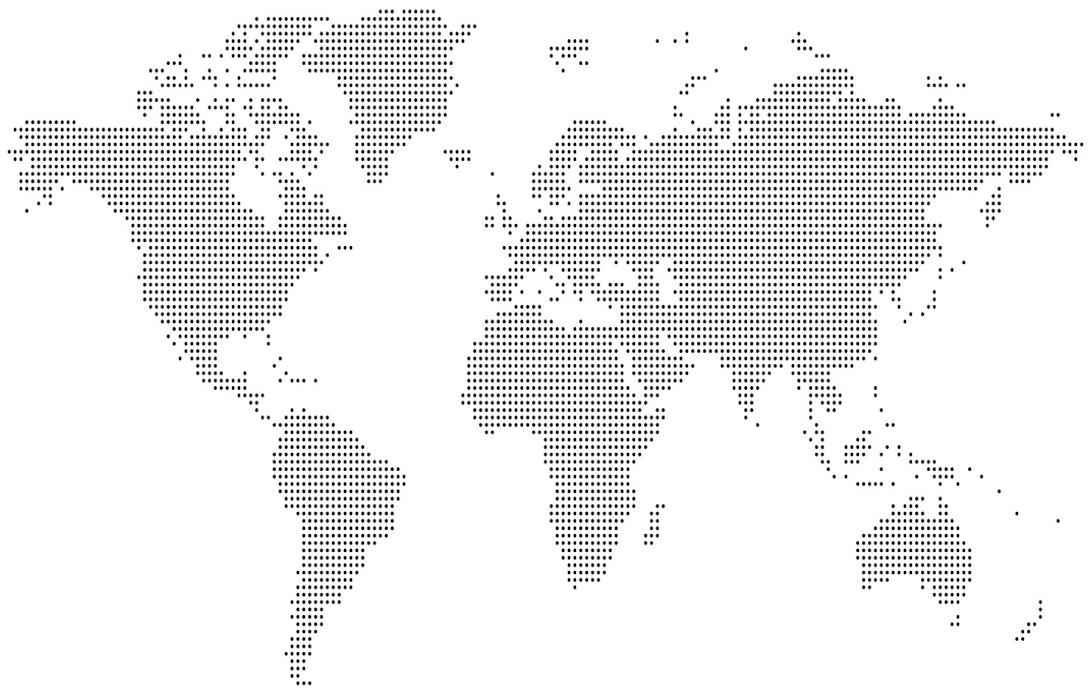


The Impact of Applying Price Regulation to Medical Devices in Emerging Markets: A Case Study-Based Analysis



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EXECUTIVE SUMMARY

Innovations in medical devices have enabled healthcare professionals to better manage patients through diagnosing, treating and preventing diseases, improving patients' health and quality of life. Given the anticipated burden on healthcare systems due to growing and aging populations, and the need to expand universal health coverage across emerging markets, payers are increasingly debating economic instruments to control the market and limit budget impact. One area of debate is the application of price regulation to medical devices. The objective of this study is to assess the potential impact of pricing regulation of medical devices in Brazil, China, Colombia and India. We have focused on two medical devices as case studies – coronary stents and implantable orthopaedic devices. Drawing on the local literature, data and interviews with local policymakers, experts and industry, the study sets out evidence on the impact of price regulation on the relationship between price and value, access to a wider number of medical devices, the intensity of competition today and the incentive to innovate in the future. The results show that price regulation can lead to a short-term price reduction for some medical devices on the market. However, this has not necessarily resulted in a reduction in the overall cost of the overall procedure, and benefits were not passed on to consumers. Price regulation has led to reduction in quality of medical devices available, increases in the price of some devices, and distortion in the relationship between price and value. In some markets, products have been withdrawn or not launched, impeding access to future innovations in emerging markets. Finally, the alternative to price regulation needs to be considered. We show that competition can work effectively, and that policies that result in patients being better-informed on the quality of devices and their relative benefits, and/or that result in an improved focus on the cost of the overall procedure, would be a preferable alternative.



1. INTRODUCTION

Medical devices play a key role in the provision of comprehensive healthcare to patients. Innovations in the past decade have led to significant health gains and improvements in the quality of life through direct intervention and disease treatment, as well as earlier diagnosis.^{1,2,3,4} In emerging markets, growing populations and efforts by governments to expand universal health coverage have posed a challenge to meeting healthcare expenditures. As a result, countries have implemented increased regulation for healthcare technologies, including price regulation for medical devices. A few examples include Brazil, China, Colombia and India, which are the focus of this analysis.

Price regulation is generally defined as the practice of restricting the minimum or maximum prices in the market by imposing legal requirements.⁵ While market access pathways differ for medical devices (see the Appendix), the regulation of prices typically involves establishing a price cap for a predefined category of devices. In line with the increasing focus on price regulation, there is a mounting local and international literature outlining arguments for and against regulating prices of medical devices. However, to date there has been limited research undertaken on the application of price regulation to medical devices and the impact this has on the healthcare system, patients and market dynamics.

The aim of this study, undertaken on behalf of Advamed, is to contribute to the debate by examining the potential impact of price regulation across different categories of medical devices. It seeks to develop some concrete evidence on the potential impact of price regulation in the context of emerging markets from the perspective of patients, physicians and the healthcare system. To do this we focused on a set of medical device categories that have been in focus during pricing debates, namely coronary stents and orthopaedic devices. In the next section we provide a detailed overview of the methods and approaches used to conduct this study. Section 3 discusses the current role of price regulation in medical devices and the economic literature on principles and impact. In Section 4, we discuss the evidence and result of the case study analysis. Sections 5 and 6 respectively set out a discussion of the results and draw conclusions.

2. METHODOLOGY

In this section, the aim is to provide an overview of the methods and approach used to conduct the analysis. First, we conducted an exhaustive literature review of the economic debate and studies on the impact of pricing regulations on health technologies in general and specifically on medical devices, with a particular focus on emerging markets. Second, we targeted two case studies to develop evidence across each of the emerging markets, based on a review of local literature and interviews with manufacturers and local policy experts and academics.

The literature review around the debate and evidence on price regulations includes international theoretical and empirical papers from the late 1990s to more recent publications from 2010 onwards, in line with the significant debate around price regulations at the time. The terms “price regulation”, “market failure” and “competition” and “medical devices” were used to search in PubMed, Google Scholar and grey literature. This yielded over 100 articles on price regulation. In terms of the economic peer-reviewed studies, more than 40 articles were international economic theoretical or empirical studies with a general focus on the application of pricing regulation in the pharmaceuticals space, but only 5 of those studied the application of pricing regulation in the medical devices market. In addition, we noted a lack of papers focusing on the economic debate and implications of pricing regulation in emerging markets. Based on learnings from the literature review, we develop a framework for assessing the impact of price regulation in medical devices in emerging markets.

To support evidence development, the analysis focuses on two device categories – coronary stents and implantable orthopaedic devices – which are frequently subject to price regulation or part of the debate on the application of this in emerging markets. These are

also highly innovative medical device categories; therefore the evidence focuses on particular subcategories in each, as follows:

- *Coronary stents*: A coronary stent is a tube-shaped device placed in one of the coronary arteries that supply blood to the heart, to keep the artery open. It is used in a procedure called percutaneous coronary intervention (PCI), also known as coronary angioplasty, used to treat coronary artery disease (CAD). Stents have been around for over 40 years, but there continues to be significant innovation. Initially, the market was served by “first-generation” bare metal stents (BMS), followed by the “second-generation” drug-eluting stents (DES).¹ These are further divided into first- and second-generation DES, according to the coating used. In particular a distinction is made depending on the associated drug: sirolimus/rapamycin-eluting (SES) and paclitaxel-eluting stents (PES) or everolimus-eluting (EES) and zotarolimus-eluting stents (ZES). Finally, recently developed “third-generation” bio-resorbable stents (BVS) offer further improvement across a number of outcomes, such as lower rate of late stent thrombosis and improved reduction in revascularisation procedures.⁶
- *Orthopaedic medical devices*: Orthopaedic devices represent one of the largest subsectors in the medical device market, covering a wide range of medical devices for dysfunctions in the musculoskeletal system to provide patients with increased mobility. The largest subcategory is implantable devices, which is further categorised into four major segments: trauma fixation devices, spine devices, and hip and knee reconstruction implants. This analysis primarily focuses on the latter, i.e. hip and knee replacements. These devices differ in their use (partial or total replacement) and in the materials used for components.⁷ Current hip implants have four main combinations of femoral head and acetabular bearing surface materials: metal-on-polyethylene, ceramic-on-polyethylene, ceramic-on-ceramic, or metal-on-metal.⁸

The evidence development is based on primary research through interviews, and on local literature review and data analysis. A total of 18 external interviews were conducted with policymakers and local academic experts as well as companies involved in the commercialisation of medical devices. The interviews were focused on understanding the application of price regulation for medical devices in each of the markets, and explored the perceived impact of the regulations across the indicators of the framework considering the case studies. An additional literature review was undertaken for each of the countries in both English and local languages in order to collate evidence across the indicators. As part of this we found around 20 government, health assessment or policy informing reports and publicly available national databases on authorisations, availability and pricing of devices. The remaining 100 articles were mainly in the grey local literature.

¹ DES are composed of a scaffold made of a metal polymer (e.g. stainless steel, cobalt-chromium, platinum-chromium, etc.) coated with gradually released drugs that prevent re-narrowing and restenosis of the vessel.

3. BACKGROUND

This section discusses prior theoretical studies and empirical evidence on application of price regulation to health technologies. In addition, it presents an overview of current price regulation to case study medical devices in a set of emerging markets.

The role of price regulation in health technologies

Countries implement different methodologies to regulate prices of health technologies. As outlined in international literature, this could comprise: (1) a price ceiling, set by a national or regional payer to public or private healthcare markets, and potentially used in tendering processes; (2) reference pricing, set by national or regional payer, based on a comparison with local or international prices for the product or comparative products; and (3) a value assessment process, through which the payer determines the price based on a health technology assessment, potentially involving the use of cost-effectiveness thresholds and/or comparison to the prices of alternative products on the market.^{9,10,11,12}

Studies advance a number of arguments for the application of price regulation, but in general, the underlying motivation for policymakers is to control healthcare expenditure. Some argue that enforcement of existing regulations leads to more competitive markets by addressing market imperfections and ultimately reduces expenditures by restoring a price, which cannot be achieved in a perfectly competitive environment.^{13,14} Furthermore, particularly in the case of out-of-pocket (OOP) markets where patients pay the whole or part of the medical bill, researchers suggest that lower, regulated prices could lead to lower overall costs and better quality healthcare by increasing the usage of health interventions.¹⁵ It is argued that price set for a health technology through free market forces often does not reflect its true value in terms of clinical efficacy or its safety profile.^{16,17} However, there is a large established literature showing that price regulation should only be applied under certain conditions, such as imperfect markets and evidence of failures.^{18,19,20}

However, although price regulation may be justified in some circumstances – and particularly in the presence of market failures – price regulation can also have some unintended costs if applied inappropriately. This includes a reduction of access to innovative products, a reduction of the therapeutic alternatives for patients and physicians, distortion of competition between suppliers, and a resulting reduction in incentives to innovate. Indeed, empirical and theoretical economic analyses show that price controls might lead to short-term savings that are outweighed in the long term by the cost of shorter life expectancy.^{21,22,23,24} Furthermore, papers have failed to establish correlation between increased price regulation and reduced healthcare expenditure.²⁵ In fact, it is argued that price regulation could lead to an increase in expenditure in the form of unnecessary regulatory costs and/or costs due to delays in access to innovative treatments.²⁶ In the long term, price regulations could discourage rounds of future innovation, leading to fewer innovative products being developed, which in turn can limit future health gains.^{27,28,29,30} Particularly in the case of developing and emerging markets, price regulation could deter manufacturers from marketing in a country.^{31,32,33,34,35} In addition, papers show that price regulation could indirectly lead to distortion of patients' and physicians' choices, toward cheaper compounds with lower therapeutic value.^{36,37} Importantly, price regulations could distort competition in the market and lead to price increases for some compounds,^{38,39} as well as lead to regional access problems in markets with significant income differentials.⁴⁰

Finally, it is recognised that the introduction of policies that strictly regulate supply without a corresponding policy to regulate the demand side may lead to market shortages.⁴¹

However, to date, this literature has focused on particular health technologies, especially innovative and generic pharmaceutical products, and there has been little consideration of the medical devices market. The medical devices market is distinct from pharmaceuticals – there is frequently intense competition between medical device manufacturers due to the regulatory process being less stringent (particularly for lower risk medical devices) and the shorter lifecycle of a product, where products are quickly replaced by newer and more innovative products being developed.⁴² In addition, devices are also often purchased by hospitals and paid for as part of a procedure, through the use of Diagnosis Related Groups (DRGs).

The application of price regulation to coronary stents and orthopaedic implants

Despite the lack of evidence on impact, some emerging markets have applied price regulation to medical devices. Focusing on the two case studies, i.e. coronary stents and orthopaedic devices, we set out evidence on the state of price regulation across four emerging markets, namely Brazil, China, Colombia and India.

In coronary stents, the application of price regulation takes different forms across the four markets, as illustrated in Table 1. Price regulation is applied in China, Colombia and India, whereas in Brazil, the proposals are focused on imposing a ceiling price in tendering processes in the private healthcare market, which purchases 68% of all medical devices in the country.^{43,44,45,46}

Table 1: Application of pricing regulation to coronary stents in Brazil, China, Colombia and India

	Brazil	China	Colombia	India
Price Regulation	A 2015 report of the Interinstitutional Working Group on orthoses, prostheses and special materials proposed reforms of the pricing of implantable devices including cardiac stents and price monitoring and transparency by ANVISA	Guideline No. 86 of the National Health and Family Planning Commission required for the regulation of high-value medical consumables including coronary stents through price ceiling applied to regional or hospital bids	Stents were proposed as the first group of medical devices under a price control pilot , legislated for in 2015 and monitored by the National Commission for the Prices of Medicines and Medical Devices	Since 2016, stents were scheduled as drugs and included in the National List of Essential Medicines , price regulated under the Drug Price Control Order of 2013 by the National Pharmaceutical Pricing Authority
Year implemented	Not yet implemented	National regulation 2007 ^[1] Provincial guideline 2012	2015	Price ceiling in 2017 (Price revision in 2018)
Methodology	External Reference Pricing of a basket of countries	The lowest average of prices of devices in a category or reference pricing of other provinces	The 25th percentile of the distribution of prices across a basket of international markets ^[2]	An average of landing cost for imported stents and an added % trade margin
Application	Price ceilings might be applied in hospital or national tenders . Expensive devices are paid separately from the procedure by the SUS (NHS)	Applied to a competitive bid amongst manufacturers at a centralized provincial level bid to qualify for hospital procurement . Variable reimbursement level as part of the procedure	The reimbursement price of the device covered for by the national health insurance fund including a 10% hospital profit margin , adjusted based on IRP and inflation	Applied to the maximum retail price of stents , paid in addition to the procedural cost in the majority of cases by patients to hospitals

Source: CRA Analysis

Note: [1]: Regulation of stents in China began in 2007 with the introduction of a regulation that controlled their price nationally, which later evolved into provincial level regulation. [2]: Colombia price references Canada, Chile, Spain, Uruguay, France, Italy, the US, Mexico, Germany, Ecuador, the UK, Panama, Portugal, Australia and Brazil.

There are similarities in the price regulation of implantable orthopaedic devices. To date, price regulation has been applied in China and India (as shown in Table 2). In India, regulation was introduced to knee implants a year after its application to coronary stents.

Table 2: Comparison of price regulation for orthopaedic devices across the four markets

	Brazil	China	Colombia	India
Price Regulation	A 2015 report of the Interinstitutional Working Group on orthoses, prostheses and special materials proposed reforms of the pricing of implantable devices including orthopaedic devices and more structured price monitoring by ANVISA	Guideline No. 86 of the National Health and Family Planning Commission required for the regulation of high-value medical consumables including orthopaedic devices through price ceiling applied to regional or hospital bids	There is current no price regulation applied to orthopaedic devices in Colombia	Orthopaedic devices are regulated under the Drug Price Control Order of 2013 by the National Pharmaceutical Pricing Authority. The NPPA has introduced price caps for knee implants
Year implemented	Not yet implemented	National regulation 2007 ^[1] Provincial guideline 2012	n/a	Price ceiling set in 2017 (extended Aug 2018)
Methodology	External Reference Pricing of a basket of countries	The lowest average of prices of devices in a category or reference pricing of other provinces	n/a	An average of landing cost for imported knee implants and an added % trade margin to determine the ceiling
Application	Price ceilings might be applied in hospital or national tenders . Expensive devices are paid separately from the procedure by the SUS (NHS)	Applied to a competitive bid amongst manufacturers of the same device at a centralized provincial level bid , necessary to qualify for hospital procurement	n/a	Applied to the maximum retail price knee implants , paid in addition to the procedural cost by patients to hospitals

Notes: [1] Regulation of orthopaedic devices in China began in 2007 with the introduction of a regulation that controlled their price nationally, which later evolved into provincial level regulation.

Source: CRA analysis

4. RESULTS

Drawing on the wider academic, economic, empirical and theoretical studies, we find that price regulation can affect the way a market performs in a number of different dimensions:

- The relationship between price and value
- Access to a wider number of medical devices
- The intensity of competition today
- The incentive to innovate in the future

The rest of the section investigates these through local literature and interviews, and draws on the perceived impact of price regulations to date.

The relationship between price and value

To understand the impact on prices, the analysis examines price reactions after the introduction of regulation, assessing impact in terms of the variation in prices and the degree to which prices reflect the differences in value offered by different medical devices.

Coronary stents

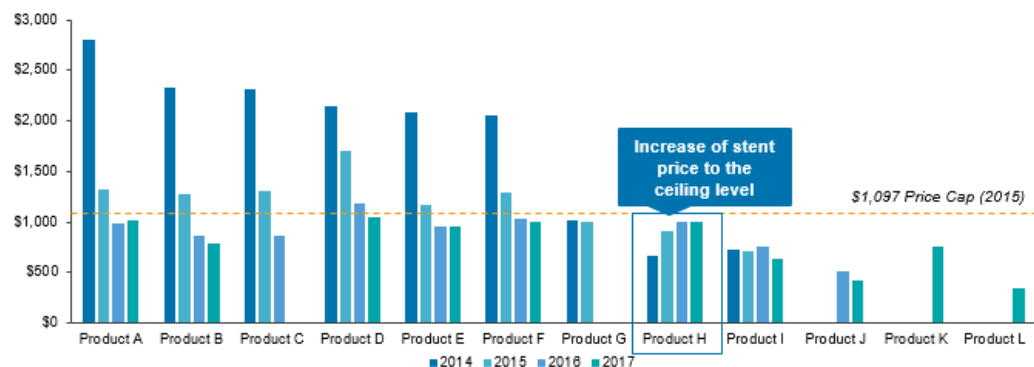
Overall, we find that although the intention of price regulation across markets is to help improve the affordability of devices for patients, these benefits may not be passed on to patients in cases where a device constitutes only part of the total procedure cost. Secondly, based on an analysis of pricing data and interviews with local stakeholders, prices of some brands of devices (previously priced below the cap) have increased as a result of the regulation, contrary to the aim of the regulation.

In India, the introduction of price regulation to the stent market has been subject to considerable debate, with many articles in the grey literature. However, there is limited evidence on the development of the price of stents since the regulation (a notable exception is a study on “*Medical devices in India – an agenda to effective healthcare delivery*” commissioned by AdvaMed and conducted by IQVIA). Whilst there is evidence to suggest that the maximum reference price (MRP) of stents charged to patients has decreased as a result of the regulation, presenting an opportunity to improve affordability and allow more patients to undergo the procedure, the price of the overall procedure has not changed in the same proportionate amount. Indeed, the cost paid by the patient for an angioplasty procedure at a private facility has not changed significantly in the short term, as a reduction of 85% in stent price has resulted in only ~8–18% reduction in the total angioplasty cost paid by patients undergoing single vessel procedure. The cost reduction of the procedure was between 5% and 20% at a public hospital. This is because the cost of a stent represents only about 20%–25% of the total angioplasty cost to patients.^{47,48} Another contributing factor is the increased charges for catheters, balloons and guide wires used as part of the procedure in hospitals, making these consumables more expensive than the stent and minimising the benefits of the price cap to patients.^{49,50} Local stakeholders are also concerned that hospitals are increasing the cost of the procedure itself to incur additional profits. As a result, both the industry and physicians have called upon the government to consider regulating the overall angioplasty cost paid by the patient, rather than the price of the stent itself.

Looking at price distribution, evidence shows that some prices have decreased but others have gone up. In India, we find that before the regulation, BMS and DES averaged \$676 (range: \$375–\$1125) and \$1821 (range: \$600–\$2971) respectively, based on data from the National Pharmaceutical Pricing Authority (NPPA).⁵¹ According to local industry experts, the introduction of the regulation represented a price decrease for the high-end imported stents but a price increase for some locally manufactured lower-end stents, resulting in an overall price convergence across manufacturers to the level of the price cap.⁵² The same is observed in Colombia, where prices of DES have converged to a level below the international reference pricing (IRP) cap introduced in February 2015. As Figure 1 shows, for many of the high-value DES, between 2014 and 2017 there was a 60% decrease in the average maximum manufacturer’s selling price, and stents introduced later in 2017 assumed prices below the level set. However, an example shows the stent price increased by 50% from 2014 to 2017. According to interviews with industry experts, given

that the price cap applies to the cost that hospitals charge patients and that hospital margins are set at 10%, manufacturers have been competing on offering a lower price to the hospital, which sees an incentive in terms of higher profits. As a result, rather than patients experiencing the decrease in prices, hospitals benefit from manufacturers competing for a better price below the ceiling. Thus, price regulation is not ultimately benefiting patients, but rather resulting in non-transparent and higher profit margins, with costs passed on to patients.

Figure 1: Evolution of manufacturer selling prices for drug-eluting cardiac stents in Colombia, Q3/2014-Q2/2017



Source: CRA Analysis of MinSalud Information⁵³

Note: The analysis includes most of the stents available on the market as per data available from Q3 in 2014 to Q2 in 2017. There was no pricing information on Xience V, Taxus Element for 2017 and on Taxus Element for 2016 and zero volume of sales for the year were reported. The prices displayed are an average of the maximum selling price for each product for a given year and hence the price of some of the stents charged in 2015 might be above the price cap only introduced in February 2015. \$1=3,000.5 pesos

In a well-performing market, we would expect prices to reflect the marginal value that patients (or the healthcare system) derive from the product. As set out above, the stents market has evolved from BMS stents to DES and finally to the third-generation stents, delivering benefits in terms of revascularisation, myocardial infarction and mortality. As illustrated by the evidence across India and Colombia, there is now little relationship between the price and the value, and this suggests prices are being determined by the regulation rather than by the value they deliver to patients.

Table 3: Median rate of selected short-term (up to 1 Year) efficacy and safety outcomes and the probability that each stent type is the best (lowest rate) from mixed-treatment comparison analysis⁵⁴

Stent Type	TVR Rate (95% CrI)	Probability Best, %	Death Rate (95% CrI)	Probability Best, %	MI Rate (95% CrI)	Probability Best, %	Rate of Any ST (95% CrI)	Probability Best, %	Rate of Def/Prob ST (95% CrI)	Probability Best, %
Bare metal	15.76 (13.83–17.46)	0.00	0.23 (0.00–1.55)	1.70	4.23 (3.63–4.89)	0.00	0.18 (0.00–1.35)	0.00	0.12 (0.00–1.19)	0.09
Sirolimus	4.11 (3.38–4.91)	58.21	0.22 (0.00–1.50)	7.07	2.85 (2.35–3.44)	0.96	0.14 (0.00–1.01)	0.53	0.08 (0.00–0.82)	2.72
Paclitaxel	7.37 (5.99–8.86)	0.00	0.22 (0.00–1.53)	2.03	3.66 (3.06–4.34)	0.00	0.17 (0.00–1.31)	0.00	0.11 (0.00–1.17)	0.02
Everolimus	4.44 (3.28–5.92)	17.65	0.20 (0.00–1.40)	5.97	2.32 (1.79–3.03)	41.99	0.08 (0.00–0.63)	80.39	0.04 (0.00–0.53)	78.31
Zotarolimus	7.60 (5.54–10.33)	0.00	0.29 (0.00–2.03)	0.42	2.77 (2.06–3.57)	10.89	0.19 (0.00–1.60)	0.24	0.12 (0.00–1.40)	0.72
Zotarolimus-R	4.90 (2.65–8.97)	24.14	0.15 (0.00–1.16)	82.81	2.30 (1.63–3.41)	46.16	0.10 (0.00–0.96)	18.84	0.07 (0.00–0.96)	18.14

Source: Bangalore, S., Kumar, S., Fusaro, M., Amoroso, N., Attubato, M. et al. 2012.⁵⁵

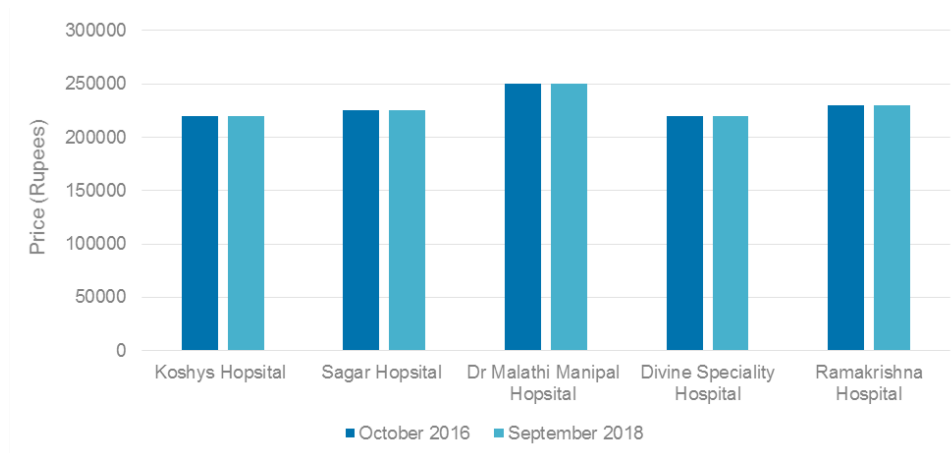
Note: TVR indicates target-vessel revascularisation; CrI, credibility interval; MI, myocardial infarction; ST, stent thrombosis; and Def/Prob, Academic Research Consortium–defined definite or probable stent thrombosis.

The impact of the regulation also discriminates against some manufacturers. In China, stents are considered high-value consumables and therefore all manufacturers must participate in the centralised bids to determine the price for follow-on hospital negotiations. This started off at the national level in 2017, but since 2012 bids have been required at provincial and in some cases city council level.⁵⁶ Stents are grouped in categories according to their characteristics and level of innovation, leading to BMS, DES and bio-resorbable stents (BVS) being priced under different categories but with prices capped by previously determined levels in the tender or the price set in other provinces. The result is that the impact has been much more significant for imported products, which are usually more innovative and build upon existing innovations, leading to considerably less price variation. Evidence suggests that in 2016 only, the price of imported DES decreased by 16%.⁵⁷ This has also resulted in more uniformity across provinces, which has had some dramatic effects on access, as discussed below.

Orthopaedic implants

Turning to orthopaedic implants, obvious similarities are noted. In India, price regulation has also recently applied to knee implants. NPPA found that expenditure on musculoskeletal conditions is a major burden on individuals, health systems and social care systems as a significant cost factor. Based on the increasing significance of orthopaedic care in India, NPPA started studying the market of knee and hip implants and collecting the requisite data from Central Drugs Standards Control Organisation (CDSCO), Central Board of Excise & Customs (CBEC), Director CGHS, and Amrit database to make a fair assessment of the market. As with coronary stents, the impact of the new ceiling price for types of knee implant has been to lower the price of the implants. However, the same concerns are emerging that this is lowering the price of one component of the procedure but not the overall procedure. Under the new price ceilings, the maximum retail price of knee implants fell by 59%–69%; however, the cost of the procedure that hospitals are charging to patients has remained the same, as shown in Figure 2.

Figure 2: Procedure costs for knee replacement surgery from a selection of hospitals in Bangalore (before and after price regulation)



Source: MediFee; Government of India — Ministry of Chemicals and Fertilizers (Press Information Bureau)

Orthopaedic implants also allow an observation on how markets perform in the absence of price regulation. Expert interviews in Brazil support that the market has been effective at controlling prices in the absence of government intervention. In fact, the 2015 report published by the Interinstitutional Working Group on Orthoses, Prostheses and Special Materials (GTI-OPME), shows that prices for all orthopaedic medical devices (spine devices; partial and full knee replacements; hip replacements) decreased between 2011 and 2014 (as shown in Table 4). This illustrates that harnessing competitive forces in Brazil has been able to drive down prices for orthopaedic implantables, without the introduction of price regulation.

Table 4: Percentage reduction in price of spine implants, knee replacements and hip replacements in Brazil (2011–2014)

Orthopaedic device category	Average percentage price change (2011-2014)
Spine implants	-29.1%
Knee replacement implants (partial and full)	-19.3%
Hip replacement implants (partial and full)	-11.1%

Source: GTI-OPME

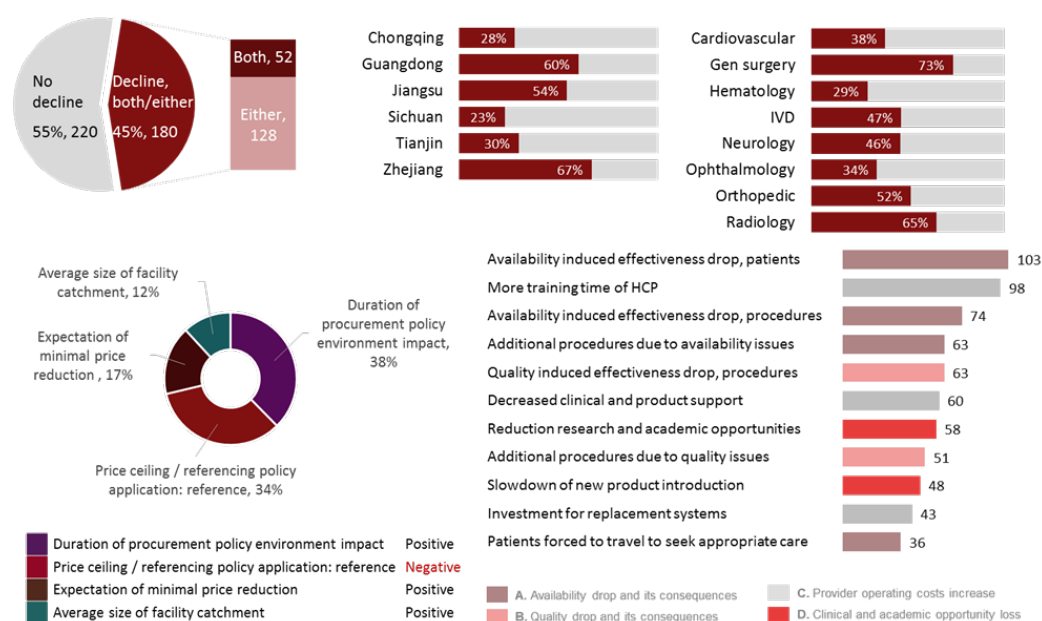
Access to a wider number of medical devices

In principle, price regulation could reduce the cost of medical devices, thus improving affordability. However, economic theory also suggests that price regulation – if applied inappropriately – can lead to shortages or lack of product launches altogether. This is investigated by examining the range of products on the market before and after the introduction of the price regulation.

A recent study surveyed the perceptions of 400 healthcare professionals across Chinese provinces (Guangdong, Jiangsu, Zhejiang, Sichuan, Tianjin and Chongqing), assessing the

availability of medical devices in general across different diseases and the perceived impact, as shown in Figure 3.⁵⁸ The study found that nearly half of the clinicians observed a decline in product quality and availability. This was attributed to the price regulation. The study also found that the key issues experienced by the physicians were deterioration in clinical effectiveness because the device most suitable for a specific patient group or specific procedure was unavailable, and in addition to that, physicians had to spend more time in training, in order to get used to replacement products, leading to additional operating costs for the hospital/provider.

Figure 3: Product quality and availability across 8 therapy areas in 6 provinces in China



Source: IQVIA

Coronary stents

To assess the impact on access, the analysis considers the use of BMS as opposed to DES. In India, reports suggest that one year after price regulation, the use of BMS had been reduced by 30% and replaced by DES.⁵⁹ This has potentially positive implications for patient outcomes. Whilst there is no proven benefit of DES over BMS in terms of reduction in mortality, DES prevent recurrence of the disease and thus re-interventions, as illustrated in a randomised control trial (RCT) showing that the rate of re-hospitalisation and recurrence of unstable angina was lower for DES than BMS.⁶⁰ Thus, the increased use of DES has a positive effect on patients' health and could accrue overall savings to patients and the healthcare system, potentially resulting in lower use of medications and repeat PCIs performed. However, it is important to note that the decreasing trend in BMS use was present prior to the regulation.

It is also important to consider the use of different types of DES, as later generations show improved health outcomes. However, price regulation drives increased sales for local manufacturers, which primarily produce first-generation DES.^{61,62} Furthermore, two companies have withdrawn their third-generation high-value DES and a first-generation bio-resorbable stent (BVS). In April 2017, Medtronic and Abbott announced the withdrawal

of selected high-value stents from the Indian market. Medtronic filed to remove its Resolute Onyx (DES) stent from the market, while Abbott filed to remove both its Absorb (a first-generation BVS) and Alpine (DES) stents due to financial sustainability concerns.⁶³ Abbot's Absorb was priced at Rs 190,000 before the cap, whereas Xience Alpine (DES) was priced at Rs 150,000.⁶⁴ Boston Scientific has also considered withdrawing its higher-end offerings from the region, due to an expected loss of \$7 million in 2017 as a result of the price capping in India.^{65,66} The implication for patients is decreased overall access to the most innovative and effective types of stents. Multiple RCTs show the safety and efficacy data of different imported DES. Indigenously manufactured Indian DES lack such supportive data.^{67,68,69} Recent findings show that when comparing EES to SES, EES shows superiority in a number of endpoints (as in Table 3 above).⁷⁰

A similar pattern is observed in China, as the change in the local market dynamics in terms of the lower price of cardiac stents and the smaller market share of foreign manufactures can impact the quality of stents used in medical practice. It is a general perception that local Chinese medical device companies often offer simplified versions of foreign devices.⁷¹ As Table 5 illustrates, all of the locally manufactured stents have a sirolimus-eluting coating and a stainless steel or cobalt chromium scaffold. As already mentioned in the case of Indian manufacturers, the second-generation DES with an everolimus coating performed better than sirolimus in terms of lower mortality, myocardial infarction, target vessel revascularisation and stent thrombosis probabilities.⁷²

Table 5: Characteristics of Chinese Drug Eluting Stents

Manufacturer	Brand name	Scaffold material	Eluting agent
Lepu	Nano	Stainless steel	Sirolimus/rapamycin
Lepu	GuReater	Cobalt chromium	Sirolimus/rapamycin
Lepu	Partner	Stainless steel	Sirolimus/rapamycin
Lepu	Biguard	Stainless steel	Sirolimus/rapamycin
MicroPort	Firebird2	Cobalt chromium	Sirolimus/rapamycin
MicroPort	Firebird1	Stainless steel	Sirolimus/rapamycin
MicroPort	Firehawk	Cobalt chromium	Sirolimus/rapamycin
JWMS	Excel	Stainless steel	Sirolimus/rapamycin

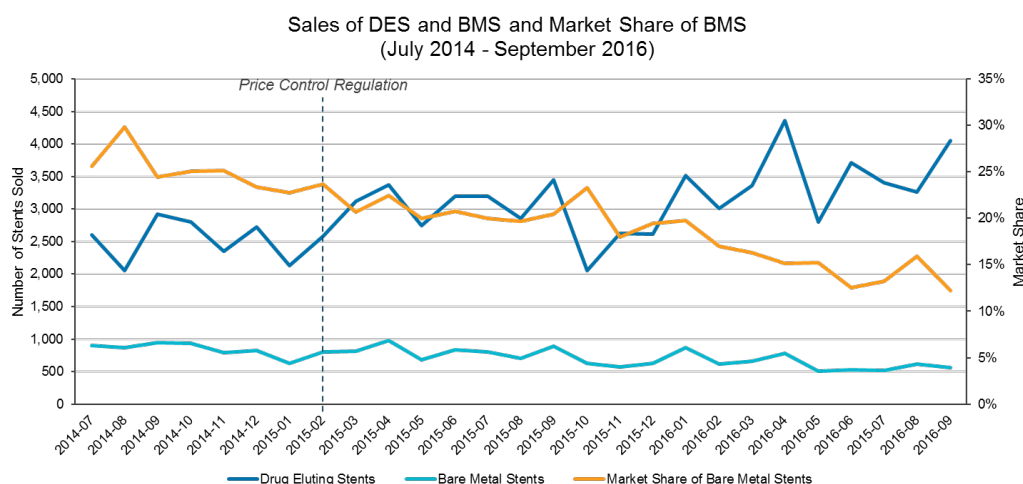
Source: CRA analysis of a number of sources

Interviews with local experts indicated that international companies have had to withdraw stents from smaller volume provinces, where the price offered did not offset costs and also led to price referencing in other provinces despite economic differences. It follows that the regulation has led to narrower choice for physicians, at least in some of the small-volume provinces. A survey conducted in China on the factors that impact physicians' choice of a stent found that whilst 60% of the physicians consider the patient's financial situation as an important factor, they also take into account stent characteristics, including (in order of decreasing importance) sufficient clinical data to support safety; long-term benefits such as low thrombosis; and sufficient clinical data to support efficacy.⁷³ The same study found that physicians rate international manufacturers higher than domestic manufacturers (except Lepu). Given that amongst the important factors of physicians' stent choice, following

affordability, are availability of clinical data to support safety, low restenosis and thrombosis rates – areas in which imported stents outperform domestically produced stents⁷⁴ – it follows that multinational manufacturers are amongst the higher-rated suppliers of stents in the market. Thus, in limiting the international manufacturers' market share, the regulation can result in limited physicians' choice.

Finally, in Colombia, increased use of DES over BMS is a sign of an improved quality of care.⁷⁵ A decrease in the price of DES and BMS as a result of the price regulation could in theory increase the usage of DES versus BMS. According to data by IETS (see Figure 4), whilst the sales of BMS have remained relatively constant, between July 2014 and September 2016 the market share of BMS decreased by 50% to 12%. A downward trend is observed even before the regulation, and little impact can be attributed to the introduction of price capping. Thus, on average, physicians tend to prefer DES, and ensuring that a range of DES are present on the market is crucial in order to meet even the most complicated patient needs.

Figure 4: Sales of BMS and DES before and after the introduction of price regulation in Colombia



Source: Budget Impact and Technology Assessment of DES, IETS 2017

Orthopaedic implants

The price regulation of knee implants was introduced more recently in India, making the assessment of impact on access more challenging. Prior to implementation of the ceiling price for knee implants, the Indian government ordered all foreign manufacturers to continue supplying all brands of devices on the market.⁷⁶ The move was expected to preempt any shortages and ensure uninterrupted supply of a variety of high-quality primary and revision knee implants to patients. This suggests that continued availability of existing products was a concern of the Indian government when implementing the regulation. The Department of Pharmaceuticals (DoP) directed all primary knee and revision knee implant manufacturers and importers to maintain supply of their brands until March 2018. The DoP invoked powers under Section 3 of the Drugs (Prices Control) Order, 2013, to mandate companies to continue sale of their brands.

In response, some stakeholders have expressed concern. Physicians fear that knee implants may face a situation similar to stents after price control introduction, where

manufacturers could no longer provide certain brands.⁷⁷ Additionally, they have voiced concern that the price cap may force foreign companies to leave the Indian market.⁷⁸ According to Dr Pradeep Bhosale, the head of joint replacement in Nanavati Hospital, Persona implant (Zimmer) and Attune (J&J) are specialised implants used for premium surgeries, which constitute 10% of total knee implants.⁷⁹ Therefore patients may suffer if a company decides to withdraw its premium product from the market. A recent survey of international knee implant manufacturers showed companies are indeed likely to withdraw or curtail products that are not economically viable to be continued in India.⁸⁰ With the price caps enforced for another year, there is a real risk that certain products will be pulled from the market.

At the time of implementation, there were access issues as a result of the price caps. Three private hospitals in Kolkata had to postpone knee replacement surgeries after distributors told physicians they could not conform to the new price cap on implants as this was lower than their procurement cost.⁸¹ Physicians are also concerned about the NPPA grouping of devices under the same ceiling price. For example, despite different categories within femoral or tibial implants and irrespective of the technical specification, the prices are uniform.⁸² Indeed, manufacturers have explained that since the price caps are undifferentiated, they do not foresee the introduction of new knee implants in the near future, as these will be subject to the same caps.⁸³ Access and quality could also be hindered by a decline in value-added services by manufacturers. Knee-implant manufacturing companies have explained that their budget for healthcare professional training is reduced by more than 50% due to their businesses not being profitable.⁸⁴ This suggests a significant reduction in suitably trained HCPs in India following the implementation of price regulation.

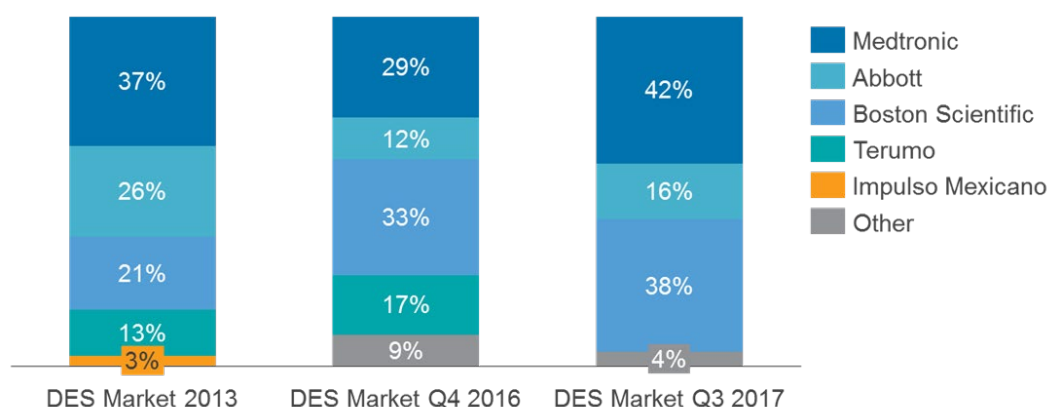
In China, procedure fees paid by patients for orthopaedic implants are itemised by individual components: surgery fees; medical consumables (including the implantable devices); medication (including anaesthetics and anticoagulants); and hospitalisation costs. As a result, the procedural cost for an orthopaedic implant can vary depending on the device used. Hospitals inform patients that if an imported joint prosthetic is used, the cost of hospitalisation for unilateral knee replacement is approximately 45,000 Yuan. However, if a domestic joint prosthetic is used, the cost of hospitalisation for unilateral knee replacement is approximately 25,000 Yuan.⁸⁵ These figures are not linked to a specific branded product, but rather a generalisation of potential costs depending on the origin of the product. Hospitals also advise that using imported joints is only a “good choice if your financial conditions permit”.⁸⁶ This creates incentives that impact use of different types of quality products, as only a few Chinese manufacturers produce high-end orthopaedic devices in the knee and hip segment. Therefore, if patients are deterred from using foreign devices, an increase in complications, failure rates and the need for surgical revision may lead to increased future costs. This is supported in expert interviews; however, to date, there are no studies that examine this impact on quality.

These access and quality issues are exacerbated by the reimbursement system in place that is applicable to foreign medical devices. Although the level of reimbursement for medical devices can vary across provinces, cities, and hospitals, in general reimbursements decisions are heavily weighted towards locally manufactured products. For example, imported orthopaedic implants receive 10%–35% of the reimbursement rates that local producers are given.⁸⁷

The intensity of competition

Price regulations are instruments that aim to correct for imperfect competition resulting from market imperfections and price regulation may have exacerbated the problem. Looking at Colombia, one of the main supporting arguments for price regulation in stents in Colombia was that the market was highly concentrated. Following the regulation, in the conventional BMS market, 80% of the sales are concentrated in 25% of the companies producing stents, and the leading company holds over 40% of the overall coronary stents market (across conventional BMS and DES). A government study reported a market concentration index in December 2014 for bare metal and drug-eluting stents to be an average of 2623 in December 2014. Looking more broadly at the market of endovascular stents (including resorbable stents, heart balloons, DES and BMS), from the third quarter of 2016 to the fourth quarter of 2017, the market concentration changed from 2418 to 3438 HHI (42% increase between 2016 and 2017). In line with this, the market share of the top manufacturer (which happens to be a foreign manufacturer) increased from 29% to 42%.^{88,89} Since the regulation was introduced, some distributors of imported stents have left the market. Ultimately this has increased concentration in the market – creating a vicious circle of unintended impact. Experts have suggested that a process that encourages competition is a preferable approach.

Figure 5: Evolution of the drug-eluting stents market in Colombia



Source: The 2014 data is sourced from GlobalData. 2016 and 2017 data are sourced from MinSalud, *Control de precios a dispositivos medicos* (Marzo, 2018). However, these represent only about 13.6% in 2016 and 16.4% in 2017 of the total market and thus can be scaled down.

The incentive to innovate in the future

The final impact of price regulation is weaker incentives to innovate. Innovation in medical devices occurs globally, and the impact of one market cannot determine overall incentives to innovate. However, price regulation can prevent the most innovative medical devices from being launched onto the market, as the cost to commercialisation and the initial investment in research and development (R&D) may not be compensated for in a price-regulated market. Thus, price regulation ultimately may prevent the commercialisation of innovative approaches and thus the dissemination of the innovation itself and the spillover of the knowledge in general.

This concern is voiced by some physicians in India. According to an industry expert, in the long term the price cap regulation will discourage innovation from entering the market.

Indeed, Abbott announced that it would not launch its newest coronary stent (Xience Sierra) in India.^{90,91} Whilst other stents of the Xience family are still available, physicians likely face a challenge in managing the more complicated cases, such as when dealing with smaller diameter blood vessels. Similarly, orthopaedic surgeons in India have explained that innovation will not be encouraged in the field of orthopaedic implants, owing to price restrictions. Importantly, patients will not be able to gain access to the most advanced technologies as companies may not introduce these in the country.⁹²

In expert interviews, industry representatives report that price regulation also had an impact on investment decisions and on the funding from multinational companies for academic research activities, which represent value-added services and expertise building. Only circumstantial evidence is available to support these claims at the current stage. First, the medical industry has argued that price control measures would affect future investment plans in India.⁹³ This could not only impact local innovation in the long term but leads to loss of jobs and income for the employed. Several leading multinational firms – including Abbott, Boston Scientific, Johnson & Johnson, and Medtronic – also have substantial investments in packaging, assembly, and R&D facilities in India, which would be impacted.⁹⁴ Some companies, including Boston Scientific, use India as a research base to develop their products for emerging markets, leading to greater impacts for employment and economic activity.⁹⁵ Finally, there is limited evidence on added-value services offered by manufacturers. Mostly, foreign manufacturers provide some services to tailor their imported devices to the needs of the Indian market.⁹⁶ However, stakeholders are concerned that manufacturers might reduce investments in such services as demonstration courses, industry grants for investigator-sponsored studies, and sponsorship of cardiologists' attendance at international and national meetings.⁹⁷





































The benefits of a local presence of foreign manufacturers go beyond the provision of safe and effective treatments and encompass job creation and raising the standard of care through awareness and training initiatives. With the current "Made in India" policy, continued foreign investment in the creation of local jobs belonging to the local manufacturing sector is essential. As emphasised by industry experts, price regulation could act in the opposite direction to the overarching policy by disincentivising foreign companies to set up manufacturing facilities in India when costs to produce – including costs for R&D – exceed the price ceiling and lead to overall losses.







5. DISCUSSION

The principles and framework developed in this analysis are based on a literature review of previous studies on the impact of introducing pricing regulation and arguments for and against this in different markets. However, there have been few studies on emerging markets or on medical devices. As a result of our analysis, we conclude that the use of price regulation in medical devices can impose costs to the healthcare system through delays to access and regulatory costs; disincentivisation to invest in R&D that leads to follow-on innovations; less choice of available treatments for patients and physicians; potential shortages; and distortion of competition to the point that it leads to increases in product prices. The motivation for price regulation is also weak – the market lacks the typical market imperfections due to its high levels of competition and lower entry barriers.

The immediate impact of price regulation is a reduction in the price of medical devices to which it applies. This aims to improve affordability for patients and lead to greater access. However, evidence in the analysis shows a series of perverse impacts and unintended consequences. *First*, reducing the price of a medical device does not result in a proportionate reduction in the cost of the procedure, if any at all. *Second*, particularly in the case of out-of-pocket markets, the potential cost savings have not been realised by patients. *Third*, price regulation has an effect on the quality of medical devices on the market as domestic manufacturers of lower-quality products begin to dominate the market. *Fourth*, in some cases, the regulation has led to an increase in the price of some medical devices, particularly those of lower quality, distorting the relationship between price and value to the detriment of patients. *Fifth*, competition can be distorted whereby the number of manufacturers (and as a result the products available) on the market has decreased, affecting price in the long term but also, in managing specific patient groups, affecting the choices of physicians and patients. It is a common perception that price regulation in emerging markets will, in the long term, result in less innovative products being available. The range of observed impacts is summarised in Table 6.

Table 6: Conclusions regarding the impact of price regulation

Indicator					
STENTS	Price				
	Access and quality				
	Innovation				
	Market competition				
IMPLANTS	Price				
	Access and quality				
	Innovation				
	Market competition				

 Strong positive
  No impact/neutral
  Strong negative
 Low positive
  No regulation
  Low negative

Source: CRA analysis

There are a number of caveats to these findings that justify further consideration. In some cases it is difficult to find comparable data from before and after the introduction of price regulation. Moreover, the price regulations in India and Colombia were only recently introduced – in 2017 and 2015, respectively, for coronary stents, and even more recently

for orthopaedic implants. Therefore, it is likely that the full extent of impact is yet to unfold. Finally, the availability of evidence remains somewhat limited in China due to lack of a strong national debate on the topic and access to nationally available databases.

6. CONCLUSIONS

The evidence presented in this analysis indicates that price regulation of medical devices in the case studies investigated can lead to negative effects and unintended consequences, including limitations to the benefits patients receive from cost savings intended by the regulation, reduced physician and patient choice anchored to lower quality and potentially less effective devices, and distorted competition amongst manufacturers as some of the most innovative medical devices are not launched or are withdrawn from the market.

An alternative approach to price regulation is improved competition. There are a range of options that could improve competition; for example, better information for patients could improve their understanding of product quality and the cost of the overall procedure. Drawing on the evidence from the impact of price regulation and competition in medical devices across emerging markets, free pricing is a more appropriate approach to regulation based on observations in the market. *First*, this leads to prices that better reflect the value of products by differentiating reward for more innovative products rather than converging towards an established cap for products of differing values. *Second*, free pricing allows a more diverse set of products in the market, priced at different price points based on their competitiveness, that is determined by the quality and level of innovation. This is key for good clinical practice and ultimately for patient outcomes. *Third*, the opportunity to competitively launch new products, and be rewarded in line with their value, is critical for continuous investment in R&D to improve on current innovations. These three conditions allow for the creation of an ecosystem that supports development and access to innovation.

APPENDIX - COMPARISON OF MARKET ACCESS PATHWAYS TO MEDICAL DEVICES

Table 7: Comparison of market access pathways to medical devices in the focus markets

	Brazil	China	India	Columbia
Regulatory approval	All medical devices by ANVISA	All medical devices by CFDA	Only 22 types by CDSCO	All medical devices by INVIMA but less stringent for low- and medium-risk devices
Pricing	Through negotiations, but price controls for some devices are	Price ceilings applied to some high-value consumables in provincial	Price ceiling for some devices (stents,	Price ceiling based on international reference pricing

	under consideration	tenders based on province or internal reference pricing	orthopaedic devices)	applied to some devices
Reimbursement	Covered by the national health insurance fund (SUS) or private insurances	Less than 100% of the costs are covered for imported ones; patients most often pay OOP for imported	Largely OOP as limited national healthcare coverage	Under the national Mandatory Health Plan
Procurement	Centralised tendering in the public and private healthcare markets	Decentralised hospital purchases of devices listed in catalogues, as a result of provincial and city council level tenders	Decentralised for cheaper devices and centralised through the Central Equipment Procurement Cell (CEPC) for more expensive ones	Hospitals and providers purchasing (can be via tenders)
Funding	Public taxation and private insurances managing nationally defined healthcare plans	Hospital profits derived from mark-ups, regional councils provide varying levels of reimbursement from centrally allocated budget to hospitals, OOP	Public taxation, but lack of universal coverage (3%–5% population covered), thus largely OOP	Public by the National Health System, Solidarity and Guarantee Fund and private insurances

Source: CRA analysis of various sources

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