

# **Risk-sharing Agreements for Medical Devices in Emerging Markets: Opportunities and Challenges**

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Risk-sharing agreements (RSA) in health care are used as a tool by payers (or insurers) and health technology manufacturers to share the risks associated with bringing new products to market. The aim is twofold: to make new therapies accessible to patients and support innovation. RSAs have been widely implemented in the pharmaceutical sector, but their application to medical devices is limited to only a few examples<sup>1</sup>. While adoption in the devices space is currently at an early stage, these types of contractual arrangements are gaining momentum, particularly in countries with mature healthcare systems.

Medical devices differ from pharmaceuticals on a number of dimensions, subjecting each sector to vastly different reimbursement strategies. Innovation in the medical device sector is rapid, with shorter product development cycles (averaging 18 to 24 months) relative to the pharmaceutical sector. Low barriers-to-entry allow new entrants to penetrate the market with similar products within a short span of a new product launch. A growing number of competitors in many segments of the device market increasingly expect payers to reimburse devices based on superior clinical outcomes and cost effectiveness. Hence there is a need for policies and regulation to ensure that innovation continues and better technologies reach patients faster.

A review of the published literature and interviews with experts were conducted to learn more about country-level experiences with RSAs in the medical device sector, particularly across emerging markets. This paper thus explores the applicability of RSAs to medical devices, recent examples from around the globe, as well as the perceived challenges of using these schemes to drive adoption or access to new medical technologies.

## Background

RSAs between health care payers and manufacturers are also referred to as “performance-based schemes”. While a large number of RSAs in pharmaceuticals are focused on outcomes-based schemes, non-outcomes-based or financial schemes may also have potential for medical devices. In addition to shorter product life cycles and investment recovery periods, the impact of medical devices on health outcomes is more difficult to establish, as medical devices are often combined with other treatments such as medicines or surgical procedures. Second, intellectual property and patenting of medical devices is more fragmented, with diverse players and greater opportunities for new entrants. Finally, the investment needed for evidence collection and development may be difficult to justify against the budget impact of medical devices.

## Taxonomy

A taxonomy of risk-sharing agreements initially developed for the pharmaceutical sector was used as a reference to explore applications of such schemes for medical devices.<sup>2</sup>

### *Non-outcomes based schemes*

- Population-level price-volume agreements might be applicable to single-use and high-price devices such as joints and stents for which quality-adjusted life-year

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<sup>1</sup> For more information on RSAs, see [http://centres.insead.edu/healthcare-management-initiative/thought-pieces/documents/RSA-OnePager-April2014\\_000.pdf](http://centres.insead.edu/healthcare-management-initiative/thought-pieces/documents/RSA-OnePager-April2014_000.pdf)

<sup>2</sup> For the taxonomy used in pharmaceuticals, see [http://centres.insead.edu/healthcare-management-initiative/thought-pieces/documents/RSATaxonomy-April2014\\_001.pdf](http://centres.insead.edu/healthcare-management-initiative/thought-pieces/documents/RSATaxonomy-April2014_001.pdf)

(QALY) cost-effectiveness calculations are more feasible than for one-time purchase large medical equipment or reusable devices used to support procedures.

- Patient-level utilization caps such as dose caps or price caps may have fewer applications for medical devices, as medical equipment is often used for diagnostic purposes and can only be used once or a set number of times per patient. Similarly, high-price devices such as stents and coils are largely implantable and hence used only once per patient or per procedure. Devices which are procedures in and of themselves, such as energy-based radiation and ultrasound therapies often used in conjunction with a particular delivery method, could potentially be launched via utilization cap schemes.
- In some instances, manufacturers may partially fund treatments for a limited period/dosage or the supporting infrastructure required for administration. These approaches may be particularly applicable to large medical equipment or diagnostic tests.

#### *Outcomes-based schemes*

- Conditional coverage (including coverage with evidence and conditional treatment continuation) agreements have already been used for the reimbursement of medical devices. An example of coverage with evidence was when Centers for Medicare and Medicaid Services (CMS) in the U.S. introduced a new policy requiring beneficiaries seeking reimbursement for certain expensive medical devices and drugs to enroll in research as a condition for medical coverage.<sup>3</sup> CMS allowed reimbursement for implantable cardioverter defibrillators (ICD) for certain subgroups on condition that patients' details were recorded by the National Cardiovascular Data Registry (maintained since 2005) and could be used to study the clinical effectiveness of ICDs. In another example, the manufacturer Given Imaging, in collaboration with the Gastroenterological Society of Australia (GESA), maintained a registry of all patients who used PillCam for capsule endoscopy from 2004 to 2009. Conditional treatment continuation schemes linked to individual patients for short-term goals could be applicable to energy-based therapies such as radiology or ultrasound if patients can be attributed to the particular device.
- Performance-linked outcome guarantee schemes for clinical endpoints or intermediate outcomes might be applied in cases where patients can be mapped to a particular device. Hence these agreements may be more suited to high-priced implantable devices for which it is easier to track the impact on patients.
- Pattern or process-of-care schemes where the reimbursement level is tied to clinical decision-making or practice patterns – e.g. whether or not patients adhere to treatment suggested by a risk-predicting genomic test – have been implemented for Oncotype DX, a genetic test used to quantify the likelihood of breast cancer recurrence and predict the likelihood of chemotherapy benefit for a large portion of early-stage breast cancer patients in the U.S.

#### *Other mechanisms for bringing new technologies to the market*

Medical device manufacturers may launch new devices through other types of collaborations including public private partnerships (PPPs) and discounts (distinct from those characterized under risk-sharing). Manufacturers may enter into a PPP with public payers in emerging markets to improve access. For example, Wipro GE Healthcare Pvt.

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<sup>3</sup> <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html>

Ltd. in partnership with Ensocare have formed a consortium with the government of Maharashtra in India to set up advanced diagnostic facilities – including installation of CT scanners, digital radiography systems, color Doppler systems, and x-ray units -- at 22 government hospitals. Additionally, manufacturers may give discounts either directly to providers or payers with the aim of increasing market share or profits. Discounts are built into the marketing costs of the product and thus not considered a mechanism to share risk.

While RSAs are widely used as a risk-sharing method, some experts question the rationale for classifying financial- or non-outcomes based agreements as RSAs since they are often payer driven. Some manufacturers offer financial discounts and rebates to improve uptake and show that the technology works, thus mitigating risk as part of the marketing strategy against low adoption of a new technology. Others offer devices to hospitals for free for a certain period to encourage trial of the equipment. In neither case is risk being shared by the payer.

### **Industry Examples**

A limited number of risk-sharing examples were identified in the medical devices sector, all of which were implemented in developed markets such as the U.S., UK and Australia, the same countries leading RSAs in the pharmaceutical sector. In the Australian example, Medicare signed a RSA with Given Imaging on PillCam Endoscopy<sup>4</sup>. An agreement was reached between Genomic Health and UnitedHealthcare (UHC)<sup>5</sup> in the U.S. and the National Institute for Health and Care Excellence<sup>6</sup> (NICE) in the UK on Oncotype DX. UHC in the U.S. agreed on a list price with the payer, with both companies tracking the results to decide if the genetic test was having the anticipated effect on actual clinical practice. NICE has begun making recommendations on medical devices in the last three to four years, and an RSA was implemented following NICE's assessment that the test was not cost-effective; Genomic Health subsequently lowered the price as part of the agreement.

Some experts in the UK suggest that RSAs in the medical device sector are not outcomes-based and that the focus is often on reaching a cost-effectiveness threshold, making them financial-based RSAs in most cases.

### **Risk Sharing in Emerging Markets**

RSAs are uncommon in developing countries. Discussions with experts revealed several interesting insights for the low number of RSA implementations. First, many experts agree that developed countries are more favourable markets since they are more economically advanced and often supported by publicly funded health care systems. In countries such as China, India and others in Southeast Asia, healthcare is largely funded out-of-pocket by patients, thus placing all the risk on patients and mitigating opportunities for risk-sharing across the different stakeholders. Therefore RSAs are

<sup>4</sup> O'Malley, SP, Selby, WS and Jordan, E. A successful practical application of Coverage with Evidence Development in Australia: Medical Services Advisory Committee interim funding and the PillCam Capsule Endoscopy Register, *International Journal of Technology Assessment in Health Care* (2009). Available at <http://journals.cambridge.org/action/displayFulltext?type=1&fid=5961428&jid=THC&volumeId=25&issueId=03&aid=5961420&bodyId=&membershipNumber=&societyETOCSession=>

<sup>5</sup> Stockholm Network, Sharing the Burden: Could risk-sharing change the way we pay for healthcare?; 2010. Available at [http://www.stockholm-network.org/downloads/publications/Sharing\\_the\\_Burden.pdf](http://www.stockholm-network.org/downloads/publications/Sharing_the_Burden.pdf).

<sup>6</sup> NICE Diagnostics Guidance 10. Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat; September 2013. Available at <http://publications.nice.org.uk/gene-expression-profiling-and-expanded-immunohistochemistry-tests-for-guiding-adjuvant-chemotherapy-dg10>.

viewed as an unlikely proposition in these markets. Second, developing countries are often playing catch-up with existing technologies, particularly devices. Thus the primary objective of manufacturers in these markets is to increase uptake of their products, whereas efficiency improvement (through RSAs and other means) is more often the focus in developed markets such as Europe.

Industry experts hinted that discussions may be underway to implement RSAs in the pharmaceutical sector in Malaysia, Indonesia and the Middle East, though details are yet to be released.

### **Device Manufacturers' Perspective**

RSAs are not so obvious or instantly desired in emerging markets, and the following reasons were cited by manufacturers. First, whether to enter a risk-sharing agreement in an emerging country is simply a commercial question. Some are keen to maintain margins on their products when attempting to penetrate new markets, in the belief that high profitability enables sustainable growth. Global brands invest significantly in these new markets to differentiate themselves with the aim of creating new markets for their devices and to grow market share. Entering into formal arrangements with governments might encourage health departments to create formularies (as with pharmaceuticals), which are often unwanted by medical device manufacturers.

Second, firms which make inroads into Asian markets face the challenge of lack of evidence-based data. The majority of evidence around disease prevalence and treatment response rates to prove device effectiveness is based on sample patient populations in the Western world, making it difficult to apply to developing economies with significantly different demographics. RSAs would require a new body of data that is relevant to local populations to serve as evidence.

Third, manufacturers must build stronger relationships with their stakeholders to have greater influence over the full continuum of care, rather than simply playing the role of treatment provider. Better partnerships are needed along the entire chain of care in order to move beyond the perceived transactional contribution and contribute effectively to disease management.

Fourth, a fair number of emerging countries are attempting to emulate the pricing policies of the West, despite the difference in economic conditions, population needs and health care systems. Some manufacturers have questioned the suitability and applicability of international reference pricing to emerging markets, out of concern about profitability in the entire region.

Nonetheless, manufacturers continue to explore ways to accelerate access to new technologies, particularly with the growing market opportunity in emerging economies. While some are evaluating cost-sharing, financial or discount schemes, others are moving into the service domain – for example, by offering an entire diagnostic facility to support their device.

### **Challenges**

RSA activity has grown in both pharmaceutical and medical device sectors, but significant challenges remain, particularly in emerging markets.

- Several pharmaceutical RSAs have shown that collecting evidence and supporting compliance can be expensive, with particularly large expenses associated with outcomes-based agreements.
- Administration can be complex.
- Infrastructure for data collection such as computers and internet access is often lacking in emerging markets.
- There is uncertainty around interpretation of results. If a drug under a RSA, for example, is used to treat an acute illness where the outcome being measured as the number of years the patient survives after taking the treatment, if the patient dies from unrelated reasons such as an accident or failure of a surgical procedure, it must be ensured that the death is not attributed to the failure of the drug. These measurements can be difficult to monitor on a large scale and measuring the impact of the therapy can be a significant challenge.
- Conflicts of confidentiality among payers and independent organizations such as NICE have emerged as another issue. When manufacturers approach NICE and negotiate a price for a therapy, they often request that the price be kept confidential, although NICE is compelled to publicly disclose the price of drugs or devices that are being reimbursed by the NHS. This is considered a significant challenge in the implementation of RSAs.
- Rapid technological improvements in the medical device industry also pose challenges. An RSA, for example, could be implemented for version 2.0 of a device, and a more effective 3.0 version might be developed 18 months later. Would the original RSA hold when the 3.0 is launched and can it be transferred to the new device? For this reason, NICE often keeps all RSAs under review in cases where a more advanced therapy might become available.
- Multiple layers of price negotiations make it difficult to enforce RSAs at a single price. Manufacturers and NICE agree on a price, but that is often not reflected at the point of delivery. Hospitals and clinics in the NHS procure therapies through a decentralized purchasing system, making it difficult to enforce the agreed price.