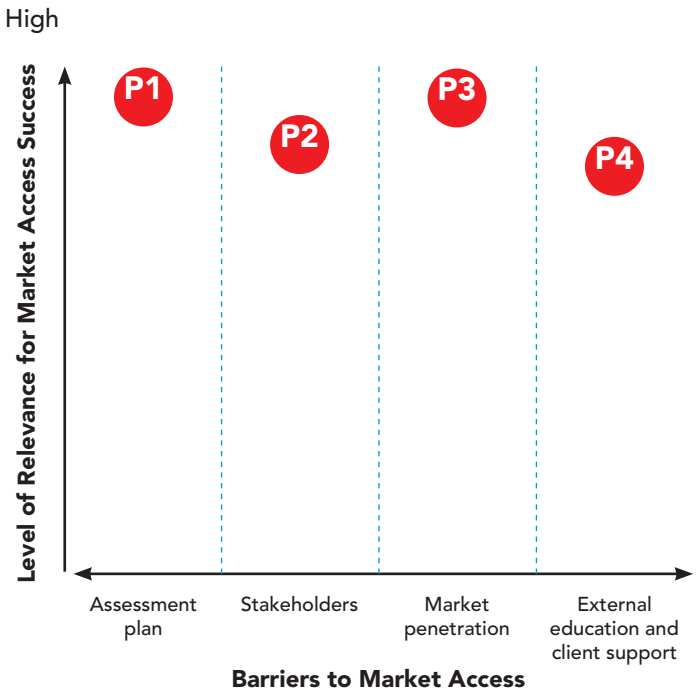
Evidera
Evidence, Value & Access by PPD

Navigating the Maze – Market Access for Medical Devices FRANCE

ACCESS OF MEDICAL DEVICES – UNDERSTAND AND IDENTIFY OPPORTUNITIES

Building on the clustering approach and identification of market specifics, several key activity areas are relevant in a centralized market access market such as France. The ability to adapt the marketing strategy in line with the expectations of the reimbursement assessment criteria is the key to success in France.

The Four Items Shaping Medical Device Market Access in France



P = Action Point

Potential Medical Device Solutions for France

P1 Meeting HTA criteria with a value proposition that is relevant in France

- Assessment criteria driven by relevance and validity of evidence and public health relevance
- Health economic evidence becoming increasingly important

P2 Identifying stakeholders – device type to guide stakeholder access

- Member of COMEDIMS, Mutuelles, purchasing groups (e.g., AP-HP), and KOLs important for innovative devices
- For smaller/non-innovative devices, targeting local hospitals and KOLs is of greater benefit and considered out-of-pocket

P3 Market penetration – contracting and rebates

- Payers manage medical device market access, initiating early discussions is recommended
- Depending on list type - LPPR or DRG rebates could be devised
- Contracts with private insurance companies could be discussed to improve market penetration

P4 External education and client support

- Determine relevance of scientific publications to support public health need and how disease burden will be addressed

COMEDIMS – Comités des Médicaments et des Dispositifs Médicaux Stériles
AP-HP – Assistance Publique, Hôspitaux de Paris
LPPR – List of products and services qualifying for reimbursement
DRG – Disease Related Group

CLUSTERS CONCEPT

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

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

Cluster 3: Market success depends on demonstrating value

Table 1 below demonstrates the contents of each barrier specific to the French market.

Table 1: Key Elements of Market Access for Medical Devices in France

	Context	France
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]
Hospital payment system	• Heavy investments on medical devices are concentrated in the hospitals	• GHMs (DRG groups)[3] • GHS (DRG tariff)
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)[4] • PHRC (Le programme hospitalier de recherche clinique)[7]
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)[3]
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)
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)[5] • Lack of prior testing of innovative devices by CNEDiMTS • Self- enrollment on an existing generic description by the manufacturer • Devices self-registered with ANSM • Reassessment of generic descriptions at least every 5 years by CNEDiMTS (Commission Nationale d'Evalutation des Dispositifs Médicaux et des Technologies de Santé)
Assessment bodies (HTA)	• Different bodies are involved in HTA assessment process of the devices	• HAS (Haute Autorité de Santé)[5] • Clinical and technical evaluation body (CNEDiMTS) • Economic evaluation: CEPS (Comité Economique Des produits de Santé) and CEESP (La Commission Evaluation Economique et de Santé Publique)

	Context	France
Data requirements	• Data requirements are not as transparent for medical devices as they are for pharmaceuticals • Very basic guidance is provided by HTA bodies	• Technical description of technology[5] • 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 data is optional until budget is not more than 20 million euros
Length of assessment	• Assessment periods vary across different countries and sometimes may be much longer than given in the guidance	• Approx. 1 to 1.5 years for new devices/new GHM[5] • Approx. 6 months if already exists in a GHM
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
Budget holders	• Budget holders are responsible for final uptake of medical devices in hospitals	• Members of COMEDIMS • Members of mutuelles[6] • Head of relevant department at university hospitals • Members of purchasing groups
Pricing (inpatient devices only)**	• Pricing covered by various bodies can be split into ambulatory and hospital sector	• CEPS and CEESP allocates a national price for products on LPPR[3,5] • 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 • 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
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
Stakeholders	• Highly influential stakeholders in decision-making (i.e., scored 5 and 4)[5]	• National/regional procurement groups • National and regional budget holders, MoH (DGS and DSS), ambulatory physicians, nurses, policy makers
	• Less influential stakeholders in decision making (i.e., scored 1-3)[5]	• Academicians, pharmacist, manufacturer, health economist • Hospital physicians (of less importance as the overall COMEDIMS overrules individual physicians) • Medical societies, patient organisations (indication dependent)

	Context	France
Benefits	• Advantages of the current procedures for the device manufacturers	• Predefined procedures laying out steps for market access[4] • Well defined and organized bodies, each with specific tasks o CNEDiMTS - responsible for overall evaluation o CEESP - committee in charge of producing medico-economic assessments o CEPS - responsible for fixing prices of devices
Challenges	• Challenges of the current procedures for the device manufacturers[5]	• Assessment of combination of medical devices and drugs • Lack of registries and outcomes data for comparison • Linking the benefits as provided by manufacturer to real-world evidence • Lack of pricing information across EU • Lack of review of generic lines of devices
Trends	• Consolidation trends currently in place for the medical device industry across various markets[5]	• CNEDiMTs - a strong member of EUneHTA, shaping early dialogues • Broadening the definition of combined drugs • Increase in home care devices as elderly patients seeking greater autonomy

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

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[3] Haute Autorité de Santé. Medical Device Assessment in France, Guidebook. 2009. Available at: http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-03/guide_dm_gb_050310.pdf. Accessed September 23, 2015.

[4] Busse R, Geissler A, Quentin W, Wiley M. ***Diagnosis-related Groups in Europe: Moving Towards Transparency, Efficiency, and Quality in Hospitals***. Maidenhead, England: Open University Press; 2011.

[5] Information Collected from a Total of 6-8 Payer Interviews done by Evidera; 1-2 in Brazil, 2-3 in France, 2-3 in Germany and 1-2 Italy.

[6] Franc C, Pierre A. Compulsory Private Complementary Health Insurance Offered by Employers in France: Implications and Current Debate. ***Health Policy***. 2015; 119(20):111-116.