in the "liste en sus" are negotiated between CEPS and the supplier. Social Health Insurance will then fund the negotiated price. A VAT of 5.5% is applicable in Section III of the LPPR (VAT of 20% for MD in Section V).

Distribution margins for MD used in hospitals are not regulated and will be freely set by the suppliers and distributors. A VAT of 20% is applicable.

4 Developments

In recent years, there have been major developments regarding the regulatory framework for MD in EU Member States, including France, with the new European Regulation on Medical Devices (MDR) [7] and the Regulation on in vitro diagnostic medical devices (IVDR) and their implementation, such as the launch of the European Medical Devices Database (EUDAMED) to monitor the safety and performance of MD under the MDR and IVDR.

Apart from the year 2020, France has seen an increase in the Social Health Insurance expenditure for MD. The Ministry of Solidarity and Health mandated CEPS to negotiate a new Framework Agreement with the associations of MD manufacturers. The Framework Agreement is an instrument to define modalities of price regulation, including negotiations. The previous Framework Agreement, signed in 2011, had expired in 2014. Negotiations between CEPS and the MD industry, which is

represented by nearly 30 organisations, started in 2019 and were not finalised by the end of 2021 [22, 23].

At the end of 2021, a proposal was discussed in the French Parliament, which aims to extend the "liste en sus" (supplementary funding in hospitals beyond the DRG system) to all ASA IV (which provide little clinical improvement) even if the comparator has not been included in the "liste en sus".

Since 2022, security of supply has been considered as an additional criterion in the price negotiation [5].

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6 Glossary

Authority	Government entity responsible for designing the regulatory framework and implementing policies (e.g. ministry, public agency). In the European context the term "competent authority" is frequently used.
CE marking / CE marking of conformity	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the EU Regulation 2017/745 or EU Regulation 2017/746 and other applicable Union harmonisation legislation providing for its affixing.
Co-payment	Insured patient's contribution towards the cost of a medical service covered by the insurer. Can be expressed as a percentage of the total cost of the service (percentage co-payment), as a fixed amount (prescription fee) or a deductible.
Diagnosis related groups (DRG)	A classification system of hospital cases used to pay hospital services, regardless of the cost to the hospital to provide services. The system is based not on the severity of the disease but on the amount of resources consumed.
Ex-factory price (manufacturer price)	The price at the level of industry, charged by a manufacturer; official ex-factory prices can be lowered by discounts or other arrangements offered by manufacturers (actual price).
External price referencing (EPR)	The practice of using the price(s) of a medical device or medicine in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country. Synonym: International price comparison (IPR), External reference pricing (ERP)
Free pricing	Pricing policy, in which governments allow medical device companies to determine the price of the device they launch.
Funding	Funding is the act of providing resources to finance a good or commodity, a service, program, or project (in this case, a medical device).
Generic device group	Means a set of medical devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics.
Health technology assessment (HTA)	A multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.
Internal price referencing	The practice of using the price(s) of similar medical devices (same category) with other medical devices in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.
Margin	The percentage of the selling price that is profit.
Notified body	A conformity assessment body designated in accordance with EU Regulation 2017/745 or EU Regulation 2017/746.
Outpatient sector	The health care setting in which ambulatory services are provided, in contrast to the hospital (inpatient) sector.
Performance	The ability of a device to achieve its intended purpose as stated by the supplier (e.g. manufacturer).
Placing on the market	The first making available of a medical device, other than an investigational device, on the market.
Positive list	List of medicines or medical devices that may be prescribed at the expense of a third party payer. It is one form of a reimbursement list.
Price control (price regulation)	Action by a government authority to set the price of a medicine / medical device and/or indirectly influence it (e.g. through pricing policies) for different price types (e.g. ex-factory price, pharmacy retail price) and to monitor and review and eventually adapt it.

Price negotiation	A pricing procedure, in which prices of medical devices are discussed and agreed (e.g. between manufacturer and third party payer).
Pricing (price setting)	Act of setting the price of a medical device which is either taken by a medical device company (free pricing) or is the competence (responsibility) of a competent authority (price control).
Pricing policies	Regulations and actions taken by government authorities to set the price of a medical device as part of exercising price control. Strategies by private sector actors (e.g. medical technology industry and supply chain actors) to determine and set these prices are not subsumed under the term "policy".
Procurement	A process to purchase goods and services (e.g. medical devices) that involves many steps and many stakeholders based on national, or supranational, regulation, policies, structures and procedures.
Reimbursable medical device	Medical devices which are eligible for reimbursement. Expenditure of reimbursable medical devices may be fully covered by third party payers, or only partially (a specific percentage).
Reimbursement	Coverage of the expenditure by a third party payer (e.g. Social Health Insurance / National Health Service).
Reimbursement list	A list that contains medical devices with regard 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 outpatient sector (usually positive lists or negative lists) or the inpatient sector (typically called hospital pharmaceutical formulary), or both.
Reimbursement process	The reimbursement process is a decision-making process on the reimbursement status, reimbursement price, reimbursement rate of medical devices. It involves the preparatory assessment and appraisal of decision-making bodies and committees, the application process, the decision-making itself, the information process around the decision and the arbitration process after the decision. The outcome of the process is the decision whether or not the medical device will be included in reimbursement lists, and at which cost.
Tendering	Any formal and competitive procurement procedure through which tenders (offers) are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose tender / offer is the most advantageous.
Value-added tax	A sales tax on products collected in stages by enterprises.

Source: PPRI MD Glossary (in development)