Value-based healthcare
Strategies for medtech

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Foreword

*Ivy Teh, Managing Director at Clearstate, an Economist Intelligence Unit business.*

The medical devices (or medtech) industry, following the path of the pharma industry, needs to adapt to a healthcare ecosystem that increasingly values better health outcomes and effective cost-containment. It is no longer enough for medtech companies to rely on their traditional market access models, which tend to be focused on commercial or sales and marketing functions. Nowadays, to gain access and obtain optimum price reimbursement, medtech companies need to showcase innovations that can clearly demonstrate evidence of better health outcomes at reasonable costs.

We understand that tighter regulatory scrutiny and the continuing pressure on healthcare budgets have combined to produce some overwhelming challenges for medtech companies. But we believe these changes also serve to create opportunities for medtech companies that are quick to adapt their business models and value propositions in an environment that is now centred on cost, quality of care, and access. We believe it is critical for medtech companies to improve on their capabilities, to monitor changes in payer and government policy trends, and to incorporate the implications into their R&D and product portfolio management decisions.

Our global healthcare practice, EIU Healthcare, was formed through the acquisitions of two established and highly specialised healthcare consultancies: Clearstate and Bazian. Together, we aim to provide in-market
insights that can help medtech companies navigate the changes in complex healthcare ecosystems that can differ widely by geography, therapy area and product type.

Clearstate, a healthcare market insight and intelligence business, is a specialist in the medtech industry, with existing and deep networks with stakeholders within the healthcare ecosystem. Bazian, a clinically-led consultancy, is dedicated to evidence-based medicine, epidemiology, health economics and outcomes. We have meshed these together with our extant analytical, econometric and strategic consultancy divisions.

The result is a practice that provides customised research, analysis and recommendations in the following areas:

- Strategic advisory: analysing global and local trends and mapping these against clients’ priorities;
- Market insight and intelligence: with global expertise, and a unique focus on emerging markets;
- Value optimisation: helping industry clients to develop propositions, products and services for a market where value is the emerging currency;
- Population health management solutions: helping payors, insurers and their partners to build healthcare ecosystems that optimise value.

As part of our continuous effort to facilitate discussion on key trends impacting our healthcare clients, we have developed this medtech-specific white paper. It is the third in a series of white papers on value-based healthcare, and discusses what the concept of value—in all its aspects—means for the medtech industry now and in the future.

We hope this white paper gives you some new perspectives to think about and look forward to your feedback. Please contact us at: VBH@eiu.com.

Ivy Teh
Introduction

So far in 2014, The Economist Intelligence Unit has produced three white papers on the trend towards value-based healthcare (VBH). The first sets out some of the arguments in favour of value-based care, which weighs the evidence on patient outcomes against the cost of an intervention, in order to determine the value of that intervention. Such assessments, we argued, are crucial to develop the best care pathways, ensuring that healthcare systems are affordable and effective.

In our second white paper, we looked at how value-based assessments have been implemented in the pharma sector, and how drugmakers can adapt their strategies in order to thrive in that environment. This third paper focuses on the medical device (or medtech) industry, in order to explore how VBH is likely to change the competitive environment there and how companies can best exploit the trend.

As a starting point, it is useful to look at how the pharma industry and the medical device sector differ. With pharma further ahead in terms of the need for value-based assessments and economic evaluation, many medtech companies are looking to pharma to provide answers about how they can cope with what is likely to be an increasing trend. Yet one danger highlighted by some of the interviewees for this report is that pharma-style health technology assessment (HTA) may end up being imposed on the medical device sector, regardless of these differences.

They include:

- Medical devices cover a far more diverse set of interventions, from syringes to brain scanners, complicating both the regulatory process and the assessment process.
- The industry itself is more diverse, ranging from large multinationals to small start-ups based around just one device and reliant on venture capital.
The life cycle of a typical medical device is far shorter, typically 18-24 months, with far weaker intellectual property protection.

Regulation is geared around safety and risk assessments; only Class III devices or active implantable medical devices (the riskiest) usually need controlled clinical trials, while for other classes much of the data on effectiveness is obtained after, rather than before, the product’s rollout.

For some categories of medical devices, purchasing is a long-term investment, traditionally made out of capital expenditure budgets.

Links with medical providers are close—indeed many devices are developed with input from physicians, while the performance of a medical device often depends on that of the medical team using it.

The implications of these differences are huge when it comes to the rollout of VBH in the medical devices industry. The lack of lengthy patent protection, the relative dearth of trial data, the shorter life-cycle, the reliance on start-up venture capital, and sheer differences in the products will all affect the way that VBH can and should be implemented for medical devices. Indeed, in many ways, pharma provides a poor model for the medical device market, where “the innovation model is more akin to software”, says Steve Ubl, president and CEO of AdvaMed, a US-based industry association.

Yet there are areas where innovative medtech companies should learn from the pharma industry. One lies in the need to avoid VBH becoming another hurdle on the way to market, which would be an even greater problem for fast-moving medical device producers than it is for pharma. The more positive lesson lies in pharma’s (partial) success in moving the discussion over regulation and competition away from cost and towards value. Far from being a further threat, the trend towards VBH can offer opportunities, if companies can prove that they are offering innovations that will feed directly into better patient outcomes.

Doing that will mean adopting several strategies that we will outline further in this paper:

- **Strategy 1:** Clarify exactly what definitions of value will count most with the relevant bodies, and how the efficacy of a product will be assessed.
- **Strategy 2:** Monitor changes in policy, including the trend towards centralisation of payment and reimbursement systems.
- **Strategy 3:** Cope with the pressure on prices, driven by both intense competition and value-based assessments.
- **Strategy 4:** Promote the idea that value does not equate to price, and that investment in real innovations can reduce overall spending.
- **Strategy 5:** Be prepared to support any assertions over value with hard data, both trial and real-world, on patient and clinician outcomes.
- **Strategy 6:** Cement relationships with providers and clinicians, using medtech experience to advise on care pathways.
Strategy 1: Understanding the definition of value

To prove value, medical devices companies first need to understand what it means. “Value” is already a common term in the medical devices industry, but mainly as a synonym for “low-cost”. Beyond mere price, the definition varies depending on who is doing the valuation. In our previous papers on value-based healthcare (VBH), we discussed some of the ways that value is assessed for pharma by payors, health technology assessment (HTA) bodies and commissioning groups. Patient outcomes, for example, can be assessed in terms of quality-adjusted life years (QALYs) in order to set a maximum cost per QALY for a treatment. But this may need to be adjusted for different population groups (for example, the elderly) or ignored altogether for rare diseases. Then there is societal value, which takes into account the patient’s potential contribution. And above all, there is the consideration of budgets, which may make a high-value product simply unaffordable.

For medical devices, however, there is an added complication in that the patient is far from the only consideration. Clinicians also have to be taken into account, to assess whether a device is easy and quick to use within a busy ward or emergency clinic. Training is often a crucial element in this. Devices that clinicians see as valuable often contribute to better patient outcomes, but the direct link may be hard to assess. Beyond that comes the assessment of value for individual hospitals, which may be determined by its impact on operational efficiency. Groups of providers or commissioning groups, meanwhile, may value equipment that is easy to share and transport, or that eases the flow of patients through the whole healthcare system.
Strategy 2: Monitoring policy changes

Given the quick turnover of medical devices products, as well as their diversity, it is no surprise that the systematic—and often lengthy—value assessments now used by most pharma companies are less common for medical devices. Indeed, for many medical devices companies, the trend towards value-based care pales into insignificance in comparison with the sheer competitive pressures they are under, from low-cost producers in developing markets, from the demand for innovation, and from regulations that would seem to be working against innovation in the industry.

Yet while value-based healthcare is not yet significant in the medical devices industry, “it is becoming important. It is just a matter of time,” says Chee Hew, Head of Greater China at Clearstate (part of EIU Healthcare). Many of the bigger med-tech companies are building up their market access and economic evaluation teams in order to support sales as the trend gathers pace.

The rollout of VBH for med-tech has often gone hand-in-hand with a move to centralise purchasing and reimbursement, as well as the development of universal healthcare systems in Asia and Latin America. Traditionally, in many markets, purchasing decisions were largely left to individual hospitals and clinics, and driven largely by clinician demand. Over the past two decades, this has changed to the extent that most countries—55%, according to the World Health Organisation (WHO)—now have some centralised purchasing of medical equipment, although this is often limited in scope. This directly affects the system’s capacity to undertake lengthy assessments and to minimise the gaps between medical device funding, approval, evaluation, reimbursement and actual purchasing.

In the US, the approval process for medical devices is already centralised. The Food and Drug Administration (FDA) assesses all classes of devices, using a fairly rigorous set of standards similar to that used for pharmaceuticals. The systems
for economic evaluation, reimbursement and purchasing, however, have developed gradually from a local level and remain a patchwork. Many hospitals have long relied on commissioning boards, required to vet purchases of equipment through a panel spanning accountants, managers and clinicians. Pushed by tighter reimbursement controls from Medicare (the US health insurance programme for those aged 65 and over) and insurers, these developed into medical groups and integrated networks of providers that manage care under risk-based, largely capitated contracts.

These, in turn, are developing into the Accountable Care Organisations now being promoted under the Affordable Care Act of 2010. Along with the rollout of bundled payments for providers, which reimburse them for the whole care cycle rather than particular services, this should lead to a joint focus on improving outcomes as well as containing costs. That will lead to tighter scrutiny of purchasing, including investments in medtech. The Centres for Medicare and Medicaid Services will play a central role in this rollout, through the new Hospital Value-Based Purchasing Programme.

Over in Europe, most countries already conduct economic evaluations of some medical devices and their scope is growing. In November 2009, the UK’s National Institute of Health and Care Excellence (NICE) launched a programme to focus specifically on the evaluation of particularly innovative medical technologies. This involved setting up a Medical Technologies Advisory Committee that determined which devices would need assessment, and what the pathway for the evaluation would be. In Spain, separate HTA organisations have developed in most regions, although policy is coordinated at a central level by the Agencia de Evaluación de Tecnologías Sanitarias (AETS). In France, meanwhile, HTA for medical devices is an integral part of the reimbursement process, with the Commission Nationale
Reducing waste in US hospitals

The US healthcare system is notorious for its waste of resources, with lacklustre health outcomes compared with its spending levels. That is partly down to unequal access to care, but among those who do have access to care, some have complained about over-testing or overtreatment. OECD data suggest the availability and use of medical devices is very high (see chart) and does not always improve the standard of care. Some clinicians may not be obeying the Medicare’s injunction that care should be “reasonable and necessary”, because of patient demand, skewed financial incentives or a fear of litigation.

As payment incentives change, providers will be encouraged to cut out this waste. For the most progressive of them, that will involve investing in the data analysis that will allow them to re-engineer their treatment pathways and processes. And for medical devices companies that provide real value to both patients and clinicians, the shift will offer an opportunity. Steve Ubl of AdvaMed says: “If this development puts a premium on coordinated care, then medical devices are going to play a key role.”

A report released in May 2014 by the President’s Council of Advisors on Science and Technology confirms this, by looking at how better systems engineering could cut wastage. Many of the recommendations were aimed at providers, but some involved areas where medical devices companies could have significant input. In critical care, for example, the Council recommended coordinating the different devices monitoring the patient’s health, reducing false alarms that prevent the patient from resting, and connecting monitors to therapeutic equipment so that action can be taken immediately when a problem is identified.

Many of the recommendations centred on more extensive collection and use of healthcare data, an area that medical device companies are keen to explore.

d’Evaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDiMTS) requiring evidence on efficacy for some categories of devices.

Yet the system remains a patchwork, in a region where the approval system is also complex. Serge Bernasconi, CEO of MedTech Europe (an alliance of European medtech industry associations), describes the situation as “very complex”, adding that “some manufacturers have to demonstrate value to up to 25 bodies, and few of them coincide. Everyone wants to do their own HTA”. A general trend towards group purchasing, driven in part by the massive squeeze on healthcare spending in the region, as well as the proposed overhaul of the notified bodies responsible for approving devices (see box) could add to the complexity.
Despite efforts at harmonisation, Mr Bernasconi expects the European HTA process to remain decentralised, a situation that may have benefits as well as disadvantages. On the one hand, a uniform approach makes life far easier for medical devices companies, clarifying what information needs to be gathered and how it should be presented. On the other hand, there is a clear need for speed in an industry where product cycles are 18-24 months. If a purchasing decision has to go through six committees and a national consultation process before it is approved, then the inventor of the device will have lost the opportunity to make any money out of it.

**Europe’s overhaul of medical devices approval**

The debate about value-based healthcare in Europe is taking place just as the system of medical device approval faces an overhaul. To gain the harmonised CE mark of approval for their products, medtech companies have to apply to one of around 80 notified bodies, which work to standards set under European law. In general, the system works well, and there is general agreement—on both sides of the Atlantic—that Europe tends to get access to new medical device innovations some three to four years ahead of the US.

Yet the system faces an overhaul in the wake of a scandal in which a French manufacturer, Poly Implant Prothese (PIP), was found to have sold breast implants filled with industrial-grade silicone. Oversight of the notified bodies has been intensified, in some cases limiting their authority. Now the European Commission and Parliament are proposing setting up several new layers of oversight, with ultimate responsibility lying with the European Medicines Agency, the same body that oversees pharmaceuticals. This could involve the introduction of randomised controlled trials for the riskiest classes of medical devices, moving Europe closer to the US model of pre-marketing authorisation.

MedTech Europe is worried that, particularly for medical devices, the new layers of bureaucracy would slow what has hitherto been a fairly swift approval process. The region’s innovation advantage could also disappear if medical devices have to undergo the same kind of pre-market testing as pharma, without the benefit of clear comparators and ten-year patent exclusivity. Yet the industry is keen to improve the current approval system, which has clearly been found wanting. “It is to our advantage to minimise dangers,” says Mr Bernasconi. This is a tricky balance to strike, but weeding out the worst notified bodies and improving the gathering of safety data would clearly help. It would also allow the industry and payors to get a better view of how the use of medical devices relates to patient (and clinician) outcomes.
In Asia, progress towards VBH is dependent to some extent on the degree of centralisation. The countries that have moved furthest are generally those with the most well-established healthcare systems, including Australia, Taiwan and South Korea. The last two have relatively mature HTA systems set up around 8-9 years ago, under the Medical Device Experts Committee and the Health Insurance Review & Assessment Service, respectively; while in Australia, devices, including those already on the market, are reviewed by the Prostheses List Advisory Committee (PLAC). All three countries are reviewing their processes as the understanding of best practice develops.

Japan, despite its established healthcare system, has been a relatively late starter in this area. In April 2012 a new committee on cost-effectiveness evaluation was established under the Central Social Insurance Medical Council (Chuikyo) but it has yet to determine how evaluations would be made or implemented. In China, meanwhile, there is no formal HTA process in place, but there is growing interest in the economic assessment of medical devices, as well as pharmaceuticals. In 2010, the China National Health Development Research Centre signed a memorandum of understanding with NICE International to start a five-year programme advising on the rollout of HTA, and Clearstate’s Chee Hew can already see the effects.

“It is going to be a progression, item by item and procedure by procedure,” she says. “As China expands its healthcare system, the government has seen pharma becoming a huge cost. Having started to clamp down on that, it will now turn to medical devices.” The move in 2013 to bar hospitals and doctors from earning money from the sale of drugs has coincided with greater scrutiny of services such as screening and imaging. In April 2014 the government expanded
its pilot reform programme to around one-half of all public hospitals, with the aim of regulating prices for drugs and services and promoting the optimal use of resources. There are also measures in place to restrict capital spending by hospitals, affecting equipment sales.

In other words, the shift towards value-based care is gathering pace in China. The first category to feel real pressure, however, has been in vitro diagnostics (IVDs), for which a handful of provinces are now trialling what is being billed as a step towards economic evaluation. In fact, cost cutting is the main motivation for the shift, which has removed the premium that used to be offered for what were seen as higher-value, often foreign, products, encouraging a shift to lower-priced local brands. Ms Hew believes that IVD prices have fallen by 20% in Shanghai, although the overall market is still growing rapidly.

The bigger problem, however, is that the regulations are unclear, and so too is the future direction of policy. Ms Hew expects the experiment to be expanded to other provinces, and also to other medtech categories. “Clients need to have clarity before they can start to develop their strategies,” she says. The same could be said for the rest of the world, where the combination of cost cutting and the emphasis on economic evaluation has left many medical devices companies uncertain about the effects on their business.

One benefit of the lack of clarity, however, is that medical device companies do have an opportunity now to have a direct influence on how VBH policies develop, at least in those countries where regulators are open to consultation. That is important, because the danger is that policymakers, HTA agencies and reimbursement committees will merely take the tools that they have developed for pharma and superimpose them on the medtech industry. As Yves Verboven of MedTech Europe says: “It is tempting to take a pharma model that is not very efficient, and impose it on the medical devices industry. But for medical devices, strategies could be designed that take a much more pragmatic approach.”

It is in the industry’s interests to ensure that the HTA process is more appropriate to medical devices and the particular make-up of the industry. Best practice needs to develop and spread quickly. Although that may involve costs now, and may even put immediate pressure on pricing, it could prevent different systems developing that are a far bigger hurdle.
The price cuts in China’s IVD market would come as no surprise to many in the pharma industry, where the trend towards value-based healthcare has become intrinsically linked with pricing pressures. Although Mr Ubl sees opportunities in the reforms being rolled out under the Affordable Care Act, he also sees downside risks. “If you have a bundled system, you could have a situation where purchasers gravitate to the lowest cost product, even though there is a product that costs more upfront may generate greater long-term savings.”

The effect is unlikely to be a dramatic one. Bereft of the effective monopolies created by pharma patent protection, medical device companies have been far more exposed to the competition created by globalisation and the rise of developing market producers. The rapid product cycle in the industry—akin to

Real change in implantable medical device prices
(2007=100; average reported prices compared with medical consumer price inflation)

Note: Survey covers 153 to 294 hospitals (depending on device category and year).
Source: AdvaMed.
that in the smartphone or software sectors—has also made competition more intense. A survey of the industry by AdvaMed in September 2013 found that inflation-adjusted prices for some categories of implantable devices had fallen by 17-34% between 2007 and 2011.

That took medtech’s share of health spending down slightly to 5.9% of total healthcare spending in 2011, a level that has declined slightly over the past two decades. In Europe, medical devices take only slightly more of the overall healthcare budget, and in both cases, the share is smaller than for pharma. Tenders and competitive pricing techniques are already commonplace throughout the industry, helping to contain any rise in medtech spending.

This real-terms deflation of medical device pricing—although it has put pressure on the industry—means that as the trend towards value-based healthcare gathers speed, the medical device sector is unlikely to receive the same kind of shock that pharma has received from pricing cuts and tighter reimbursement conditions over the past few years. What is more, in those markets where shocks are occurring, notably in Chinese IVDs, the continued rise in sales volumes will often disguise the effect.

Even so the VBH trend is likely to add to existing pressures within the industry, where margins at some companies are already thin (see box, page 15). Compared with pharma, there are fewer automatic pricing mechanisms in place to drive down prices as cost-containment measures bite. However, there has also been less innovation in terms of pricing policies: risk-sharing deals with hospitals, insurers or reimbursement bodies have yet to emerge, for example. Most decisions still rely on competitive pricing, while closed tenders or bidding can often make acceptable market pricing opaque even to those involved. The shift to value-based healthcare seems unlikely to change the process quickly.

With global competition intense, many companies have already been forced to take some of the costs out of their operations in terms of marketing or research and development, in order to bolster margins. In 2013 Boston Scientific, Medtronic, Quest Diagnostics and the medical devices arm of Abbott Laboratories all announced large-scale job cuts. Other companies are also looking again at production processes and supply costs, in the hope that low-cost countries could offer cheaper alternatives.
Other operational efficiencies are also possible. Medtronic’s recent US$43bn acquisition of Covidien of Ireland, for example, offers the opportunity to move its tax-base to Ireland, which would allow the company to repatriate around US$14bn in funds kept in its international operations without paying US tax rates. Medtronic also expects to generate pre-tax synergy savings of US$850m a year by the end of the 2018 fiscal year, by combining the two companies’ back-office admin, manufacturing operations, supply chains and listing costs. Zimmer, a US manufacturer of orthopaedic devices, expects to achieve net annual synergies of approximately US$270m if its US$13bn acquisition of Biomet (also US) is allowed to go ahead.

With global sales of medical devices still rising, however, most companies have been able to find growth areas to offset the effect of price declines. In some cases, this has involved moving into developing markets such as China where, until recently, the rapid rise in healthcare spending has resulted in a surge in sales. Medtronic spent more than US$800m in 2012 buying Kanghui, a Chinese maker of replacement hips and knees. Covidien’s relatively low-cost product line-up of feeding pumps, stomach staples and devices for plaque build-up should also play well in China. The US should benefit, too, with Medtronic pledging US$10bn in investment there, partly thanks to the funds freed up by moving its tax base to Ireland.

### Strategic overview: Boston Scientific

At Boston Scientific, sales of heart products such as stents and implantable cardioverter defibrillators (ICDs) have been sluggish in recent years, as a result of factors including slow economic growth in the company’s more established markets, intense competition in certain product areas and safety concerns regarding some devices. As a result, the company saw overall sales fall by 1% in 2013, to US$7.1bn. It also made a net loss of US$121m in 2013, although this was a considerable improvement on a US$4.1bn loss the year before, which reflected one-time charges and expenses.

In response, Boston Scientific, which employs some 23,000 people worldwide, has been cutting jobs and shifting some of its operations overseas in a bid to trim costs. In the search for higher growth and added value, however, it has also been trying to move its business away from heart products, partly through acquisitions. In May 2014, for example, it paid Bayer of Germany US$415m in cash for Bayer Interventional, which makes products that remove blockages from blood vessels. These include the JetStream device, which removes plaque from arteries, a procedure with considerable potential for market growth. That same month Boston Scientific bought IoGyn Inc, a start-up that develops ground-breaking gynaecological devices. The company has not given up on its core cardiology business, however: it is also pinning high hopes on its new Promus Premier drug-eluting stent, which received Food and Drug Administration (FDA) approval in November 2013 and recently launched in Japan.
If they are to avoid yet more pressure on prices, the challenge for medical devices companies is to ensure that spending on medical technologies is seen not as a cost but as an investment, both in terms of patient outcomes and in terms of treatment times. Mr Bernasconi at MedTech Europe cites the example of heart valves. By allowing less invasive treatments, these have reduced operation times, hospital stays and the patient’s time off work. “Innovative medical technology can fundamentally transform how healthcare is being effected,” says Mr Bernasconi.

The danger is, of course, that if the shift to value-based healthcare does lead to increased pricing pressure, even in fast-growing developing markets, then that will have an instant effect on innovation in the industry. Thus far, there are no clear signs that it has. Indeed, in theory VBH should offer a premium for innovation, offsetting some of the pressures from lower-cost but less effective

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Source: Company reports.
competitors. R&D spending at major research-based medtech companies varies widely as a percentage of sales, but the general trend in nominal terms has been upwards over the past few years. New product pipelines look promising.

As with pharma, however, there are some danger signs. One is the slowdown in FDA approvals over the past decade, which has put strains on the innovation model in the US. The FDA fee for medical devices, introduced in 2013, was the price the industry paid to get approval rates back on track, allowing the agency to recruit 200 staff to deal with some of the backlog of applications. In June 2014, moreover, the FDA issued a proposal for a two-stage action plan to make the approval process more efficient. The first stage, which largely entails researching best practice and using that to train staff, is due to be implemented in 2015. That should help to reduce some of the gap between the US and Europe in terms of when patients gain access to innovation.

Yet unlike with the patented pharma market, the speed of product turnover in the medical devices industry can in itself make the payback for innovation insecure. Take the drug-eluting stent. Invented by Johnson & Johnson (J&J) in a bid to improve patient outcomes after heart operations, it became so successful an innovation that Boston Scientific came out with its own version just four months later. By 2011, there were so many competing products that J&J took the decision to exit the market entirely.

Clearly an industry with that kind of lifecycle cannot rely on the innovation model that has sustained pharma and is now threatening to break down even there. Moreover, innovation at medical devices companies is far less reliant on company R&D than is the case for pharma. As Yves Verboven, Director for Market Access and Economic Policies at MedTech Europe, says, the innovation model in the medical devices industry is built around constant feedback from patients and clinicians: “Needs that you identify for patients and physicians lead to further improvement, and that rapidly feeds into incremental value.”

This model of innovation relies not only on big-company R&D funding, therefore, but also on the investment climate for start-ups and mid-sized companies. As a result, if the requirement to prove value becomes a pre-requisite to gain access to the market, then that is “not entirely positive” for the medical devices industry, says David Nexon, senior executive vice-president at AdvaMed. “If you raise the evidence bar to get into the market, then it will affect investment into the industry and into medical devices innovation.”

This is already taking a toll on the venture capital (VC) funds available for the thousands of small companies that play such an important role in the eco-system of the medical devices industry. In 2013, VC investment in medical devices fell by 17% year on year, with just US$2.1bn going into 308 deals, according to the PriceWaterhouseCoopers LLP/National Venture Capital Association MoneyTree Report (data by Thomson Reuters). There are several reasons for this decline,
including the drop in approvals and the difficulties involved in market entry, but interest was also dampened by the dearth of initial public offerings for medical devices companies, which means that investors lack an exit route.

The pick-up in IPOs, as well as mergers and acquisitions, in the first few months of 2014 has breathed new life into the market in both the US and Europe, although medical devices investment continues to underperform VC investment as a whole. The recent revival, however, has been far stronger for the “development” stage of investment than for any other stage, suggesting that investors are still playing it safe. Investment at the “seed money” stage was still in decline in the first half of 2014, according to the report.

When attracting investors, the US and European medical devices industries do have a major advantage in their market size. This makes the payback for innovation that much greater, encouraging investment in established R&D centres. Even Medtronic, while proposing to move its tax base to Ireland after its Covidien acquisition, is promising to keep its operational base in the US. It has also pledged to invest an extra US$10bn in the US over the next ten years, in areas such as R&D, early-stage venture capital, and acquisitions.

Outside the US and EU, however, smaller market sizes may act as a deterrent for investors. In Australia, which accounts for just 2% of the global medical devices market according to government data, the HTA Review drawn up by the former Labor-led government in 2010 noted there were major risks for innovation in tightening up on economic evaluations. “There is a risk that if regulatory arrangements impede timely market access, niche players may opt to set up
overseas and market back to Australia, resulting in lost innovation and economic opportunities.”

Australia’s proximity to the low-cost production bases of Asia, where companies are already climbing up the value chain, makes this a very real danger. In September 2013, Boston Scientific inaugurated an R&D centre in Shanghai in order to foster local talent, although its initial focus will be on training and awareness rather than ground-breaking research. Over the next few years, more such investments are likely not only in China but also in other developing markets, helped by initiatives designed explicitly to foster home-grown innovations (see box).

Fast-track approval in China

On March 1st 2014, China’s new Fast-Track Approval Process for Innovative Medical Devices came into operation, designed to encourage R&D investment into China’s medical devices sector. The process will be handled by the Examination Office for Innovative Medical Devices, which will decide whether devices qualify for the pathway. If they do, then the China Food and Drug Administration and provincial FDAs will prioritise them through the whole review process, while dedicated regulatory officials will be appointed to liaise with applicants.

The innovative device itself must be patented and part-developed in China, and it must represent a significant global improvement on current devices. Moreover, companies can only apply for fast-track investment if they have a registered operation in China, such as a joint venture. In fact, when the fast-track process was first announced in 2013, the government had identified only domestic medical device manufacturers as “qualified applicants” for the fast-track process.

By opening the fast track process to foreign players, albeit ones with a significant Chinese presence, the government is likely to entice more investment from global companies such as Philips, General Electric and Siemens, which have already set up R&D and production operations in China. Together they dominate the Chinese market for high-tech imaging equipment, although lower-tech Chinese companies are rapidly moving up the value scale.
There are two other areas where the shift to VBH may also entail a change of approach. One is in terms of links with providers and clinicians, and the other is in terms of data. The latter will be crucial for proving the value of innovations, but it is also where some of the biggest challenges lie.

There is no lack of evidence over the effectiveness and safety of medical devices, which is vital to gain marketing authorisation. Moreover, while pharma companies can often find it hard to gather real-world evidence about patient outcomes, for medical devices companies the feedback is almost continual as these devices are put into use. Indeed, they are under a constant obligation to report on any adverse reactions, with severe penalties for any omissions. Yet despite this, with only the riskiest devices requiring controlled clinical trials, systematic evidence on the link between cost and patient outcomes may be hard to compile.

To support assertions over value, medical devices companies have to use any pre-marketing trials to gather as much evidence as possible about cost-effectiveness as well as safety, even if this means redesigning or even lengthening those trials. Any additional costs could turn into savings or extra revenue later on in the marketing process. They also have to ensure that any pre-marketing data on patient outcomes is backed up by real-world assessments. Beyond this, they also have to collect real-world data on how the device works for clinicians and providers, including shorter hospital stays (see chart).

In some cases, it may be possible to fill any gaps from registries. The Dutch National Intensive Care Evaluation registry, for example, contains data from patients who have been admitted to intensive care units. These may be used to assess outcomes such as:

- Reduced mortality rates;
- Reduced infections;
(value-based healthcare)

Strategies for medtech

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- Reduced readmissions;
- Reduced need for further treatment;
- Better quality of life outcomes;
- Shorter operation durations;
- Shorter hospital stays.

The challenge is to quantify these advantages clearly, and then to present them using appropriate methodologies, unbiased assessment, and peer-reviewed publication. That not only means knowing the requirements of the HTA agency or reimbursement committee in terms of this device, but also knowing which comparators are needed and how to collect the data for those efficiently.

One development that will help is the adoption of a unique device identifier (UDI), which makes it easier to track outcomes—as well as safety problems—associated with each device. The US FDA is in the process of implementing one, which will not only identify the device but also give information such as the batch number, the manufacturing date and the expiry date. Each UDI will also be registered with the Global Unique Device Identification Database, a publicly searchable database that could eventually be used worldwide. The US project is being conducted in consultation with the International Medical Device Regulators Forum, a body that works to harmonise national UDI standards in Australia, Brazil, Canada, China, the EU, Japan and the US.

Despite these efforts, data collection will still involve challenges, says Clearstate’s Ms Hew. One of the biggest is over who owns the data—the device manufacturer or the provider. Both have an incentive to collect it in order to aid analysis of cost effectiveness, but any data-sharing arrangement has to be

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Acute myocardial infarction, average hospital stay

(4)

Source: OECD.
explicit, particularly if it goes beyond the device itself and into broader clinical processes. Some device manufacturers are also starting to explore opportunities to collect data beyond clinical settings, for example through social media or patient group websites, although it will be several years before this becomes systematic enough to help in the process of proving value.

**Intelligent devices**

Despite their increasing complexity, infusion pumps have failed to keep pace with advances in information technology and the development of electronic medical records. Thanks to this, as well as user errors, infusion pumps cause more deaths and adverse events than any other medical technology. More than 56,000 adverse events and 710 deaths were reported to the Food and Drug Administration (FDA) between 2005 and 2009, adding more than US$2bn to US healthcare costs.

To address these problems, Ivenix has invented a new infusion management system that uses a smartphone-based monitor that it claims can be integrated with any IT or electronic medical record (EMR) system. The innovation, which has yet to be approved by the FDA, is designed to be intuitive, secure and accurate, to eliminate mistakes. This will become even more important as patient care moves from hospitals to home: the flow rate, for example, is automatically adjusted regardless of the height difference between the medical bag and the pump.

But while Ivenix’s main aim is safety and effectiveness, the technology would also offer a direct opportunity to monitor and analyse patient outcomes. This can feed into cost-effectiveness and value analysis for both the hospital and Ivenix, as long as they can come to an agreement over data use.
In gathering evidence of value, medical devices companies have an advantage over their peers in the pharmaceuticals industry: their strong links with providers. Whereas pharma companies have little direct contact with patients (particularly outside the US) and are increasingly barred from direct contact with clinicians, the medical devices industry necessarily works alongside providers. Given that the performance of many devices relies on the skill of the user, training is an integral part of the offering and feeds into the development cycle.

These links and skills will become even more useful as the VBH trend pushes the industry even further away from a product-led approach to one that encompasses the whole care pathway. Many of the bigger companies in the sector, quite apart from investing in market access and economic evaluation teams, have also spent much of the past few years rolling out healthcare solutions arms. These aim to advise providers on treatment routes, to improve care delivery, or even to take over managed care programmes entirely.

Siemens Healthcare is one of the companies that has moved in this direction (see box page 25) but it is far from alone. In September 2013 Medtronic launched a Hospital Solutions arm, aimed at boosting efficiency in a range of services carried out by hospitals. The aim is to focus on cardiac surgery and neurology in both developed and developing countries. The division began with long-term contracts with two National Health Service (NHS) hospitals in the UK, South Manchester NHS Trust and Imperial College Healthcare NHS Trust in London, to manage their catheterisation laboratories.

At Philips Healthcare, the Healthcare Transformation Services business aims to “optimise patient care by presenting the right information at the right time to the right people”. It forms part of a strategy that has seen the Dutch company transformed from a consumer-products and medical-devices company into a health and well being company. “For Philips it is an opportunity to become
more solution-orientated as a business, playing to our strengths and our long history of technology services,” says Bob Reese, senior vice-president at Philips Healthcare.

In some cases, such solutions and services are closely tied into the sale of software systems, or are based around the sale of particular product sets. Consultancy contracts may even stipulate that a proportion of products purchased must come from the same company. Mr Reese claims that new types of partnerships and business models with a longer-term perspective allow Philips to create solutions for customers that would not be possible under a conventional model tied to product sales: “We know that Philips has great technology but there may also be technology that we may not own. It’s an end-to-end process and there are many other enabling technologies.”

In terms of the shift towards value-based healthcare, the most informative projects may be those focusing on data analysis and the redesign of patient pathways. GE Healthcare Partners works as an advisory service within the US-based company, implementing changes to improve patient experience, outcomes and cost. A recent white paper, called Care Redesign and Strategic Simulation, outlines some of the stages that a typical consultation process might involve.

- **Stage 1:** Current-state assessment. This involves collecting data on how providers currently carry out patient care activities, including the layout of the clinic or ward.
- **Stage 2:** Current-state model development. The data collected during Stage 1 are used to model how the ward or clinic currently operates, often through 3D animation.
- **Stage 3:** Analysis. GE advisers look in details at the processes involved, often comparing them with similar processes used by other providers, and discuss any problems or requirements with staff.
- **Stage 4:** Consultation. GE presents its findings to the provider and discusses the scope for improvements.
- **Stage 5:** Experimental design and testing and review of results. This is where alternative models are designed and tested through computer simulation, in order to come up with a final recommendation.

In many ways such advisory services are just another way of earning revenue, says Ms Hew. Yet as the GE process shows, these kinds of care solutions add to the close scrutiny of patient outcomes, allowing an opportunity to see devices in action and laying the groundwork for value-based assessments. The same kind of process may be useful not only when working with providers, but also for payors, governments and even non-governmental organisations (NGOs).
Medtronic, for example, has set its sights on India and is rapidly expanding its presence in the country. At the same time, its philanthropic arm last year began a five-year programme with the MAMTA Health Institute for Mother and Child, investigating non-communicable disease needs in two regions, with the aim of contributing to the debate over healthcare provision. This kind of initiative provides an opportunity to be involved at the beginning, as India and countries at a similar stage of development build up their healthcare systems and try to avoid the wastage common in developed countries.

Strategic overview: Siemens Healthcare

Siemens Healthcare—like its main competitors—faces plenty of challenges. Tight government budgets and pricing pressures have led to stringent cost controls, with fewer resources for research and innovation, at a time when advances in treatment are changing customer demands. Siemens Healthcare has already implemented several strategies in response. Its Agenda 2013 programme, launched in 2011, was aimed at generating efficiency gains and trimming costs. Others were aimed at strengthening Siemens’ position in the mid-price segment and expanding into fast-growing emerging markets. Diagnostics emerged as a core business within the division.

At the end of May 2014, however, the Siemens conglomerate announced a new strategy, Vision 2020, which may be its most radical yet. The strategy aims to cut costs across the whole company by €1bn (US$1.4bn) a year by 2016, increase employee ownership of the company, and streamline its current 16 business units into just nine. Under the new structure, which is due to be implemented by October 2014, Siemens Healthcare will become a separate unit outside the core businesses of engineering and electronics.

This prompted rumours that Siemens may eventually sell the healthcare division—whose audiology business is already being prepared for a public listing. Siemens’ chief executive, Joe Kaeser, denies that, but says the aim of the split is to give Siemens Healthcare a more entrepreneurial spirit to promote growth. As of 2015, all divisions will have been set target profit margins, which in the case of healthcare will be 15–19%. To achieve this, Mr Kaeser is calling for investment in patient care solutions order to cope with the shift to value-based reimbursement, the increasing use of companion
diagnostics, and the disruption caused by new technologies, including mobile healthcare.

Several examples of this flexible investment strategy have already emerged. In Saudi Arabia, Siemens signed a deal with the Specialized Medical Center, a healthcare complex in Riyadh, to provide medical training. In the UK, it has teamed up with Spire Hospitals, a private hospital group, with plans to develop a combined business and healthcare park near Manchester. In the Netherlands, meanwhile, the division has won contracts from two university hospitals to implement IT systems, including electronic patient records.
This paper began by comparing the differences between the pharma and medical devices industries, in order to explore the ways that the trend towards value-based healthcare could affect the latter industry. With pharma clearly ahead in terms of HTA, there are lessons to be learnt, but also problems to be avoided. As with pharma, the trend towards value-based care is likely to put pressure on the medical devices industry but it will also offer opportunities.

In order to take advantages of those opportunities, companies may need to make significant investments, notably into data capture and analysis, in an effort to persuade cash-strapped payors and providers that cheapest is not always best when it comes to medical devices. The shift will also require management time to ensure that the company’s whole strategy is geared towards proving value.

For larger companies, that is investment that is already happening, although many are waiting to see how policies will develop, and how payors and providers will react. But for the smaller companies in the industry, the scope for such strategies is limited. The debate over value-based healthcare is taking place at a time when the industry’s “eco-system is clearly under duress,” says Mr Ubl.

Yet a “business as usual” approach to the pressures exerted by VBH will continue to hold sway. Costs will have to be minimised in order to cope with the industry’s intense international competition and the trend towards commoditisation. As for innovation, Mr Nexon of AdvaMed for one is sure that the familiar model of incremental, physician-led innovation will continue to drive the industry, particularly at research-led companies or small high-tech start-ups.

Nevertheless, says Mr Verboven of MedTech Europe, value assessments will need to be incorporated at a far earlier stage of product development. “Experts in economic evaluation must be at the heart of the demonstration process”, even if that kills some potential products.

In all cases, rather than simply waiting for the shift to VBH to affect the industry, companies need to be shaping the debate. They need to ensure that:
Attitudes on the part of providers, payors and politicians change, so that they adopt a longer-term attitude to investment in new technologies; HTA processes are appropriate for medical devices, rather than simply transferred from pharma, and that best practice spreads quickly; Providers view medical devices companies as partners, with both sides having an incentive to collect and analyse data in order to improve care pathways and patient outcomes.

The results could help with the much-needed transformation of healthcare systems in both developed and developing countries.
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As the emerging markets continue to be a key driver of growth in the anemic global climate, the search continues for the next China. After their initial dash, multinationals have come to realize that the other three BRIC markets are not performing up to expectations, resulting in an urgency to identify the next growth story. Conventional paradigms will not help identify the “next China” simply because there isn’t another economy that can replicate China’s success over the past 20 years.

With EIU Healthcare’s deep country knowledge and highly specialized healthcare expertise, we adjust the prism to identify emerging markets that multinationals in the healthcare space need to focus on now.

Register here
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