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

Findings and analysis from Australia, Colombia, Japan, Russia, South Africa, Thailand and Turkey

CRA Charles River Associates

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AdvaMed
Advanced Medical Technology Association

Agenda

- Introduction
- Approach for the analysis
- Summary of the main findings
- Next steps
- 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

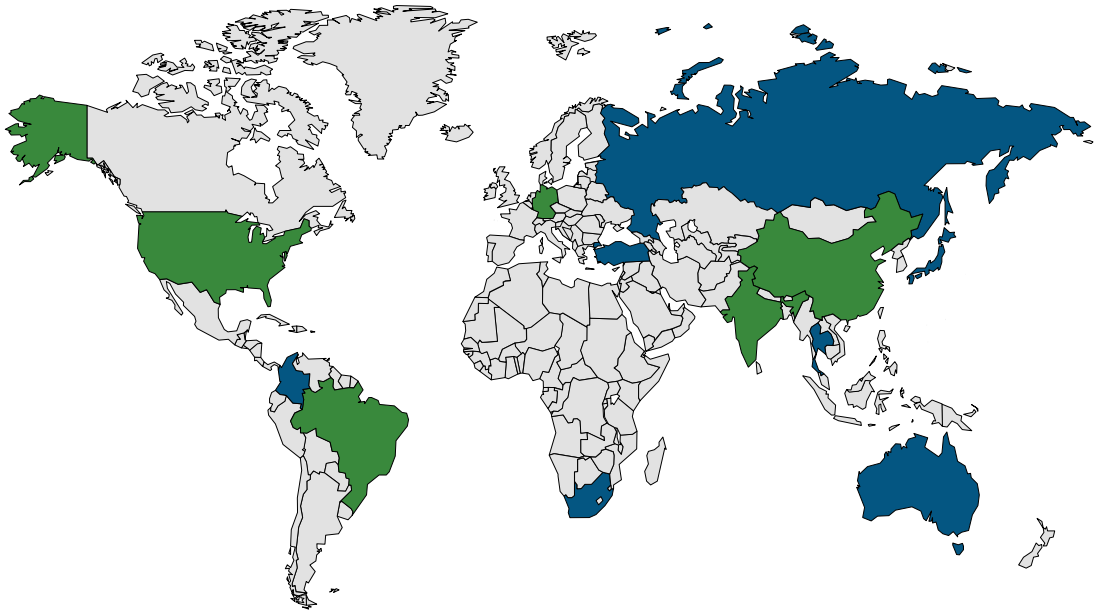
Project objective and planned activities

- **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

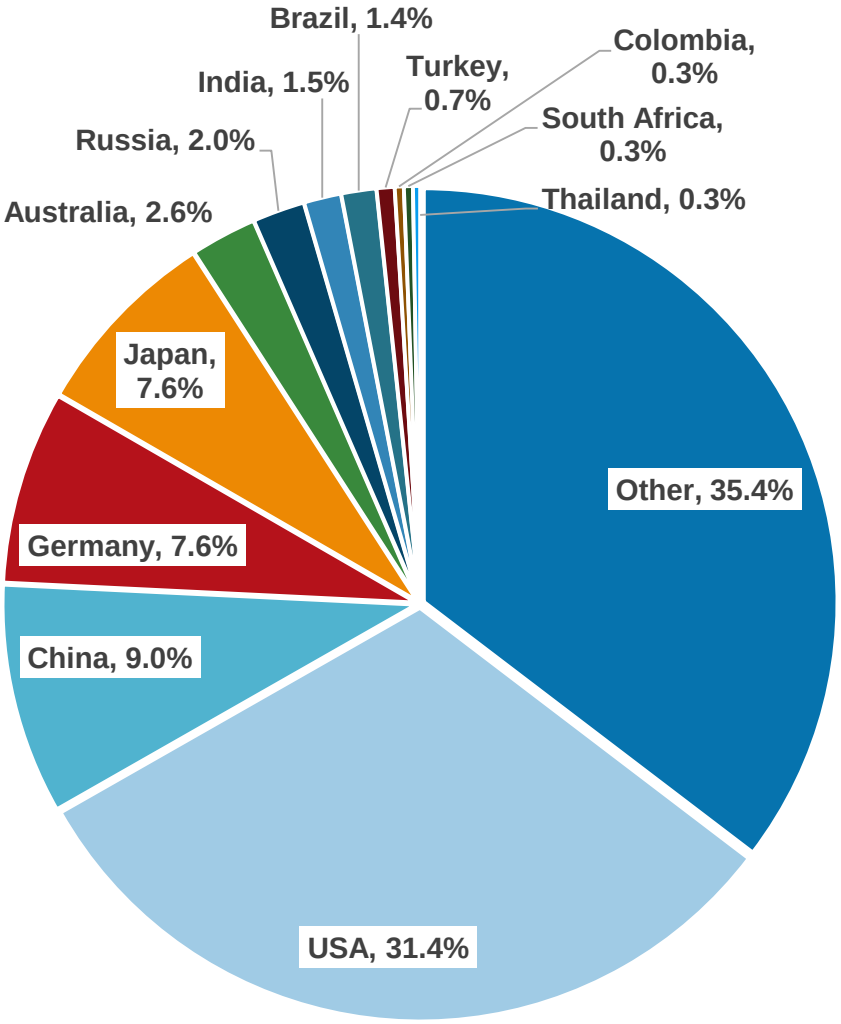
- Brazil
- China
- Germany
- India
- USA

Second wave of countries

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

The first wave of countries has been discussed and reviewed in a separate deck

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 different types of payer/purchaser)? 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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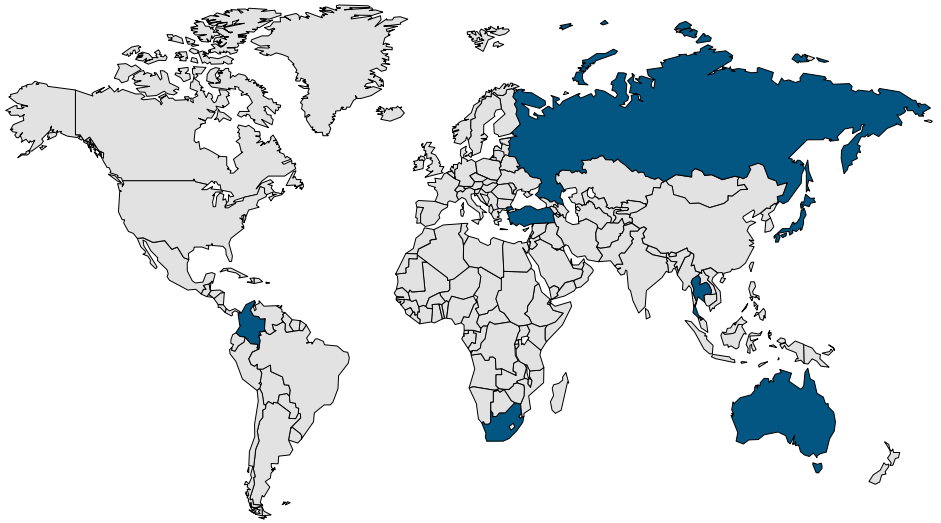
Second wave* of countries

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



- Wave 2 countries are for discussion during the next progress meeting

*Wave 1 countries have already been discussed and reviewed

Economic indicators overview: comparison across countries

		Australia	Colombia	Japan	Russia
Wealth indicators (2015)	World Bank income group	High Income	Upper-Middle	High Income	Upper-Middle
	GDP	USD 1.34 trillion	USD 292 billion	USD 4.12 trillion	USD 1.33 trillion
	GDP per capita	USD 56,311	USD 6,056	USD 37,322	USD 9,092
	GDP growth	1.4%	3.08%	0.6%	-3.7%
	Inflation	1.6%	2.6%	0.1%	7.7%
	Population	24 million	48 million	127 million	144 million
Health indicators (2014)	Health expenditure	USD 114 billion	USD 27 billion	USD 527 million	USD 86.8 billion
	Health exp. per capita	USD 4,750	USD 569	USD 4,150	USD 604
	Health exp. % of GDP	8.8%	7.2%	11.4%	7.1%
	% out of pocket	19%	15%	14%	46%
	Pharmaceutical exp.	USD 9.6 billion	USD 3.3 billion	USD 96 billion	USD 54.8 billion
	Medical devices exp.	USD 8.9 billion	USD 1.2 billion	USD 26 billion	USD 7 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

	Australia	Colombia	Japan	Russia
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- and medium-risk devices going through a simplified procedure • More complex process for high risk devices	Yes • Simplified process for low-risk devices • More complex process for medium, medium-high and high risk devices	Yes • Simplified process for low risk devices • More complex process for medium, medium-high and high risk devices
How does the approval process work (for each category of medical devices, if relevant)?	All medical devices must be approved by the Therapeutic Goods Administration (TGA) - a division of the Australian Department of Health	All medical devices obtain approval from the National Food and Drug Surveillance Institute, INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos)	All medical devices need approval from the Pharmaceutical Medical Device Agency (PMDA)	All medical devices need approval from the Roszdravnadzor (RZN)

Approval environment: summary findings – 2/2

	Australia 	Colombia 	Japan 	Russia 
Does the approval process have any implications on value or price determination?	None	None	None	None
Are there any policy debates about changing the current environment?	None	INVIMA is speeding up registration renewals for low- and medium-risk medical devices. Registrants must still submit applications for INVIMA renewal, but now it will grant those renewals within three day	None	• Between January 2016 and January 2022, for registrations submitted after January 2016: approval granted in one country under the Eurasian Customs (EAC) procedure will be recognised across all EAC union • All products must reregistered by 31 December 2021 under EAC procedure. Approval granted under EAC procedure will be recognised across all EA Economic union

Pricing environment: summary findings – 1/3

	Australia	Colombia	Japan	Russia
Is the price decided or directly controlled by the Government?	No	Yes • New system for price regulation of some medical device (currently applied to some categories, with plans to extend price control to all medical devices)	No	Not currently • Price of implantable devices will be regulated in 2017
Is there a different pricing process for particular categories of medical devices?	Yes • There are different pricing methods for standard and innovative devices	Yes • Price regulation for particular categories of devices	Yes • There are different pricing methods for imported devices and innovative devices	Not currently • Price regulation is expected to be implemented in 2017 for some categories of devices

Pricing environment: summary findings – 2/3

	Australia	Colombia	Japan	Russia
How does the pricing process work (for different types of payer/purchaser)?	**Public sector** • For "standard" devices that are reimbursed as part of a procedure, price is negotiated between healthcare providers and manufacturers • For "innovative" devices that are not reimbursed as part of the procedure, effectiveness and economic considerations inform price negotiations **Private sector** • Price is negotiated between manufacturers and healthcare providers	**Public sector** • For selected categories of devices there is a new price regulation process: the price of some categories of devices (e.g. coronary stents, cochlear implants, hearing aids) is regulated via international reference pricing • The price of the other categories is not regulated and is determined through market negotiations **Private sector** • Price is negotiated between manufacturers and healthcare providers	**Public sector** • Imported medical devices are priced based on foreign reference pricing (of at least two countries – Australia, France, Germany, the UK or the US) • For new medical devices with no similar alternatives already on the market, price is set using the cost plus method **Private sector** • Price is negotiated between manufacturers and healthcare providers	**Public (currently) and private sector** • Price is not regulated for all devices and is determined through negotiations **Price regulation for public sector (to be implemented)** • Price regulation for 362 types of devices included in a list for implantable devices is due to start in 2017 • Price regulation would take the form of a cap, where the maximum manufacturer's prices for implantable medical devices and the maximum regional mark-ups. Current methodology goes through the revision process.

Pricing environment: summary findings – 3/3

	Australia	Colombia	Japan	Russia
Are there any policy debates about changing the current pricing environment?	None	The Colombia's Ministry of Health & Social Protection announced new price regulations for medical devices effective March 5th, 2015. This is initially applied to some categories of devices – it could be expanded to all devices in the near future	None	Yes. The price of some implantable devices is going to be capped in 2017. There is a debate on further classification details for implantable devices under this policy. Currently 362 products and groupings are not fully clarified.

Reimbursement environment: summary findings – 1/4

	Australia	Colombia	Japan	Russia
Are devices usually reimbursed to healthcare providers (both public and private) by a third-party payer?	Yes	Yes	Yes	Yes
Is the reimbursement process different for different types of medical devices?	Yes • Different reimbursement process between standard devices reimbursed as part of a procedure and innovative devices not reimbursed as part of a procedure	Yes • Different reimbursement treatments between standard devices and “high-cost” devices	Yes • Different reimbursement process between “standard” and “innovative” devices	No

Reimbursement environment: summary findings – 2/4

	Australia	Colombia	Japan	Russia
How do third-party payers decide whether to reimburse a device or not (for each category of medical devices, if relevant)?	**Standard devices that are part of a procedure** • No decision is made specifically to device as payers reimburse the medical procedure **Innovative devices that are not part of the procedure** • Before a device can gain reimbursement, it must be included on the Medical Benefits Scheme (MBS)	**"Standard" devices** • No decision is made specifically to device as payers reimburse the medical procedure **"High-cost" devices** • Assessment and positive decision from a scientific panel (HTA-style review of the procedures) • Legal action for the protection of fundamental rights	**"Standard", non-costly devices** • No decision is made specifically to device as payers reimburse the medical procedure **"Innovative" devices** • Assessment of value, efficacy, incremental benefit	No decision is made specifically to device as devices are reimbursed as part of the hospital and procedure budget. Number of procedures is limited and defined by 'quata' by the Regional Health Care Ministries/Committee

Reimbursement environment: summary findings – 3/4

	Australia	Colombia	Japan	Russia
How is the reimbursement rate to healthcare providers established (for each category of medical devices, if relevant)?	**Standard devices that are part of a procedure** • Devices are reimbursed with the cost of the procedure **Innovative devices that are not part of the procedure** There are HTA agencies that are relevant to the reimbursement rate decisions: • Medical Services Advisory Committee (MSAC): • Prostheses List Advisory Committee (PLAC): The 'Prosthesis List' is a list of surgically	**"Standard" devices** • The reimbursement for the procedure (also covering the cost of the device) is provided with the national Mandatory Health Plan ("POS") **"High-cost" devices** • The rate of reimbursement depends on the HTA assessment of value	**"Standard" devices** • Devices are reimbursed with the cost of the procedure **Cost-intensive / innovative devices** • The rate of reimbursement depends on the HTA assessment of value	The cost of the devices is reimbursed as part of the cost of the procedure
Is there an "innovation clause" available?	Yes, there is an innovation premium	No	Yes, there is an innovation premium	No

Reimbursement environment: summary findings – 4/4

	Australia	Colombia	Japan	Russia
Are there any policy debates about changing the current reimbursement environment?	None	None	Devices not reimbursed are paid for out-of-pocket by the patients. In 2016, the government introduced a program under which patients can request (individually) the use of a medical device to the MHLW	None

Procurement environment: summary findings – 1/2

	Australia	Colombia	Japan	Russia
Is the procurement process different for different types of medical devices?	Yes • Procurement varies by private or public health system (state-level legislation may also influence procurement process)	No	Yes • Procurement varies by private or public health system	No. • There are NO different procurement process for low and high cost devices. Tender is the only procedure applicable in Russia.
Are there any existing or proposed preferential policies (for example domestic preferences or localization requirements)?	No	No	No	Yes • Tenders for state procurements of certain types of devices included in the Limitation list (362 products) are closed for foreign manufacturers if at least two bids with devices from local manufacturers are submitted • Local products have 15% price preference.

Procurement environment: summary findings – 2/2

	Australia	Colombia	Japan	Russia
How does the procurement process work?	**Public providers** Devices are purchased under state, regional or hospital arrangements, typically through a competitive tender process **Private providers** Devices are purchased by private hospital/hospital groups with categories of devices reimbursed by means of contractual arrangements with health funds	**Public sector** • Hospitals and providers purchase medical devices for use in procedures (rarely purchased by out-of-pocket patient) • Procurement can occur via a tender process	**Public providers** Tendering is mandatory for medical device contracts over the value of USD73,000 **Private providers** There is no formal process. It is typically reflective of the distribution channel	**Low cost devices** Medical equipment with a cost of less than USD 7,000 can be sold directly to hospitals also through tenders **High cost devices** Purchases of expensive equipment are always done through tenders
Are there any other debates about changing the current procurement environment?	None	The country's healthcare infrastructure is adequate in the larger urban areas, but is in need of modernization	None	The Russian government considers to expand the Limitation List of medical devices of foreign origin to participation in the procurement for state and municipal needs

Funding environment: summary findings

	Australia	Colombia	Japan	Russia
How does the funding process work?	**Public healthcare system** Hospital costs are reimbursed under Activity Based Funding **Private healthcare system** Insurers are only obliged to pay if the procedure is included on the MBS. The Prostheses List lists the devices for which private health insurers are mandated to pay a co-payment	Medical devices can be financed through both public and private funding, depending on the insurance plan of the patients	The majority of medical devices are reimbursed by the NHI (National Health Insurance) such that the NHI is the ultimate funder of medical devices	Funding for medical equipment, devices and supplies purchases for public healthcare establishments now comes only from mandatory insurance funds. Federal and regional government budgets are now not providing any funding for medical devices/equipment.
Are there any policy debates about changing the current environment?	None	Despite sweeping healthcare reform, funding and spending for medical equipment is still relatively low	None	None

Economic indicators overview: comparison across countries

		South Africa	Thailand (2013)	Turkey
Wealth indicators (2015)	World Bank income group	Upper Middle	Upper Middle	Middle Income
	GDP	USD 313 billion	USD 420 billion	USD 718 billion
	GDP per capita	USD 7,575	USD 5,779	USD 9,130
	GDP growth	0.7%	2.7%	4%
	Inflation	5.3%	2.2%	7.7%
	Population	54.5 million	67.5 million	78 million
Health indicators (2014)	Health expenditure	USD 18 billion	USD 44.3 billion	USD 82.6 million
	Health exp. per capita	USD 589	USD 658	USD 568
	Health exp. % of GDP	8.8%	6.2%	5.2%
	% out of pocket	16%	15%	18%
	Pharmaceutical exp.	USD 3.9 billion	N/A	USD 7.6 billion
	Medical devices exp.	USD 1.2 billion	USD 950 million	USD 2.4 billion (2013)

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

Approval environment: summary findings – 1/2

	South Africa	Thailand	Turkey
Is the approval process different for different types of medical devices?	Yes • Low-risk devices going through a simplified procedure • Medium- and high-risk devices go through a more formal process • Regulations are new as of December 2016 and are not fully operationalized	Yes • Low-risk devices going through a simplified procedure • Medium- and high-risk devices go through a more formal process	Yes • All medical devices must be registered to TITUBB/UTS. MDR requirements dictate approval. • There is a simplified process for low-risk devices • More complex process for medium- and high-risk devices
How does the approval process work (for each category of medical devices, if relevant)?	All medical devices must be approved by the Medicines Control Council (MCC). This will be a temporary arrangement until the new authority (SAHPRA) is established.	All medical devices obtain approval from the Thai Medical Device Control Division, Food and Drug Administration (TFDA)	All medical devices need approval from the Ministry of Health (MoH)

Approval environment: summary findings – 2/2

	South Africa	Thailand	Turkey
Does the approval process have any implications on value or price determination?	None. However, worth noting is a new Act as of June 2017 that prohibits rebates and bonusing.	None	None
Are there any policy debates about changing the current environment?	• The South African Health Products Regulatory Authority (SAHPRA) was established as of June 1st. A government notice calling for nominations has been published. This entity will be responsible for regulation of drugs, biologics, medical devices, in vitro diagnostics, complementary medicinal products, food, and cosmetics	None	MOH has recently announced a product tracking system to track medical devices.

Pricing environment: summary findings – 1/2

	South Africa	Thailand	Turkey
Is the price decided or directly controlled by the Government?	No	Yes • Price regulation for essential devices	No
Is there a different pricing process for particular categories of medical devices?	Yes • There are different pricing methods private and public sectors	Yes • Price ceiling for particular categories of devices	No
How does the pricing process work (for different types of payer/purchaser)?	**Private sector** • A single exit price (SEP) mechanism applies only to medicines and not devices. Device prices are negotiated with payors and hospital groups. **Public Sector** • The National Department of Health (DoH) negotiates a national tender price with manufacturers for medical devices used in government hospitals.	**Public sector** • All publically reimbursed medical devices are listed in the National List of Essential Drugs (NLED). Their price is negotiated and regulated by the Ministry of Finance and the Ministry of Public Health • If the medical device is reimbursed by the NLED, then the purchase price cannot deviate more than 3% from the reference price (public hospitals obtain capitation reimbursement) • For medical devices that are not included in the NLED, there is no price regulation (no price ceilings nor reference sets) **Private sector** • Price is negotiated between manufacturers and healthcare providers	**Public and private sector** • Price is negotiated between manufacturers and healthcare providers for the private sector. • Public sector relies primarily on hospital tenders where compliance with tender specs and price are primary considerations. Low price is overriding criteria.

Pricing environment: summary findings – 2/2

	South Africa 	Thailand 	Turkey 
Are there any policy debates about changing the current pricing environment?	The Competition Commission Inquiry could potentially result in policy recommendations on pricing. This process is ongoing and therefore timelines are difficult to predict at this stage.	None	None

Reimbursement environment: summary findings – 1/3

	South Africa	Thailand	Turkey
Are devices usually reimbursed to healthcare providers (both public and private) by a third-party payer?	Yes	Yes	Yes
Is the reimbursement process different for different types of medical devices?	No • Distinction in reimbursement exists for public vs. private sector reimbursement, NOT for different types of devices.	Yes • Different reimbursement treatments between "low-cost" devices and "high-cost" devices	No • The reimbursement price is dependent on the state hospital tender prices of the last three years.
How do third-party payers decide whether to reimburse a device or not (for each category of medical devices, if relevant)?	**Private sector** • Reimbursement decision depends on the healthcare plan and preferred supplier agreements **Public sector** • All public primary-sector devices are reimbursed if they have been awarded on tender	**Low cost devices (devices that cost less than USD $3.3 million)** • No decision is made specifically to device as payers reimburse the medical procedure **High cost devices (devices that cost more than USD $3.3 million)** • These devices must undergo social economic and ethical impact assessments	• There is no set calculation, but generally reimbursement is set using lowest price calculations that derive from a combination of information gleaned from public and private hospitals, prices of similar devices on the market, prices in other countries and cost effectiveness and budget impact studies. • A list (SUT) is updated every few years that sets a price that acts as a maximum reimbursement price.

Reimbursement environment: summary findings – 2/3

	South Africa	Thailand	Turkey
How is the reimbursement rate to healthcare providers established (for each category of medical devices, if relevant)?	**Private sector** There is no separate reimbursement scheme for medical devices and each private healthcare insurer has its own method of reimbursement **Public sector** Devices are fully reimbursed if made available on tenders.	**Low cost devices (devices that cost less than USD $3.3 million)** • All publically reimbursed medical devices listed in the National List of Essential Drugs (NLED) are fully reimbursed **High cost devices (devices that cost more than USD $3.3 million)** • Reimbursement rate depends on impact assessment	Reimbursement price is dependent upon state hospital tender prices over the previous three years.
Is there an “innovation clause” available?	No	No	No

Reimbursement environment: summary findings – 3/3

	South Africa 	Thailand 	Turkey 
Are there any policy debates about changing the current reimbursement environment?	Yes. Recent discussions on National Health Insurance mean changes could be imminent.	No	No

Procurement environment: summary findings

	South Africa 	Thailand 	Turkey 
Is the procurement process different for different types of medical devices?	No	No	No
Are there any existing or proposed preferential policies (for example domestic preferences or localization requirements)?	Yes. There are regulations that give procurement preferences to local manufacturers. The government is also concerned about the high level of imports in the medical devices sector - about 98% of medical devices are imported.	No	Recently, almost all regulations and laws support preferences for domestic products.
How does the procurement process work (for each category of medical devices, if relevant)?	**Private sector** Service providers may buy directly from suppliers. The costs of some items used in hospital may be recovered via a specific ward or theatre tariff while others are recovered as fee for services or as part of a fixed fee. **Public sector** Public procurement occurs at the provincial level. All medical devices are procured through a tender procedure with price being a key determining factor	Typically, public procurement occurs at the individual level • Healthcare providers purchase medical devices through closed auctions and procurement occurs directly from supplier to purchaser	For public, Government announces a tender. All companies are subject to public tender law. Government gives strong preferences to lower prices.
Are there any other debates about changing the current procurement	Yes. There is an attempt to centralize all tenders, but not a lot of progress has been made in this	None	None

Funding environment: summary findings

	South Africa	Thailand	Turkey
How does the funding process work?	There are no specific budgets for medical devices, and these are linked to spending on pharmaceuticals and other areas of healthcare	• The medical devices covered by social insurance could be financed by general tax • Healthcare providers would need to finance medical devices themselves or pass the cost onto the patients for medical devices not covered by social insurance	Healthcare providers often have insufficient financial resources to purchase new and costly medical devices. Common practice is to: • Purchase refurbished medical devices (less than 5 to 10 years old) • "Rent" medical devices, which provides healthcare providers with necessary medical devices and charges healthcare providers on a per use fee/ monthly payments • Late payment issues are prevalent. • Uneven compliance by purchasers with rules in tender criteria
Are there any policy debates about changing the current environment?	The South African health system is currently undergoing a transition in its public healthcare Funding system through the introduction of the National Health Insurance (NHI)	None	None

Approval environment: preliminary analysis

Approval process	• In all countries, devices are usually classified into classes of risk, with regulatory control increasing with risk • Currently, regulatory approval has no implications from regulatory approval to value assessment and/or P&R (in all countries)
Known issues	• None highlighted
Potential future changes	• Acceleration of the approval process for low- and medium-risk devices (Colombia) • International recognition of cross-country approval (recognition of approval granted by countries belonging to Eurasian Customs: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia) • New regulatory body to be established in April 2017 (South Africa)

Pricing environment: preliminary analysis

Pricing process	• Prices are not directly controlled by the Government but are negotiated between payers/healthcare providers and manufacturers (Australia, Japan, Russia, Turkey)
	  • International reference pricing for some categories (e.g. stents) in Colombia
	  • Regulation of the maximum price (South Africa)
	  • Price ceilings for essential devices (Thailand)

Known issues	• Increasing use of price regulation (Colombia, Russia, South Africa, Thailand)
Potential future changes	• Price regulation for 362 types of devices included in a list for implantable devices is due to start in 2017 (Russia)

Reimbursement environment: preliminary analysis

Reimbursement process	• Devices are usually reimbursed to healthcare providers by a third-party payer (in all countries)
	• Differentiation between "standard" and "innovative/high cost" devices
	  • Reimbursement of standard devices as part of other medical procedures (in all countries)
	  • Cost considerations and dedicated reimbursement process for some innovative devices not reimbursed as part of procedures (Australia, Colombia, Japan, Thailand, Turkey)
	  • Availability of an "innovation clause" (Australia, Japan)

Process to determine payment	• Use of fixed payments to reimburse procedures (e.g. DRGs) using devices (providers can retain any "profit") • Devices that are not part of a procedure are fully or partly reimbursed (the difference can be covered by a private insurance or paid OOP by patients)
Known issues	• None reported
Potential future changes	• Dedicated program to cover OOP payments (Japan) • Improved affordability and access (South Africa)

Procurement environment: preliminary analysis

Procurement process	• Different procurement processes in public and private sectors
	• In the public sector
	  • The procurement process is conducted individually by hospitals through a competitive tender process (Australia, Colombia, Japan, South Africa, Turkey)
	  • Devices can be sold directly to hospital with no tendering process (Russia)
	  • Hospitals can use closed auctions to purchase devices (Thailand)
	• In the private sector, usually there are not specific rules
	• Devices can be sold directly to hospital with no tendering process (Russia) only in public sector.

Known issues	• Aim to restrict the admission of medical devices of foreign origin to participation in the procurement for state and municipal needs (Russia)
Potential future changes	• Need for modernization of the healthcare infrastructure and procurement environment (Colombia)

Funding environment: preliminary analysis

Funding process	• Funding for payments to healthcare providers come from different sources
	  • Primarily public taxation and own hospital revenues in the public sector (Australia, Japan, South Africa, Thailand, Turkey)
	  • Mix of public and private insurers and out-of-pocket payments in the public sectors (Colombia, Russia)

Known issues	• Funding and spending for medical equipment is still relatively low (Colombia) • Healthcare providers often have insufficient financial resources to purchase new and costly medical devices (Turkey)
Potential future changes	• Transition in its public healthcare funding system through the introduction of the National Health Insurance (NHI) in South Africa

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Next steps

- Collection of feedback on the current analysis
- Revision of the slides according to the feedback
- Discussion of the analysis with the wider group

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- Appendix: Individual market analysis

Australia

Australia: Country Overview

Wealth Indicators (2015)

State of development	High Income	**GDP growth**	1.4%
GDP	USD 1.339 trillion	**Inflation**	1.6%
GDP per capita	USD 10,058	**Population**	24 million

Healthcare Expenditure (2014)

Health expenditure	USD 114 billion	**Pharma expenditure**	USD 9.6 billion
Health exp. per capita	USD 4,750	**Pharma exp. per capita**	USD 409
Health exp. % of GDP	8.8%	**Device expenditure**	USD 8.85 billion
% Out of Pocket	57%	**Device exp. per capita**	USD 369

Approval: current environment

Regulatory approval procedure

- The Therapeutic Goods Administration (TGA) - a division of the Australian Department of Health- is the regulatory authority responsible for issuing marketing authorisation for medical devices
- If authorised, medical devices are included on the Australian Register of Therapeutic Goods (ARTG)

- Since 2002 the fundamental principles underlying medical device assessment and licensing have been based on principles similar to those developed for the European Union in an attempt to create global harmonization
- Australia's medical devices regulatory framework covers three products:
  1. Medical Devices
  2. In Vitro Diagnostics
  3. Active Implantable Medical Devices
- Manufacturers must determine and demonstrate the **level of risk** their device poses to patient safety
- The device must undergo a **Conformity Assessment** procedure and comply with the **Essential Principles** of safety and performance

- Although the TGA authorisation process recognises the European CE Marking for medical devices, devices with CE Marking must still be registered with the TGA and undergo mandatory audit (depending on risk-class of product)

Approval environment: classification of medical devices – 1/2

Product	Classification	Level of risk (to public health and/or personal risk)	Conformity Assessment (CA) Procedure	Device Examples
Medical Devices	I	Low	General devices apply for CA and if successful are included on ARTG automatically. Sterile and Measuring devices must be supported by evidence of conformity assessment (e.g. CE certification), which indicates that the device has been fully examined by TGA or under another TGA-accepted regulatory system	Scalpels, compression bandages, dental kits.
	IIa	Low – Medium	Similar to Class I (sterile and measuring) - must be supported by evidence of conformity assessment (e.g. CE certification), which indicates that the device has been fully examined by TGA or under another TGA-accepted regulatory system	Hearing aids, masks for providing anaesthesia,
	IIb	Medium – High		Condoms, blood bags, infusion pumps,
	III	High	Evidence of conformity assessment (by TGA or TGA-accepted regulatory authority) and also a detailed and certified assessment of their design dossier. Of Class III devices that contain a medicine, human blood or plasma, or material of animal, microbial or recombinant origin -TGA undertakes full conformity assessment	Cardio-vascular stents, joint prostheses, heart valves
Active Implantable Medical Devices	AIMD	High	Evidence of conformity assessment (by TGA or TGA-accepted regulatory authority) and also a detailed and certified assessment of their design dossier.	Pacemakers, implantable cardiac defibrillators

Approval environment: classification of medical devices – 2/2

Product	Classification	Level of risk (to public health and/or personal risk)	Conformity Assessment (CA) Procedure	Device Examples
In Vitro Diagnostics	I	Low	Declaration of Conformity, not requiring assessment by the Secretary	A specimen receptacle, a microbiological culture medium, enzyme immunoassay analyser, glucose meter
	II	Low – Medium	Declaration of Conformity, not requiring assessment by the Secretary and product quality management system	Non-assay specific control plasmas for use in coagulation studies, biochemistry tests for vitamins and hormones, pregnancy and fertility self-testing kits
	III	Medium – High	Declaration of Conformity, not requiring assessment by the Secretary and product Quality Assurance	Tests for tumour markers, test to detect sexually transmitted diseases, pharmacogenetic tests
	IV	High	Full Quality Assurance excluding examination of design	Assays for clinical diagnosis of Hepatitis B, Hepatitis C and HIV

Approval environment: Essential Principles and Conformity Assessment

Conformity Assessment

- The classification of a medical device determines the conformity assessment procedure: higher classifications are required to undergo more a stringent form of conformity assessment
- Responsibility for conformity assessment rests with the medical device manufacturer

- For imported Class I devices, the manufacturer self-certifies and signs a declaration of conformity
- For all higher classes of devices and Class I devices manufactured in Australia the TGA confirms that conformity assessment procedures are appropriate before issuing certification
- Alternatively

Essential Principles (of safety and performance)

- Compromise of' General principles' (applicable to all devices) and Design and Construction principles (applicable to specific devices).
- Manufacturer must determine which principles are applicable and justify accordingly

General Principles:

- Use of a medical device must not compromise health and safety
- Design and construction of a medical device must conform with safety principles
- Medical device is appropriate for its intended purpose
- Long term safety of user has been ensured
- Not adversely affected by storage or transport
- Benefits of a medical device outweigh any side effects

Design and Construction:

- Materials have appropriate chemical, physical and biological properties for purpose
- Designed and produced in a way that minimizes the risk of infection and microbial contamination
- Designed and produced in a way that minimizes the risk of injury associated with its construction and environmental properties
- If has a measuring function must be designed and produced to ensure accurate, precise and stable measurements

Approval environment: Approval timelines vary by classification

Device classification	Class I Non-sterile; Non-Measuring	Class I Sterile or Measuring	Class IIa	Class IIb	Class III
Time between submission and approval	< 1 month	2 - 3 months	2 - 3 months	2 - 3 months	7 – 14 months
Validity period of device registration	Does not expire	Does not expire	Does not expire	Does not expire	Does not expire
Renewal – time in advance	1 month	1 month	1 month	1 month	1 month
Complexity of registration process					
Overall cost of regulatory approval					

Pricing environment

Pricing process	
Medical Services Advisory Committee	• Following MSAC recommendation and prior to being listed on the MBS schedule, prices of medical devices are recommended on the basis of MSAC's assessment results (e.g. economic evaluation) • They are then negotiated with the manufacturer • While not mandatory, applicants are encouraged to provide their marketing and distribution costs, as well as public hospital and foreign prices
Prostheses List Advisory Committee	• The Prostheses List groups devices based on a functional category system and lists both the medical devices and the corresponding co-payment amounts that private health insurers are required to reimburse (in addition to the predominantly DRG-based payment for hospital charges) • Within the various functional categories listed on the Prostheses List, medical devices are grouped according to the features and characteristics that define their clinical effectiveness • Medical devices considered to have similar clinical effectiveness are listed with similar benefits (reimbursement prices) • Prices on the Prostheses List are determined via a benefit validation process which does not follow health economic conventions but rather considers whether a proposed price is 'fair and reasonable'

Sources: IQWiG website

Reimbursement Environment – varies by private or public health system

Reimbursement procedure

- Before a device can gain reimbursement, it must be included on the Medical Benefits Scheme (MBS). This list of includes both in and outpatient products and services

- There are two Health Technology Assessment (HTA) agencies that are relevant to the reimbursement decisions of medical devices in Australia. These are:

- **Medical Services Advisory Committee (MSAC):** The main body supporting the Australian public healthcare system (Medicare) in its reimbursement decisions. The main evidence the MSAC focuses on during their assessments is safety, effectiveness, cost-effectiveness and budgetary impact. MSAC recommends whether procedures and devices should be included on the MBS. The MBS has an uncapped budget and recommendations can take years

- **Prostheses List Advisory Committee (PLAC):** The 'Prosthesis List' is a list of surgically implanted prostheses, human tissue items and other medical devices for which private health insurers must pay a subsidy for when provided to a patient with appropriate health insurance coverage as part of hospital treatment or hospital substitute treatment along with a Medicare benefit payable for the professional service. Inclusion on the 'Prostheses List' ensures that the implantable medical device will be reimbursed by health funds or insurers. There are two clinical evidence pathways to inclusion on the List:

    - '**Substantial Clinical Equivalence'.** The manufacturer must prove that the device is similar enough in design and function to a device that is already included that similar outcomes and complications can be expected. Similar performance to this device may be assumed in the absence of clinical trials.
    - However devices that are considered **'high risk'** or require long term durability or are considered novel in design require clinical evidence with a minimum of two years follow up

Procurement Environment

Procurement process
Public healthcare system • Medical devices are purchased under state, regional or hospital arrangements and are provided free of charge for patient use • Medical devices are typically purchased through a competitive tender process • Any device that is able to demonstrate improved clinical performance or a reduction in the use of resources should be able to be successful in their tender
Private healthcare system • Medical devices are purchased by private hospital/hospital groups with categories of devices reimbursed by means of contractual arrangements with health funds, e.g. procedure banding or the Prostheses List

Sources: IXPOS

Funding Environment

Funding process

Public healthcare system

- Hospital costs are reimbursed under Activity Based Funding using the Australian Refined Diagnosis Related Groups Scheme (AR-DRG) to reimburse episodes of care, which includes hospital and physician costs
- For products are included on the MBS list, Medicare will usually cover 75% the fee MBS fee and health insurers are obliged to pay the remainder

Private healthcare system

- Private health insurers pay both hospitals and doctors to conduct procedures in private hospitals. Insurers are only obliged to pay if the procedure is included on the Medical Benefits Schedule (MBS)
- The Prostheses List lists the devices for which private health insurers are mandated to pay a co-payment if the devices is used during an episode of care

Sources: IXPOS

Colombia

Colombia: Country Overview

Wealth Indicators (2015)

State of development	Upper Middle Income	**GDP growth**	3.08%
GDP	USD 292.08 billion	**Nat. income per capita**	USD 7,140
GDP per capita	USD 6,056.15	**Population**	48.23 million

Healthcare Expenditure (2014)

Health expenditure	USD 27.45 billion	**Pharma expenditure**	USD 3.31 billion
Health exp. per capita	USD 569.19	**Pharma exp. per capita**	USD 68.63
Health exp. % of GDP	7.20%	**Device expenditure**	USD 1.2 billion
% Out of Pocket	15.36%	**Device exp. per capita**	USD 25.47

Sources: World Bank; BMI Report.

Approval: current environment

Regulatory Agency - INVIMA

- The National Food and Drug Surveillance Institute, INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos), is in charge of supervising health product marketing and manufacturing, evaluating standard/procedure violations, and providing medical approval for the import and export of medical products
  - Within INVIMA, the Directorate for Medical Devices and other Technologies monitors and controls medical devices, tracks pre- and post-marketing programs, and suggests technical standards for device manufacturing, marketing, surveillance, and quality assurance
- The system has a Mutual Recognition Agreement with the EU with respect to Class I, IIA, and IIB devices

Medical Devices

- The most important regulations for medical devices in Colombia are Decreto No. 4725 (2005), Decreto No. 3275 (2009), and Resolution No. 004816 (2008)
  - An exhaustive definition for which products classify as medical devices are listed in Decreto No. 4725 (2005)
- Devices are classified using a four-tiered risk model (similar to the classification scheme used in Europe)
  - Devices of higher price or complexity from all classes are designated as "medical devices of controlled technology"

Other Regulatory Features

- The technical dossier, comprising of both technical and legal documents, a Certificate of Free Sale (CFS) from the country of origin, and a letter of authorization from the manufacturer, must be submitted via hardcopy in Spanish
- Registrations can be modified by their owners in cases where no major changes have been made to the device.
  - i.e. owners can add new references or models and new manufacturing plants; can change the authorized importer or the labelling; etc.

Source: Emergo Group; Regulatory Affairs Professional Society; Arazy Group; Scrip.

Approval: current environment

	Automatic Registration	Regular Registration
Type of Device	Low-/medium-risk devices	High risk devices
Device Classifications	Class I and IIa devices (exempting "medical devices of controlled technology")	Class IIb and III devices, as well as Class I/IIa "medical devices of controlled technology"
Time until Regulatory Approval	Less than a month	4-6 months
Registration Expiry	10 years	10 years
Complexity	Simple (less complex than European CE Marking process)	Simple (less complex than European CE Marking process)
Cost	Less than USD $5,000	Less than USD $5,000.
Registration Renewals	Should be started 3 months in advance	Should be started 9 months in advance
Other process features	• INVIMA automatically approves applications, then proceeds to review • May request additional information • Technical evaluation is performed in parallel	• INVIMA must review and approve application before marketing can begin • If the institute requires additional information to evaluate the device's safety and efficacy, the process can take longer (8-9 months)

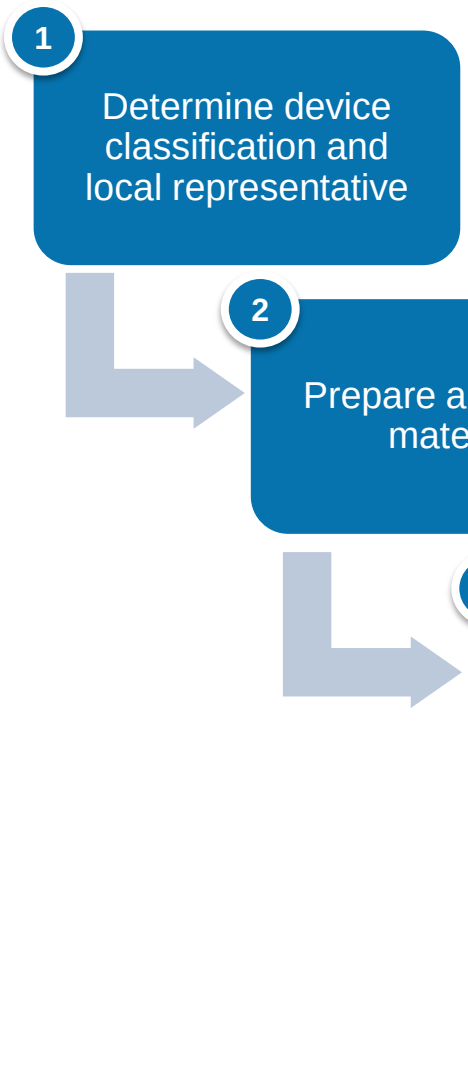
Source: Emergo.

Approval environment: Categorisations of devices

Class	Description
Class I (Low Risk)	• Represent the lowest amount of risk • Applications are usually filed using automatic registration, except for "medical devices of controlled technology" • Examples can include: most non-invasive medical devices, exempting those linked with blood; invasive medical devices for transitory use
Class IIa (Moderate Risk)	• For most devices, applications are filed using the automatic registration, exempting "medical devices of controlled technology" • Require test reports • Examples can include invasive "use of short delay" medical devices
Class IIb (High Risk)	• Devices are classified using the regular application process • Require clinical and non-clinical data, test reports, and a literature review • Examples can include invasive "prolonged use" medical devices
Class III (Very High Risk)	• Represent the highest amount of risk • Devices are classified using the regular application process • Require clinical and non-clinical data, test reports, and a literature review

Source: Emergo group; Product Life Group.

Approval environment: flow chart of current process



- Determine device classification according to Chapter II of Decree 4725/2005
- Foreign manufacturers must appoint an in-country representative before starting INVIMA application.
  - Must also obtain a Certificate of Free Sale (CFS) or Certificate of Foreign Government from their home market or an INVIMA recognized market (i.e. Australia, Canada, Japan, Europe, or the US)

- Prepare application materials, based on product class:
  - Product information and commercial history of the product, test reports (if required), and clinical data (if required)
- Provide quality system certificate (i.e. ISO 13485, proof of FDA QSR compliance

- Submit application dossier to INVIMA in Spanish
  - Pay required application fee
- Automatic registrations approved immediately; regular applications undergo review

- Once approved, INVIMA will issue a registration certificate
- Begin marketing device in Colombia
- Renew registration every 10 years

Source: Emergo.

Approval environment: proposed policy changes

Ongoing discussions and recent changes

- In 2014, INVIMA introduced registration requirements for more than 30 types of medical devices previously exempt from market authorization requirements
  - These devices included lamps used in medical procedures, hospital beds, diagnostic imaging sound systems, breast milk extractors, blood component dividing equipment, blood bank centrifuges, among others
- INVIMA is speeding up registration renewals for Class I and IIa medical devices
  - Registrants must still submit applications for INVIMA renewal, but now it will grant those renewals within three day
  - Effective October 3, 2016
- INVIMA also sets requirements regarding medical device advertising and marketing according to their classifications
  - Class I devices may be advertised using mass media
  - Class IIa, IIb, and III devices used and prescribed by healthcare professionals may only be advertised through scientific, trade, or technical publications

Source: Emergo.

Pricing: current environment

Regulated pricing

- Colombia is a price sensitive market, where prices are a major selling factor for most providers, insurers, and patients
  - Whether through direct or indirect measures, attempts have been made to constrain the price of medical devices in order to provide healthcare systems with the best quality of care for the lowest cost
- Columbia's Ministry of Health & Social Protection announced new price regulations for medical devices effective March 5th, 2015:
  - Medicated coronary stents - first device to come under price regulation
    - Prices are based on international standards decided by national commission
  - Followed by cochlear implants, hearing aids and orthopedic devices
  - Additionally, a national commission now keeps all coronary stents on probation – manufacturers must report current market prices
    - Expected to result in 36% reduction in prices of medical devices; USD14 billion worth annual savings for the national health system

Non-regulated pricing

- All other devices will continue to be priced by the market, until further price controls are extended

Colombia has recently begun using price controls for high-value devices

Source: Export.gov; Global Health Intelligence; Pharma Board Room; Panam Post.

Reimbursement: current environment

Reimbursement

- The Mandatory Health Plan, POS (Plan Obligatorio de Salud) is a comprehensive list of treatments, services, and drugs that healthcare provider entities ("EPS") members are entitled to. Since 2008, it has to provide the same coverage to both the subsidized and contributory systems
  - Health Regulation Commission (Comisión de Regulación en Salud) defines and modifies the POS, defines premiums for both plans, and updates unified system of fees
- Coverage policies are defined for procedures and do not specify device brand or model
  - Reimbursements occur without one by one device regulation
  - An applicant submits reimbursement requests for procedure and medication
- For high-cost devices, there are two approaches to obtain reimbursement:
  - Scientific panel (Comisión técnico científica) – HTA-style review of procedures (Colombia has introduced a Health Technology Assessment (HTA) process in the past few years)
  - Legal action for the protection of fundamental rights (*tutelas*) - a legal procedure where Colombians can exercising their constitutional right to health care (it can provide access high-cost drugs and procedures not included plans)
- Recent changes to healthcare statutory law name healthcare as a fundamental right
  - Redesign and modernization of POS
  - Increases opportunities for *tutelas*
  - Do not address problems with healthcare provider entities (EPSs) i.e. irregularities in providing services, double charging for drugs, and alleged collusion

The *Plan Obligatorio de Salud* determines provider reimbursement

Source: Colombian Ministerio de Salud; International Society for Pharmacoeconomics and Outcomes Research; IHS Markit.

Procurement: current environment

Medical device procurement

- Hospitals and providers purchase medical devices for use in procedures (rarely purchased by out-of-pocket patient)
  - Procurement can occur via a tender process
- Despite the availability of medical devices, patient access still remains a problem in Colombia
- Both access to healthcare and health outcomes vary widely between regions
  - Access issues are predominantly attributable to supply-side constraints
    - 70 percent of health providers are the only providers available for Colombians enrolled in the nation's subsidized coverage regime in rural areas
  - The country's healthcare infrastructure is adequate in the larger urban areas, but is in need of modernization

In Colombia, medical device use is concentrated in more urban areas

Source: Export.gov; World Bank; Pharma Board Room.

Funding: current environment

Healthcare Funding

- Colombia has the most extensive health insurance system and medical financial protection in Latin America
  - In 2014, there were 45.6M people covered by the system
  - The healthcare system is complex, and coverage is not yet universal
- Despite sweeping healthcare reform, funding and spending for medical equipment is still relatively low

Public Funding

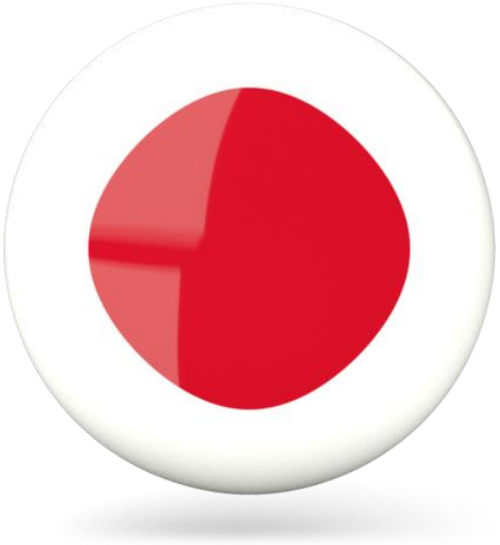
- The Unique Health Accreditation System (SUAS) launched in July 2014 to ensure the highest standards in healthcare provision at both public and private healthcare institutions
  - The system has greatly increased access to and use of health services and has reduced the incidence of catastrophic health spending
  - The impact has been more dramatic among those most vulnerable to health shocks: those living in rural areas, the poorest, and the self-employed

Private Funding

- Patients can opt to use private insurance (82% of non-subsidized insurers), who operate within the universal healthcare system
- While the public health system is improved, the private sector continues to be a stable and attractive investment opportunity (particularly with the rise in medical tourism to some of the best hospitals in Latin America)

Source: Export.gov; Health Affairs; Arazy Group.

Japan



Japan: Country Overview

Wealth Indicators (2015)

State of development	High Income	**GDP growth p.a.**	0.61%
GDP	USD 4.12 trillion	**Inflation**	0.10 %
GDP per capita	USD 37,322	**Population**	127 million

Healthcare Expenditure (2014)

Health expenditure	USD 527.5 million	**Pharma expenditure**	USD 96 billion
Health exp. per capita	USD 4,150	**Pharma exp. per capita**	USD 756
Health exp. % of GDP	11.4%	**Device expenditure**	USD 26 billion
% Out of Pocket	14%	**Device exp. per capita**	USD 205

Sources: World Bank; WHO; OECD; Statistica.
NB. Per capita figure for device expenditure and pharmaceutical expenditure are CRA calculated.

Approval: current environment

Regulatory framework

- The 2014 Pharmaceutical Medical Device Act* dictates the regulatory process and the Pharmaceutical Medical Device Agency (PMDA) is responsible for the approval process
- There are four classes of medical devices in Japan based on their risk profile:
  - Class I (General Medical Devices) –negligible risk to patients [ex: X-ray film]
  - Class II (Controlled Medical Devices, Specially Controlled Medical Devices) – low risk to patients [ex: MRI]
  - Class III (Highly Controlled Medical Devices) – high risk to patients [ex: artificial bones]
  - Class IV (Highly Controlled Medical Devices) – invasive and potentially fatal [ex: pacemaker]
- All manufacturers must register their manufacturing facilitates with the PMDA and ensure their Quality Management System (QMS) complies with Japanese regulations

Class I

- A local Marketing Authorisation Holder (MAH) will make a pre-market submission to the PMDA and for some devices the PMDA will conduct a QMS assessment
- Once approved, the MAH will receive notification but no certification from the PMDA

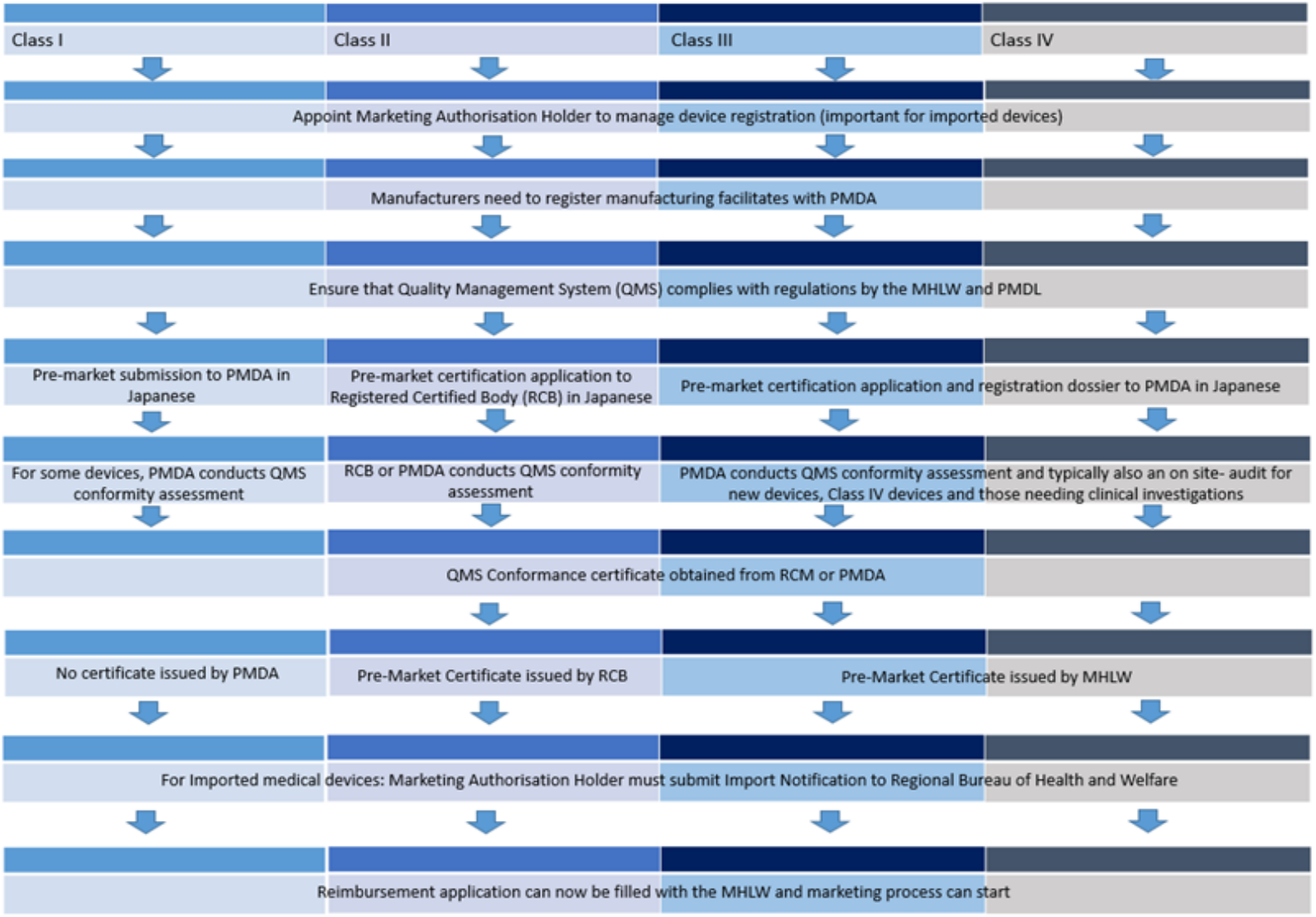
Class II, III, IV

- A local MAH will make a pre-market submission to the PMDA or Registered Certified Body (RCB) to obtain a QMS certificate
- Once approved, the MAH will receive a certificate from the RCM or PMDA

Regulatory approval process and classification do not have any implications on the P&R process

Notes: *The Act of securing quality, efficacy, and safety of pharmaceuticals, medical devices, regenerative and cellular therapy products, gene therapy products and cosmetics.
Source: Pacific Bridge Medical; TUV SUD (2014)

Approval environment: Japan's medical device regulatory structure



 Source: Emergo (2016)

Pricing: current environment

Current pricing framework for all medical devices

- Pricing is decided by the MHLW and the Health Insurance Bureau (HIN), the Health Policy Bureau (HPB) and the Drug Pricing Organisation
  - Imported medical devices are priced based on foreign reference pricing (of at least two countries – Australia, France, Germany, the UK or the US)
  - For new medical devices with no similar alternatives already on the market, price is set using the cost plus method
- Until an official price is published, a provisional price can be set (this price will be set according to the most similar device already on the market)

Price control: Direct government approach for all medical devices

- Set prices are valid for 2 years
- Thereafter, price revisions are made by the MHLW. The MHLW considers:
  - R Zone (Reasonable Zone) – If pricing survey finds that margins on current reimbursement rates is higher than 4%, then reimbursement rates are re-adjusted
  - Foreign average price (international reference pricing) - Reimbursement prices cannot be more than 1.3 – 1.5 times that of the same product in reference countries
- In 2015, the price of new medical devices seemed to lean towards European prices, which is lower than the US prices

The pricing of medical devices is directly controlled

Notes: MHLW -Ministry of Health, Labour and Wealth
Source: Barry (2008),Sealey (2014)

Reimbursement: current environment

Reimbursement framework

- Reimbursement is led by the Ministry of Health, Labour and Wealth (MHLW) and the Central Social Insurance Medical Council and precedes pricing
- The reimbursement process and timeframe is different according to the medical device category for reimbursement
  - Assessment is straightforward for Categories A and B but more complex for Categories C and F, which include more innovative medical devices

Category A1 and A2

- These device are often not costly (needles, syringes) but can also be costly (MRI, CT machines)
- Category A devices do not need a unique reimbursement code, lending to a relatively quick reimbursement process (approx. 20 days after submission)

Category B

- These devices need a unique reimbursement code (e.g. pacemaker) and also has a relatively quick reimbursement process (approx. 20 days)

Category C and F

- These devices are characterised as “innovative”
- Category C reimbursement procedure involves value assessment of innovation, efficacy, incremental benefit by Device Insurance Committees
- Category F is a new innovative category (e.g. artificial heart)
- Given additional assessments, reimbursement process is more lengthy (approx. 80-100 days)

Reimbursement for Category C medical devices involves value assessment

Notes: MHLW -Ministry of Health, Labour and Wealth

Source: Medical Device and Diagnostic Industry (2016); Biomedical Japan, Sealey (2014)

Reimbursement: recent changes in environment

Reimbursement for medical devices not covered by NHI

Devices not reimbursed by the NHI can be paid for out-of-pocket by the patients. Until recently, this meant that the patient must pay for the device and all accompanying care out-of-pocket

- In 2016, the government introduced a program under which patients can request (individually) the use of a medical device to the MHLW
- Upon approval from the MHLW, the patient would pay out-of-pocket for the medical device but the cost of accompanying care would be afforded by the MHLW

Notes: NHI – National Health Insurance; MHLW – Ministry of Health, Labour and Wealth
Source: Medical Device and Diagnostic Industry (2016); Pacific Bridge Medical (2016)

Procurement: current environment

Current procurement framework

- No national procurement process for medical devices
- Healthcare facilities wish to make a profit from the difference between the purchase price and the NHI reimbursement price so procurement negotiations take place at healthcare facility level

Public procurement process

- Tendering is mandatory for medical device contracts over the value of USD 73,000
- Often, competitive bidding will be used before making a purchase

Private procurement process

- There is no formal process
- The procurement procedure is typically reflective of the distribution channel and tends to be based on physician preferences and relationships with providers and distributors

Procurement is mostly conducted at healthcare provider level; tendering is mandatory for high value procurement contracts

Source: Junicon (2010), US Gov; Ando (2012)

Funding: current environment

Current sources of Funding

- The National Health Insurance system is funded by individual contributions, employer contributions and general tax
- Major Funding mechanisms are insurance (49%) and tax (37%), a minor element of finance is attributed to patient out-of-pocket contributions (14%)
- To date, the majority of medical devices are reimbursed by the NHI such that the NHI is the ultimate funder of medical devices

Source: The Commonwealth Fund (2014); Daiwa (2011); Kholti (2016)

Russia

Russia: Country Overview

Wealth Indicators (2015)

State of development	Upper middle income	**GDP growth p.a.**	-3.7%
GDP	USD 1.33 trillion	**Inflation**	7.7%
GDP per capita	USD 9,092	**Population**	144 million

Healthcare Expenditure (2014)

Health expenditure	USD 86.8 billion	**Pharma expenditure**	USD 54.8 billion
Health exp. per capita	USD 603.8	**Pharma exp. per capita**	USD 381
Health exp. % of GDP	7.1%	**Device expenditure**	USD 7 billion
% Out of Pocket	46%	**Device exp. per capita**	USD 48.7

Sources: World Bank; WHO; World Bank; USA Export.gov

Approval environment: Overview of regulatory framework

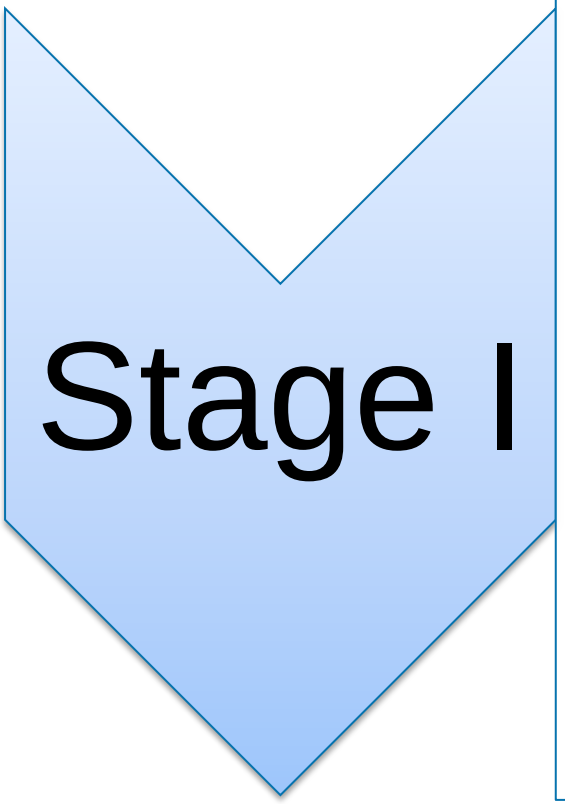
Current framework

- Medical devices in the Russian Federation are regulated by MOH but execution and safety monitoring functions are within RZN
- The regulatory approval process required for specific medical devices is dependent on the risk to the individual or environment, as categorised by the class of device
- Russian medical devices are classified in much the same manner as Europe's risk-based model

Approval environment: Classes of medical devices

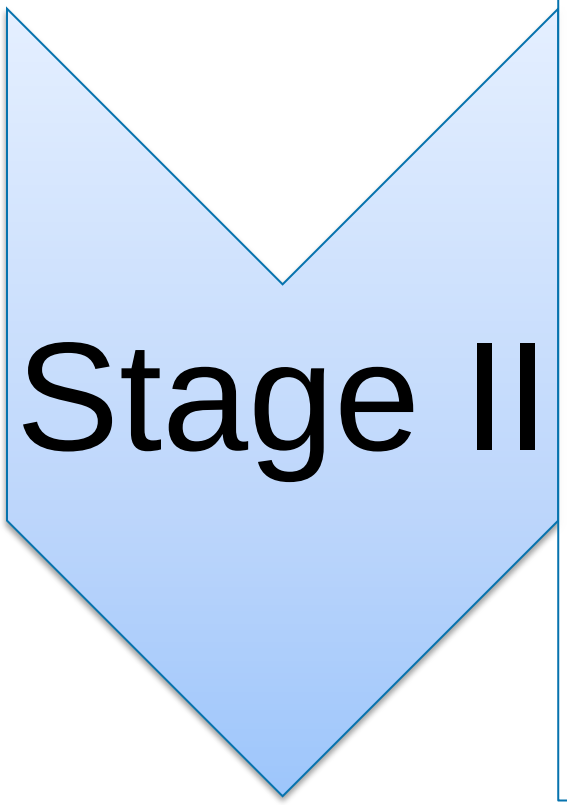
Category	Risk	Example
Class I	Low	Microscopes, medical scales, audio reaction testers
Class IIa	Medium	Audiometers, laboratory equipment, spirometers
Class IIb	Medium - high	Cardiocheck analysers, plethysmographs, defibrillators
Class III	High	Implants, endoprostheses, lithotripters

Approval environment: Stage I of approval



- **Required for Class IIa, IIb, and III devices**
- This stage includes RZN's completeness review of the registration documentation, in order to verify that all required elements are addressed
- Once confirmed, RZN will provide the application to an Expertise Center, which are independent entities authorized by RZN to assist with conformity assessments. RZN has given the Expertise Centers responsibility for the technical review, while RZN still maintains responsibility for issuing the final approval and registration certificate (RC)
- Once the Expertise Center has reviewed the information, they will provide their opinion to RZN about proceeding to the next step, which is the clinical trial
- RZN will then make the final decision regarding this possibility and inform the authorised representative (AR) accordingly
- **Since 2015, Class I devices can bypass the Stage I review**, and will instead provide their application and Russian clinical evaluation report to RZN for the final Stage II review

Approval environment: Stage II of approval



- **Required for Class I, IIa, IIb, and III devices**
- There will be an initial completeness review by RZN, and then a technical review of the data by an Expertise Center
- If acceptable, RZN issues a Registration Certificate and lists product in registration database on RZN's website. Registrations do not expire

Approval environment: Approval timelines vary by classification

Device classification	Class I	Class IIa	Class IIb	Class III
Time between submission and approval	6-10 months	8-12 months	8-12 months	8-12 months
Validity period of device registration	Does not expire	Does not expire	Does not expire	Does not expire
Renewal	Not applicable	Not applicable	Not applicable	Not applicable
Complexity of registration process				
Overall cost of regulatory approval				

Approval environment: Looking ahead

The impact of the Eurasian Economic Union

- On 1 January 2016, Russia, Kazakhstan, Belarus, Armenia and Kyrgyzstan formally introduced a common market and regulatory system for medical devices within the Eurasian Economic Union (EAEU)
- Prior to 2016, registrations in Russia, Belarus and Kazakhstan will remain valid until expiration date or 31 December 2021. Approval granted in one country is not valid for another
- Between January 2016 and January 2022, for registrations submitted after January 2016: approval granted in one country under the Eurasian Customs (EAC) procedure will be recognised across all EAC union
- After January 2022, all products need to be registered in accordance to EAEU procedure of new product registration.

Pricing: current environment and proposed changes

Current pricing framework

- Currently prices of medical devices in Russia are unregulated

Proposed changes: price regulation for implantable devices

- In 2015, through Federal Law amendments, the Russian government imposed “State Regulation of Prices for Medical Devices on the List of Medical Devices Implantable in the Human Body when Providing Health Care as Part of the State’s Guaranteed Free Health Care Program for Citizens”
- Initially, 202 medical devices were listed as subject to price regulation. In November 2016, a further 160 new devices were added to the list
- Guidelines for determining the maximum wholesale mark-up that could be made to the actual selling price of medical devices implanted into the human body were approved and published in 2015
- Price regulation would take the form of a cap, where the maximum manufacturer’s prices for implantable medical devices and the maximum wholesale mark-ups on actual manufacturer’s prices for those medical devices are to be calculated in accordance with an approved methodology – a weighted-average of similar medical device group prices
- In addition, the maximum manufacturer’s prices for implantable devices are also to be registered and tracked in the appropriate state register
- However in August 2016, the deadlines for implementation of price regulation were postponed for one year. Current methodology is enforced, but will undergo further revisions.

Reimbursement: current environment

Reimbursement framework

- Mandatory insurance funds cover all purchases of small medical devices, supplies and disposables
- The Russian public sector is the main user of medical products: approximately 85% of medical products are sold to state medical facilities. Private hospitals and patients represent the other 15% with purchases of primarily in-vitro diagnostics, dentistry and functional diagnostics (including ultrasound machines)

Procurement: current environment

Current hospital procurement framework

- According to the law, medical equipment with a cost of less than 200,000 Rouble (USD 7,000) can be sold directly to hospitals also through tenders. All purchases of medical equipment are alwas done through tenders

- The tender of expensive medical devices are usually performed through open (electronic) auctions

- Around 70% of all public procurement procedures are conducted in the form of an auction. In a tender procedure, the contract will be awarded to the bidder that has offered the best terms and conditions for implementation of the pertinent contract, including, but not limited to, the contract price. Each criterion of the bidder is listed in the tender documentation and its importance determined. As for an auction, the winner of an auction is the bidder that has offered the lowest contract price. The bidder that has filled a bid complying with all the bidding requirements and that provides the lowest contract price is declared the winner. When several bidders present similarly low prices priority is given to the bidder whose completed bid is received first

Procurement environment: recent changes

“Made in Russia”

- In 2015, Federal Law decreed that tenders for state procurements of certain types of medical devices originating from foreign countries the will be closed for foreign manufacturers if at least two bids with medical devices from local manufacturers (Russia, Kazakhstan or Belarus) were submitted
- Types of medical devices subject to this will typically be low-technology, such as syringes, scissors and gynaecological toolkits
- In 2016, the ‘Development of Pharmaceutical and Medical Industries in the Russian Federation’ was approved. This Federal target program aims to increase the market share of medical devices manufactured in Russia up to 40% by 2020
- The Russian government aims to provide for incentives for domestic manufacturers, including granting of subsidies for organization of clinical trials and manufacturing of medical devices; and restriction for admission of medical devices of foreign origin to participation in the procurement for state and municipal needs

Funding: current environment

Current Funding trends

- Funding for medical equipment, devices and supplies purchases for public healthcare establishments comes from two major sources: mandatory insurance funds and federal and regional Government budgets. The latter accounts for almost 80% of purchases
- The purchase of expensive medical equipment is usually financed by federal and local health budgets. Local government finances support 97% of the purchases of medical equipment and supplies, while the federal government finances 3%
- Generally, public funding for purchasing medical equipment and supplies for hospitals and clinics is insufficient. According to the Audit Chamber of Accounts of the Russian Federation, public hospitals and clinics are only able to procure 30%-40% of the medical equipment and supplies they require to operate
- As a result, a significant proportion of medical device expenses are paid out of patients' pockets

South Africa

South Africa: Country Overview

Wealth Indicators (2015)

State of development	Upper Middle Income	**GDP growth p.a.**	0.7%
GDP	USD 312.8 billion	**Inflation**	5.3%
GDP per capita	USD 7,575	**Population**	54.5 million

Healthcare Expenditure (2014)

Health expenditure	USD 18 billion	**Pharma expenditure**	USD 3.9 billion (2013)
Health exp. per capita	USD 589	**Pharma exp. per capita**	USD 81 (2013)
Health exp. % of GDP	8.8%	**Device expenditure**	USD 1.2 billion (2013)
% Out of Pocket	16%	**Device exp. per capita**	USD 24 (2013)

Sources: World Bank; Deloitte; Trading Economics

Approval: Current Environment

Regulatory legislation

- The registration of medical devices and in-vitro diagnostic devices (IVDs) in South Africa is governed by the provisions of the Medicines and Related Substances Control Act No. 101 of 1965
- The Medicines Control Council (MCC) applies standards laid down by the Act, governing the manufacture, distribution, sale, and marketing of medicines and medical devices, as well as regulating clinical trials

Regulatory approval procedure

- Prior to commencing business in South Africa, a foreign manufacturer must apply for a licence to manufacture, import or export medical devices or IVDs and appoint a designated representative who must reside in South Africa to be responsible for compliance with the Act
- Through their authorized representatives, registrants would have to provide materials to Medicines Control Council for review, including:
  - Completed application forms and proposed device labelling
  - Proof of current quality management system certification
  - Safety and performance data
  - Country of origin and registration status data
  - Clinical data, if applicable
- The MCC review registration applications and issue registration certificates. A licence is valid for a period of five years and an application for renewal must be made at least 90 days before expiry
- If the medical device is withdrawn (by the regulator) or recalled (by the manufacturer) from the market which was submitted as the “originating approval”, the Council must be notified immediately and a withdrawal plan of action is to be agreed with Council

Sources: Medicines Control Council South Africa; Emergo Group

Approval: Current Environment

- The manufacturer or distributor is responsible for determining the risk classification of a medical device using a set of classification rules supplied by the MCC, which include:
  - Manufacturer's or distributor's intended use of the device or IVD
  - Level of risk to patients (the probability of occurrence of harm and the severity of that harm)
  - Degree of invasiveness in the human body
  - Duration of use and exposure

Classification	Level of Risk	High Level Description	Examples
Class A	Low risk	Non-invasive devices intended contact the skin, channel/store body liquids or active medical devices not covered by other rules	Wound dressing, Surgical microscopes, Dental impression materials
Class B	Low-moderate risk	Non-invasive devices intended to have biological or chemical modifications or surgically invasive devices intended for transient use (less than 60 minutes)	Syringes, Muscle stimulators, Diagnostic ultrasound, Chest retractors for cardiac surgery, Hearing aids
Class C	Moderate-high risk	Invasive medical devices intended for short-term use (at least 60 minutes but less than 30 days)	Lung ventilators, X-rays, Personal insulin injectors, Surgical adhesives
Class D	High risk	Surgically invasive devices that are intended to be life supporting or have a biological effect for long-term use (more than 30 days)	Pacemakers, Implants claimed to be bioactive, Nerve stimulators

Sources: Medicines Control Council South Africa

Approval: Current Environment

Guidelines for different risk classifications

- As of August 2016 new guidelines issued by the South African Department of Health and MCC apply to the manufacturing, importing, exporting and distribution of medium- and high-risk devices
- For a medium-high risk (Class C) and high risk (Class D) medical devices proof of pre-market approval from at least one of the following regulatory authorities is required:
  - Australia's Therapeutic Goods Administration (TGA)
  - Brazil's ANVISA (National Health Surveillance Agency) approval and registration
  - Canada's Medical Device Licence to market
  - The European Union's CE certificate
  - Japan's Marketing Authorization Holder (MAH) licence
  - USA's FDA's Center for Devices and Radiological Health (CDRH) premarket approval
- Class C and D medical devices licence holders must be able to provide full technical documentation on request by the MCC
- For a Class B, C and D medical device, Certificate of Free sale from country of manufacture or final assembly is required, which evidences that the medical devices are legally sold or distributed in the open market, freely without restriction, and approved by the authorities in the country of origin

Regulations for medical devices have only been in place since December 2016, so analysis of approval times is premature.

Approval: Future Environment

New regulatory authority

- Effective June 1, 2017, the South African Department of Health has established the South African Health Products Regulatory Authority (SAHPRA)
- SAHPRA will have a much larger domain of regulation than the MCC, and be responsible for regulation of drugs, biologics, medical devices, in vitro diagnostics, complementary medicinal products, food, and cosmetics
- In regards to medicinal products, two regulatory councils will be created to have oversight over specific products; one council will review medicines and the other council will review medical devices and in vitro diagnostics (some lack of clarity on this from new legislation)

Overall, the current or future regulatory approval process and risk classification does not have any direct implications on the pricing and reimbursement process. However this appears likely to change.

Sources: Medical Brief

Pricing Environment

Pricing system

- South Africa has a two-tiered pricing system: one for the large public sector (approximately 83% of the population) and one for the wealthier private sector (approximately 17% of the population)
- A single exit price (SEP) mechanism is used to list the maximum price that pharmaceuticals can charge, but does not apply to medical devices.

Sources: South African Government; South African Legal Information Institute

Reimbursement – Public Sector

Current Environment

- The National Department of Health (DoH) establishes a tender and companies meeting the criteria are awarded contract.
- The South African government encourages competition between companies in order to help reduce tender prices
- All public primary-sector treatment is fully reimbursed by the government, and at present there is no public-sector national health insurance system in place or official HTA process
- Reimbursement of medical devices is linked to the hospital ordering process through the procurement procedure

Future Environment

- Formerly, the National Health Reference Price List (NHRPL) was published by the DoH on the department website and was easily accessible by service providers and patients. However, NHRPL was abolished and the DoH is in the process of developing a new pricing determination process to create a new set of billing codes and tariffs
- The Essential Drug List (EDL), standard treatment guidelines and improved affordability and access of medical products

Reforms will include the development of a National Health Insurance Benefits Advisory Committee, who will play a role in standardising and centralising a health technology assessment procedure to assess whether or not medical products are more cost-effective than existing health service interventions

Sources: South African Government; Medtech Switzerland; South Africa Medical and Pharmaceutical Industry Business Law Handbook

Reimbursement – Private Sector

Current Environment

- It can take 4-8 weeks to release a single exit price for a medical device to enable it to then be sold in the private sector
- Limitations on bonuses, rebates and samples (S18A&B of the Act) were implemented as of June 2017 and apply to medical devices
- There is no separate reimbursement scheme for medical devices and each private healthcare insurer has its own method of reimbursement
- Private insurance schemes typically prescribe benefits based on budget impact and affordability at lowest plan option, and have implemented their own versions of HTA as part of the negotiation process

Sources: Medicines and Related Substances Act; ISPOR

Procurement Environment – Public Sector

Public Sector Procurement

- **Public procurement in South Africa occurs at the provincial level.** There are nine provinces across the country and each will have a number of government run hospitals split into three categories: Academic, District and Regional Hospitals
- All consumable medical devices require an inventory control number (ICN) that can be obtained from the respective provincial medical depots. This number is used to identify and list the item for ordering purposes
- Depending on the nature of the device and whether or not it is listed and on tender, standard ordering procedures apply. As the device becomes more unique, specialized, and expensive it becomes more difficult for the device to enter into the public sector market. Innovative medical devices that are more expensive and not required in large quantities typically require publishing a tender for purchase, these tenders may run for up to a maximum of 3 years for consumables (Question this statement).

- **All medical devices are procured through a tender procedure** with price being a key determining factor. Each province operates in a similar way whereby the hospital needing the item will submit a request to the provincial buying authority. If a tender agreement exists, an order will be made to the supplier, if not, they will request a quote from the supplier. If possible, ad hoc ordering requires 3 price quotes before an order can be issued
- The order specifies where the device is to be delivered, and the invoice and delivery note is handed to the hospital. Each hospital will process the order on the central computer system and send the documentation to the provincial buying authority for reimbursement

- **The Preferential Procurement Policy Framework Act (PPPFA)** governs all government procurement within South Africa. The PPPFA stipulates that when government assesses contracts, it must take into account a preference point system which facilitates securing contracts at low cost

Sources: Medtech Switzerland; South African Medical Device Industry Association

Procurement Environment – Private Sector

Private Sector Procurement

- Service providers (medical practitioners and hospitals) may buy directly from suppliers or from wholesalers, pharmacies and associated hospitals, with the hospitals being the distribution channel
- Service providers are unlikely to purchase items which do not offer reimbursement. In the hospital environment, the pharmacy will usually purchase a stock of all consumable products used in the hospital departments; these purchases are only approved once by the central procurement offices of the respective hospital groups
- The costs of some items used in hospital may be recovered via a specific ward or theatre tariff while others are recovered as fee for services or as part of a fixed fee

- The sale of a medical device that is not normally recovered as part of any existing hospital or service tariff will require the application of a National Pharmaceutical Product Interface (NAPPI) code if it is to be reimbursed in the private sector. The NAPPI code is a unique identifier for a given product allowing identification of identify surgical and consumable products used by pharmacists, doctors and hospitals
- NAPPI is a service offering of MediKredit, an independent information technology company, and has become the national standard in the South African private sector; aiming to create standards for the private reimbursement of medicines and medical devices
- Product information received from manufacturers and suppliers is incorporated onto the MediKredit product file database which contains the recommended wholesale prices of the respective products and is available to stakeholders in the healthcare industry

Sources: Medtech Switzerland; South African Medical Device Industry Association

Funding Environment

Public Sector – Environment in transition

- There are no specific budgets for medical devices, and these are linked to spending on pharmaceuticals and other areas of healthcare. The South African health system is currently undergoing a transition in its public healthcare Funding system through the introduction of the **National Health Insurance (NHI)**
- The NHI will create a unified health system by improving equity in Funding, reducing fragmentation in funding pools, and by making health care delivery more affordable and accessible for the population. Starting in 2012, the NHI is currently being implemented in phases over a 14-year period. It will be established through the creation of a single fund that will buy services on behalf of the entire population. The funding for NHI will be through a combination of various mandatory pre-payment sources, primarily based on general taxes
- Part of the rollout involves implementation of an inventory of pharmaceutical, medical supplies and devices linked to the Essential Drug List (EDL) and will be updated on a regular basis by the NHI Benefits Advisory Committee. As part of the process of moving to NHI, various procurement strategies will be applied to obtain fair prices, access to innovation and a secure supply of medicinal products. A centralised function will be established to assume responsibility for facilitating and coordinating all functions related to procurement of health-related products, including medical devices used within the NHI (This will need to be updated upon release of forthcoming policy).

Private Sector

- In the private sector expenditure is typically funded through private health insurance schemes or out-of-pocket expenditure

Sources: South African Government; Medtech Switzerland; South African Medical Device Industry Association

Thailand

Thailand: Country Overview

Wealth Indicators (2013)

State of development	Upper Middle Income	**GDP growth**	2.70%
GDP	USD 419.8 Billion	**Inflation**	2.18%
GDP per capita	USD 5,779	**Population**	67.45 million

Healthcare Expenditure (2013)

Health expenditure*	USD 44.3 billion	**Pharma expenditure**	n/a
Health exp. per capita	USD $658	**Pharma exp. per capita**	n/a
Health exp. % of GDP	6.18%	**Device expenditure**	Size of market – USD 950 million
% Out of Pocket	14.73%	**Device exp. per capita***	USD 14

Notes: * Calculated as total expenditure multiplied/divided by 2013 population (67.45 million) ;
Sources: World Bank; WHO; Pacific Bridge Medical (2014)

Approval: current environment

Regulatory framework

- The Thai Medical Device Control Division, Food and Drug Administration (TFDA), established in 1990, regulates the manufacturing, importing, selling and advertising of medical devices in Thailand
- Medical devices are classified into 3 categories
  - It is important note that the Thai FDA plans to re-classify medical devices based on the level of associated risk to comply with the Association of Southeast Asian Nations (ASEAN) Medical Device Directive

Class 1

Licensed Medical Devices which are the most strictly controlled and are considered high risk. For example, these are examination gloves, contact lenses, and HIV test kits. These products are deemed important for preventing "unreasonable risk of illness or injury"

Class 2

Notification Medical Devices are considered moderate risk and have a less intensive TFDA review procedure. Examples are: implanted silicone breast prostheses, alcohol detectors and physical therapy products

Class 3

General Medical Devices are considered low risk and have the least stringent review process. These include items like laser equipment products

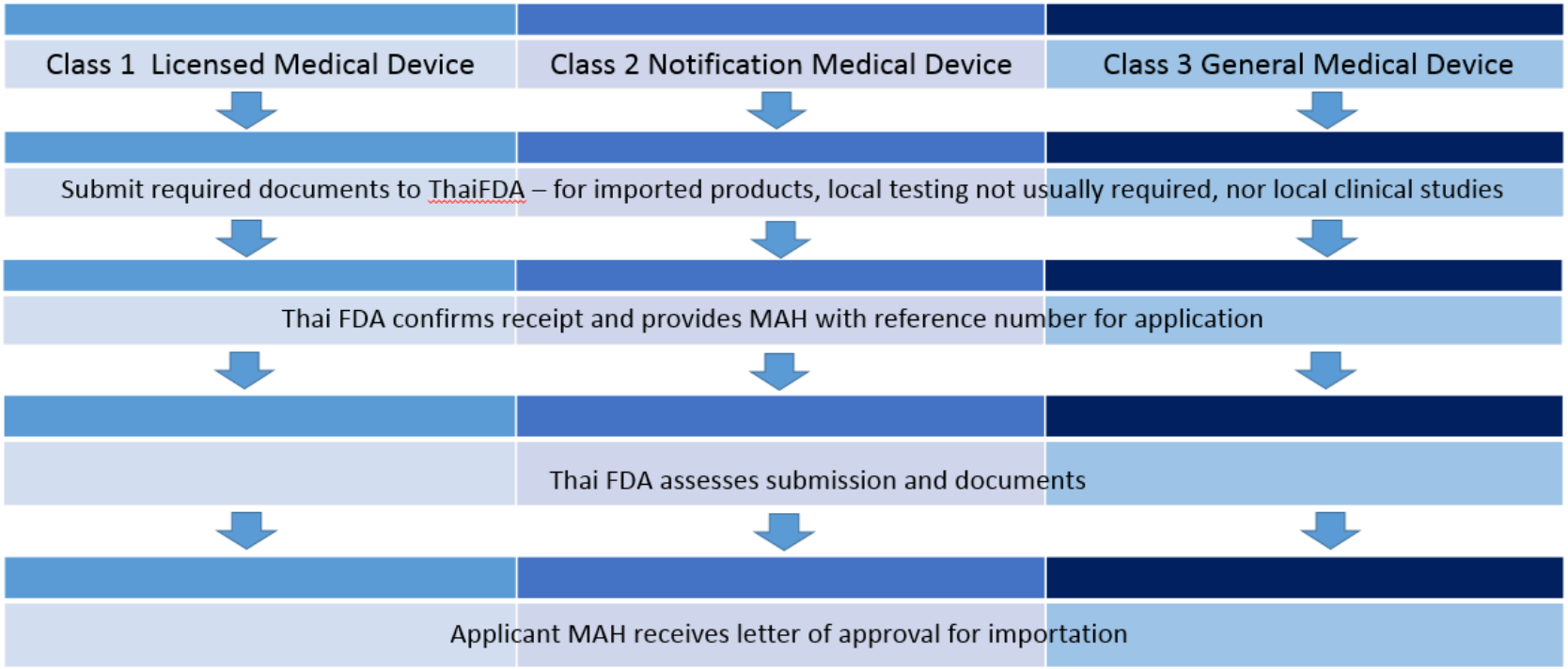
Regulatory approval process and classification do not have any implications on the P&R process

Source: Phanudulkitti,R (2012); Licensale.com (2015)

Approval: current environment

Regulatory process

- The approval process for Class I and Class II devices requires a manufacturer submission of required documents in the Common Submission Dossier Template format. For Class III products, the approval process is simpler and there are fewer documents required
- An import licence for medical devices is valid for five years



Source: Pacific Bridge Medical (2016)

Pricing and Reimbursement: current environments

Reimbursement process for publically reimbursed medical device

All publically reimbursed medical devices are listed in the National List of Essential Drugs (NLED)

Medical devices that cost less than USD $3.3 million

- A manufacturer submits an application to the NLED and the Health Intervention and Technolgoy Assessment Program (HITAP)
  - There is no formal HTA process for medical devices

Medical devices that cost more than USD $3.3 million

- According to the Medical Device Act B.E.2551 (2008), these devices must undergo social economic and ethical impact assessments

Pricing for medical devices that are publically reimbursed

- Alongside the reimbursement decision, the price of the medical device is negotiated and regulated by the Ministry of Finance and the Ministry of Public Health

Pricing for medical devices not publically reimbursed

- For medical devices that are not included in the NLED, there is no price regulation (no price ceilings nor reference sets)

Source: Asia Pacific Observatory on Health Systems and Policies (2015), Teerawattananon Y et al (2014), Practice Law (2016), Jirawattanapisal T et al (2009)

Procurement: current environment

Procurement process for public institutions

As of 2015, public health insurance schemes (Universal Coverage Scheme, Social Health Insurance and Civil Servant Medical Benefit Scheme) cover a range of medical devices (88 items - 387 items)

Typically, procurement occurs at the individual level

- Healthcare providers purchase medical devices through closed auctions and procurement occurs directly from supplier to purchaser. If the medical device is reimbursed by the NLED, then the purchase price cannot deviate more than 3% from the reference price (public hospitals obtain capitation reimbursement)
- In 2014, an e-procurement system was launched to facilitate procurement

But procurement can also occur centrally - The National Health Security Office (NHSO), responsible for the Universal Health Coverage Scheme will buy commodities at the central level and then distribute these locally

Procurement for private institutions

Procurement of medical devices in private hospitals is dependent on their executive team, who makes procurement decisions. Decisions are made on a demand and return on investment basis

Source: WHO SEAR (2014); Jirawattanapisal T et al (2009); |Asia Pacific Observatory on Health Systems and Policies (2015); Ipsos (2015); Velasco RP (2013)

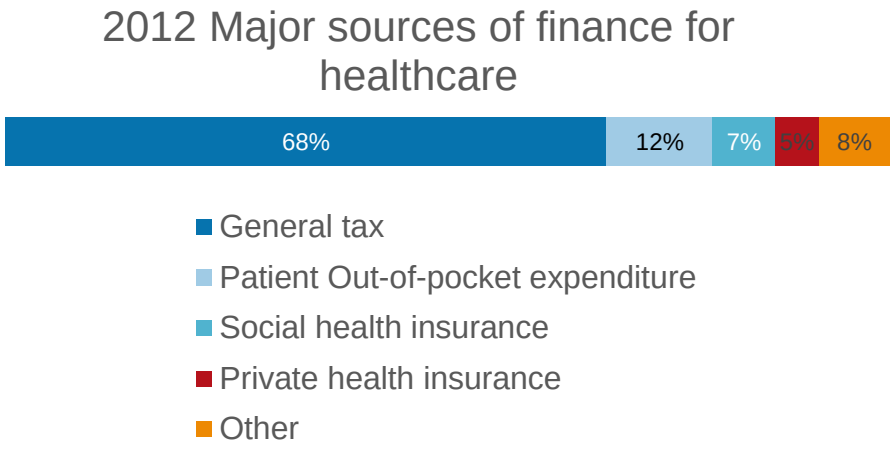
Funding: current environment

Public and Private Funding

- The Civil Service Medical Benefit Scheme is financed by the government and in 2006, covered 4.2 million people
- The majority of finance for healthcare comes from the taxes

Funding process

- The medical devices covered by social insurance could be financed by general tax
- Healthcare providers would need to finance medical devices themselves or pass the cost onto the patients for medical devices not covered by social insurance



Source: International Labour Organisation ; WPRO, Velasco RP et al (2013)

Turkey

Turkey: Country Overview

Wealth Indicators (2015)

State of development	Middle Income
GDP	USD 718 billion
GDP per capita	USD 9,130

GDP growth p.a.	4 %
Inflation	7.7%
Population	78 million

Healthcare Expenditure (2014)

Health expenditure	USD 76.4 billion
Health exp. per capita	USD 568
Health exp. % of GDP	5.1%
% Out of Pocket	78%

Pharma expenditure	USD 7.6 billion
Pharma exp. per capita	USD 97
Device market	USD 2.4 billion (2013)
Device market per capita	USD 32 (2013)

Sources: World Bank; WHO; OECD.
NB: Per capita figure for device expenditure and pharmaceutical expenditure are CRA calculated.

Approval: current environment

Regulatory framework

- Classification of medical devices is risk based, akin to the European medical devices directive and there are three classes:
  - Class I – sterile and non sterile, low risk, non invasive devices (sticking plasters)
  - Class II – medium low risk devices (tracheal tubes)
  - Class IIb – medium high risk (X-ray machines)
  - Class III – high risk (heart valves)
- All imported products must find a local partner to make regulatory submission to MoH*

Regulatory process

- All product documentation, including the certification of CE* marking, quality system, Global Medical Device Nomenclature are sent to MoH for review
- The MoH passes this information to its national database TITUBB*

Class I

- MoH grants approval and makes publication in national database
- MoH approval does not expire

Class II and Class III

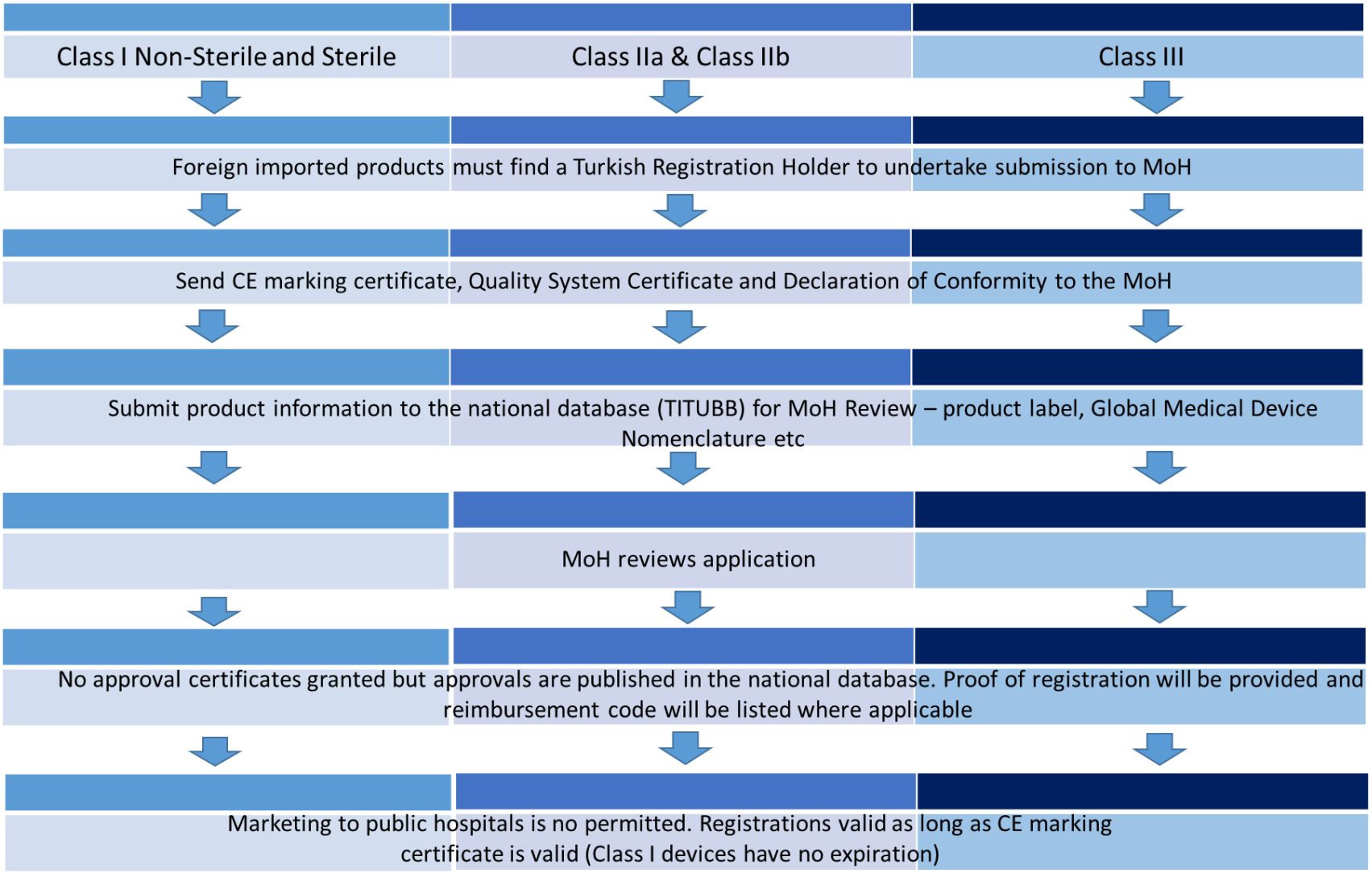
- MoH grants approval and makes publication in national database
- MoH approval expires when CE

Regulatory approval process does not have any implications on the P&R process

*Notes: CE - Conformité Européene; MoH – Ministry of Health; TITUBB – Turkish National Information Database for Medicines and Medical Devices

Source: EC (2012); CPhI & GBR (2015), Kockaya (2012)

Approval environment: medical device regulatory structure



Source: Emergo (2016)

Pricing: current environment

Current pricing framework for reimbursed medical devices

- Once reimbursement is granted, the pricing process begins
- The reimbursement price is dependent on the state hospital tender price of the previous year. Calculation uses the lowest:
  - Prices from 5 private hospitals
  - Prices from 3 foundation university hospitals
  - Prices of similar products already on the market
- There are no minimum or maximum prices for medical devices

Current pricing framework for medical devices sold in private market

- No government pricing regulations currently exist for medical devices sold in the private market; prices are market regulated

Reimbursed medical devices undergo a pricing process

Source: Kockaya (2012)

Reimbursement: current environment

Reimbursement framework

- All medical devices seek reimbursement through the SGK*
- Expensive/innovative medical devices undergo efficacy and economic assessment by a number of governmental departments – the Clinical and Economic Evaluation Commission, the Reimbursement Communication, the Ministry of Health and the Ministry of Finance. Assessments are done using the patient perspective
- Approved products are listed on the national e-catalogue EKAP* for public procurement

Low cost medical devices

- These are often reimbursed as part of existing diagnostic or procedural reimbursement codes

More costly medical devices

- These are reimbursed with unique codes that are used in addition to diagnostic related payment codes
- Reimbursement codes are akin to the ATC classification codes for pharmaceutical products

The reimbursement process for more costly medical devices is more complex and often requires the development of a new reimbursement code

*Notes: SGK - Social Security Institution; EKAP – Electronic Public Purchase Platform

Source: Kockaya (2012), Goksin (2010)

Reimbursement environment: forthcoming changes in environment

Creating a connected pricing and reimbursement process

- For some products, the reimbursement process is still manually between different governmental departments
- There are plans to formalise the reimbursement process through a joint system between the TITUBB, the MoH and SGK

Notes: MoH – Ministry of Health; SGK - Social Security Institution; TITUBB – Turkish National Information Database for Medicines and Medical Devices
Source: Medtronic (2015)

Procurement: current environment

Current public procurement framework

- The main procurement process is competitive bidding. Since 2013, hospitals commonly unite and put out tenders and procure together
- Typically, healthcare providers seek a 15% profit from the difference between procurement price and SGK reimbursement price

Public procurement process for low cost medical devices

- For medical devices reimbursed as part of another diagnostic or procedural code, healthcare institutions are incentivised to purchase from the cheapest supplier

Public procurement process for more costly medical devices

- For medical devices with unique reimbursement codes, all public healthcare institutions must make purchases using that reimbursement code

 Source: Goksin (2010), Kockaya (2012)

Funding: current environment

Current sources of Funding

- Healthcare providers often have insufficient financial resources to purchase new and costly medical devices
- Common practice is to:
  - Purchase refurbished medical devices (less than 5 to 10 years old)
  - "Rent" medical devices, which provides healthcare providers with necessary medical devices and charges healthcare providers on a per use fee/ monthly payments
- In 2007, 80 hospitals in five big Turkish cities indicated that 75% of their medical devices were "rented", on lease from the medical device manufacturer

There seems to be limited financial resource amongst healthcare providers to purchase costly medical devices

Source: US Department of Commerce, International Trade Administration (2011), Simens (2011), Yigit (2007)