Navigating the Maze – Market Access for Medical Devices: Planning Beyond Regulatory Approval

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In order to achieve successful market access, it is essential for medical device manufacturers to understand market dynamics, requirements, assessment criteria and most importantly, associated stakeholders.

However, in contrast to pharmaceutical market access where information, guidance and learned insights are often in the public domain, only seldom is public information or best practices available for medical devices. Additionally, market access requirements and processes for medical devices vary greatly from country to country. Examples are listed below.

Classification varies by country. In Brazil, medical devices are defined as Class I, II, III or IV, while in France, Italy and Germany medical devices are defined as Class I, IIa, IIb or III. Product types in each class include, for example:

- Class I: Stethoscopes, incision drapes, conductive gels
- Class IIa / II (Brazil): Cannula or insulin syringe, lancets, tracheal tubes
- Class IIb / III (Brazil): Intra-ocular lenses, surgical lasers
- Class II / IV (Brazil): Stents, pacemakers, defibrillators

Health economic evidence is valuable in all markets; however, cost savings are of highest importance in Brazil and increasingly across Italian regions, whereas cost effectiveness is of greatest importance in markets such as the United Kingdom (UK) and, increasingly, in France.

Health technology assessment (HTA) is a central, well-defined, formal process for medical devices in France and Germany, is regionalized across Italy with a few prominent regions having individual HTA bodies, and is still an emerging process in Brazil.

Introduction of novel, high cost devices into the market varies greatly. Germany, France and Italy have additional budgets and formal procedures, whereas Brazil does not have any specific procedures under the Sistema Único de Saúde (SUS), Brazil's publicly funded healthcare system. Private systems are usually the early adopters of new technologies but often serve a smaller segment of the market catering to high income individuals. Private (out-of-pocket) healthcare - and therefore access to medical devices - is very common in Brazil; however, it is of moderate value across other markets. *(Note: discussion excludes specific targeting of Brazilian private market.)*

As a result of these country-specific intricacies, stakeholders and evidence requirements for medical device market access are difficult to identify. Medical device companies must carry out meticulous country-by-country analyses to obtain a thorough understanding of which evidence drives value and what requirements and processes must be met to launch a particular medical device. There is limited transferability of learning from one device launch to another due to rapidly changing evidence requirements, different classifications, and ever-growing stakeholder communities; this challenges product teams and leads to the collection of new, device-specific information for each launch.

First step into the maze – understand the differences and their origins

Planning for a medical device launch starts with understanding the most fundamental conditions of accessing a market, including procedures, stakeholders, and requirements. It is also essential to be aware of any recent or anticipated changes to the market access environment.

To allow efficient global launch planning for medical devices, markets can be clustered according to access conditions. All clusters assume technical controls and regulatory assessments as needed.

Cluster 1: Market success depends on strength and reach of marketing

Launch planning: Driven by marketing groundwork, including messaging, coalition with end-target users, and price sensitivity

Launch targets: Users (physicians or patients), purchasers (hospitals, physicians, nurses, wholesalers or/ and pharmacists), and/or recipients (patients or family members of patients), depending on the device

Price: Defined by market demand, price of comparator products and discounts, available technology, and improvements in overall benefits

Coverage: Largely out of pocket or copayments

Requirements of manufacturer's local team: Knowledge of demand, target size, messaging and sales force needs

Example markets: China, India, select markets in South America and the Middle East

Cluster 2: Market success depends on meeting pricing and reimbursement requirements and marketing

Launch planning: Needs to meet local reimbursement conditions (e.g., medical devices of a particular class can/ cannot be reimbursed) and price assessment or maximum price fix; price and reimbursement opportunities are driven by marketing and similar marketing planning as in Cluster 1 applies

Launch targets: All of Cluster 1 audiences, plus government, semi-government, or private agencies that regulate reimbursement or price, often associated with purchasing

Price: Price must balance the affordability versus the innovation premium; generic devices need to consider the price of comparator products

Coverage: In some markets, all eligible medical devices are covered independent of class; in other markets, coverage is only for Class I-IIb devices; significant out-of-pocket or copayments

Requirements of manufacturer's local team: Expertise in reimbursement, price negotiations, and local requirements. Knowledge of demand, target size, messaging, and sales force needs

Example markets: Russia, Brazil, select Central Eastern European markets

Cluster 3: Market success depends on demonstrating value

Launch planning: Needs to be based on providing scientific evidence which demonstrates the value of the medical device to patients, caregivers, and the health system (or innovation in some markets); requires knowledge on what type of evidence is recognized in different markets as valid for value demonstration; penetration of the market requires detailed marketing planning as in Clusters 1 and 2

Launch targets: All of Cluster 1 audiences, plus government, semi-government or private agencies that conduct value assessments; important launch targets are national, regional, or budget holders and purchasing groups

Price: Pricing depends on level of demonstrated value (level of innovation in some markets), comparator products price, and either mandatory or negotiated discounts

Coverage: Depends on co-pay regulations per market and prescription requirements (e.g., copayments are more common across France and Italy than in Germany, especially true for devices of Class I to IIa

Requirements of manufacturer's local team: Expertise in scientific and health economic value demonstration, knowledge of reimbursement and price negotiations and local requirements; knowledge of demand, target size, messaging, sales force needs, purchasing requirements, and fund holding

Example markets: European Union (EU), United States (U.S.), Canada and Australia

The prescriptiveness of clusters and the factor of time

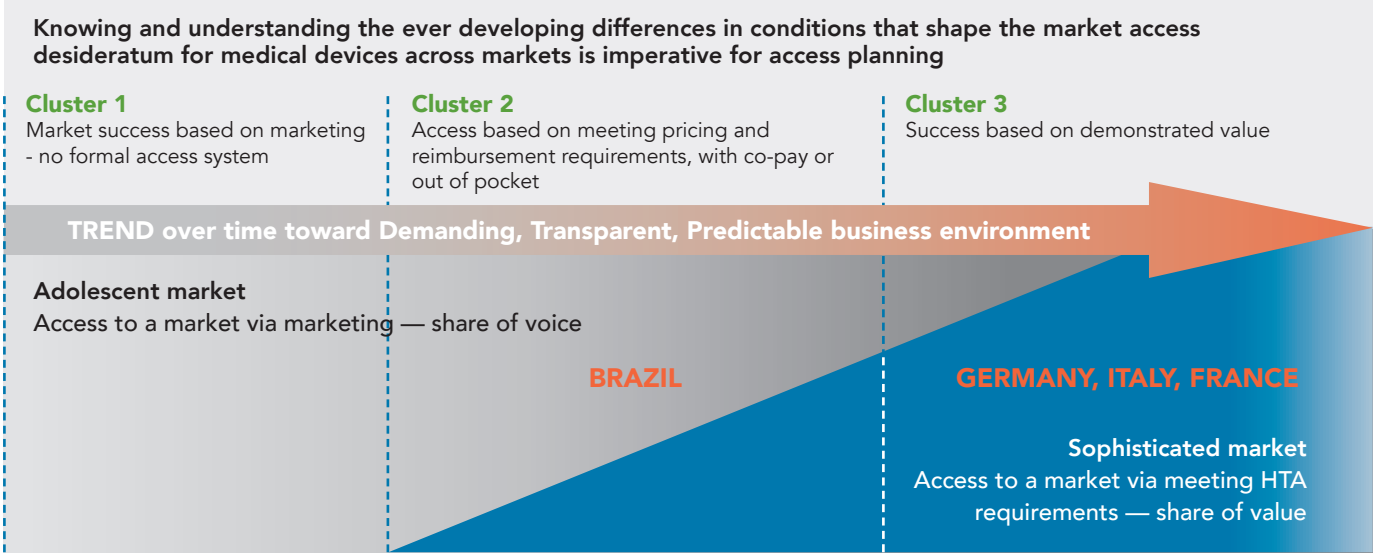
The use of clusters allows for recognition of the basic information and formulation of a plan, including anticipated timing of execution and planning of resources. It is important to obtain this information early in the planning phase in order to calculate the benefits/ risks of different routes and allow for any missing information to be obtained.

However, country access systems for medical devices develop fast. The natural progression is for markets to transition from Cluster 1 to Cluster 2 and 3, while markets rarely shift in the opposite direction. Therefore, over time, markets are likely to increase their demands, requirements for access, and number of stakeholders involved. As a result, more health technology skills in medical device companies are required. Clustering allows the monitoring of requirements by market attributes and can help to anticipate future changes to requirements, although country-specific differences should also be considered.

Limitations of clustering and transparency

Most of the critical requirements for medical device market access planning for Clusters 2 and 3 are not well

Figure 1: Model for Medical Device Market Access



published or promoted by the relevant organizations. This contrasts to the pharmaceutical access pathways, where processes, timelines, data requirements, and evidence needs are well communicated and stakeholders are generally easier to identify.

Therefore, clustering is only a first step in creating transparency. Appropriate launch planning requires additional details to allow for a full assessment of preparation needs, investment, risks, and benefits. The critical differences between markets that were described earlier often only transpire when individual markets are investigated in depth.

Start with the End in Mind

To allow for launch opportunity assessment, an early comparative definition of value and opportunity needs to be conducted as outlined below.

1. A ***value repository*** adapted to the device class and market requirements

- Technical profile of the device and its value proposition, as well as identification of competitors and their value propositions
- Summary of market access environment, including: a) Current funding and coding; b) Expected changes and challenges; and c) Price of current products (if applicable)
- Map assessment process in a specific market and associated timelines

2. ***Stakeholder mapping*** identifying level of relevance and importance for the market access of the device (adapted to the device)

- Consider stakeholders: Market access assessment, budget decision makers, purchasers, and users
- Per SWOT (strengths, weaknesses, opportunities, threats) assessment, identify the stakeholder action points needed to ensure that the market access process is well supported and accompanied by the appropriate communication of evidence for each audience

3. An ***environment compendium*** allowing for the assessment of risks and identification of ways to manage risks. Components of the compendium should be adapted to the device, and include the following basic parameters - across device classes – to be investigated for a) timelines; b) processes; and c) strategic imperatives:

- Purchasing and distribution pathways
- Funding and budget holding
- Pricing, copays, and discounting
- National/regional renegotiation of price

4. ***Prospective influences*** that potentially offset additional planning imperatives, adapted to the device (the list below is non-exhaustive):

- External business environment: competitor developments and their potential positioning and request for funding; changes in copayments or fees for service/use; new stakeholders and evidence requirements; new pathways to integrate medical devices in health service delivery (including push for homecare)
- Internal business capability: organization of responses to address new evidence needs

Table 1 highlights selected country-specific market access information that is important for launch opportunity planning and market access preparation of a device in Cluster 2 and 3 markets.

Table 1: Cross-Country Comparison of the Key Elements of Market Access for Medical Devices Based on Information Obtained in 2014 and 2015

	Context	FRANCE	GERMANY	ITALY	BRAZIL
Health system	• More than 70% expenditure on devices comes from public health system in the EU • Variations in Brazil	• National social insurance • Over 90% population covered under compulsory, additional, complimentary health insurance called mutuelles[1,2]	• Statutory health insurance (Approx. 77% of healthcare spending is sourced from the public sector)[2] • Small percentage covered under private health insurance or competitive governmental schemes (only approx. 20%)	• Tax funded healthcare system. More than 75% of device expenditure covered by public healthcare system • The role of private health insurance is very limited; in 2009, it accounted for only 1% of total health spending[3] • Very fragmented, regionalized system; regions have their own HTA bodies (e.g., Lombardy, Vento); outcomes may differ by regions	• Statutory health insurance provided to all (150 million patients), a third of which (50 million patients) also pay for private health insurance[4]
Hospital payment system	• Heavy investments on medical devices are concentrated in the hospitals	• GHMs (Diagnosis Related Groups [DRG])[5] • GHS (DRG tariff)	• G-DRG[6]	• DRGs are nation-wide; however, regions can adapt tariffs and codes to some extent	• Public sector: Capital budget-national budget distributed amongst regional/municipal bodies[4] • Private sector: ANS (Agência Nacional de Saúde; CEPS: The Healthcare Products Pricing Committee) decides on annual budget
Mechanism to support innovative devices?	• Rather than routine HTA processes, additional routes are available for early access of innovative devices	• PSTIC (Programme de soutien aux techniques innovantes, coûteuses ou non)[7] • PHRC (Le programme hospitalier de recherche clinique)[7]	• NUB (for devices not included in G-DRG; hospital specific)[6] • ZE (zusatzentgelte; supplementary national payments)[6]	• Additional payments for high-cost, innovative devices are regionally controlled; when regions publish the updated DRG lists, there is a section which specifies the devices/ procedures for which an additional payment can be claimed.	• No specific mechanisms available to support innovative high-cost devices[4] • However, there is greater adaptability in the private sector as HMOs (health maintenance organizations) need to be competitive (i.e., private market mechanisms); greater resistance in public sector on new/ expensive device uptake
Classification system	• Devices are classified from a regulatory level into different grades based on level of risk and invasiveness	CE mark (Class I, IIa, IIb, III)[5]	CE mark (Class I, IIa, IIb, III)[5]	CE mark (Class I, IIa, IIb, III)[5]	ANVISA (Brazilian health Surveillance Agency) registration (Class I, II, III, IV)[8]
Process of assessment for low risk devices (Classes I-II)	• Not all devices are assessed by HTA bodies; generic and low-risk devices pass through simpler routes	• Class I devices • Generic medical devices and implants • Innovative Class I medical devices are usually assessed by doctors/ pharmacists within hospital committees (COMEDIMS -Comité des Médicaments et des Dispositifs Médicaux Stériles -)	• Not assessed by GBA (Der Gemeinsame Bundesausschuss) if new product has low innovation value (class independent) or if generic medical device/ implant – straight to SHI (statutory health insurance) for assessment	• Low-risk devices likely to be assessed by CPTOs(Commissione Prontuario Terapeutico Ospedaliero) • For generic devices i.e., devices for which a code already exists (usually the device is an improvement of another device that already exists and is used), it does not need to be assessed by an HTA agency; these devices can go straight to tender	• Public sector: CONITEC (Comissao Nacional de Incorporaca de Technologias) does not assess lower risk devices (i.e. Class I/II); however, some higher risk/more novel Class I/II devices may still be subject to assessment[4] • Private sector: mainly price orientated i.e., will assess lower risk/Class I and II devices based on comparative price.
Process of assessment for high risk devices (Classes II-III for EU and II-IV for Brazil)	• Devices are assessed by various HTA bodies only under given circumstances	Conducted in the following cases (mainly Class II-III):[4] • Lack of prior testing of innovative devices by CNEDiMTS (Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé) • Self-enrollment on an existing generic description by the manufacturer • Devices self-registered with ANSM (Agence Nationale de Sécurité du Médicament et des Produits de Santé) • Reassessment of generic descriptions at least every 5 years by CNEDiMTS	• If new product has high innovation value or there has been a lack of prior assessments of similar products in the past (mainly Class II-III)[4]	• No national level HTA body exists, national bodies have a role of consulting/supervising regional bodies[9] • Regional HTA bodies (e.g., Lombardy, Veneto) are responsible for conducting individual assessments • If a new code needs to be created (i.e., due to innovativeness of product) CPTOs*/ASLs (hospital committees/local health agencies) are responsible for assessing (mainly Class II-III)[9]	• Public sector: Higher risk devices (primarily Classes III and IV) are assessed by CONITEC[4] • Private sector: novel/high risk devices assessed by individual HMOs

	Context	FRANCE	GERMANY	ITALY	BRAZIL
Assessment bodies (HTA)	• Different bodies are involved in HTA assessment process of the devices	• HAS(Haute Autorité de santé)[4] • Clinical and technical evaluation body (CNEDiMTS) • Economic evaluation: CEPS and CEEPS (La Commission évaluation économique et de santé publique)	• IQWIG (Instituts für Qualität und Wirtschaftlichkeit im Gesundheitswesen) and GBA[4]	• The larger, more prominent regions have regional HTA agencies; e.g., Emilia Romagna (The Agenzia Sanitaria e Sociale Regionale; ASSR), and Lombardy (Direzione Generale Sanita • These bodies formulate decrees (mandatory) or recommendations (non-mandatory) for budget holders/local or hospital committees	• Public: CONITEC • Private: HMOs
Data requirements	• Data requirements are not that transparent for medical devices as they are for pharmaceuticals • Very basic guidance is provided by HTA bodies	• Technical description of technology[4] • Specification of use • Severity of targeted condition • Clinical evidence demonstrating effectiveness • Alternative option: medication or surgery • Population estimate: those who may use the technology • Health economic (HE) data is optional until budget is not more than 20 million Euros	• Lack of specific guidance[4] • Follows directive of pharmaceutical products	Technical, place in therapy, expected numbers of patients/procedures and 'healthcare professionals interested', economic analysis not formally required but may be considered • Physicians must submit the applications to the CPTOs (Commissione Prontuario Terapeutico Ospedaliero) (although they are likely to have been given the dossier/data by the manufacturer)	• Public (CONITEC): Technical, clinical, economic data; QoL data also considered; no QALY limits but there are standards and some HE evidence is expected[4] • Private: pharmacoeconomic data but less robust and rigid process; should also provide technical and clinical data also
Length of assessment	• Assessment period varies across different countries and sometimes may be much longer than given in the guidance	• Approx. 1 to1.5 years for new devices/ new GHM[4] • Approx. 6 months, if already exists in a GHM	• Approx. 3 to 6 months if assessed by SHI only/G-DRG code exists[4] • 1.5 to 3 years GBA/IQWiG	• 1 to 3 years (if have to codify new procedure)[4] • 6 months to 1 year if DRG already exists	• Public: 6 to 9 months[4] • Private: as little as 2 months
Final decision	• Final assessment decision may be made at the national/regional level	• Ministry of Health (MoH)/HAS are the final decision-makers • Decision published in Official Journal of the French Republic	• GBA responsible for final decision • Decision not officially published, manufacturer can decide to publish the outcome[4]	• Depending on the region, CPTOs, which are hospital drug committees, may be involved, however, because medical device costs fall under hospital budgets and the hospital is funded through DRG tariffs, the local committees can play a larger role in acquisition of devices. • Final decision highly guided by CPTOs/local committees	• Public: MoH/SUS • MoH has 180 days to publish a final reimbursement deliberation in the Official Gazette from the request date, which can be extended by up to 90 days.[10] • Private: ANS (Health insurer)
Budget holders	• Budget holders are responsible for final uptake of medical devices in hospitals	• Members of COMEDIMS • Members of mutuelles • Head of relevant department at university hospitals • Members of purchasing groups	• SHI, GKV (National Association of Statutory Health Insurance Funds) • Head of relevant department at university hospitals	• Regional budget holders • Local health units • Head of relevant department at hospitals	• Public: Government; Ministry of Health will decide who should pay for the device • E.g., very expensive novel technologies may be funded from the national budget, while all others will be funded by the State or Municipality budgets • Private: HMOs and private hospitals

	Context	FRANCE	GERMANY	ITALY	BRAZIL
Pricing (inpatient devices only)**	• Pricing covered by various bodies can be split into ambulatory and hospital sector	• CEPS and CEEPS allocate a national price for products on LPPR (Liste des produits et prestations remboursables) [4,5] • Hospital-only products are covered by GHM codes and if new code is to be created it is drafted by CCAM and price negotiated by UNCAM (Union Nationale des Caisses d'Assurance Maladie) • Tendering/negotiating with manufacturer for generic devices	• GKV[4] • Tendering/negotiating with manufacturer for generic devices	• Regional budget holders[4] • Tendering/negotiating with manufacturer for generic devices	• Government (MoH, states, municipalities depending on who pays for it)[4] • Tendering/negotiating with manufacturer for generic devices
Early scientific advice	• Similar to pharmaceutical sector, seeking early scientific advice is considered beneficial in countries where the possibility exists	Available	Available	Not available	Not available
Templates	• Guidance templates are provided by national and regional bodies for submitting the required information for HTA assessment	Yes for HAS, not COMEDIMS templates http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-03/guide_dm_gb_050310.pdf	No for GBA/IQWiG Yes for SHI http://www.gkv-spitzenverband.de/krankenversicherung/hilfsmittel/hilfsmittelverzeichnis/antragsverfahren/antragsverfahren.jsp	Yes http://www.sanita.regione.lombardia.it/cs/Satellite?c=Redazionale_P&childpagename=DG_Sanita%2FDetail&cid=1213334815354&pagename=DG_SANWrapper	Yes (guidance) http://portalsaude.saude.gov.br/index.php/o-ministerio/principal/leia-mais-o-ministerio/259-sctie-raiz/dgits-raiz/conitec/l2-conitec/8995-orientacoes-para-preparar-a-proposta
Stakeholders	• Highly influential stakeholders in decision making (i.e., scored 5 and 4)[4]	• National/regional procurement groups • National and regional budget holders, MoH (DGS and DSS), ambulatory physicians, nurses, policy makers	• National/regional procurement groups, alliance between manufacturer and budget holders, SHI • MoH (DGS and DSS), IQWiG, manufacturer*, national and regional budget holders, policy makers	• Medical societies and physicians – main players (company works behind the scenes), HTA bodies (only in regions where these exist), university hospitals (best relationships with agencies), regional budget holders (very important)	• Public: HTA (CONITEC), government departments (SUS, States, municipalities) • Private; HMOs and hospitals
	• Less influential stakeholders in decision making (i.e., scored 1-3)[4]	• Academicians, pharmacists, manufacturers, health economists • Hospital physicians (of less importance as the overall COMEDIMS overrules individual physicians) • Medical societies, patient organizations (indication dependent)	• Academicians, pharmacists, manufacturers, health economists • Hospital and ambulatory physicians • Medical societies, patient organizations (indication dependent)	• Ambulatory physicians • Medical device budget holders • Pharmacists and nurses • Health economists (although gaining influence)	• Physicians in hospital, ambulatory physicians, patients, nurses, and health economists • Pharmacists • Purchasing groups or national/regional procurement

Benefits	• Advantages of the current procedures for the device manufacturers	• Predefined procedures laying out steps for market access[4]
		• Well defined and organised bodies, each with specific tasks
		  • CNEDIMTS - responsible for overall evaluation
		  • CEESP - committee in charge of producing medico-economic assessments
		  • CEPS - responsible for fixing prices of devices
			• No pricing threshold. Reimbursement guaranteed as long as additional benefit can be clearly demonstrated. In addition, cost-effectiveness always a benefit[4]	• Independent regional decisions could ensure entry to at least some of the markets	**Public and Private:**
					• If you can demonstrate that the product is clinically and economically effective, chances of successful reimbursement are high.
					• Prices for medical devices are not controlled

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Challenges	• Challenges of the current procedures for the device manufacturers[4]	• Assessment of combination of medical devices and drugs • Lack of registries and outcomes data for comparison • Linking the benefits as provided by the manufacturer to real-world evidence • Lack of pricing information across EU • Lack of review of generic lines of devices	• A very complex system; no transparency; administrative barriers, mistakes in filing can lead to considerable delays	• Limited economic resources (even more so than rest of Europe) • Regional variability • Almost best if you have competitors already in market so the pathway already exists and is a lot more straightforward than obtaining novel code • Companies should have regional strategies • Different template/application for each region	**Public:** • Production of robust clinical and economic evidence; a good economic analysis needs local data whereas clinical data does not need to be local and foreign studies in reliable centers anywhere in the world are acceptable. • Pharmacoeconomic evaluation is very new in Brazil so local data is scarce. • Public health system is very ambitious; budget constraints are very important. **Private:** • Access to private market is limited to regions with more money (i.e., Sao Paulo)
Trends	• Consolidation trends currently in place for the medical device industry across various markets	• CNEDIMTs - a strong member of the European Network for Health Technology Assessment (EUneHTA), shaping early dialogues • Broadening the definition of combined drugs • Increase in home care devices as elderly patients seek greater autonomy	• No major changes expected in HTA processes in the foreseeable future. • HTA procedures and requirements are expected to get even stricter in the future. The additional benefit offered by the new device will be questioned in more depth, making it more difficult to get reimbursement for me-too devices that are more expensive than the standard of care. • However, innovation will remain of paramount importance	• Increasingly frequent grouping of hospitals which results in greater procurement power and control	• Private segment will grow substantially – the population obtaining private insurance is growing, and with this the level of investment and access to new technologies will also increase • CONITEC will introduce more medical devices for coverage; however, they will likely train medical societies and nurses to develop a network which will contribute to the decision-making process • Continued investment in local production; incentives for Brazilian companies to produce locally • Robustness of technology evaluation will increase in private sector • Increased patient power/ importance of patient organizations

**The manufacturer can contact the SHI (usually via consulting agencies) at the very beginning of the process to inform them of the upcoming submission and try to make them curious. This might lead to collaboration between the manufacturer and the budget holders with the aim to save costs and speed up the process (e.g., manufacturer can get consultation and even help with planning and conducting the trials). An alliance between the manufacturer and budget holder is very influential.*

***Pricing processes for ambulatory devices were not discussed specifically with interviewees.*

How to arrive on the other side of the maze: recommendations

- Know the access systems and decision makers for medical devices well
- Define your key strategic value substantiation objectives at product investigation stage to meet HTA requirements or marketing needs
- Start planning early for stakeholder engagement for marketing and HTA activities, and use the support of early advice where appropriate
- Focus on the end user, while not losing sight of the buyer
- Value proposition is a function of having a clear understanding per market on how to meet requirements, communicating the need, and creating a win-win situation for both buyer and seller

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