

CACTUS[®]

USA | Japan | India | South Korea | China

MARKET ACCESS FOR MEDICAL DEVICES: CHALLENGES AND POTENTIAL SOLUTIONS

2016

WHITE PAPER
KAVITA LAMROR, MBBS, MPH



INTRODUCTION

According to the World Health Organization (WHO) definition, a medical device is “an article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose.”¹ Medical devices range from simple tongue depressors to complex programmable pacemakers and computed tomography scanners.

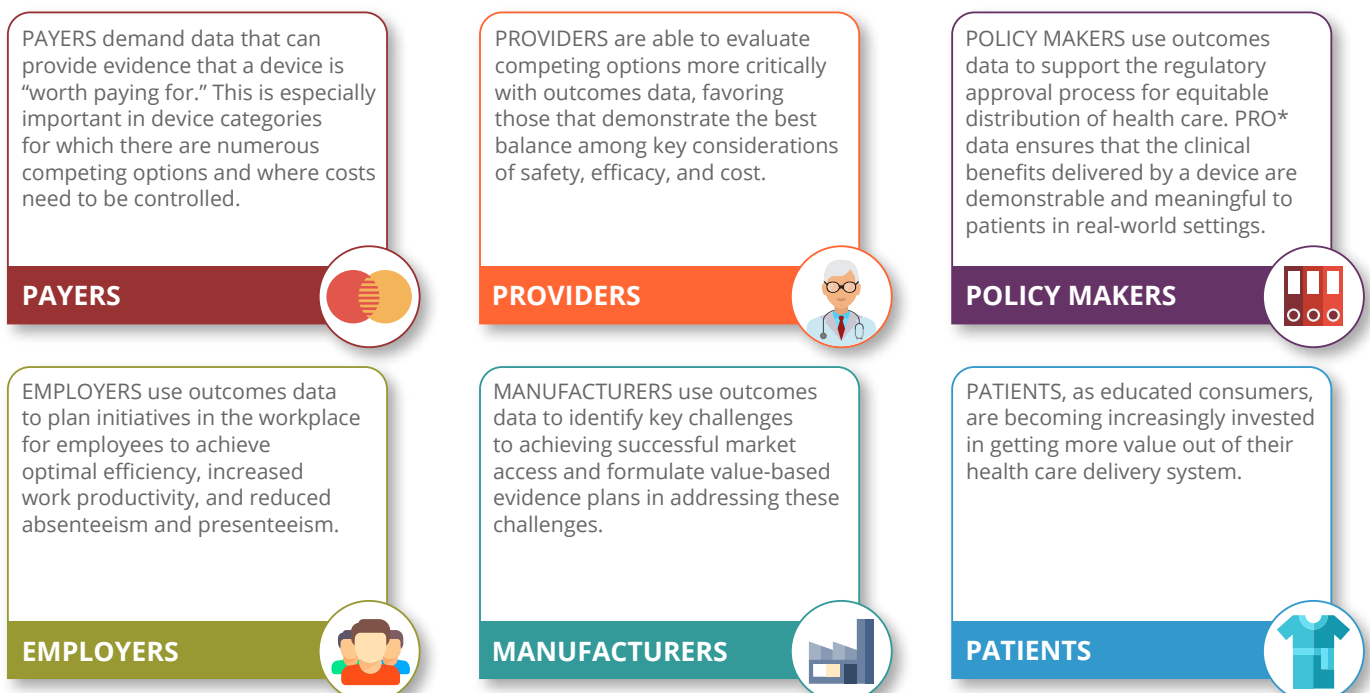
Devices play an important role in modern health care. Although cutting-edge medical devices are often seen as significant cost drivers for hospitals operating within limited budgets, these devices may offer considerable long-term cost savings, improve patient outcomes, and create more efficient and effective health practices.³ They can promote less invasive procedures, reduce patient recovery time, shorten the length of hospital stays, and enhance health system sustainability.

Table 1. US & EU device classifications²

Classification	Type of Device
Class I	<ul style="list-style-type: none"> • Generally regarded as low-risk • Self-certify to general safety standards
Class II (US), and Class IIa and IIb (EU)	<ul style="list-style-type: none"> • Generally regarded as medium-risk • General standards, special controls, quality systems
Class III	<ul style="list-style-type: none"> • Generally regarded as high-risk • Require pre-market review, including bench testing, animal studies, and clinical trials providing proof of safety and effectiveness

The last decade has seen unprecedented growth in innovative and improved technologies, which has led to the development of state-of-the-art medical devices and catalyzed growth and advancement in the health care industry. The world market for medical devices reached \$381 billion in 2015.⁴ The traditional value chain for the medical device industry, which historically has been driven by innovation and research and development (R&D), is undergoing a paradigm shift. Medical device companies have been focusing more on creating value for payers, practitioners, providers, and patients not only by providing innovative, quality products but also by considering cost efficiency.⁵ It is a question of determining the value of and economic justification for a given device and not simply how much payers are willing to pay for it.

Figure 1. Customized value messages



*PRO: Patient-reported outcomes

DIFFERENCES BETWEEN MEDICAL DEVICES AND PHARMACEUTICALS

Health care products and services represent an ever-increasing share of global output. This has caused governments and payers to examine critically the value they receive from products and services

purchased.⁵ While pharmaceutical companies have been under scrutiny for well over a decade, this is a more recent phenomenon in the medical device industry, which represents a smaller share of health care spend and has far fewer blockbuster products compared to pharmaceuticals.⁶ Some key differences between medical devices and pharmaceutical drugs are highlighted in the table below.

Table 2. Key differences between medical devices and pharmaceuticals⁷⁻¹⁰

Feature	Devices	Pharmaceuticals
Concept to commercialization	Average 3–5 years.	Average 8–10 years.
Development milestones	Product development in medical devices is focused on milestones such as prototype development, design validation, and manufacturing scale-up.	Drug development is focused on health care milestones such as clinical indications and reimbursement.
Nature of product	Medical devices are typically based on mechanical, electrical, information technology, and systems engineering, and stem from ideas typically generated in a clinician's practice.	Pharmaceuticals are based on chemistry, biotechnology, and genetics, originating in an R&D laboratory.
Patent coverage	Multiple fields of art contribute to the development of a medical device as compared to a pharmaceutical drug. Medical device patents are typically directed to the structure, function, and methods of using the device. As a result, many more patents are used to cover a medical device than a pharmaceutical.	Since there are a finite number of molecules that may be used to elicit a desired biological response and clinical outcome, a single patent covering the class of molecules that comprise the pharmaceutical product is sufficient.
Patent types	The ultimate effectiveness and benefit of a medical device is dependent in part on the skill of the clinician using or implanting the device. In this regard, medical device patents may cover method of implant, installation, surgical navigation, placement, adjustment, calibration, and adaptation to particular patients. Specifically, medical device patents may also have method claims such as method of manufacturing, implanting, operating and initiating.	Most pharmaceutical products are either ingested or introduced into the body directly and therefore constitute therapies themselves. Accordingly, with very few exceptions, pharmaceutical patents do not have method claims regarding delivery mechanisms. Further, pharmaceutical product patents are usually directed to the structure of the molecules themselves or methods of manufacturing or purifying that compound.

Feature	Devices	Pharmaceuticals
Alternate designs	<p>“Design-arounds” are common for medical devices.</p> <p>The prevalence of alternate medical device designs typically precludes an exclusive position in the marketplace.</p>	<p>Pharmaceutical products generally do not lend themselves to “design-around” efforts and do not require several patents covering variations or alternate designs.</p> <p>Once a key pharmaceutical patent has expired, it will be possible for other manufacturers to make “generic” versions of the same pharmaceutical.</p>
Improvements and product life cycle	<p>As new technologies continue to develop, each field of art may implement these new technologies, which make frequent iterative improvements possible.</p> <p>As a result, medical devices have a short commercial life cycle, typically 18–24 months.</p> <p>Each new component or improvement (with the new technology implemented in the product) may be individually patentable.</p>	<p>Pharmaceuticals typically have a long commercial life cycle (10 to 20+ years), during which they do not undergo significant changes.</p>
Number of patents	<p>A single medical device may be covered by hundreds of patents.</p>	<p>A single drug can have a maximum of 2 patents.</p>

MARKET ACCESS FOR MEDICAL DEVICES

Market access assists the right patients to get timely and easy access to a medical device at an affordable price. Availability, accessibility, affordability, adoption (by health care professionals and patients), and willingness to pay (reimbursement) should be achieved while ensuring equity and quality at each level. Quality is defined here as compliance with international, regional, and national standards.⁵ Equitable access refers to the imperative to ensure access according to needs.⁵

In the medical device arena, where new technologies and products are developed at a rapid pace and gain regulatory clearance relatively quickly compared to pharmaceuticals, it is crucial that proper forethought is given to a strategy that addresses the real concerns of relevant stakeholders on the path to

getting products and services adopted.⁶ It requires a combined regulatory, reimbursement, and market access strategy and early engagement with payers and regulators throughout the product development phase.

CHALLENGES TO SUCCESSFUL MARKET ACCESS

Industry forces (e.g., patent expirations and achieving return on investment in high-growth therapy areas) and politico-economic forces (e.g., payers rewarding only true innovation and continuous health care reform) pressure the medical device industry in unprecedented ways.¹¹

Multiple challenges and inefficiencies in health care systems and uncertainty for manufacturers lead to unnecessary delays in access to innovative technologies, slow adoption of new and effective

technologies, and inequalities in guaranteeing that patients receive the most effective and efficient treatment.⁷

Figure 2. Challenges to successful market access



Creation of value: Principal concerns of market access during the development and commercialization processes are creation, substantiation, and communication of value to stakeholders via health technology assessment (HTA), health economics and outcomes research, pricing and reimbursement, clinical trials, and patient registries, both in the pre- and post-launch periods.

Varied decision-making criteria: Some reimbursement decisions are based on cost-utility analysis by estimating the cost of interventions vis-à-vis the obtained health benefit (e.g., quality-adjusted life-year). Some countries, such as France and Germany, account for clinical added value, followed by “value for money” pricing debates. The lack of clear definition of “value” prompts reimbursement and funding decision makers to prioritize cost-based pricing over value-based pricing.¹²

Technological evolution: Technological research exceeds the pace at which regulations are updated. New products that fulfill unmet needs are being developed, and existing products are regularly optimized and improved.⁵

Resources: Payer systems and governments have been expressing increased concern over the rising cost of health care and the financial sustainability of health care systems and call for more effective and strategic public spending on health. However, this has raised concerns that even in strong, comprehensive health systems, austerity measures and cuts in public spending may endanger people’s access to health care and medicines. The economic crisis might be used as an excuse for drastic rationing and reductions in resources for health.⁵ Occasionally, calls for effectiveness may be misinterpreted to mean budget cuts.

Stakeholder engagement: A high level of engagement from payers, physicians, and industry has not been seen with medical devices because of the faster market entry for new products and the fragmented and often-evolving market access pathways, which can have a detrimental effect on commercial success.¹³

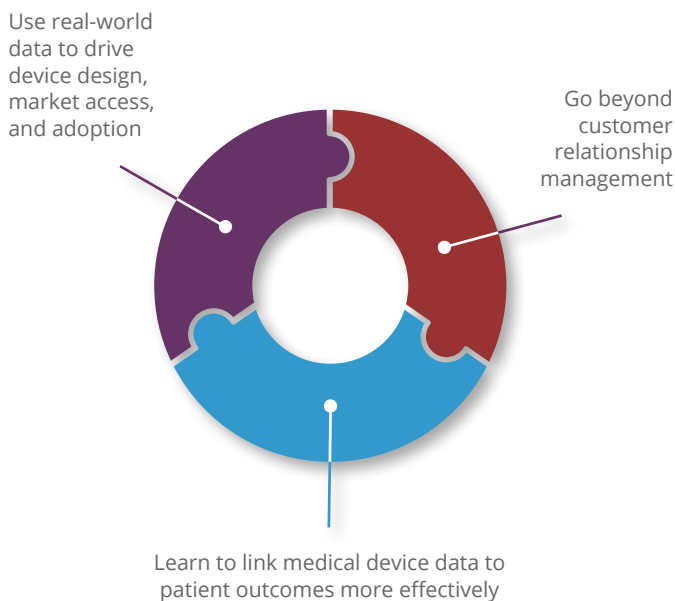
Lack of evidence: Most evidence for the economic value of medical devices is anecdotal.¹⁴ Medical device industries are in need of consultative partnerships with health professionals in clinical practice.

Communication of value: Early adoption of a product depends largely on a manufacturer’s ability to increase physicians’ and patients’ uptake and to generate timely post-marketing real-life data customized for each stakeholder’s requirement and expectation.¹²

WAY FORWARD

Medical device manufacturers should envision a triple aim of improving patient experience, improving population health, and reducing the cost of care.³ The role of hospital value analysis committees and purchase of devices is based on clinical efficacy, product evaluation, and financial impact should be clearly understood.⁵

Figure 3. Crucial steps to better decisions and outcomes



Successful market access depends on the capacity of the buyer to understand and properly evaluate, firstly, the “cost” vs “value” of a medical technology, especially in the long term and, secondly, the short-term fiscal challenge and constraints faced by every institution in the health care system.³ In the light of increasing budgetary constraints and high out-of-pocket expenses of patients, HTA becomes one of the prominent tools obligatory for a transparent, non-biased basis for decisions on the uptake of a medical device.¹³ HTA platforms evaluate the costs, effectiveness, and broader impact of health care solutions for those who plan, provide, or receive care, taking into account clinical, social, humanistic, economic, legal, and ethical issues.

Device manufacturers understand the growing need for evidence generation and communication of value, beyond the traditional approach of stakeholder relationship management, as critical elements of successful market access.¹²

A robust market access strategy has multiple components that focus on obtaining adequate and sustainable reimbursement prior to launching a new technology.

HTA processes: HTA is a decision-making strategy that compares the effectiveness and cost of a new

technology with competing existing technologies. The ultimate goal of HTA is to provide policy recommendations relevant to a new technology’s potential for safety, efficacy, health innovation, and return on investment.¹⁵ HTA groups can support medical device innovation in several key capacities and guide device manufacturers regarding timely generation of outcomes data.¹⁶

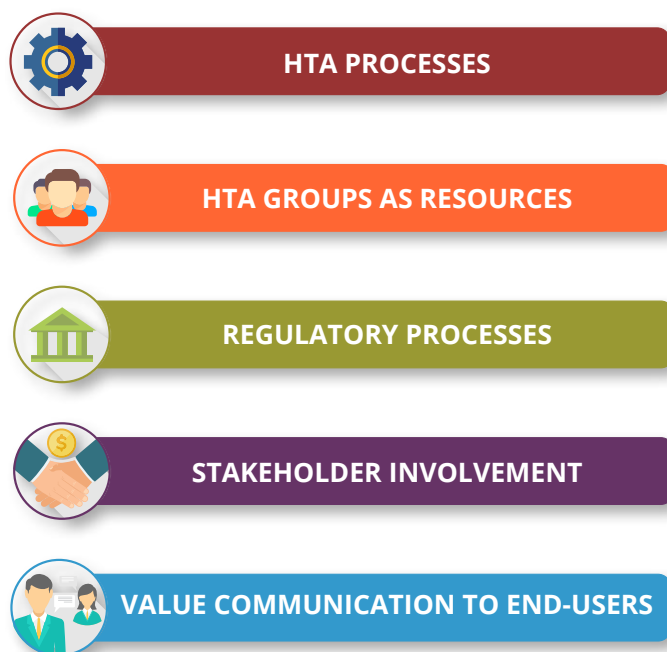
HTA groups as resources: HTA groups can also function as valuable knowledge resource centers for device manufacturers. Partnership between regulators and developers may help to expedite regulatory reform and improve innovative adoption. The goal of all medical device innovations should be to reduce the burden on health care system while providing access to the latest innovations.¹⁶

Regulatory processes: Another solution would be reforming regulatory processes to reduce the time-to-market for medical devices and supporting R&D, while adhering to high standards of safety and risk reduction.¹⁷ Timely and well-defined pathways as well as transparency in decision-making will enable better predictability and consistency of reimbursement decisions, ensure greater stakeholder involvement, facilitate improved access to care, reward and encourage innovation, and create a seamless health care system.¹⁸ These principles will maximize the effectiveness, value, and overall sustainability of health care systems, support innovation, guarantee value for payers, and ensure that patients are able to receive the health care they need and deserve.

Stakeholder involvement: Research and experience show that physician partnership and consultation throughout the design, testing, and validation phases of new medical device technologies is key to success for the device manufacturers.¹⁸ Physicians assume an important role in medical device companies by sharing expert knowledge of health care trends and the health needs of specific populations, which is the basis for device development. This encourages knowledge transfer between industrial, academic, clinical, and developmental researchers. It is advisable to build a national strategy to enable links and partnerships among industrial, government, and health care system stakeholders to develop a strong and vibrant medical device industry.^{19,20}

Value communication to end-users: Companies should communicate their value messages through open events in a multidisciplinary learning environment, where all physicians (not only medical specialists, but also interventional radiologists, pathologists, and others) can meet and share their experiences. Collaboration with patient advocacy and support groups is another crucial component in raising awareness of the device.^{21,22}

Figure 4. Critical elements of market access strategy



FUTURE TRENDS

As per the FDA definition, “combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products”²³ and can include combinations of the following types: drug–device, biologic–device, drug–biologic and drug–device–biologic. They can be physically or chemically combined, packaged together as a kit, or separate cross-labeled products.²³ Examples of combination products include prefilled syringes, antimicrobial-coated catheters, co-packaged products that are required to be delivered sequentially for therapeutic effect, and biologic or synthetic surgical patches that are pre-packaged into delivery. The drug–device combination products market will report a market value worth \$115 billion by 2019.²⁴

Regulatory frameworks will continue to be challenged in the near future by two emerging types of devices: combination devices that facilitate drug delivery; and connected devices that record, store, transmit, and display patient information. The majority of new medical devices have one or both of these functions.^{25,26}

The challenge for obtaining approval for these new-generation devices is managing three distinct, and sometimes conflicting, regulatory processes: (a) device regulations; (b) drug/pharmaceutical regulations; and (c) privacy of information laws. If market access for these devices is not successful, the loss to the industry is profound, but the loss of these innovations to the health care system could be even more costly.²⁶⁻²⁸

Health care systems need to encourage the introduction and development of innovative new devices that provide relevant benefits to patients, physicians, payers, providers, and the overall health care system.²⁹ The need for value-driven innovation is particularly important because of an ageing population and the increasing burden of chronic diseases. Reimbursement of medical devices and services becomes a core component of a sustainable, effective, and patient-centered health care system.^{30,31} There exists a pressing need to review and adapt the existing regulatory and reimbursement systems for efficient and sustainable health care infrastructures.

REFERENCES

1. http://www.who.int/topics/medical_devices/en/
2. Rebecca S. Drug vs device studies are they so different? 2014. www.icr-global.org
3. Mark W. Accessing the US medical device market. 2016. <http://www.alacramed.com/news/usmedicaldevicemarketaccess/>
4. Kalorama: global medical device market reaches \$381 billion. 2016. <http://www.prnewswire.com/news/kalorama+information>
5. Sarah C. A must read overview of the medical device industry. 2015. <http://marketrealist.com/2015/11/must-read-overview-medical-device-industry/>
6. Scott TH. Mapping the medical device development process. 2010. <http://digitalcommons.calpoly.edu/cgi/viewcontent.cgi?article=1015&context=itisp>
7. <http://www.globalmedicaltechnologyalliance.org/differences-between-medical-devices-and-drugs.html>

8. Outlining the key differences between medical device and drug trials. 2015. <http://www.clinicaltrialsarena.com/news/medical-devices/outlining-the-key-differences-between-medical-deviceand-drug-trials-to-determine-how-device-trials-can-best-be-run-effectively-4644599>
9. <http://www.globalmedicaltechnologyalliance.org/differences-between-medical-devices-and-drugs.html>
10. Paul S. Medical devices vs pharmaceuticals - a brief guide to the differences. 2016. <https://social.hays.com/2016/06/21/medical-devices-vs-pharmaceuticals-a-brief-guide-to-the-differences/>
11. Heather T. Obamacare is changing market access. 2013. <http://www.mddionline.com/article/obamacare-changing-market-access>
12. Intersystems Corporation. The key challenges facing medical device manufacturers. 2014
13. Andrew MS. Studies criticize U.S. medical device approval process. 2014. <http://www.reuters.com/article/us-fda-devices-idUSKCN0HP05Z20140930>
14. Mark M. Reimbursement 101: evidence for devices is often still lacking. 2010. http://www.medicaldevicedaily.com/servlet/com.accumedia.web.Dispatcher?next=bioWorldHeadlines_article&forceid=73525
15. Ridhima A. Risk-sharing agreements for medical devices in emerging markets: opportunities and challenges. 2014. <http://centres.insead.edu/healthcare-management-initiative/thought-pieces/documents/RiskSharingforMedtech-INSEAD-HMI.pdf>
16. Michael M. UK to launch new office for market access. 2015. <http://www.raps.org/SearchRegFocus.aspx?name=Michael%20Mezher>
17. How to transform the product launch process for better outcomes. 2015. <https://zephyrhealth.com/pharma-and-medical-device-companies-use-real-world-insights-to-transform-the-product-launch-process/>
18. Eucomed six key principles for the efficient and sustainable funding & reimbursement of medical devices. 2014. http://www.medtecheurope.org/sites/default/files/eucomed_position_paper_reimbursement_0.pdf
19. Latesha R. Medical devices and HEOR: positioning yourself to meet payer needs in 2015. 2015. <https://www.pm360online.com/medical-devices-and-heor-positioning-yourself-to-meet-payer-needs-in-2015/>
20. Marketing: medical devices vs pharma. 2012. <http://www.pharmexec.com/marketing-medical-devices-vs-pharma>
21. Ken S. Improving patient access through early collaboration. CDRH 2014-2015 Strategic Priorities. 2015. <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm384132.htm>
22. Zachary B. RAPS Switzerland chapter to host 2015 EU medtech reimbursement roundtable. 2015. <http://www.raps.org/SearchRegFocus.aspx?name=Zachary%20Brousseau>
23. Combination Products. <http://www.fda.gov/CombinationProducts/>
24. Drug-device combination products market will report a market value worth US \$115 billion by 2019: Transparency Market Research. 2015. <http://www.prnewswire.com/news-releases/drug-device-combination-products-market-will-report-a-market-value-worth-us-115-billion-by-2019-transparency-market-research-520759211.html>
25. Bo W; Aaron SK. Promoting therapeutic innovation: what do we do about drug-device combinations? 2016. <https://newsatjama.jama.com/2016/01/21/jama-forum-promoting-therapeutic-innovation-what-do-we-do-about-drug-device-combinations/>
26. Theresa J. A European perspective and guide to key regulatory considerations for combination products. 2015. https://embed.topra.org/sites/default/files/regrapart/1/6118/regulatory_rapporteur_june_2015_a_european_perspective.pdf
27. Gordon BS. Reimbursement coding systems and innovative medical devices. 2016. <https://www.medtechtelligence.com/column/reimbursement-coding-systems-innovative-medical-devices/>
28. Reed FB; Jason WN; Warren AK; Amir A. Is patent “evergreening” restricting access to medicine/device combination products? 2016. <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0148939>
29. Shayesteh F; Lyndsey K. Bridging the regulatory gaps between combination product makers. 2015. http://www.sfl-services.com/media/609Y3CQF/121_Bridging_the_regulatory_gaps.pdf
30. Ildar A; Rakshambikai R; Illias A; Phani KT. Market access advancements and challenges in “drug-companion diagnostic test” co-development in Europe. 2015. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4493497/>
31. Drug-device convergence. 2014. http://www.pmlive.com/pharma_news/drug-device_convergence_554852

CACTUS[®]

USA | Japan | India | South Korea | China

NANCY CONNELLY

Business Development, USA

Tel: +1-631-206-4340

nancy.connelly@cactusglobal.com

GARY GROESBECK

Business Development, USA

Tel: +1-267-332-0051 Ext:100

gary.groesbeck@cactusglobal.com

IVAN D'SOUZA

Business Development, Europe/Asia

Tel: +1-267-332-0051 Ext:167

ivan.dsouza@cactusglobal.com