The case for and against the use of price regulation for medical devices: Landscape analysis

Update on the findings and analysis from Brazil, China, Germany, India and the USA

CRA Charles River Associates

May 2017

AdvaMed
Advanced Medical Technology Association

Agenda

- Introduction
- Approach for the analysis
- Summary of the main findings
- Appendix: Individual market analysis

Background & Approach

- **Background:** There are currently a number of markets considering the application of price regulation to medical device markets
  - However, there is a large established literature showing that price regulation should only be applied under certain conditions, particularly when there is evidence of market failure
  - Where competition can work to establish prices, then market forces or unregulated pricing is preferred from a societal perspective
- **Approach:**
  - First, set out the price and reimbursement landscape for medical devices across a variety of international markets
  - Then consider merits of developing a white paper on the arguments for and against the application of price regulation to medical devices

Examples where prices regulations of medical devices have been suggested

- The Indian Department of Pharmaceuticals published draft proposals for the creation of medical devices approval regulations and pricing regulations in 2015
- The Russian Ministry of Health published guidelines for determining the maximum amount of wholesale mark-up, to the actual selling price, on medical devices implanted in the human body and intends to implement price regulation in 2018

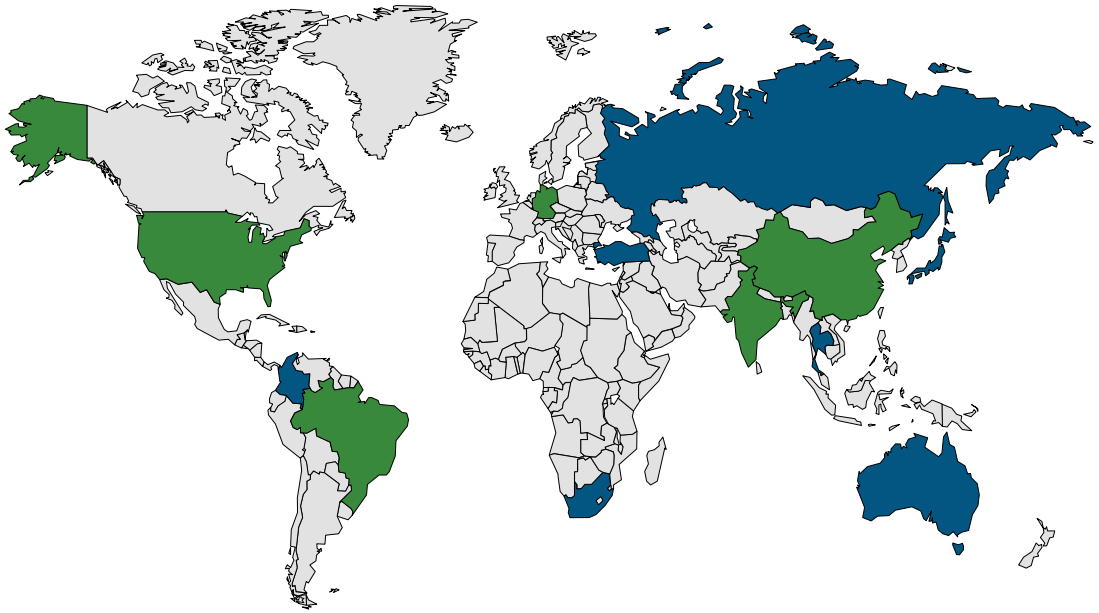
Project objective and planned activities

- **Policy landscape analysis:** establishing a baseline on the policy landscape by undertaking a systematic overview of the medical device policy environment in 12 international markets
  - The objective will be to set out the different approaches at a national, regional or provider level to:
    - Product approval
    - Pricing
    - Reimbursement
    - Procurement
    - Funding

Markets covered

Each of the 12 markets selected have different important characteristics:

- There is an ongoing or expected policy debate
- Key commercial importance of the market to AdvaMed
- Can be used to extrapolate to a wider set of markets (archetype countries)
- Geographic coverage
- Important future market



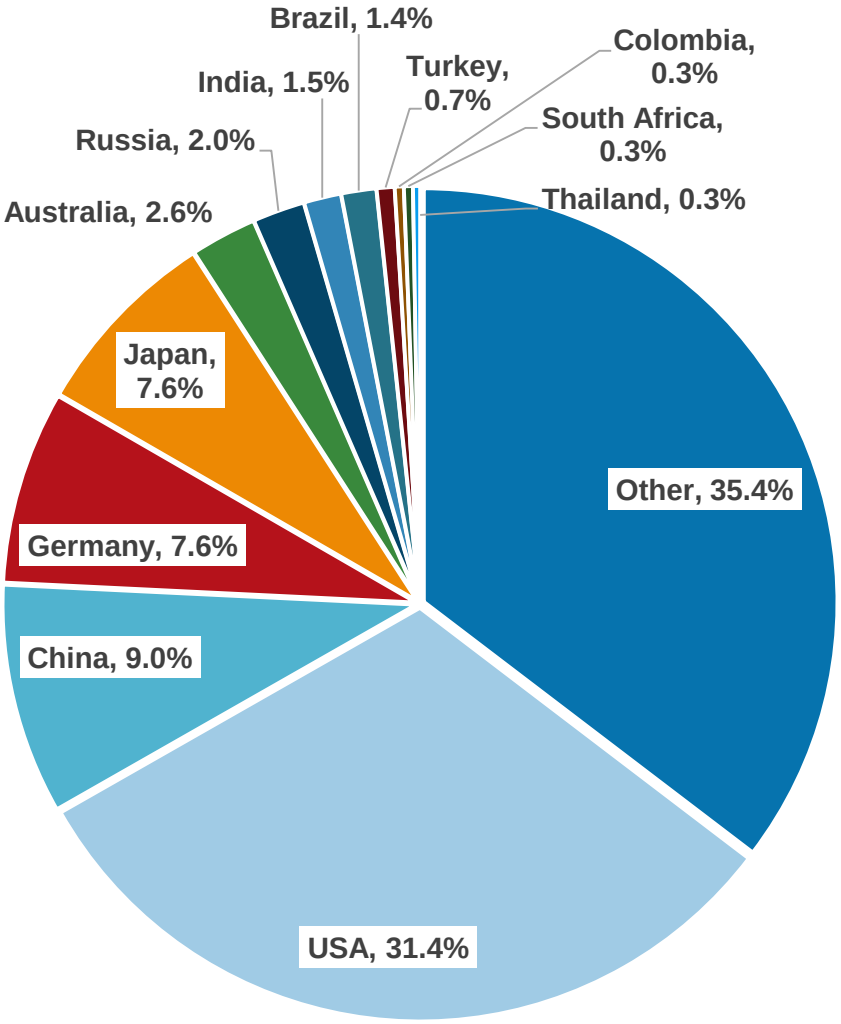
First wave of countries

- Brazil
- China
- Germany
- India
- USA

Second wave of countries

- Australia
- Colombia
- Japan
- Russia
- South Africa
- Thailand
- Turkey

Medical devices market in the selected countries



- In 2015 the global medical devices market was estimated to be **worth USD $344 billion** (estimated by CRA based on data from the International Trade Administration, US Department of Commerce)*
- The markets we examine in this report accounts for approximately 65% of the global medical devices market

*SelectUSA website: International Trade Administration, US Department of Commerce

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Method

1. Definition of key concepts and a framework for the analysis
   - Preparation of a set of questions to define the landscape in each country
2. Secondary research:
   - Review of existing literature
     - Peer-reviewed literature
     - Grey literature
     - Internet sources (national bodies, specialised press, …)
   - Search conducted in English and local language
   - Analysis and organisation of the information
3. Preliminary discussion of findings on the five countries with AdvaMed and incorporation of their feedback in the subsequent analysis

Definitions

	Working definition
Regulatory approval	The registration process required to place a new product on market, typically implying after-sale obligations[1]
Pricing	The process used to establish the price paid to the manufacturer for a new product (e.g. a price unilaterally established by the manufacturer, a price negotiated between the manufacturer and the purchaser, a price unilaterally decided by the purchaser)[2]
Reimbursement	The process used to establish the criteria under which a product will be paid to a healthcare provider by a third party public or private insurer for payments or costs the provider incurred while using a medical device.[3] The process involves deciding: • Whether a device will be reimbursed by the third-party payer • Whether the device is reimbursed as part of a procedure as opposed to a direct payment The reimbursement rate may or may not be influenced by the actual prices paid
Procurement	The process used by a healthcare provider to purchase medical devices for use with patients[4] • In many countries, a public tendering process is used • In other countries providers use a "RFP" process that is not public (however, it is similar to tenders)
Funding of the expenditure	The process to allocate financial resources to purchasers of medical devices (including public transfers, public and private insurance schemes, out-of-pocket payments)[5]

Payer	Entity setting the payment (or reimbursement) rates for procedures and (sometimes) devices. The payer makes payments based on payment rates to providers of services (e.g., hospitals, clinics, etc.)
Purchaser	Entity actually purchasing devices that are used in a procedure. Devices purchased at an agreed upon price after negotiations between purchaser and device seller, most commonly occurring through procurement processes

Framework for the analysis

Topic	Questions for research
Approval environment	1. Is the approval process different for different types of medical devices? 2. How does the approval process work (for each category of medical devices, if relevant)? 3. Does the approval process have any implications on value or price determination? 4. Are there any policy debates about changing the current environment?
Pricing environment	1. Is the price decided or directly controlled by the Government? 2. Is there a different pricing process for particular categories of medical devices? 3. How does the pricing process work (for each category of medical devices, if relevant)? 4. Are there any policy debates about changing the current pricing environment?
Reimbursement environment	1. Are devices usually reimbursed to healthcare providers (both public and private) by a third-party payer? 2. Is the reimbursement process different for different types of medical devices? 3. How do third-party payers decide whether to reimburse a device or not (for each category of medical devices, if relevant)? 4. How is the reimbursement rate to healthcare providers established (for each category of medical devices, if relevant)? 5. Are there any policy debates about changing the current reimbursement environment? 6. Is there an “innovation clause” available?
Procurement environment	1. Is the procurement process different for different types of medical devices? 2. Are there any existing or proposed preferential policies (for example domestic preferences or localization requirements)? 3. How does the procurement process work (for each category of medical devices, if relevant)? 4. Are there any other policy debates about changing the current procurement environment?
Funding environment	1. How does the funding process work? 2. Are there any policy debates about changing the current environment?

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First wave of countries

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- Germany
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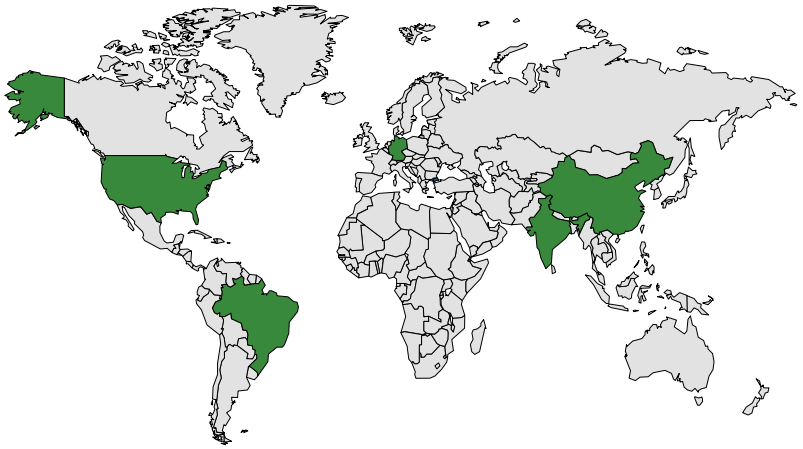
- USA



- Preliminary discussion with AdvaMed and companies
- Feedback already provided and changes incorporated into this version

Economic indicators overview: comparison across countries

		Brazil	China	Germany	India	USA
Wealth indicators (2015)	World Bank income group	Upper-middle income	Upper-middle income	High income	Lower-middle income	High Income
	GDP	USD 1.78 trillion	USD 10.87 trillion	USD 3.9 trillion	USD 2.07 trillion	USD 18 trillion
	GDP per capita	USD 8,566	USD 7,820	USD 47,774	USD 1,590	USD 55,840
	GDP growth	-3.8%	6.9%	1.6%	7.6%	2.4%
	Inflation	9.0%	1.4%	0.2%	5.9%	USD 54,960
	Population	207.8 million	1.4 billion	80.9 million	1.3 billion	321 million
Health indicators (2014)	Health expenditure	USD 193 billion	USD 517 billion	USD 390 billion	USD 27 billion	USD 3.0 trillion
	Health exp. per capita	USD 947	USD 382	USD 4,812	USD 21	USD 9,403
	Health exp. % of GDP	8.3%	5.6%	12%	1.3%	17%
	% out of pocket	25.5%	33.2%	13%	89%	11%
	Pharmaceutical exp.	USD 26.5 billion[1]	USD 108 billion	USD 54 billion	USD 30 billion	USD 325 billion
	Medical devices exp.	USD 4.7 billion	USD 28 billion	USD 26 billion	USD 5 billion	USD 108 billion

Sources:
Wealth indicators: World Bank
Health indicators: World Bank, WHO; OECD; USA Department of Commerce; Emergo; BMI Research

Approval environment: summary findings – 1/2

	Brazil 	China 	Germany 	India 	USA 
Is the approval process different for different types of medical devices?	Yes • Simplified process for low- and medium-risk devices • Dedicated, more-complex process for higher risk devices	Yes • Low-risk devices go through a filing procedure • Medium to high risk devices undergo in-country testing and clinical trials.	Yes • Simplified procedure for low-risk devices • Audit of higher-risk devices	Yes • Short list of devices requiring regulatory approval (22 types)	Yes • Devices are classified into three class of risk (Class I, II, and III), with increasing regulatory control
How does the approval process work?	All medical devices must be registered through ANVISA (the Brazilian National Health Surveillance Agency)	• All class I undergo filing process and domestic class II approved by provincial FDA; all class II and class III foreign devices and class III domestic devices approved by central CFDA.	All medical devices need approval from one competent authority in Europe (CE marking, which permits access across the entire European Union to be registered European Union)	Only 22 types of medical devices are required to go through a registration and approval process by the Central Drugs Standard Control Organization (CDSCO)	All medical devices need approval from the FDA's Center for Devices and Radiological Health (CDRH), which is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the US

Approval environment: summary findings – 2/2

	Brazil 	China 	Germany 	India 	USA 
Does the approval process have any implications on value or price determination?	None	None, but being considered for drugs.	None	None	None
Are there any policy debates about changing the current environment?	Currently, there is a pilot program to allow for the exchange of reports/information between Brazil, Australia, Canada, and the United States and MERCOSUR	CFDA is overhauling their pre-market review and approval process to increase capacity and efficiencies to bring product to market more quickly; however, unnecessarily burdensome country of origin and clinical trial requirements remain.	The European Commission has recently adopted (on 5 April 2017) the proposal for two Regulations on medical devices which establish a modernised and more robust EU legislative framework	• The Medical Device Rules, 2016 aimed to establish two separate laws for pharmaceuticals and medical devices • Discussions on the separate law for medical devices are ongoing	None

Pricing environment: summary findings – 1/3

	Brazil	China	Germany	India	USA
Is the price decided or directly controlled by the Government?	Not formally, but maximum reimbursement rates for public sector purchases of medical devices effectively work as price ceiling for public sector and informal reference point for private sector	• Pricing policies are decided at provincial level for both foreign and domestic, with price ceiling common in tenders and applied to both foreign and domestic. • No central government price controls.	No	Yes, there is a price ceiling for stents	No
Is there a different pricing process for particular categories of medical devices?	No	• Yes; Allocation license required for equipment over specific value or enlisted in the Type A or B capital equipment; high-value implants most commonly subjected to ceilings in tenders.	No	Yes (stents are regulated)	No

Pricing environment: summary findings – 2/3

	Brazil	China	Germany	India	USA
How does the pricing process work (for different types of payer/ purchaser)?	**Private payers** Price negotiations between the manufactures and providers (hospitals), in some cases and increasingly, directly with third party payers (insurance companies) **Public payers** Law forbids negotiation with public payers, done via public procurement, without negotiation. Public funds may be used to pay for medical devices in either public or non-public hospitals. Public sector hospitals can purchase from private sector, but only under specific constraints	**Public purchasers** • Foreign and domestic undergo same processes (unless explicitly stated otherwise). • Tender determines winning companies, which negotiate with hospital purchasing department (HPD). • If product not subject to tenders, companies negotiate directly with HPDs. **Private purchasers** • Buy foreign or domestic products however they wish, unless they seek government insurance, in which case use tenders.	**Private and public purchasers** Price negotiations between the manufactures and purchasers	**Private purchasers** The price is negotiated between the manufacturers and the healthcare providers **Public purchasers** For devices included on the National List of Essential Medicines (NLEM), price considerations also take into account the need for reimbursement	**Private and public purchasers** Medical device pricing is driven by competition for hospital/clinic purchasers

Pricing environment: summary findings – 3/3

	Brazil	China	Germany	India	USA
Are there any policy debates about changing the current pricing environment?	Yes. The topic has been widely debated after congressional and senate investigations and judiciary probe. An inter-ministerial working group was put in place to address issues. There are divergent recommendations from each group ranging from tightening price monitoring to implementing price controls similar to those for drugs, with international reference pricing. Congress is considering several legislative options. It is likely some control will be imposed	Yes. • The central government is examining impact of tenders on anti-competitive practices and considering new guidelines on tenders. • Also, currently planning to move to DRGs. If implemented, this is expected to impact device prices. • Debates on methodology-based IVD pricing since 2012.	None	Discussion to introduce a price control specific to medical devices by including medical devices separately from drugs in the list of commodities controlled under the Essential Commodities Act and regulated under a separate Medical Devices (Price Control) Order	None

Reimbursement environment: summary findings – 1/4

	Brazil	China	Germany	India	USA
Are devices usually reimbursed to healthcare providers (both public and private) by a third-party purchaser?	Yes	No. • Hospitals purchase devices, but no third party reimburses hospitals for devices – only for procedures covered by health plan. • Hospitals often sell devices to patients, requiring purchases as condition for being able to undergo the procedure.	Yes	No, devices are mostly self-paid by patients	Yes
Does the reimbursement process different for different types of medical devices?	Yes • For private sector, the distinction is whether the procedure or treatment that includes the device is part of the Procedure RoI (determined by ANS) or not. For public sector,	Yes • National health system tends to cover most consumables by patient co-payment rate, which varies by locality.	Yes • Different reimbursement process between “standard” and “innovative” devices	Yes • Different reimbursement process between “standard” and “essential innovative” devices • Devices included on the National List of Essential Medicines are	Yes • Different reimbursement process between “standard” and “innovative” devices • Reimbursement processes can also differ by purchaser type (public vs private

Reimbursement environment: summary findings – 2/4

	Brazil	China	Germany	India	USA
How do third-party payers decide whether to reimburse a device or not?	**"Standard" devices** • No decision is made specifically to devices as payers reimburse the medical procedure **"Innovative" devices not part of a procedure** *Public sector* • HTA recommendation for reimbursement based on scientific evidence regarding efficacy, safety and economic evaluation studies • The final decision remains heavily dependent on expected budget impact *Private sector* • Expected budget impact plays a minor role	• No decision is made specifically to devices as they are most often reimbursed as part of a medical procedure if reimbursed at all. • There is no distinction between imported and domestic devices. However, hospitals are incentivized to purchase cheaper device/ IVD reagents to increase margin.	**"Standard" devices** • No decision is made specifically to devices as purchasers reimburse the medical procedure **Cost-intensive / innovative devices which are not part of a procedure** • National cost-effectiveness evaluation and reimbursement decision for some cost-intensive devices	**Essential, "standard" devices** • For medicinal products such as heart valves, stents etc., devices are reimbursed as part of the procedure if the procedure is reimbursed **Essential, "new" devices** • For relatively new products such as Left Ventricular Assist Devices (LVAD s) reimbursement has not been established	**"Standard" devices as part of a procedure** • Many medical devices are used as part of inpatient and outpatient procedures that are covered by a single payment to the hospital for the procedure **Devices not part of a procedure** *Public insurers* • Most public insurers follow the CMS guidelines *Private insurers* • Most private insurers use a Technology Assessment Committees, along with CMS guidelines

Reimbursement environment: summary findings – 3/4

	Brazil	China	Germany	India	USA
How is the reimbursement rate to healthcare providers?	**"Standard" devices** • No specific reimbursement rate for devices: fixed reimbursement amounts for procedures based on global averages **"Innovative" devices not part of a procedure** *Public sector* • Only cost-effective devices are fully reimbursed *Private sector* • Devices are fully reimbursed only if included in the purchaser's plan	• Reimbursement of the procedure, which often does not cover 100% of the procedure cost or the product price. • There is no difference in regulation between foreign and domestic, but the latter is often cheaper so more likely to be covered by procedure payment. • Some provinces have different reimbursement rates for foreign vs. domestic	**"Standard" devices** • In-patient devices are covered through the diagnosis-related group (DRG) system **Cost-intensive / innovative devices** • In-patient devices can receive a payment on the top of the DRG • Outpatient devices are partly reimbursed and excess can be covered by a private health insurance fee schedule (GOÄ)	**Essential, "standard" devices** • For medicinal products such as heart valves, stents etc., reimbursement is generally very low **Essential, "new" devices** • There is generally no reimbursement	**Public insurers** • Public insurers use CPT and HCPCS codes, as well as CMS-DRG codes – patients co-payments may be needed **Private insurers** • Private insurers commonly use DRG, CPT, and HCPCS codes – patients co-payments may be needed
Is there an "innovation clause" available?	Yes, there is an innovation premium	No. Typically based on functionality, e.g. mature and innovative devices in	Yes, there is an innovation premium	No	Yes, there is an innovation premium

Reimbursement environment: summary findings – 4/4

	Brazil	China	Germany	India	USA
Are there any policy debates about changing the current reimbursement environment?	Yes. Strong push by private insurers to merge reimbursement decisions and mandates of the private sector with the public sector	Yes. The central government is addressing reimbursement payment method reform. Policy trends include - • General: Global Budgeting; • Primary care: Pay Per Capita; • Outpatient: Fee For Service; • Inpatient: Case-based Payment, DRGs, Pay Per Inpatient Day	None	Introduce a separate price control specific to medical devices by including medical devices separately from drugs in the list of commodities controlled under the Essential Commodities Act and regulated under a separate Medical Devices (Price Control) Order	None

Procurement environment: summary findings – 1/3

	Brazil	China	Germany	India	USA
Is the procurement process different for different types of medical devices?	No • Differences are between public and private procurement	Yes • Central government exerts more control over high value capital equipment procurement, must obtain a license.	There are no specific regulations pertaining to medical device procurement	There are no specific regulations pertaining to medical device procurement	No • Governmental process for departments (such as Veterans Affairs and Department of Defense)
Are there any existing or proposed preferential policies (for example domestic preferences or localization requirements)?	Yes • Brazil imposes high tariffs on non-MERCOSUR imports • For some products, local manufacturers can charge a premium of up to 25% compared to imported products	Yes • Some provinces suggested introducing domestic preference policies which would exclude foreign medical products when domestic products are available.	No	Yes • The import duties on medical devices and equipment have been increased almost across the board by 7.3% and proposals have been discussed to have the Central Government Health Scheme (CGHS) to purchase a minimum percentage of devices from Indian companies	No • However, the new administration trade policy could prioritize domestic production

Procurement environment: summary findings – 2/3

	Brazil	China	Germany	India	USA
How does the procurement process work?	**Public sector** The purchasing process depends on the value of the purchase: direct purchase, RFP, price surveys, tenders **Private sector** Purchasing can be direct, or involve price survey or RFP (depending on the price of the device)	**Public sector** • For most medical devices, especially 'low value' medical devices, hospitals make purchases individually • In recent years, provinces have begun to use centralized procurement tenders for medical consumables including IVD reagents. • Some provinces now utilizing a two invoice policy to limit distributor markups. • Capital equipment purchases must have a license. Private sector. • Buy foreign or domestic products however they wish, unless they	**Public/private sector** • Most medical devices are procured by hospitals • Individual hospitals can choose to negotiate independently with suppliers or multiple hospitals can band together to form a purchasing syndicate (group purchasing organizations)	**Public sector** • All purchases of priced of cheap devices are made by individual hospitals and those more expensive are under the control of the Central Equipment Procurement Cell (CEPC) • Procurement models can vary according to whether the state procurement budget is divided between the centralised, decentralised • Global tenders are allowed **Private sector** No specific rules, global tender are allowed	**Public/private sector** • Medical devices are primarily purchased by hospitals and clinics, typically through competitive tenders • Governmental departments (VA, DOD) follow public procurement rules

Procurement environment: summary findings – 3/3

	Brazil	China	Germany	India	USA
Are there any other debates about changing the current procurement environment?	None	• Tendering in particular is changing frequently largely at the provincial level with the incorporation of new models and features designed to drive down price down • There is central level guidance on large equipment procurement from CAME, however it is unclear to what extent the provinces are following this. • Two-Invoice Policy, a two-level distribution system expanded to medical devices in some provinces, which initially started from pharmaceutical policy	None	None	None

Funding environment: summary findings – 1/2

	Brazil	China	Germany	India	USA
How does the funding process work?	**Public sector** Payments funded by public taxation **Private sector** Brazil's system remains highly privatized (out-of-pocket payments and private insurance)	**Public sector** Public hospitals mostly rely on their own revenue to purchase devices. Hospital revenue derives from mark ups of drugs and devices sold by the hospital directly to patients. Out of pocket varies by domestic/import (because of price), hospital layer inpatient/outpatient, etc. **Private sector** Usually funded through private insurers or paid OOP. Less private insurance in China today, but growing.	**Public/private sector** • The Statutory Health Insurance (GKV) pays for the medical device services offered by the DRG (in-patient) and EBM (out-patient) • Private access is usually funded through private insurers or paid OOP	**Public sector** Funding through taxation – however universal health coverage is absent **Private sector** OOP contributes approximately 86% of private expenditure and 60% of overall healthcare expenditure in the country	**Public/private sector** US healthcare providers are financed by a mix of private insurance, government programs, and out of pocket funds: of the total population, 56% use private insurance, 36% use public programs, and 9% are uninsured

Funding environment: summary findings – 2/2

	Brazil	China	Germany	India	USA
Are there any policy debates about changing the current environment?	Current debate on a number of current reforms could have significant impact on how private sector is funded, primarily through increases in out of pocket expenses and restricting benefit plans	The Chinese government is investing tens of billions RMB under Healthy China 2030 and the 13th Five Year Plan to improve medical insurance, reduce mark-ups of drugs and consumables, ensure transparency in the procurement process, prop up domestic industry and blacklist certain companies/ distributors.	None	There is a debate on the absence of universal health coverage and limited social health coverage that has led to a high burden of OOP • Evidence suggest that only 3%-5% of Indians are covered under any form of health insurance	New administration plans to cut public funding to healthcare expenditure

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Brazil

Brazil: Country Overview

Wealth Indicators (2015)

State of development	Upper Middle Income	**GDP growth**	-3.8%
GDP	USD 1.775 trillion	**Inflation**	9.0%
GDP per capita	USD 8.539	**Population**	207.8 million

Healthcare Expenditure (2014)

Health expenditure	USD 193 billion	**Pharma expenditure**	USD 26.5 billion (2013, Deloitte outlook)
Health exp. per capita	USD 947	**Pharma exp. per capita**	USD 130 (2013)
Health exp. % of GDP	8.3%	**Device expenditure**	USD 4.7 billion
% Out of Pocket	25.5%	**Device exp. per capita**	USD 22

Sources: World Bank; Emergo

Approval: current environment

Regulatory framework

- All medical devices must be registered through ANVISA (the Brazilian National Health Surveillance Agency)
- There are two different registration processes: *cadastro* (for low-risk devices) and *registro* (for high risk devices)
- Some devices (i.e. electromedical devices) may also need a certification from INMETRO, the National Institute of Metrology, Standardization, and Industrial Quality

ANVISA

- Resolution RDC No. 185/2001 defines a medical device as “any healthcare product… intended for prevention, diagnosis, treatment, rehabilitation, or anti-conception and that does not use pharmacological, immunological, or metabolic means to fulfill its main function in human beings, but can have its functions assisted by such means.”
- Examples include:
  - Heart valves
  - Blood bags
  - Infusion sets
  - Sterile Hypodermic syringes
  - Condoms
  - Examination/surgical gloves

INMETRO certification

- INMETRO is responsible for ensuring products in Brazil meet quality and safety standards and follows IEC60601-1-x electrical safety requirements
- They certify products ranging from bottled water to school supplies and boilers
- INMETRO also accredits organizations responsible for certifying compliance and authorizing entry to certain markets
- Some medical devices must obtain a compliance certificate in order to apply for ANVISA registration. Examples include:
  - Electro-medical devices Some non-electro-medical devices like mattresses and hand-pieces

Source: “Country at a Glance: Brazil”, Arazy Group.

Approval: current environment

	Cadastro process	*Registro* process
Type of Device	Designed for lower-risk devices	Typically for higher risk classes
Device Classifications	Class I and most Class II	Class III and IV. Some Class II (Class II requires registration if it is related to a Class III or IV product where it then falls in that respective category)
Time until Regulatory Approval	1 to 3 months	If the submission is complete, the typical registration time is now six months
Registration Expiry	Does not expire	Expires after 5 years
Complexity	Moderate (similar to European CE Marking process)	Highly complex (more than European CE Marking process)
Cost	Relatively low (<USD $,5000)	High (>USD $30,000)
Good Manufacturing Process Certification	Must comply, but will not be audited by ANVISA	Must be audited for compliance by ANVISA or by a 3rd-party through the IMDRF/MDSAP program (single audits are allowed)
Other process features	Manufacturers must prepare a Technical Dossier	• Manufacturers should prepare a more extensive Technical File • GMP fees due every two years • Registration renewals must be initiated one year, and no later than six months, prior to expiration

Source: Emergo.

Approval environment: Categorisations of devices

Class	Description
Class I (Low Risk)	• Represent lowest amount of risk • Applications are filed using the *cadastro* process
Class II (Medium Risk)	• Applications are for the most part filed using the *cadastro* process • ANVISA does not issue a GMP certificate and, after RDC 40/2015, this is now identical to Class I
Class III (High Risk)	• Must follow the lengthier *registro* submission process • Devices must obtain a GMP certificate
Class IV (Very High Risk)	• Represent the highest amount of risk • Registration submissions must undergo the *registro* process • Also require a GMP certificate

Source: "Brazil ANVISA Regulatory Approval Process for Medical Devices" & "Brazil relaxes BGMP requirements for manufacturers holding INMETRO certification", Emergo.

Approval environment: flow chart of current process

1. **Determine device classification**
   - Using Annex II of RDC 185/2001
   - Importers must appoint Brazilian company as their "Brazilian Registration Holder" (BRH). BRH must have letter of authorization from manufacturers to apply for ANVISA registration
2. **If required, get INMETRO certification**
   - Testing for electro-medical products performed outside Brazil is usually accepted, if performed by an ILAC-certified lab
   - INMETRO certification is valid for 5 years, and annual audits and fees are required
3. **Prepare materials for *cadastro* or *registro* process**
   - Prepare and submit required technical documentation
   - All documents should be submitted in Brazilian Portuguese, although ANVISA accepts some technical documents in English or Spanish (RDC 50/2013)
4. **Submit ANVISA application**
   - Pay application fee
   - Upon approval, ANVISA publishes the registration number in the Diário Oficial da União (DOU) and manufacturers can begin legally marketing the device

Source:"Brazil ANVISA Regulatory Approval Process for Medical Devices", Emergo.

Approval environment: proposed policy changes

Ongoing discussions

Some potential reforms the Brazilian government is assessing to streamline the registration process include:

- Temporarily accepting some alternative pathways through the judicial system that allow manufacturers to initiate the application process before the Good Manufacturing Practice (GMP) certificate has been obtained
- Mutual Recognition Programs for the exchange of reports/information:
  - Currently, there is a pilot program for exchange of information between Brazil, Australia, Canada, and the United States
  - Program for exchange of reports/information between MERCOSUR countries

Source:“Country at a Glance: Brazil”, Arazy Group.

Pricing: current environment

Pricing Process

- While drug prices are fixed by the Medicines Market Regulation Board (CMED), medical devices are not currently subject to price controls
- ANVISA registration requires applicants to provide an economic report about the price of the device for some types of products

Factors affecting Pricing

- **Import tariffs:** Brazil imposes high tariffs on non-MERCOSUR imports
  - MERCOSUR's Common External Tariff (CET) - standardized by types of merchandise (avg.14%)
  - Industrial Products Tax (IPI) - vary depending on how essential the government believes the good is and by Brazilian state. Rates fluctuate between 0% to 15%
  - Merchandise and Service Circulation Tax (ICMS) - vary depending on how essential the government believes the good is and by Brazilian state. Rates range from 7% to 25%
- **Budget control:** Entities like health maintenance organizations (HMOs) are putting strong pressure on prices:
  - Most HMOs pay very little money to doctors for routine procedures
  - For more complex and expensive treatments, HMOs may refuse payment and refer patients back to the public system
  - HMO's may authorize treatments only after special doctor requests or even legal action
- **Public reimbursement rate:** Brazil's public health system's reimbursement for medical devices is defined by a price list that has not changed appreciably in the 2010s despite fluctuations of the local currency

Presently, there is no national pricing process for medical devices

Source: OSEC, International Trade Administration, Emergo, Med-tech Innovation.

Reimbursement: current environment

Reimbursement for public institutions

- **"Standard devices"** are included into the Brazil's reimbursement program, which involves fixed reimbursement amounts for procedures based on global averages:
  - Fixed payments present a risk for hospitals, putting financial constraints around the procedures and reducing demand
  - Reimbursements vary, since generally they operate on a regional scale
- CONITEC (Comissão Nacional de Incorporação de Tecnologias no Sus) develops clinical guidelines and recommends incorporation or disinvestments of health technologies into Brazil's public healthcare system, Unified Health Systems (SUS)
  - Recommendations for **innovative / high-cost technologies** are issued based on scientific evidence regarding efficacy, safety and economic evaluation studies of medical devices
  - CONITEC has one of the most mature Health Technology Assessment systems in emerging markets. However, it remains heavily dependent on expected budget impact rather than cost-effectiveness
- Public coverage is growing, following lawsuits by patients demanding coverage for more and more complex procedures

Reimbursement for private institutions

Although the Constitution establishes that health is everyone's right, the Brazilian national healthcare system is in practice not comprehensive and assists mostly poor citizens. Most middle-class Brazilians rely on private medical insurance, which is often subsidised by employers (including all branches of government)

- Law No. 9,656 of 3 June 1998 establishes the rules for private insurances and healthcare plans

Source: Datamonitor Healthcare, CONITEC Website, Emergo, WHO, Export.gov.

Procurement: current environment

Procurement process for public institutions

The public sector has a tiered procurement process:

- For purchases over 650,000 BRL (~USD192,000), there must be a public tender process:
  - It can take anywhere from one month to half a year and can occur on surprisingly short notice
  - Local companies are favored in the public tender process and resulting contracts vary
  - Different types of tenders (Concorrência, Tomada de Preços, Leilão, Concurso, Convite/Carta Convite, etc.)
- Contracts between 80,000 BRL (~USD24,000) and 650,000 BRL (~USD192,000) use price surveys
- Purchases between 8,000 BRL (~USD2,400) and 80,000 BRL (~USD24,000) are required to solicit at least three RFPs (requests for proposal) from suppliers
- Direct purchases are made under 8,000 BRL (~USD2,400)

Procurement for private institutions

- Procurement methods include direct purchase (53%), price survey (24%), and RFPs (13%)
  - Private institutions can also use public tenders for procurement
- The private sector accounts for 68% of device purchases

Provisions for domestic manufacturers

- In June 2012, a list of 80 items for which local producers can charge a premium of up to 25% compared to imported products had been released

Procurement in Brazil is highly decentralized, with philanthropic, local public, and private institutions contracting suppliers on their own

Note: USD amounts are approximations calculated using Bloomberg's BRL-USD exchange rate on Dec 8th, 2016.

Source: Market Realist, OSEC Website, Switzerland Global Enterprise.

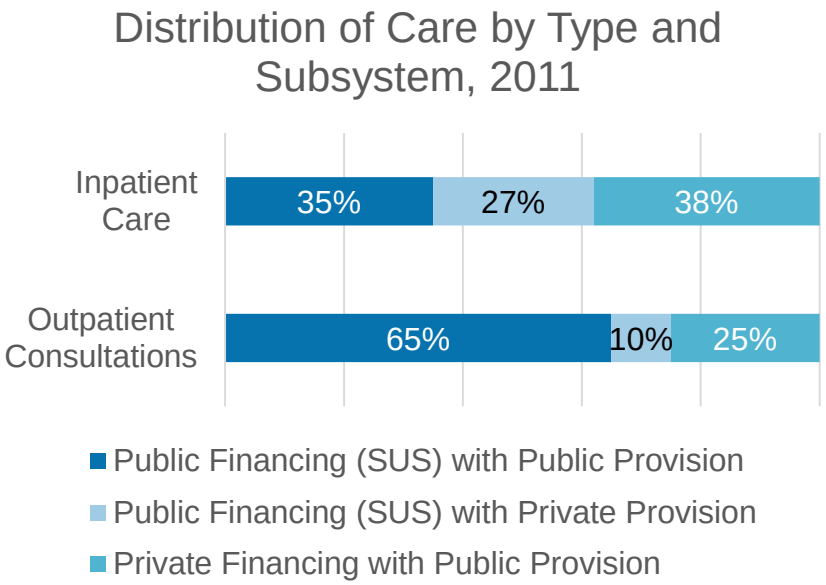
Funding: current environment

Public and Private Funding

- Brazil's system remains highly privatized (out-of-pocket payments and private insurance). More than 1,500 private health insurance providers serve close to a quarter of Brazil's population
- General government health expenditure remains below 50% of total health expenditure

SUS Funding process

- Each government level makes a mandatory minimum contribution of their tax revenues:
  - Federal – 6-7%
  - State – 12%
  - Municipal – 15%
- Federal government is the largest SUS funder.
  - Contribution declining: around 70% in 1980s to less than 50% now.
  - States and municipalities now contribute over 25% each.
- 98% of the municipalities meet their budgetary requirement. Some spend more than 30%.
- More than half of 26 states fail to meet the required 12% funding target.



Both public and private funding helps providers acquire medical devices

Source: The World Bank; WHO; Health Affairs.

China

China: Country Overview

Wealth Indicators (2015)

State of development	Upper middle-income
GDP	$ 10.87 trillion
GDP per capita	$ 7,820

GDP growth	6.9%
Inflation	1.4%
Population	1.37 billion

Healthcare Expenditure (2014)

Health expenditure	$ 517 billion
Health exp. per capita	$ 382
Health exp. % of GDP	5.6%
% Out of Pocket	33.2%

Pharma expenditure	$ 108 billion
Pharma exp. per capita	$ 79
Device expenditure	$ 28 billion
Device exp. per capita	$ 20

Sources: World Bank (2015 data); OECD 2016, USA Department of Commerce, China Pharmaceutical Materials Association Medical Device Branch; 2015 China Health Year Book

Approval: Current Environment

Regulatory Framework

- Medical devices are classified into three categories Class I, Class II and Class III, according to their risk profile (Class I being lowest risk).
- Class I is subject to filing process, and Class II and Class III re subject to different approval requirements **Most FDA Class II devices are considered Class III by CFDA.*
- Low-risk devices go through a simplified procedure.
- Medium to high risk devices undergo in-country testing and clinical evaluation or clinical trials.
- Domestic approved by provincial FDA; all foreign Class II and III devices and Class III domestic devices approved by central CFDA.
- Re-registration is required every five years.
- CFDA is overhauling their pre-market review and approval process to increase capacity and efficiencies to bring product to market more quickly, however, unnecessarily burdensome country of origin and clinical trial requirements remain.

Expedited Approval Processes for Innovative Devices & Unmet Needs

- (Priority Review) Devices for orphan, oncology, paediatric and elderly diseases that fulfil CFDA requirements can obtain approval faster as well as (Green Channel) innovative devices with a China patent.

Regulatory approval process and classification do not have any direct implication on the P&R process, however this is likely to change for drugs.

Source: China Food and Drug Administration (CFDA)

Financing: Current Environment

Financing Process

- While China covers 95% of it's populations with some basic plan, healthcare spending is well below other advanced economies at 5.6% of GDP in 2015 ($450/capita) compared to US roughly 17%.
- Public hospitals are under increasing financial pressure due to lack of government funding and reforms, e.g. increased government scrutiny into pricing (mark-ups).
- Hospitals finance medical devices largely using their own revenue:
  - Public hospital revenue stems primarily from mark ups of drugs and medical consumables.
  - Government subsidies account for as high as 60% (30% central government, 30% provincial government) to as low as 8% of a hospital operating budget, they are working to increase.
  - Hospitals are looking to diagnostic services, e.g. high priced imaging tests to generate more revenues with high priced tests. NHFPC efforts to reign in have been unsuccessful offering no financial alternative.
- Government has invested over $3 billion in recent years to help compensate hospitals for loss of income from capping mark-ups.

Source: Medtech Switzerland; Guan (2016), Huang (2013), Guang Dong Daily Newspaper (2014), Clifford Change (2015)

Pricing: Current Environment

Pricing Process

- The price of medical devices are more or less market regulated, through the use of tenders. In addition to price caps that unfairly impact imports (because tend to be higher value and more R&D intensive), tenders are sometimes differentiated by import vs. domestic and/or both mature and innovative devices categorized together.
- Pricing policies are decided at provincial level for both foreign and domestic, with price ceiling common in tenders and applied to foreign and domestic.
- Central government voluntary guidelines, but not followed by provinces. No central government price controls.
- Public Purchasers:
  - Foreign and domestic undergo same processes (unless explicitly stated otherwise, e.g. domestic preference in Sichuan and Zhejiang).
  - Tender determines winning companies, which have to negotiate again with HCPs.
  - If product not subject to tenders, companies negotiate directly with HCPs.
- Private Purchasers:
  - Buy foreign or domestic products however they wish, unless they seek government insurance, in which case use tenders.

Source: Pacific bridge medical (2015), Gross (2010)

Reimbursement: Current Environment

Reimbursement Process

- There are three national health insurance plans that cover 95% of the population (urban working/unemployed and rural) with basic coverage; private insurers are growing with rising incomes, demand for higher end products (typically import) and/or to cover unmet needs in public scheme.
- Hospitals often sell devices to patients, requiring purchases as condition for procedure, consumables typically covered 100%, implantables higher percentage out of pocket and more expensive for import vs. domestic,
- Provinces set procedure fees and they vary e.g. 30% out of pocket for outpatient vs. 50% for emergency room, out of pocket ceilings exists for adults and students, deductibles vary based on level of hospital.
- Government looking to lower patient financial burden by partnering with private insurers to provide supplementary coverage in certain types of severe chronic diseases.
- There is no difference in regulation between foreign and domestic, but the latter is often cheaper so likely to be more covered by procedure payment.

Source: Torsekar (2014), Gross (2010), XYZ.com (2010)

Pricing and Reimbursement Environment: Proposed Policy Changes

Ongoing Discussions

- NDRC and NHFPC are taking steps to reign in drug and devices mark-ups and increase hospital funding to make up for lost margin, but still long way to go.
- Tenders are changing frequently at the provincial level with the incorporation of different models (double envelope, sunshine, exchange) and features (ceiling price, pricing stairs, categorization, elimination) designed to drive down price further and further
- At the same time, the central government is examining impact of tenders on anti-competitive practices and considering new guidelines on tenders.
- The central government is also planning a move to DRGs, which is expected to impact price of devices through procedure payments. This has been discussed for over a decade, but new pilots appear to be gaining traction.
- Growth in private hospitals and insurance plans as government tightens controls on public system.
- The foreign medical device industry has become a primary target of antitrust investigations in China.

Source: SDPC (2006), SDA (2016), Osmuda (2015), Basic Technology (2016), China Price Association (2004), China Business Review (2010), Expert Network (2016)

Procurement: Current Environment

Procurement Process

- Centralized procurement at the provincial level began with the eight-province tender in 2006. The Ministry of Health issued guidelines on the centralized procurement of high-value medical consumables, but many provinces have formulated their own province-wide regulation of centralized procurement adopting different models for high value devices (low value purchased directly by hospitals) through competitive bidding.
- Amongst the priority provinces covered in this research, three models – double envelope, exchange and sunshine procurement - have been adopted.
- Across the different models, there are common prominent objectives: (1) regulate the consumables procurement market; (2) reduce the price of medical consumables; (3) reduce patient's out-of-pocket payment.
- Various policy features, some concerning and controversial, have been utilized to achieve the policy goals by individual provinces including the stipulation of ceiling price, pricing stairs, categorization, and elimination rate
- Some provinces are looking to introduce domestic preference policies, which would exclude foreign medical products when domestic products are available.
- NHFPC dictates procurement of large capital equipment, and these purchases must have a license.
- Hospitals are incentivized to purchase cheaper devices to increase margins, and are encouraged to procure domestic devices; however limited evidence that guidance being followed.

Source: USCBC (2010),China Medical Devices (2015), EUSME and China Britain Business Council (2015), CNZZ (2012),Xie (2015), Liu (2006), Wu (2016)

Germany

Germany: Country Overview

Wealth Indicators (2015)

State of development	High Income	**GDP growth**	1.6%
GDP	USD 3.868 trillion	**Inflation**	0.2%
GDP per capita	USD 47,774	**Population**	80.970 million

Healthcare Expenditure (2014)

Health expenditure	USD 389.631 billion	**Pharma expenditure**	USD 54.088 billion
Health exp. per capita	USD 4,812	**Pharma exp. per capita**	USD 668
Health exp. % of GDP	12%	**Device expenditure**	USD 26.256 billion
% Out of Pocket	13%	**Device exp. per capita**	USD 313

Sources: World Bank; WHO; OECD; Emergo; BMI Research (2015)

Regulatory Approval: Current Environment

Regulatory approval procedure

Medical devices cannot be placed on the European market without conforming to the requirements of the European Union

- CE marking is the medical device manufacturer's claim that a product meets the essential requirements of all relevant European Medical Device Directives, of which there are three:
  1. Medical Devices
  2. In Vitro Diagnostics
  3. Active Implantable Medical Devices (AIMD)
- Each EU country has a competent authority responsible for transposing the requirements of the Medical Device Directives
  - In Germany, the Federal Institute for Drugs and Medical Devices (BfArM) is the competent authority
  - Approval from one competent authority in Europe permits access across the entire European Union

- In 2012, the European Commission published initial proposals for the Regulations for Medical Devices (MDR). This approach is similar to the life-cycle view advocated by the US FDA. It is expected that the CE Marking process will change as this comes into force in late 2019

The European CE marking and regulatory approval process has no influence on pricing and reimbursement across member states

Sources: BSI Group; European Commission; BVMed

Regulatory Approval: Current Environment

Directive	Category	Category Description	Conformity Assessment Procedure	Device Examples
Medical Devices	Class I	Low risk. Most non-invasive devices that do not interact with the body	Manufacturer self-declares the device's conformity with the essential requirements of the Directive	Wheelchairs, Corrective glasses
	Class IIa	Medium risk. Devices that exchange energy with the patient in a therapeutic manner or are used to diagnose/monitor medical conditions	Manufacturers self-declares the device and can choose between the following four conformity assessments: 1. An examination and testing of each product 2. An audit of the production quality assurance system 3. An audit of final inspection and testing 4. An audit of the full quality assurance system	Disposable contacts, Sutures, Dental fillings, Hearing aids
	Class IIb	Medium risk. Most surgically invasive devices that are partially or totally implantable by the body	A Notified Body must carry out either an audit of the full quality assurance system or an "Annex III examination", coupled with one of the assessments 1, 2 or 3 above	Baby incubators, Dialysis equipment, Ventilators
	Class III	High risk. Used to support or sustain human life and are of substantial importance in preventing impairment of human health	Subject to a similar assessment procedure to Class IIb devices. However they must also submit a design dossier for examination by the Notified Body.	Hip replacements, Drug eluting stents, Devices that connect directly with the CNS
In Vitro Diagnostics	General	General devices include all IVDs other than those covered by Annex II and IVDs for self-testing	Manufacture self-declares and no notified body assessment required	Tests for hormones, Cardiac markers
	Self-Test	A device intended by the manufacturer to be able to be used by lay persons in a home environment	The manufacturer prepares a declaration of conformity in a similar way to the general devices but a Notified Body review is also required.	Pregnancy tests, Cholesterol home tests
	Annex II List B	The annex is sub-divided into two lists, List A and List B. All Annex II IVDs require the involvement of a Notified Body before the product can be placed on the market.	Audit of technical documentation and quality management system	Rubella, Prostate Cancer testing
	Annex II List A		Design dossier review. Audit of quality management system. Batches released by the Notified Body.	HIV tests, Hepatitis ABO Blood grouping
Active Implantable Medical Devices	AIMD	Due to their nature, all are classified as high risk items	All must undergo full quality assurance, including design of the product and post-market surveillance.	Implanted cardiac pacemakers

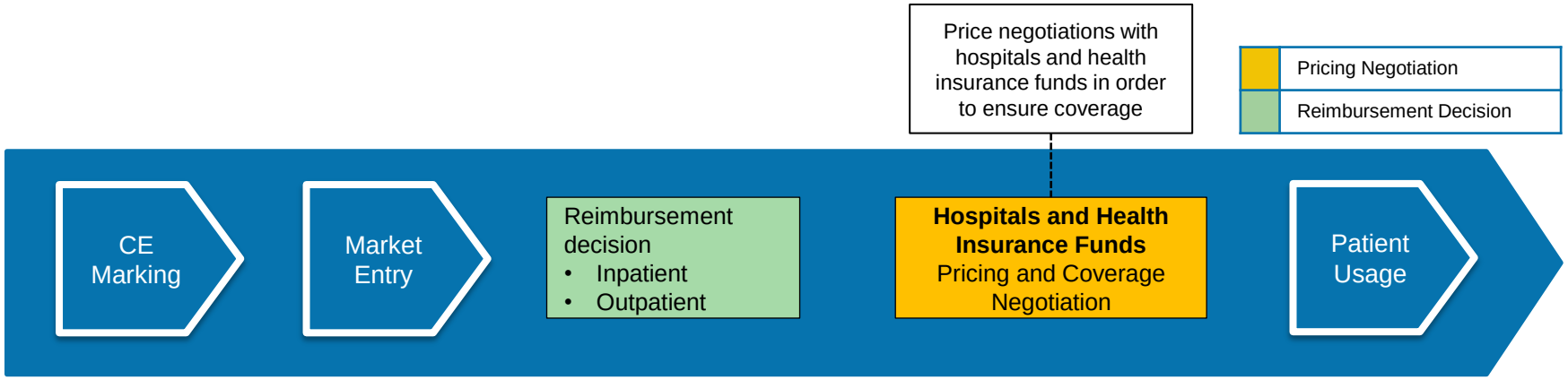
Pricing and Reimbursement Environment

Reimbursement procedure

- For the reimbursement of innovative medical devices it is crucial whether the device will be used in the hospital (inpatient) or ambulatory (outpatient) setting
  - In the inpatient setting, medical devices are reimbursed without prior assessment, as long as fundamental principles of quality and cost-effectiveness are not violated
  - All ambulatory medical devices must be evaluated before being reimbursed: only products “which show a benefit, are medically necessary and efficient” can be reimbursed

Pricing procedure

- Once the reimbursement decision has taken place there are price negotiations between the manufactures and individual hospital and insurance funds
- In principle, pricing is not regulated and rebates are permissible. However, reimbursement by sick funds (which greatly determines the manufacturer price) is subject to reference price schedules and contractual agreements with the statutory health insurance (GKV-SV)



Sources: IXPOS

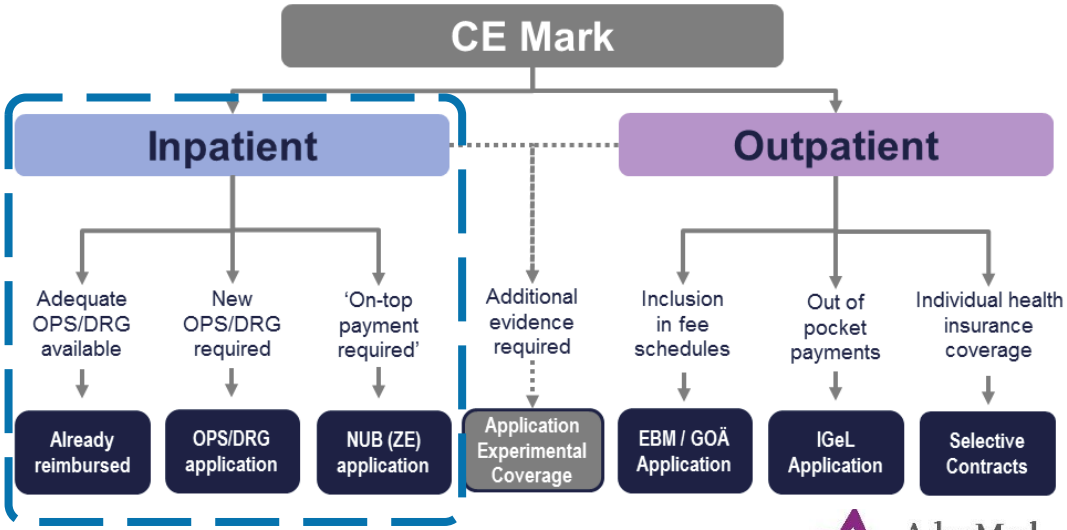
Reimbursement environment for in-patient care – 1/2

Reimbursement procedure

The reimbursement of in-patient care medical devices dispensed through hospitals is regulated by the diagnosis-related-group (DRG) system

Reimbursement procedure for "standard" devices

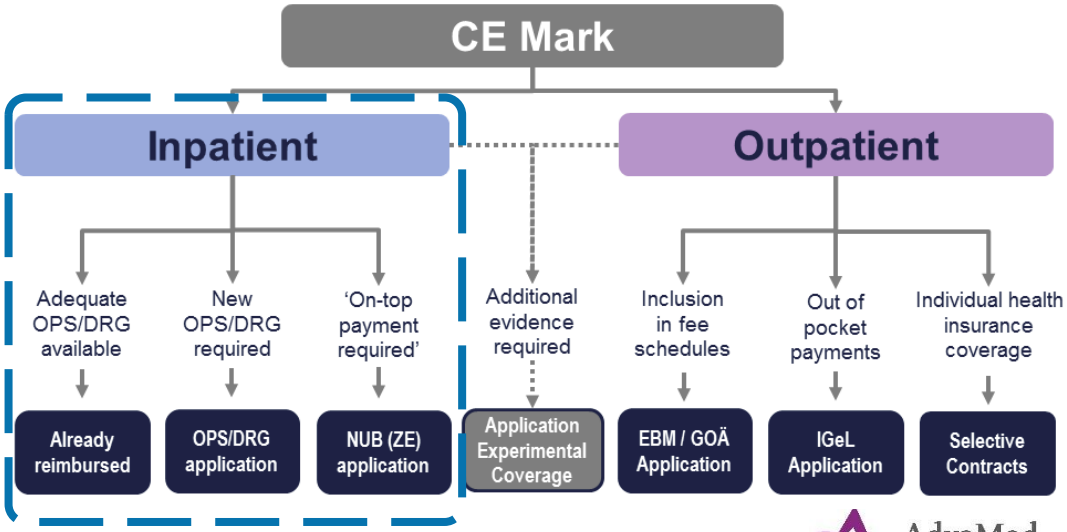
- DRGs list which treatments (including medical devices) can be given to patients according to the individual diagnosis and the hospital receives a fixed amount that is set-up by the DRG system for the entire treatment of the patient
- DRGs in Germany and the DRG classification system uses case-related coding rules that apply medical devices to either diagnoses (ICD-10 GM) or procedures (OPS)
- For novel devices new OPS codes can be requested by actors within the health care system. Such a request can be filed once a year at the DIMDI (German Institute of Medical Documentation and Information)
- With the DRG-case-based-flat-rate all costs related to the treatment and the hospitalization of the patient are covered, including medical devices
- In general, the in-patient reimbursement applications all take around 1-1.5 years from application and require no specific clinical or health economic evidence



Reimbursement environment for in-patient care – 2/2

Reimbursement procedure for cost-intensive, innovative devices

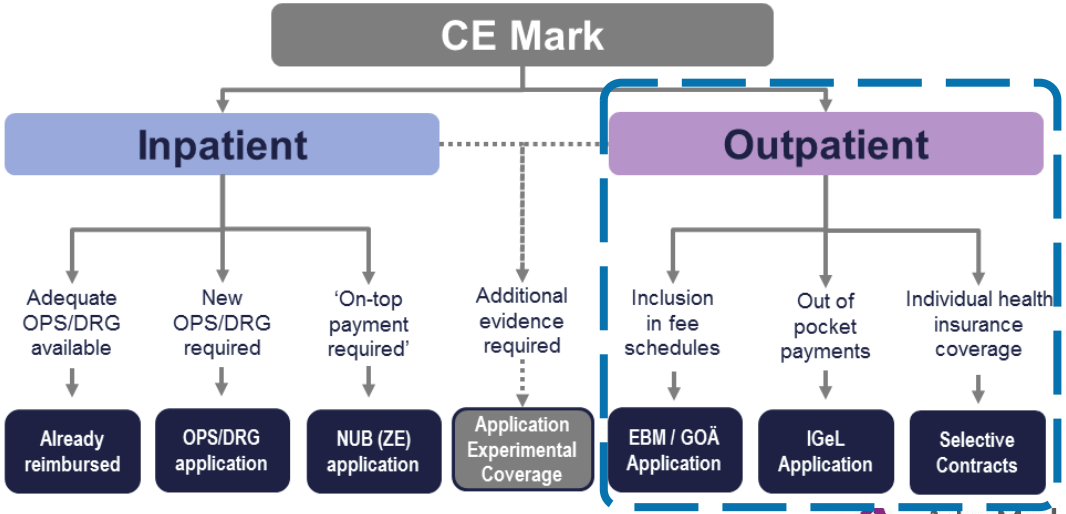
- The NUB-procedure (NUB: New Methods for Treatment and Screening) is a payment scheme to remunerate cost-intensive, innovative services or technologies that are used additionally to the procedures captured by the valid DRG case-based flat rate
  - This procedure is only open to technologies / procedures that are considered as being new in Germany
- Hospitals can file requests to the Institute for the remuneration system in hospitals (InEK) once a year to find out whether the conditions are set to negotiate with the health payer hospital-specific temporary “on-top” payments (NUB-payments)
  - If the request receives a favourable reply, the hospital can enter into negotiations with the respective local health payer. Every hospital will need to apply separately. The “on-top” payment (if the application is approved) will be available only to the hospital that applied for it and successfully negotiated afterwards
- In addition to the NUB-process there is as a further option to invoice an extra fee above the DRG-case-based flat-rate, which, however, is not restricted to innovations
  - It is called “additional charge”
  - In most cases the monetary value of the additional charge is based on empirical cost data supplied by reference hospitals



Reimbursement environment for out-patient care

Reimbursement procedure

- The G-BA makes the decision on all out-patient or 'ambulatory procedures' covered by the GKV
  - Only procedures which "show a benefit, are medically necessary and efficient" can be reimbursed
  - During the evaluation procedure, the G-BA may request a Health Technology Assessment (HTA) by the Institute for Quality and Efficiency in Healthcare (IQWiG)
  - In the case of a positive outcome of the G-BA-evaluation, the medical device must be covered by the GKV and included on the "Uniform Evaluation Scale" catalogue, also known as EBM, of reimbursable devices
  - Out of pocket payments can be covered through the private health insurance fee schedule (GOÄ)
- Many innovative medical services are also at first reimbursed on the basis of individual, regional and time-limited contracts between providers and payers, as the demands for clinical evidence are typically lower for such contracts
- Some procedures that are neither listed in the EBM nor covered by individual contracts between provider and payers can be received by the patients, but have to be paid out of the pocket. These services are called IGeL (Individual Healthcare Services). In general, they are paid entirely by the patients, as GKV does not consider them as "necessary, appropriate, and economic"



Pricing environment

Pricing process

- GKV conclude contracts with service providers (e.g. homecare companies) on the provision of healthcare services which entail the supply, use or application of medical devices
- For comparable services and related devices used when rendering these services, the contracts contain detailed provisions on prices and quality requirements etc.
  - Such contracts are subject to public tender procedures if, within such a contract, the service provider is retained by a GKV fund on an exclusive basis
  - If there is no exclusive retaining foreseen in a contract the public tender procedures are not applied since other healthcare providers may also enter into similar contract with the respective GKV funds and, thus, will also be allowed to render healthcare services for the patients of this very GKV fund based on such contracts
- Healthcare providers which do not have any contract with the GKV fund are generally not entitled to render healthcare services (and supply, use or apply medical devices) to the patients of such GKV fund
  - However, recent judgements confirm the patients' right to procure a necessary medical device themselves and have it reimbursed by the respective GKV if the product supplied by the service provider, for which the patient's GKV concluded a contract, does not prove to be sufficient, appropriate or functional

Sources: IQWiG website

Procurement Environment

Procurement process

- There are no specific regulations pertaining to medical device procurement as they are linked to the overall service delivery for patients

- Most medical devices, whether administered in the in-patient or out-patient setting, are procured by hospitals and individual hospitals can choose to negotiate independently with suppliers or multiple hospitals can band together to form a purchasing syndicate
- **Group purchasing organizations** (GPOs) are becoming more common in Germany, and about 80% of hospitals use GPOs to procure hospital products
    - GPOs have greater bargaining power than any single hospital gains when negotiating the price with medical device manufacturers
    - Some examples of preeminent GPOs in Germany include Prospitalia, Clinicpartner and Agkamed

Sources: IXPOS

Funding Environment

- There are no specific budgets for medical devices, and these are linked to spending on pharmaceuticals and other areas of healthcare
- The Statutory Health Insurance (GKV) pays for the medical device services offered by the DRG (in-patient) and EBM (out-patient)

In-patient medical devices	Out-patient medical devices
• Funding is administered at the DRG level to allocate financial resources to hospitals • As the various DRGs differ in terms of their clinical contents and resource consumption, each are budgeted independently • The aim of the DRG system is to represent all in-patient services in a 'lump-sum' payment system corresponding to the service provided • Under the NUB process, hospitals are able to apply individually for financing a new procedure, however the reimbursement for NUBs is negotiated separately with the GKV	• Medical devices in ambulatory care are provided by physicians who are subject to pre-determined price schemes by the regional Sickness-Fund Physician Association (KV) • Ambulatory-care physicians are paid on a fee-for-service basis, and the fee schedules have fixed Euro prices, where physicians are subject to budget caps on an individual basis • Physicians negotiate KV for the global budget for GP's, who in turn negotiate regional budgets with the Statutory Health Insurance at the federal level

 Sources: IXPOS

India

India: Country Overview

Wealth Indicators (2015)

State of development	Lower middle income	**GDP growth p.a.**	7.6%
GDP	USD 2.07 trillion	**Inflation**	5.9%
GDP per capita	USD 1,590	**Population**	1.3 billion

Healthcare Expenditure (2014)

Health expenditure	USD 27 billion	**Pharma expenditure**	USD 30 billion
Health exp. per capita	USD 21	**Pharma exp. per capita**	USD 23
Health exp. % of GDP	1.3%	**Device expenditure**	USD 5 billion
% Out of Pocket	89%	**Device exp. per capita**	USD 3.85

Sources: World Bank; WHO; OECD; Emergo; BMI Research (2015)

Approval: current environment

Regulatory framework

- Currently, no specific medical devices regulation exists in India
- Medical devices are regulated in the same way as drugs – through the Drugs and Cosmetics Act 1940
- Only 22 types of medical devices are required to go through a registration and approval process

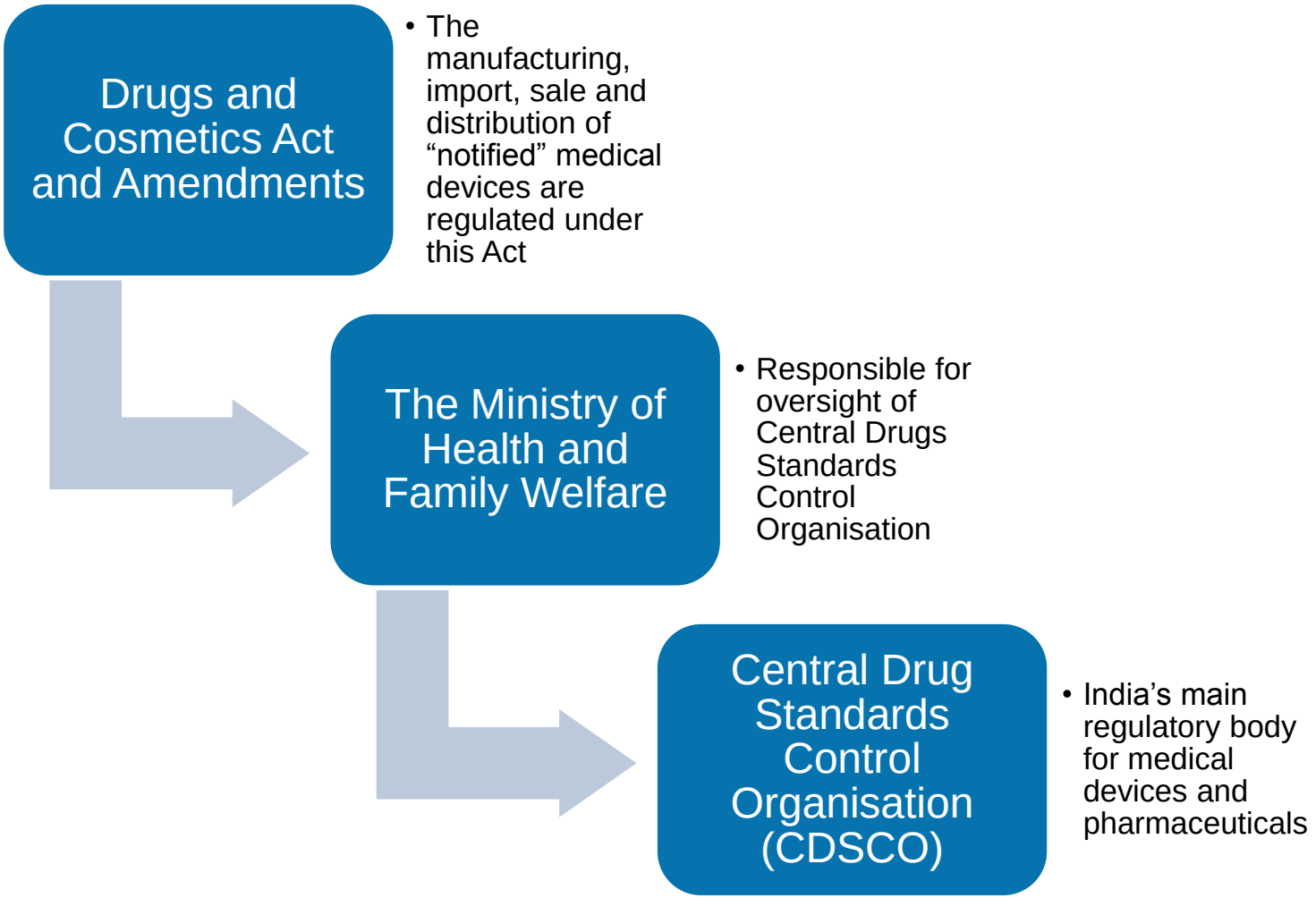
Regulated devices

- Devices notified (regulated) by the Indian government must register with India's regulatory body, the Central Drugs Standard Control Organization (CDSCO)
- Included on the list of 22 notified devices are:
  - disposable hypodermic syringes and needles
  - disposable perfusion sets
  - in-vitro diagnostic devices for HIV
  - HBSAG and HCV
  - cardiac and drug-eluting stents catheters and IV cannulas
  - bone cements
  - intra-ocular lenses
  - orthopaedic implants
  - prosthetic replacements
  - heart valves

Non-Regulated devices

- Non-notified devices do not require CDSCO registration, and may be distributed and imported into India according to formal customs rules
- If a product does not appear on the notified devices list, then it is categorized as non-notified

Approval environment: India's medical device regulatory structure



Approval environment: proposed policy changes

Past discussions

- **2006**: The Medical Devices Regulation Bill (MDRB) was proposed by the Ministry of Science and Technology
  - The MDRB was designed to consolidate laws related to medical devices and establish the Medical Device Regulatory Authority of India (MDRA), a national regulatory body for medical devices. This Act was dropped

- **2013**: The Drugs and Cosmetics (Amendment) Act purposed to establish the Central Drug Authority to regulate medical devices in addition to Drugs Cosmetics. This Act was shelved

Ongoing discussions

- **2016**: The Medical Device Rules, 2016 aimed to establish two separate laws for pharmaceuticals and medical devices
  - The Rules recommended the establishment of a National Medical Device Authority (NDMA) which would shift the oversight of medical devices through the Drugs and Cosmetics Act 1940 to this separate regulatory system
  - In addition, the new Rules would break medical devices and in vitro diagnostics up into four groups (Class A – Class D), based on risk-level [see next slide]

Approval environment: proposed categorisations of device

- The proposed 2016 Medical Devices Rules have outlined potential regulatory classification system that is more aligned with international systems

Category	Risk	Example
Class A	Low	Thermometers, tongue depressors
Class B	Low-moderate	Hypodermic needs, suction equipment
Class C	Moderate - high	Lung ventilators, bone fixations
Class D	High	Heart valves, implantable devices

Pricing: current environment and proposed changes

Current pricing framework

- Currently, the price of medical devices is negotiated between the manufacturers and the healthcare providers
- For devices defined as an essential product and included on the National List of Essential Medicines (NLEM), price considerations also take into account the reimbursement decision and prices are estimated to be 40% – 70% lower than market prices

Recommendations for change: Taskforce on Medical Devices (2015)

- Introduce a separate price control specific to medical devices by including medical devices separately from drugs in the list of commodities controlled under the Essential Commodities Act and regulated under a separate Medical Devices (Price Control) Order
- Empower a separate division within medicine pricing regulatory, the National Pharmaceutical Pricing Authority (NPPA), to fix and monitor the prices of medical devices
- Pricing of medical devices should be differentiated to that of drugs. When deciding on price, the costs of a basket of medical devices should be considered to account for industry cross-subsidisation and ensure the industry remains viable
- Liaise with the Insurance Regulatory and Development Authority (IRDA) and the Payer (Health insurance) industry to cover new technology on risk based pricing models

Reimbursement: current environment

Reimbursement framework

- Generally, reimbursement is very low or non-existent and reimbursement schemes vary depending on the medical equipment used and the procedure being done

- State governments provide health insurance schemes that are geared towards helping poor people who cannot otherwise afford treatment benefit from free treatment in affiliate hospitals. Apart from state coverage, central government has specific health insurance schemes

- **Existing products:** For some medicinal products such as heart valves and stents etc. coverage has been determined and available for insurers

- **New products:** For relatively new products such as Left Ventricular Assist Devices (LVADs) coverage has not been established, thereby making these products expensive
  - Prior to 2013, the government had a differentiated pricing strategy for drug-eluting stents, depending on the standard of approval. India- and USA- approved drug-eluting stents were reimbursed up to $1,200 and EU-approved drug-eluting stents at $923
  - However in February 2013 the reimbursement rates were capped at $461, irrespective of the standard of stent (in addition, reimbursement rates for bare metal stents were capped at $221)

Procurement: current environment

Current hospital procurement framework

- For the purchase of medical equipment/devices, the government authorizes the government owned and private hospitals to issue global tenders
  - These tenders are permitted even if a product is manufactured domestically. Most of the government tenders follow two parts: technical bid and commercial bid

- All government tenders are time consuming as public hospitals often have extensive bureaucratic structures and decisions are sometimes hard to reach. Generally the government decides on the lowest bidder but preference is given to domestic/ Indian manufactures.
  - The private hospitals evaluate the products on the basis of the technology, cost and price. Decision-making is faster in the private hospitals

- All purchases of medicines and medical equipment priced below Rs 5 lakh (approx. USD 7,450) are made by individual hospitals and those above Rs 5 lakh (approx. USD 7,450) were under the control of the Central Equipment Procurement Cell (CEPC) under the Health department

- Procurement varies according to the level of autotomy of the procurement systems in India's 29 States. Procurement models can vary according to whether the state procurement budget is divided between the centralised, decentralised and mixed methods of acquiring medical services
  - Autonomy refers to the extent of government involvement in the decisions of the procurement organisation; 'fully autonomous' implies minimal involvement while 'government owned' indicates a high degree of involvement

Procurement: current environment and proposed policy changes

Physician influence in purchasing decisions

- A majority of Indians are unable to afford proper healthcare. This has led to healthcare providers paying careful attention to costs while making any purchases. While big hospitals in Tier I cities* are typically driven by quality when it comes to purchasing medical equipment, smaller hospitals in Tier II and Tier III cities and rural areas prefer to purchase cheaper products

- Indian physicians exert influence on hospital purchasing decisions. Enhancements and advancements remain important but affordability is a key component of product innovation has definitely moved-up the food chain and physicians are applying greater scrutiny when assessing the value of innovative medical devices

Recent and proposed policy changes

- The import duties on medical devices and equipment have been increased almost across the board by 7.3%

***Indian cities are classified according to the level of House Rent Allowance (HRA) and income tax exemption provided by the Government – essentially categorising cities by cost of living. Tier I cities have large populations and are highly commercialised metropolises. Tier II cities are usually regional hubs such as state capitals. Tier III captures all other cities.

Funding: current environment

Current funding trends

- Absence of universal health coverage and limited social health coverage has led to a high burden of Out-Of-Pocket expenditure (OOP) in India. OOP contributes approximately 86% of private expenditure and 60% of overall healthcare expenditure in the country

- Evidence suggest that only 3%-5% of Indians are covered under any form of health insurance. The Indian health insurance scenario is a mix of mandatory social health insurance, voluntary private health insurance, and community-based health insurance. This includes those covered under the Central Government Health Scheme (CGHS; 4 million beneficiaries), the Railways Health Scheme (1.2 million), and the Employees' State Insurance Scheme (0.3 million), all examples of social health insurance

- Premiums collected by private health insurance agencies are a meagre 0.3% of the total health expenditure, further emphasizing the lack of general acceptance of the concept risk pooling

USA

United States: Country Overview

Wealth Indicators (2015)

State of development	High Income	**GDP growth**	2.43 %
GDP	USD 17.95 trillion	**Nat. income per capita**	USD 54,960
GDP per capita	USD 55,836.79	**Population**	321.4 million

Healthcare Expenditure (2014)

Health expenditure	USD 3.02 trillion	**Pharma expenditure**	USD 324.6 billion
Health exp. per capita	USD 9,402.54	**Pharma exp. per capita**	USD 1009.96
Health exp. % of GDP	17.14%	**Device expenditure**	USD 107.5 billion
% Out of Pocket	11.05%	**Device exp. per capita**	USD 334.47

Sources: World Bank; Centers for Medicare and Medicaid Services

Approval: current environment

Regulatory framework

- FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the US
- Code of Federal Regulations (CFR) outlines policies [see below]
- A medical devices is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article… which is intended for use in the diagnosis… or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Classifications

- FDA organizes devices into 16 medical specialty "panels" using descriptions in Title 21 of CFR
  - I.e. cardiovascular devices, ear, nose, and throat devices, neurology devices, etc.
- Each of these generic types of devices are classified as Class I, II, and III, with increasing regulatory control

CFR – other key features

- Medical device manufacturers (domestic and foreign) and initial distributors of must register their establishments with the FDA
- Contract distributors, labelers, repackagers, etc. must also list their devices with the FDA
- Manufacturing facilities undergo FDA inspections to assure compliance with QS requirements
- Incidents in which a device may have caused or contributed to a death or serious injury must to be reported to FDA (Medical Device Reporting program)

Source: FDA Website

Approval environment: Categorisations of devices

Class	Description
Class I	• Most devices in this class are exempt from Premarket Notification 510(K) • Generally very low-risk devices
Class II	• Most Class II devices require Premarket Notification 510(k), though some are exempt
Class III	• Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury • Associated with a higher risk levels • Most devices in this class require Premarket Approval: • FDA determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices

Source: FDA Website

Approval: current environment

501(k) – Lower Risk and/or with predicate

- A premarket submission made to FDA that demonstrates the device to be marketed is at least as safe and effective, or substantially equivalent, to a legally marketed device
- A device cannot be commercially distributed until the manufacturer/distributor receives an FDA letter of substantial equivalence authorizing commercial distribution, if 501(k) is required
- No 510(k) form - 21 CFR 807 Subpart E describes requirements for a 510(k) submission
- "Predicate" - the legally marketed device(s) to which equivalence is drawn. A device is substantially equivalent if, in comparison to a predicate, it:
  - Has the same intended use as the predicate and has the same technological characteristics as the predicate; OR
  - Has the same intended use as the predicate, has different technological characteristics and the information submitted to FDA, does not raise new questions of safety and effectiveness, and demonstrates that the device is at least as safe and effective as the legally marketed device

Pre-Market Approval (PMA) – higher risk and/or no predicate

- Required for high risk devices that pose significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process
- More involved process - includes submission of clinical data to support claims made for the device
  - Sections on non-clinical laboratory studies & on clinical investigations
- Approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)
- Approval is, in effect, a private license granting the applicant permission to market the device

Source: FDA Website

Approval environment: flow chart of current process

1 Classify device and prepare materials

- Using the FDA classification database, determine device classification by researching "Predicate Devices" already registered in the US market
  - If no predicate found, 513(g) or De Novo process can recommend class
- Implement Quality Management System (QMS)
- Develop clinical trial protocol and conduct studies, if needed

2 Prepare and submit 510(k) or PMA application

- Prepare and submit 510(k) or PMA application and pay fee
- Facility inspections:
  - Class III – FDA inspects all major suppliers involved in design/production (must comply with FDA QSR)
  - Class I or II – no inspection prior to device registration, but random inspections conducted after approval

3 Check for approval

- FDA issues 510(k) clearance or PMA approval letter
- Foreign manufacturers appoint an FDA US Agent representative as a local point of contact
  - Required for listing company on FDA website

4 List and begin selling device

- List device and register company using FURLS system on FDA website.
- Begin selling device.
- Authorization does not expire as long as certain types of changes are not made (design, intended use)

Source: Emergo

Approval environment: proposed policy changes

Ongoing discussions

- The 21st Century Cures Act establishes a priority review program for breakthrough devices, loosens some device clinical trial requirements and clarifies how and whether to regulate medical software
  - Result of desire by members of Congress to revamp device premarket reviews and clinical trial requirements
  - The controversial act is set to fast-track “breakthrough” and novel device registration
  - Critics warn of public health repercussion with lax regulations
- FDA recently issued a guideline on Medical Device Post-Market “emerging signals”
  - Guideline explains how the agency notifies the public of potential links between registered medical devices and adverse events
- FDA is starting to seek coverage organizations’ input for medical device clinical trial designs
  - Has implications for insurance and reimbursement
  - Has potential to impact future regulation

Source: Emergo

Pricing and Reimbursement: current environment

Medical device pricing is not regulated and is driven by competition for hospital/clinic purchasers

Factors affecting pricing

The US prices for many medical devices have been dropping. This trend is driven by a few key changes:

- Hospitals buying most of the implantable medical devices have grown wary of incremental improvements long used by device makers to prop up prices on pacemakers, defibrillators, etc.
- Medical device manufacturers are finding it much harder to rely on physician brand loyalty to drive purchasing decisions
- Since medical devices are purchased by hospitals and clinics, rather than insurers, manufacturers have to acknowledge hospital's finances when pricing their products

Manufacturer pricing power

Despite these trends, medical device manufacturers still have significant pricing power:

- Limited competition
- Patent protection
- Confidentiality clauses - device manufacturers have designed sales contracts that include language forbidding buyers from disclosing the final negotiated price to other buyers, or even to patients or insurers
- Low price visibility - though retail drug prescription spending amounts are commonly reported, similar figures for implantable devices are not available because their costs are largely borne by hospitals and lumped into the overall category of hospital spending

Source: Health Affairs, StarTribune

Pricing and Reimbursement: current environment

Both private and public insurers look for on superiority of a product relative to the gold standard in order to determine reimbursement

Reimbursement: general process

- Most insurers (private and public) follow the Centers for Medicare & Medicaid Services (CMS) guidelines to determine reimbursement schemes
  - The FDA approval process emphasizes different features than those that insurance companies use to determine reimbursement schemes
    - FDA stresses safety and efficacy
    - CMS focuses on superiority of a product relative to the gold standard
- Medical devices are identified in insurer's data systems using codes:
  - Many medical devices are used as part of inpatient and outpatient procedures that are covered by a single payment to the hospital for the procedure
  - Multiple standardized coding systems used by public and private payers during the electronic medical billing process:
    - Examples: Diagnosis related group (DRG), Healthcare Common Procedure Coding System (HCPCS), Ambulatory Payment Classifications (APC), Current Procedural Terminology (CPT), ICD-9-CM, ICD-10-CM, etc.
    - Assignment of Category 1 CPT codes by the American Medical Association require:
      - The existence of published peer-reviewed clinical studies
      - Widespread use of the new technology or procedure
    - Applications to acquire a Health-care Common Procedure Coding System (HCPCS) code may be made only after the accumulation of three months of market experience

Source: The new England Journal of Medicine, Nature Biotechnology, Pharmacy and Therapeutics, Medicare Website.

Pricing and Reimbursement: coverage

Overall, US public and private payers provide similar coverage, with individual variation

Reimbursement: : Public versus Private

- Reimbursement processes and coverage schemes can differ by payer type and individual payer
- Despite some differences, public and private insurers tend to offer similar coverages:
  - Analysis of medical coverage decisions by Medicare shows:
    - ~50% were equivalent to corresponding private payer policies
    - ~25% were more restrictive
    - ~25% were less restrictive
- Public insurers: while the CMS administers public programs that covers the reimbursement of medical devices, the Veterans Administration is the key agency responsible for negotiating an agreement with manufacturers/distributors for medical devices procurement by certain government agencies
- Most private insurers use a Technology Assessment Committees to determine coverage, along with CMS guidelines
- Americans under Medicare are turning towards accountable care organizations (ACOs), meant to provide better coordinated care by connecting healthcare providers
  - Purchasing decisions are made across the value chain
  - Increases cost and preferred supplier constraints
  - Trend also affecting private insurers
- Medicare and Medicaid payers can use different billing codes than private payers:
  - Private insurers commonly use DRG, CPT, and HCPCS codes
  - Public insurers use CPT and HCPCS codes, as well as CMS-DRG codes

Source: TechTarget, CMS, Pharmacy and Therapeutics, Medicare Website.

Procurement: current environment

Medical device procurement

Medical devices are primarily purchased by hospitals and clinics (unlike pharmaceuticals, which are primarily bought by insurers or PBMs). Thus, procurement processes evolved with hospital systems

- When more physicians worked for independent practices, doctors dictated what devices to buy. Price was not a factor that swayed them
- Today, doctors are more likely to work directly for hospitals and are expected to back up personal preferences with data good enough to sway other physicians on the purchasing committee
- Financial ties between doctors and manufacturers are under increased scrutiny

The decision on how much and what type of device to buy is heavily influenced by the attending physicians who will use, monitor, or implant the device and who have a range of device preferences

Procurement committees

Procurement decisions are made by hospital medical committees (rather than a doctor-by-doctor basis)

- In a national survey, the percentage of surgeons reporting that their procurement department makes most of the purchasing decisions for tools and devices has doubled in the past three years
- Cost and value considerations much bigger factors under administrators (vs. practitioners)
- The reimbursement playing field has tilted toward larger-tier MD manufacturers able to leverage value proposition and product differentiation to these larger, more cost-conscious customers

Medical devices do not undergo standard Pharmacy and Therapeutics (P&T) committee review processes. P&T committees, who decide which drugs appear on a hospital/plan's drug formulary, would get involved only to make sure MD authorizations coordinate with everything else in a hospital

US procurement is driven by administrator, rather than practitioner, decisions

Source: Bain; Emergo; Pharmacy and Therapeutics; Star Tribune; Health Affairs

Funding: current environment

Healthcare Funding

- US healthcare providers are financed by a mix of private insurance, government programs, and out of pocket funds: of the total population, 56% use private insurance, 36% use public programs, and 9% are uninsured
- Also, the Government directly provides some health care through government hospitals and clinics staffed by government employees

Public Funding

- Tax-funded expenditures accounted for 64.3% of US health spending in 2013
- The largest government programs are Medicare and Medicaid
- Other government programs include:
  - State Children's health insurance program
  - Tricare
  - Veteran's Health Administration
  - Indian Health Service
- Two commonly overlooked tax-funded health expenditures are government outlays for public employees' private health insurance coverage and tax subsidies to health care

Private Funding

- The majority of the population (49%) access insurance through employer-based programs
- About 7% of the population uses non-group insurance, purchased individually
- Medical devices covered by Government programs are not always covered by private insurers (and vice-versa)
  - I.e. some insurers cover hearing tests, but not a hearing aid itself
- In the US, about 17% of health care costs are paid for out-of-pocket
  - Having to pay for health care out-of-pocket contributes significantly to many bankruptcies in the US

Source: Kaiser Family Foundation; Merck Manuals; New England Journal of Medicine.
Note: All percentages for 2015, unless otherwise specified.