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White paper

A DIGITAL FUTURE FOR VALUE ADDED MEDICINES

Supporting positive patient behaviour

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OBJECTIVES

In the haste to focus on the latest technological advance for increasingly tiny patient populations, something's been lost by the pharmaceutical industry - the desire to improve treatments for the many millions of patients who take mainstream, older medications. This is where value added medicines, one of the rising sources of industry innovation and value growth, comes in.

In this paper, we analyse the drivers behind the sector, its challenges and what the future holds for value added medicines.

GENERICS: A SECTOR UNDER PRESSURE

BACKGROUND

Over the past five years, global generics volume has decelerated, and not only in developed markets but for emerging economies as well. The projected 3% of future global generics growth is only marginally faster than growth driven by the shifts in demographics alone[1].

Recent small molecule loss of exclusivity (LOE) events have generally had lower peak sales and lower volumes than those seen in 2012, when atorvastatin's patent expired. As innovation specialises and moves definitively away from mass-market small molecules, the business model for traditional generics manufacturers has to change. The generic pipe has changed, and the emerging market opportunities are not as strong as they could be.

Moreover, this innovation shift means that the majority of treated patients, those taking generic medicines, are not benefitting from potential improvements to their therapies due to a lack of incentives to innovate in major therapy areas which are largely generic, like hypertension, depression, or pain.

In developed countries, a greater number of manufacturers in the market, payer consolidation and a focus on cost containment have driven prices down. This is especially problematic as the US has long been seen as a principal source of return on investment.

In emerging economies, the dynamics are similar. Intense competition, cost-reduction policies and a saturation of generics usage has slowed down volume growth in recent years. This trend does not look like it will slow anytime soon as payer mechanisms, such as China's volume-based purchasing, are set to expand.

This leaves generics manufacturers stuck between a rock and a hard place. Traditionally they have sought growth by moving into new markets to seek volume expansion or refreshing their portfolio to be first movers in new LOE opportunities. The reality is that increased competition, payer pressure and sluggish volume has meant troubled companies are discarding assets, primarily from large western companies to eastern ones able to operate at a lower cost base, such as Aurobindo's acquisition of US dermatology from Sandoz.

UNMET NEEDS

Globally, four of every five medicines consumed in 2017 were generics. As generics of the current standard of care become available, cost-conscious

payers tend to adopt a 'good enough' mindset, where budgetary concerns drive procurement of the least costly product. This can, however, be a false economy.

Patients value greater convenience when taking their medicines. Increasing administration convenience is a large factor in addressing adherence, a major source of healthcare inefficiency. For example, a 2012 meta-analysis[2] on avoidable costs from suboptimal medical use showed that non-adherence contributed $105bn (57% of total avoidable costs, $269bn) in the US alone.

The potential of these medicines are not limited to adherence. Improvements in other metrics such as safety and tolerability (see Figure 1) also offer opportunities to enhance caregiving using smarter therapy design.

If companies wish to compete effectively in the small molecule market, they need to change their business models to address the opportunities brought by unmet needs that remain.

Value added medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvement for patients, healthcare professionals and/or payers.

BREATHING LIFE INTO OLD DRUGS

One such emerging sector promising to tackle these unmet needs is that of value added medicines, formerly known by IQVIA as the Third Sector.

Value added medicines are at their core modified off-patent medicines, they can be both small-molecules and biologics, although examples of the latter are only beginning to emerge as the universe of off-patent biologics is small. Value added medicines hold the promise to bring about significant positive societal and economic improvements to healthcare as outlined in Figure 1[4].

Figure 1: Medicines for Europe criteria for description of value added medicines

IMPROVEMENTS	CONTRIBUTE TO	ACHIEVED THROUGH
• Efficacy	• Adherence/convenience	• Repositioning
• Safety	• Efficiency/optimisation of HCP resources	• Reformulation
• Tolerability	• Efficiency/optimisation of healthcare systems resources	• Combination (drug/device/service/technology)
• Mode of Administration	• Quality of life	
• Ease of use	• Improved safety/efficacy	
• New therapeutic uses	• New treatment options	
• … any improvement in an existing treatment that brings an additional benefit	• Any potential to improve other health outcomes	

Importantly, companies are taking a serious stance in re-focusing their portfolio strategies towards a value play: investing in complex generics, biosimilars and value added medicines.

INNOVATION SPECTRUM

A natural advantage of value added medicines is that they encompass a broad range of technologies, giving interested parties a large degree of flexibility in choosing their optimal product strategies. This innovation spectrum ranges from continuous, stepwise improvements through to disruptive hi-tech solutions as shown in Figure 2.

At the continuous innovation level, companies operating in this space may look to combine or reformulate off-patent medicines to improve convenience. They achieve this by decreasing administration frequency with long-acting formulations or reducing side-effects with complementary combinations.

Continuous innovation is a powerful route to creating fit-for-purpose products. It is seen in various high-tech industries, such as the evolution of microchips, battery technology and indeed smartphones themselves; value added medicines created in this way will likely treat the largest proportion of eligible patients.

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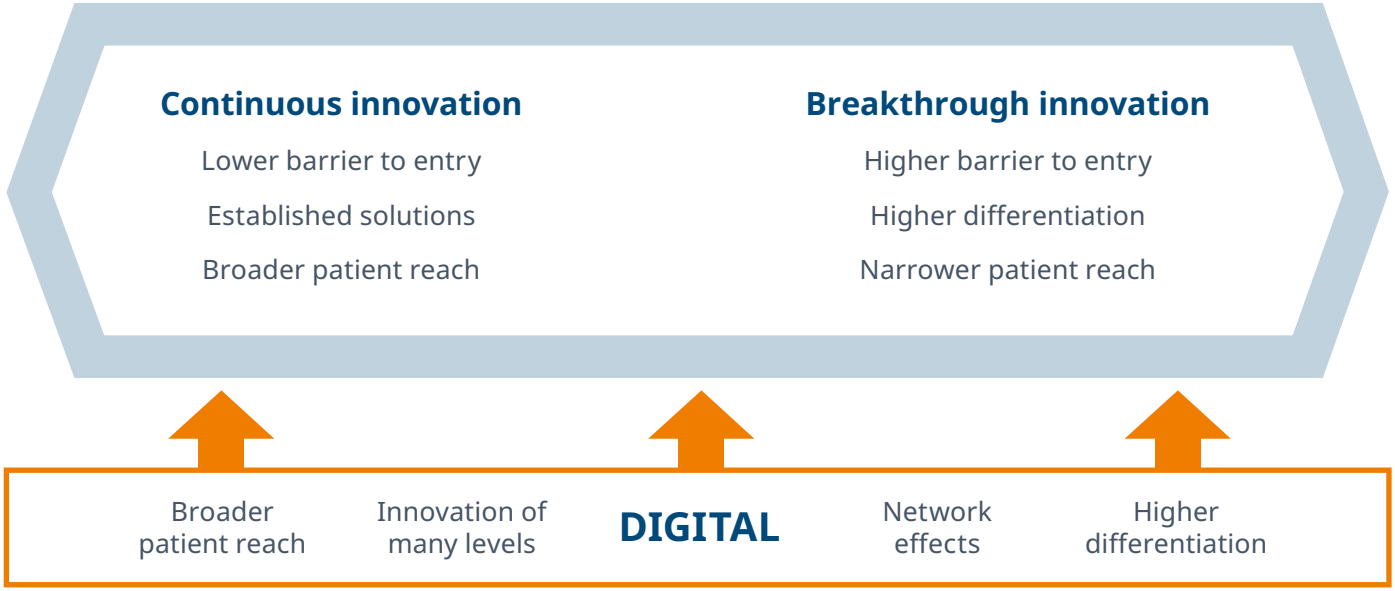
Further up the innovation spectrum, companies combine off-patent molecules with medical devices such as modifying the route of administration by using enhanced inhalers and autoinjectors. This requires a larger investment in R&D and sees a greater use of partnering between molecule producer and device manufacturer.

Figure 2: Value added medicines fall on a spectrum of innovation



Medtech companies typically occupy the high-innovation end of the spectrum, where their products provide a novel solution to higher unmet needs. The larger R&D investment into these bespoke products contributes a sizeable expense to the producer and so will tend to command a higher value recognition.

Digital services and therapeutics also play an active role in this space where partnerships between pharma and tech companies are the norm. They break the mould in the innovation spectrum by facilitating novel solutions that are theoretically not constrained by physical factors and so can achieve scale at a lower cost base.

The successful value added medicines manufacturers of tomorrow seeking to capitalise on growth opportunities should look ahead and position themselves further up the innovation spectrum to increase the differentiation of their therapies.

PUTTING A NUMBER ON IT: IQVIA'S TAKE ON VALUE ADDED MEDICINES

Sizing the market enables stakeholders to be consistent in identifying growth opportunities and communicating challenges effectively. The primary dataset used is from IQVIA's MIDAS, a comprehensive database of audited medicines covering nearly 90% of total global prescription spend and over a million products globally.

The successful manufacturers of tomorrow should look ahead and position themselves further up the innovation spectrum to increase the differentiation of their therapies

The methodology for measuring value added medicines is based on elimination, where filters are used to exclude products that are not within the definition of value added medicines presented above. The result is a list of medicines that can be confidently classed as containing value added medicines.

Due to the nature of the database, where information on medicine packs are audited, the types of value added medicines that can be characterised are listed in Figure 3.

Using IQVIA's MIDAS analytics database, originator and licensed products are filtered out along with any medicines that are patent-protected. This is to exclude products that fall under lifecycle management (LCM) strategies. Although LCM could be thought of as value added medicines developed by the originator, advantages such as years of data, marketing team in place, established pricing and

Figure 3: Limitations of databases based on medicine pack information

IN SCOPE	OUT OF SCOPE
Reformulated	New Indications/Repositioning (under investigation for future inclusion)
Combination (Drug-drug, Drug-Device, Drug-Service)	Details and categorisation of the device or service are currently out of scope

less need to recover initial investment means that the mix of companies who execute LCM strategies differ from third parties who seek a distinct value added medicines strategy.

In keeping with the differentiated nature of value added medicines, the methodology is limited to products bearing a brand name, but biosimilars and non-original biologics are not included at this time. There are limited value added medicine biologic candidates as non-original biologics and biosimilars are a recent phenomenon that have by and large copied their reference product.

The criteria used to create the dataset are listed in Figure 4.

A limitation in this methodology is that certain products that have no defined expiry or protection status will not have been captured. This quirk can occur when the molecule was discovered decades ago, as is the case with adrenaline.

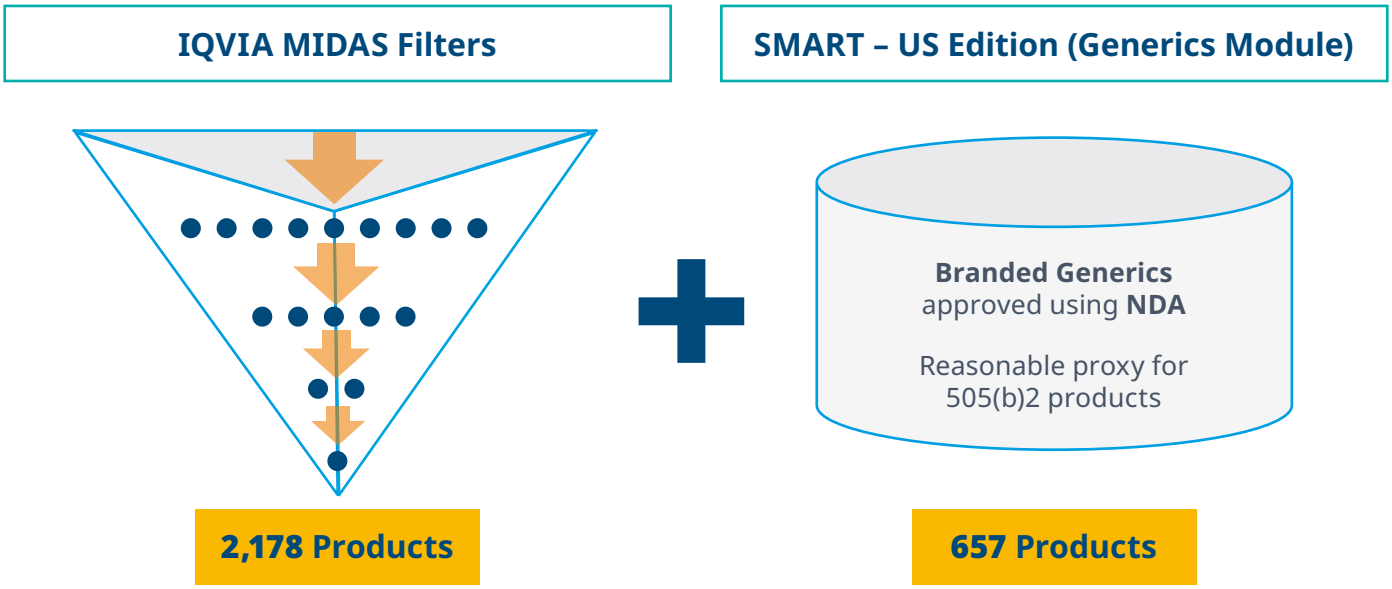
Both to address this issue and further increase the product coverage in the US, IQVIA's SMART US Edition database using the Generics Module can identify Branded Generic products that were approved using an NDA regulatory pathway, that is either 505(b)(1) (full submission application) or 505(b)(2) (partial application: hybrid between full NDA and ANDA). As the products use off-patent molecules, they would have been approved through the latter pathway. A reasonable proxy for 505(b)(2) molecules can be generated in this way.

Sizing the market enables stakeholders to be consistent in identifying growth opportunities and communicating challenges effectively.

Figure 4: Rules used to generate dataset from IQVIA MIDAS

IQVIA MIDAS ATTRIBUTE	VALUE	REASON
Licensing status	Other Brands	Product has not been launched or licenced by the originator of the molecule. This restricts our products to those developed by third-parties
Protection	Protected, No Longer Protected	Product (not the molecule) has been or is currently protected. These protections include device protection, SPC, data and orphan exclusivity
Name Type	Branded	Product is Branded, indicating the presence of innovative IP the manufacturer would like to promote
Biologics	Excluding Biologics	Non-original biologics and biosimilars are their own sector and are currently not defined as value added medicines
Patent Expiry	Expired, Unknown	Molecules are not patent protected

Figure 5: Using SMART database to boost USA product coverage



The combined database extractions characterise over 2,000 unique brands globally (Figure 5).

The following analyses in this white paper are based on the methodology and definitions outlined here.

TRENDS IN VALUE ADDED MEDICINES

GEOGRAPHIC DYNAMICS: US STILL DOMINANT, BUT GROWTH SHIFTING TOWARDS EMERGING MARKETS

The IQVIA calculated value added medicines dataset represents $44bn or 4% of total global prescription value at list price as of MAT Q1 2019. This figure is substantially larger than the market size given in our previous white paper on the Third Sector. This is due to methodology enhancements providing greater coverage of US brands. If value added medicines represented a country's total pharmaceutical expenditure, it would be the 5th largest in the world, ahead of France (Figure 6).

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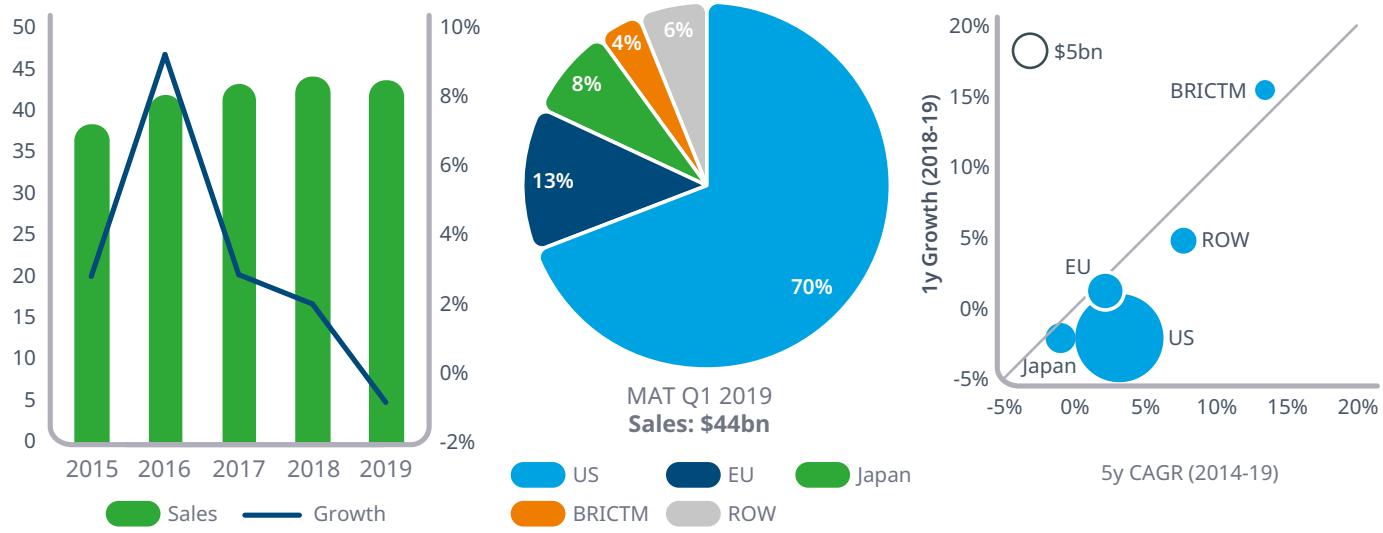
The US remains the largest market for value added medicines, not least because of its dedicated 505(b)(2) pathway and pricing flexibility. The decline in growth since 2016 is predominantly driven by continued pricing pressures in the US that have affected top brands for the past few years, such as adrenaline in anaphylaxis treatment, but the US still dominates global sales at 70%.

Within Europe (EU member states, Norway and Switzerland), EU5 countries (France, Germany, Italy, Spain, UK) are the largest contributors to value added medicines value, taking 70% of the European market. EU5 countries have declined in the last year, except for Italy which has grown slightly thanks to the Nervous System therapy area. Japan, smaller than EU countries, has declined over the last few years as sales of pain medications drop.

BRICTM (Brazil, Russia, India, China, Turkey, Mexico) sales grew by 15% in 2019, continuing a high-growth trend over the last five years. Growth in the region has been driven by China and Brazil, in the areas of Oncology and Antifungals respectively. Emerging economies remain small in absolute terms for value added medicines, but as markets that are less payer-dominated and driven by patient choice, they represent an attractive future opportunity.

Figure 6: Geographic split



Notes: Sales at list price, excluding rebates and discounts
Source: IQVIA European Thought Leadership Analysis; IQVIA MIDAS MAT Q1 2019; Rx only

As there is no singular global regulatory framework, and because value added medicines are generated in some cases by smaller companies with limited geographical reach, the market is regionally specific. For example, top products in China and Brazil are domestic brands whereas the US and EU5 countries use a higher proportion of global brands such as Mirena (levonorgestrel, drug-device combination) but there is little cross-over amongst the top brands across continents. Bar a few key exceptions, value added medicines tend to not find equal success in all global markets.

WHERE DO WE FIND GROWTH?

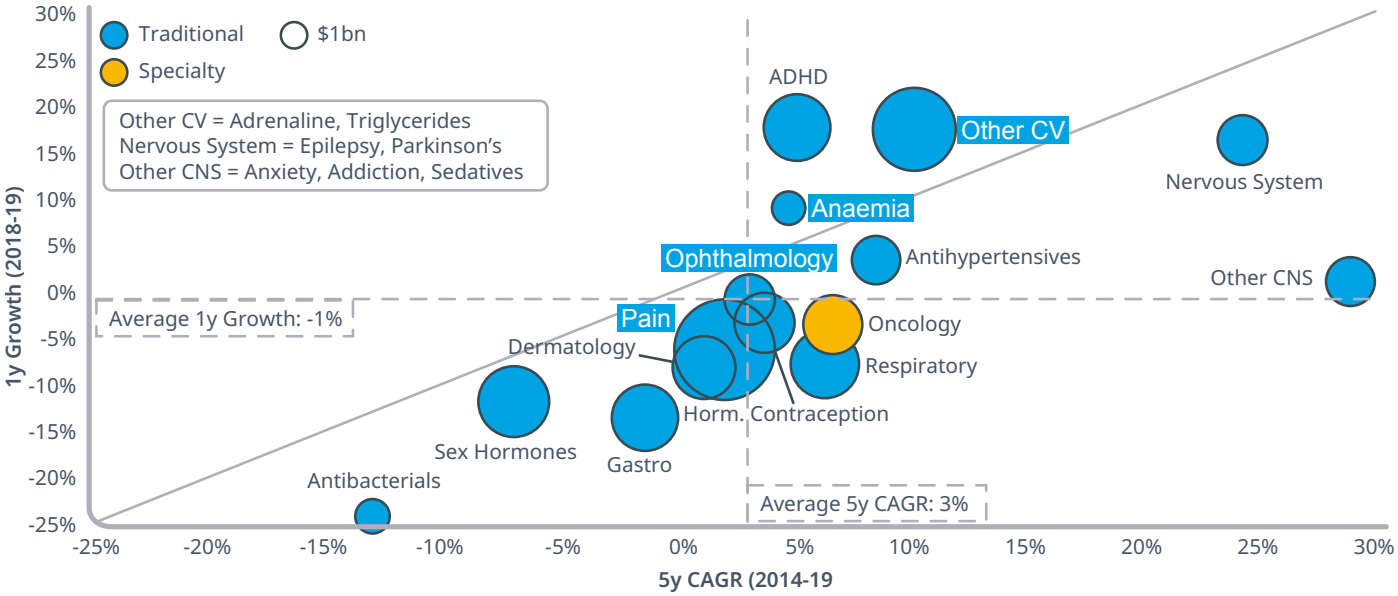
THERAPY AREAS

14 of the top 15 therapy areas are made up of predominantly traditional medicines[6], those seen in the primary care setting, supporting the notion that value added medicines currently fulfil an important role in continuous innovation in primary care (Figure 7). This is set to shift as the generic pipe becomes more specialty and biologic, pulling through value added medicines into those domains. Currently, the only specialty therapy area in the top 15 is Oncology, driven by Celgene's Abraxane (albumin-bound paclitaxel, increased efficacy) and Teva's Treanda (bendamustine HCl, formulation).

Central nervous system drugs have led the way in terms of growth over the past five years (MAT Q1 2014-19), these typically through extended-release formulations such as Supernus' Trokendi XR (topiramate, long-acting) for migraines and Assertio's Gralise (gabentin, long acting) for postherpetic neuralgia. The absence of much pharmacotherapeutic innovation and the typically frequent dosing of the current standard of care in pain lends itself to differentiation through continuous innovation.

Pain remains the largest therapy area within value added medicines, and that is because manufacturers have multiple administration modalities to explore, such as medicated patches, injectables and topical forms, and there has been a drive from governments, particularly in the US, to control exposure to opioids. This constitutes a major tool that can be used to combat substance abuse and is a real positive benefit for healthcare systems.

Figure 7: Therapy area growth dynamics



Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q1 2019; Rx only

Oncology and respiratory show double-digit growth, with the former primarily driven by Abraxane's albumin-bound reformulation of paclitaxel that eliminates the need for solvents and the latter by aerosols such as Salamol (salbutamol, drug-device) and Beclazone (beclomethasone, drug-device).

In the US, Auvi-Q (adrenaline, drug-device), the largest drug by sales, has also shown the largest growth over the last five years and has propelled this therapy area. Salamol Easi-Breathe (salbutamol, drug-device combination) is second largest with a modest five-year growth.

Analgesics led the way last year in the EU5 through Grünenthal's Versatis (lidocaine, drug-device) patches and Mundipharma's Targin (oxycodone/naloxone, drug-drug) tablets, while pain relief brands such as Sector (ketoprofen, formulation and device) and Artz (sodium hyaluronate, formulation) were also among the largest value added medicine brands in Japan.

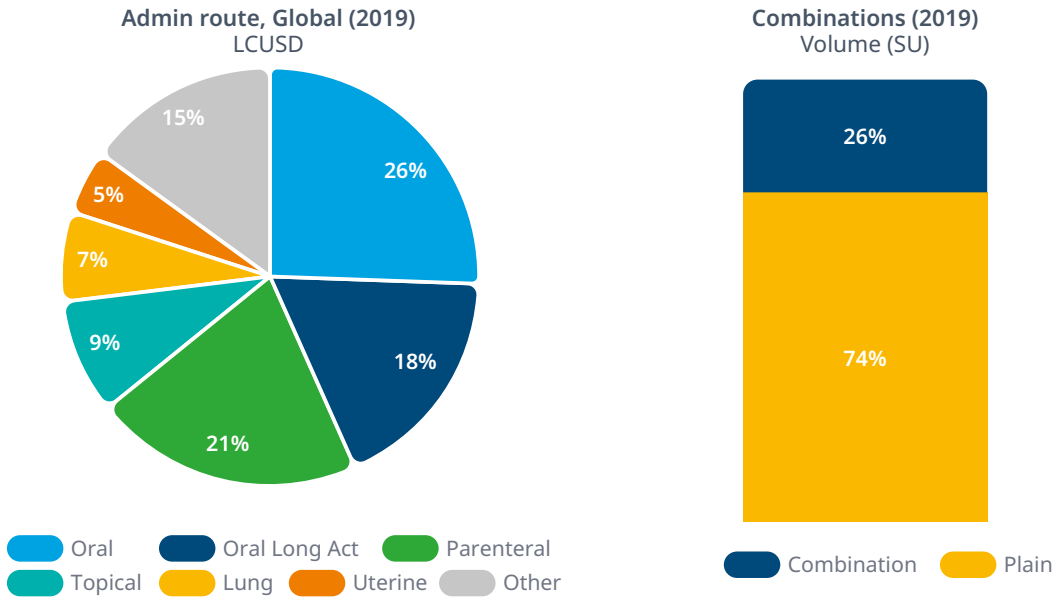
ADMINISTRATION FORMS

Splitting value added medicines by route of administration shows that nearly half of value comes from oral medicines, including long-acting formulations as displayed in Figure 8. A quarter of products are combinations of different active ingredients.

The fastest-growing major segment however, comes from injectables (Figure 9), with a five-year compound annual growth rate (CAGR) of 14%. This growth rate has almost doubled the injectables segment to $11bn over the five years. Within injectables, prefilled syringes have been outperformers with 24% 5y CAGR, followed closely by vials (11% 5y CAGR) and infusions (9% 5y CAGR). Over 80% of the global value growth in injectables has been in the US, followed by BRICTM at 10% and the EU at 4%.

The phenomenal growth in injectables over the last five years in the US has been driven by products that decrease opioid usage, such as Alkermes' Vivitrol (naltrexone, long-acting) and Pacira's Exparel (bupivacaine, formulation). There is a clear proposition for value added medicines to be used as tools by healthcare systems wanting to control substance abuse such as the current opioid epidemic.

Figure 8: VAM segmentation by form

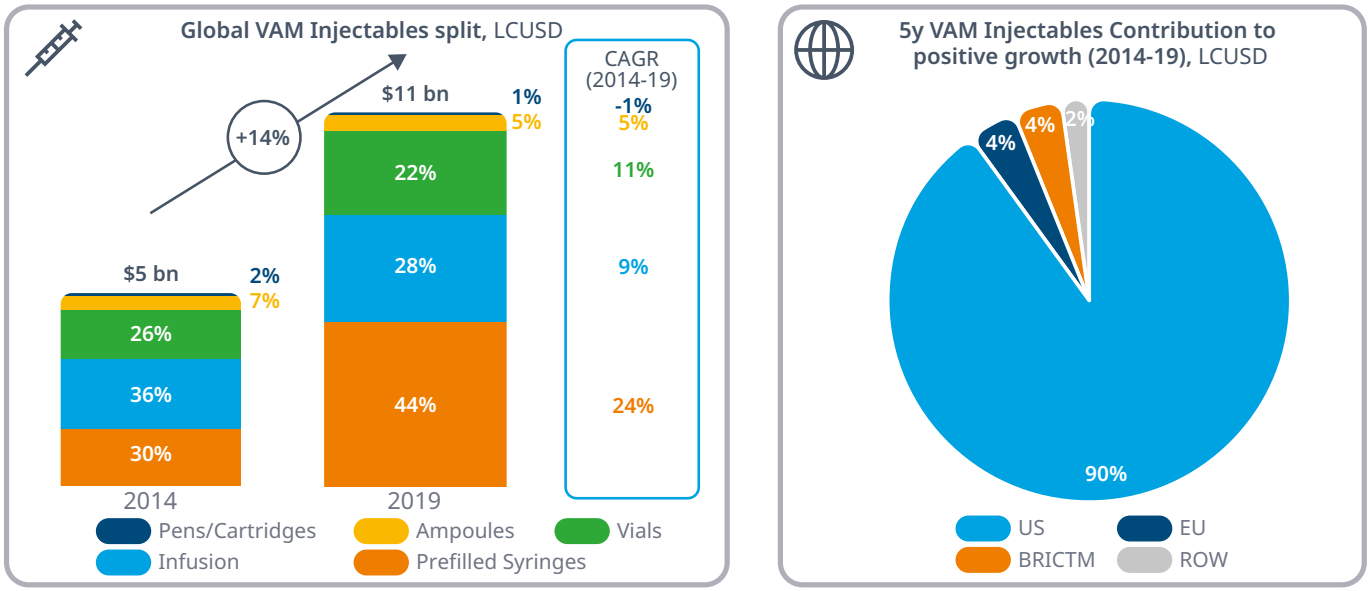


Notes: Sales at list price, excluding rebates and discounts
Source: IQVIA European Thought Leadership Analysis; IQVIA MIDAS MAT Q1 2019; Rx only

Emerging economies, contributing a tenth of injectable growth, are driven by antifungals and oncology products. They are however, an important source of volume, particularly China as it has ramped up its specialty medicines consumption in recent years.

Looking to the future, injectables will grow in importance in emerging economies their usage of specialty medicines increases. Developed markets such as Europe and the US will continue to lead the world on adopting specialist devices, such as pens and auto-injectors, that can be used outside the hospital setting.

Figure 9: Injectables



Notes: Sales at list price, excluding rebates and discounts
Source: IQVIA European Thought Leadership Analysis; IQVIA MIDAS MAT Q1 2019; Rx only

Packaging firms have also taken an interest in operating within the sector as they seek to offer additional services to their pharmaceutical clients. They see packaging considerations to not only be crucial for branding purposes, but to also play a significant role in patient convenience and adherence. For example, some manufacturers who have traditionally specialised in blister packaging have used their vacuum forming expertise to produce single-use disposable inhalers that allow patients to carry small, portable inhalers in situations where they would normally find their standard devices bulky to conveniently transport e.g. sports, travel, social events.

FUTURE OUTLOOK

THE IMPORTANCE OF COMMUNICATING VALUE

The challenges experienced by value added medicine commercialisers have historically been the:

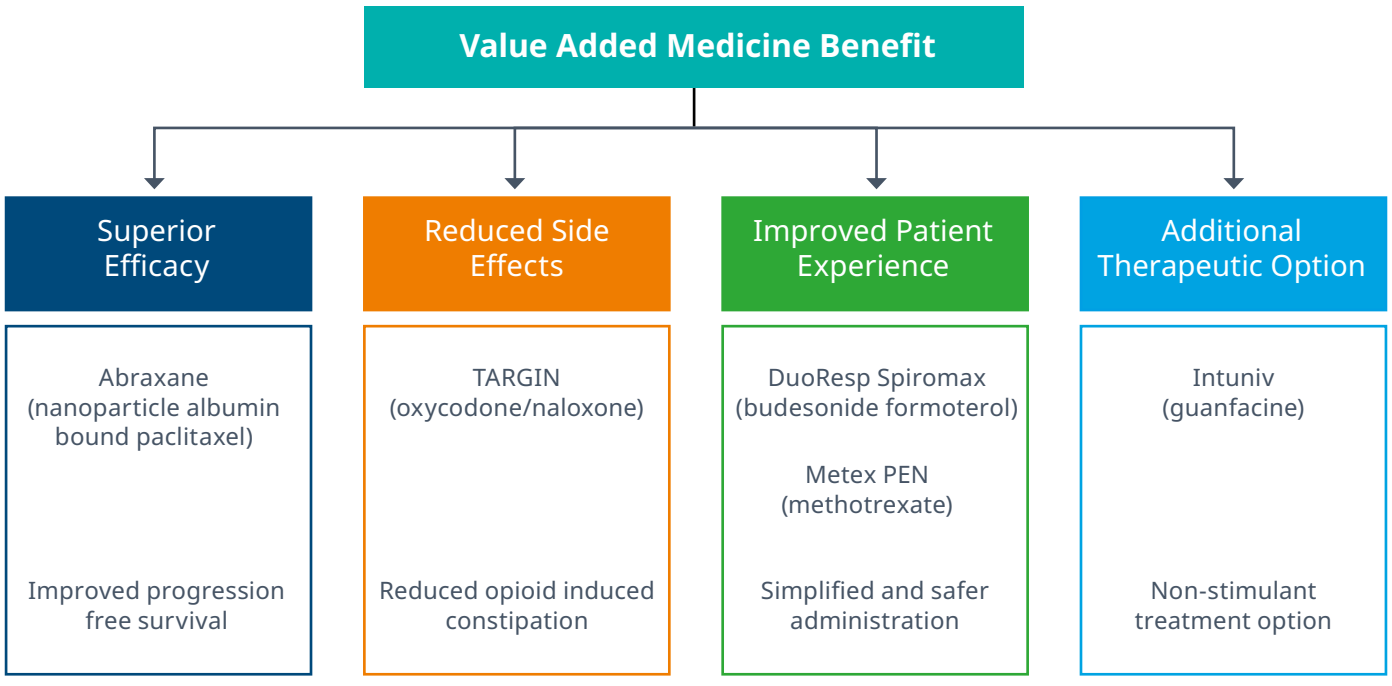
- lack of recognition by payers of the additional benefits that value added medicines can bring
- discrepancy between the level of reward (low pricing and market access) and the level of evidence required (in the EU: Phase III trials, post-marketing studies and full submission dossiers)

Effective communication of the benefits of continuous innovation to payers and regulators would go a long way to building a case for adoption of value added medicines by stakeholders.

Payers and regulators do care about outcomes, and value added medicines provide a range of different and important benefits to patients and healthcare systems (Figure 10).[7]

Clearly, the future for value added medicines lies in demonstration of their superior value in the real world compared to plain generics. In the long term, this opportunity will be realised using data from outside the clinical trial setting.

Figure 10: Selected benefits demonstrated by Value Added Medicines



The future for value added medicines lies in demonstration of their superior value in the real world compared to plain generics. In the long term, this opportunity will be realised using data from outside the clinical trial setting.

A successful commercialiser will need to consider the following points when designing a future value added medicine:

- **Early engagement with stakeholders.**
    - Including patients and healthcare practitioners to identify unmet needs and to collaboratively find solutions for these.
    - Close discussion with payers will give an early indication of the commercial viability of brands.
    - Patient advocacy groups will be the first to see the benefits of value added medicines and so they should take part in the process of product design.
- **Smart data capture.**
    - A strategy in place to collect relevant usage data during trials and post-launch.
- **Real-world evidence (RWE) solutions that are cost-effective.**
    - Bespoke data sets and studies can be expensive, so rewards must match outlay cost.
- **Digital integration where possible**
    - Using digital tools, including wearables, that can assist in generating a vast wealth of data.

Underpinning these innovations is a mastery of RWE and digital tools by manufacturers as useful methods to communicate value and differentiate their products.

REAL-WORLD SOLUTIONS

Real-world evidence strategies are being successfully implemented by innovator companies but as offerings mature, it provides an opportunity for other manufacturers to use these tools.

The rise of RWE has been fuelled by supply and demand. The volume of electronic patient data has grown exponentially, facilitated by digitisation of healthcare, advances in technology and sources of data generation. The initial uncertainty of the robustness of real-world data and the analytics used to derive them have given way to increased acceptance by stakeholders to address their needs such as quantifying disease burden, satisfying post-marketing regulatory commitments, maintaining optimal market access and revising clinical guidelines amongst others.

However, companies that produce value added medicines need to understand the return on investment as many markets, such as those in Europe, have an imbalance between the reward and the expected burden of proof to ascertain superior value[8].

Utilising device-generated real-world data, such as patient-reported outcomes, offers a unique opportunity for value added medicines manufacturers

This is further compounded by the dominance of primary care indications among value added medicines. The nature of these indications presents challenges with regards to population size and balancing breadth and depth of coverage within real-world data sets. Payers should be pragmatic in recognising these limitations and request fit-for-purpose evidence proof dependent on the type of innovation.

In this situation, utilising device-generated real-world data, such as patient-reported outcomes, offers a unique opportunity for value added medicines manufacturers.

DIGITAL HEALTH TO THE RESCUE

Digital healthcare continues its relentless growth driven by a multitude of factors including greater personalisation, scale and cost-effectiveness. Technology companies are investing heavily in the $7tn opportunity that healthcare represents[9] and have made heavy investments in the area to safeguard their future.

Mass-market consumer devices

A real opportunity for engagement at scale is provided by mass-market platforms. Manufacturers of these consumer devices, predominantly smartphones and smartwatches, have implemented healthcare services offerings and encouraged third parties to develop apps that have generated a wealth of data. At the same time, we have seen efforts to improve the quality of available applications, as major app stores have enforced specific quality criteria.

This is a positive development as it is important to have an emphasis on secure custodianship of research-grade data. In fact, a major challenge facing wearable healthcare is that the data generated cannot always be used to track, diagnose and manage health conditions as there are continuing concerns around data accuracy, consistency and privacy.

Manufacturers should explore broader value propositions, beyond the drug, that are focused on user experience and heavily integrated in the personal device ecosystem

Concurrently, the FDA has recognised digital therapeutics through de novo pathways and these regulations will likely be adopted by other regulatory agencies as they seek to introduce pioneering therapies into their markets.

Manufacturers should explore broader value propositions, beyond the drug, that are focused on user experience and heavily integrated in the personal device ecosystem. This will deliver a superior patient experience and make the most of gathering robust health data.

Consumer device manufacturers see these health offerings as a future growth driver and are willing to invest in high-quality sensors such as Apple's decision to add an FDA approved ECG monitor into their smartwatches.

Dedicated Medical Devices

Often, consumer devices may not adequately capture the specific data required to track necessary data such as the strength and frequency of doses administered, and this provides a valuable opportunity open to medical devices.

Smart medical devices that have undergone rigorous testing and sanctioned by a governing body could have the ability to generate data that is better suited for targeted observational studies. Such smart devices like inhalers, autoinjectors and insulin pumps can provide specific metrics and communicate them to interested stakeholders. Devices that are designed to operate seamlessly

OTSUKA ABILIFY MYCITE

One of the largest unmet needs in schizophrenia is adherence, as patients are not consistently in the right frame of mind to remember to take their medications. Having physicians tracking exactly when patients take their medications would go a long way in addressing this.

Otsuka has partnered with Proteus Digital Health to integrate a microsensor within its Abilify Mycite tablets that activates when in contact with gastric acid. This technology allows patients and physicians to effectively track when the patient takes their medication.

This offers unprecedented remote tracking of administration to the point of ingestion, a valuable proposition for mental health patients.

Moreover, Otsuka has further established itself as a leading manufacturer in the digital psychiatry field by partnering with Click Therapeutics to develop digital therapy for depression. It hopes to classify the software application as a medical device (SaMD).

with smartphones offer a high level of user familiarity as well as a wealth of tools provided by the smartphone manufacturer to build upon their platforms.

PARTNERSHIPS WITH THE TECH SECTOR

The coupling of software with medicines will lead to tailored therapies that complement each other and are adaptive to response from prescribers or patients.

To create these high-tech products, pharma companies would need to invest significant capital in creating in-house tech and digital teams able to attract top talent. Conversely, the tech sector needs the know-how from pharma companies for navigating complex regulatory landscapes and effective market access. The necessity for partnerships is stronger than ever.

Innovative branded manufacturers have been first to integrate digital solutions to their offerings and most have originated through collaborative efforts such as Otsuka with Click Therapeutics for smart pills and GlaxoSmithKline with Propeller Health for smart inhalers.

In 2018, Sandoz became one of the first major off-patent companies to partner with a prescription digital therapeutic company, Pear Therapeutics, a tech company focused on digital interventions. The partnership consists of integrating reSET and reSET-O technologies with the goal of increasing patient abstinence from substance abuse during therapy and increase their retention in outpatient treatment programs.

This is significant as it marks one of the first applications of digital technologies to augment the value proposition of the medicines from a large company operating in the off-patent space.

Solutions can be cost-effective and need not initiate as a commercial venture to begin with. The Nightscout project is a volunteer-led open-source initiative designed to fill a gap in the market by creating a platform that allows real-time access to continuous glucose monitor data to a personal device such as a phone or smartwatch. A similar commercial solution could drive adoption through patient-centric convenience first and monetised further down the road.

EVOLVING THE DIGITAL MODEL

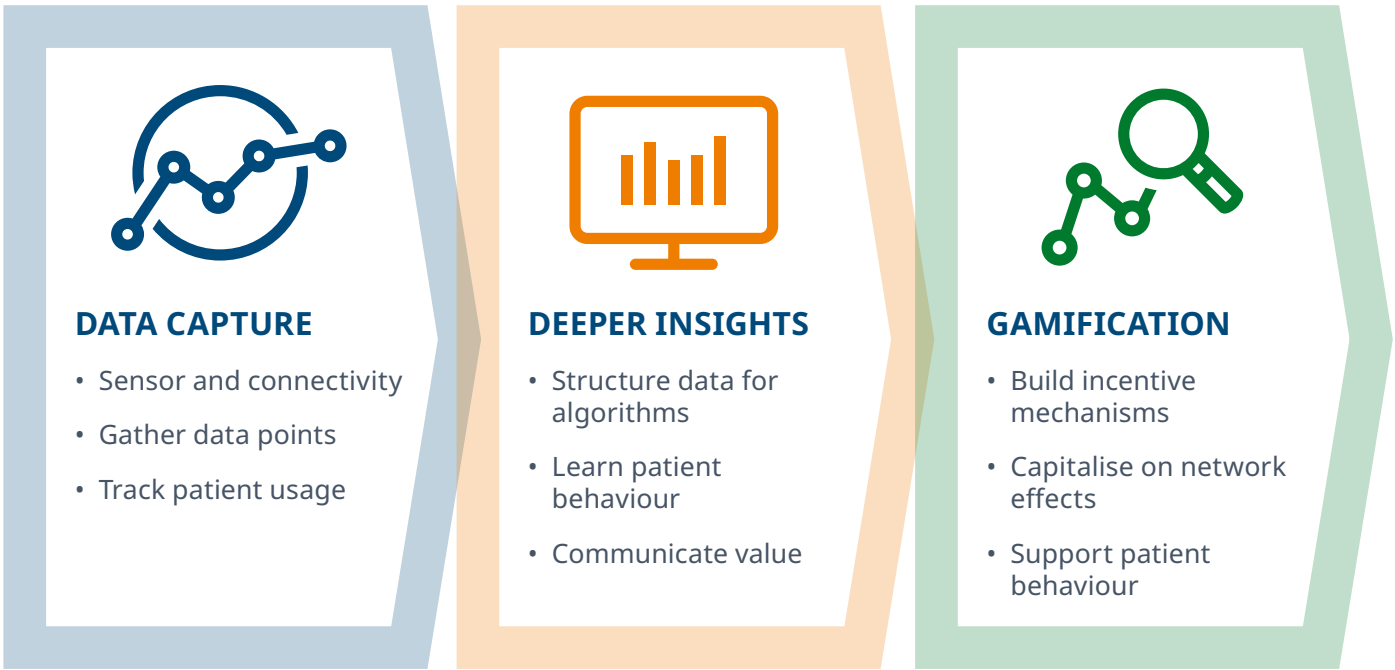
The evolution of digital value added medicines will trend towards capitalising on network effects to form communities in which patients can be incentivised to behave in a positive manner (Figure 11). Specifically, the first stage will involve data capture by using increasingly accessible sensors for devices and mobile applications. The data will need to be structured effectively, and be compliant with data regulations such as GDPR, so algorithms can be constructed to mine for insights.

The valuable intelligence gathered from this wealth of data will be in understanding how patients use the therapy; this is important to provide evidence of value to stakeholders and feed back into the process informing future product design.

The evolution of digital value added medicines will trend towards capitalising on network effects to form communities in which patients can be incentivised to behave in a positive manner

Learning patient usage patterns are necessary for the final step where gamification concepts, those that introduce behavioural rewards, can be deployed to incentivise positive patient behaviour for the express goal of increasing adherence.

Figure 11: Evolution of Digital Value Added Medicines



FINAL NOTE

We believe value added medicines are a promising emerging sector that provides new growth opportunities for pharmaceutical companies.

These opportunities extend well beyond physical innovations to include digital integration. Digital evidence can be used to demonstrate value to payers, which will be key for success in the sector.

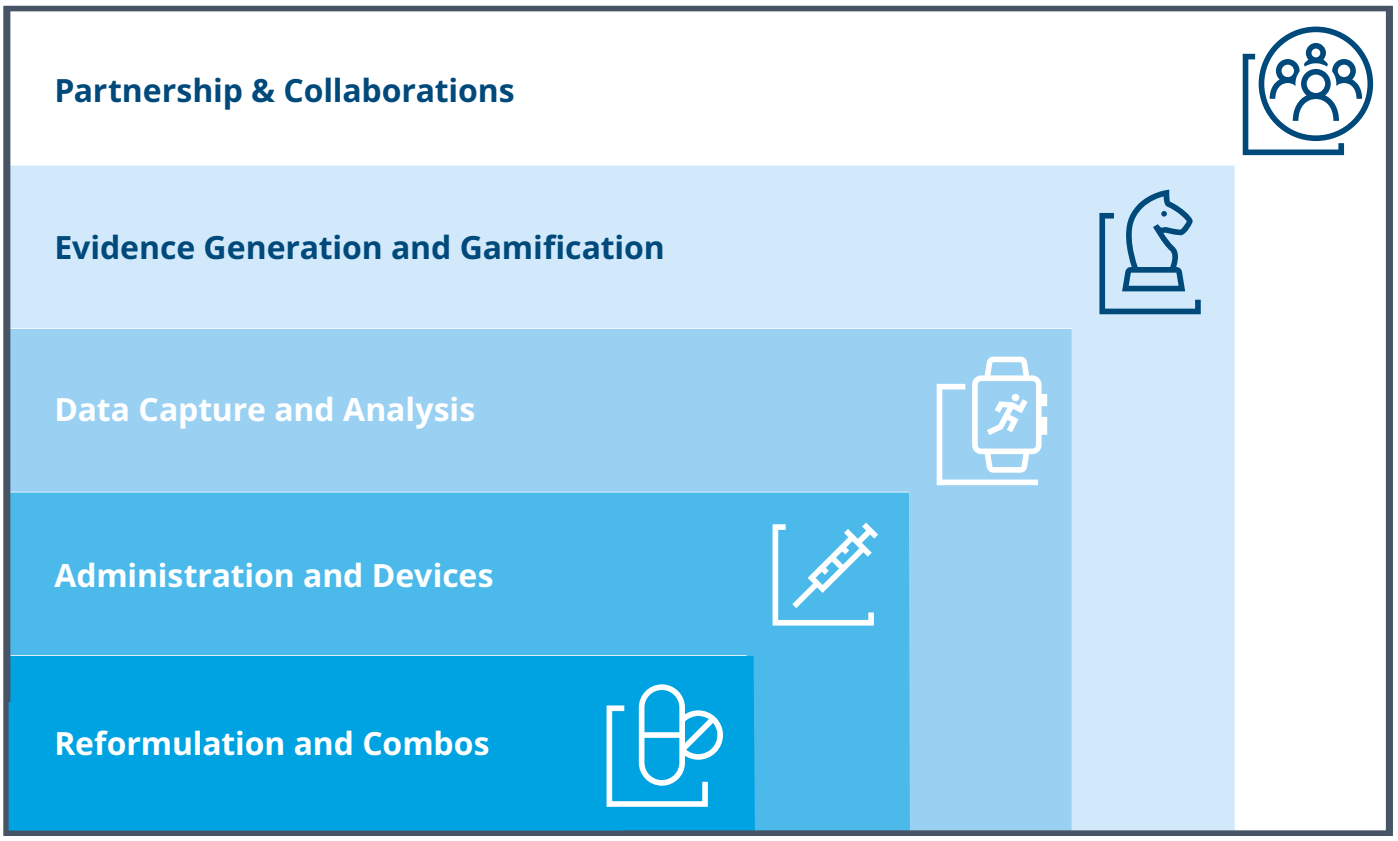
Therefore, the value added medicines business model needs to evolve to include mastery of devices, a digital ecosystem and evidence generation. In the fast-moving and highly competitive tech sector, the risk of building all these critical capabilities in-house is considerable; instead, companies should look to cultivate a network of partnerships to succeed (see Figure 12).

The challenges of an emerging sector remain. Companies should be careful in pacing the rate of adoption of these technologies to match those of other stakeholders to ensure their investments are sufficiently recognised by regulators and payers.

There is a need for stimulating the sector from a payer and regulator perspective[10]. Amongst others, these payer mechanisms aim to introduce a pragmatic approach to evaluating benefit from value added medicines so that the reward is proportional to the evidence requirements. Equally, regulatory frameworks should be adopted to differentiate value added medicines from standard generics.

These flexible mechanisms should aim to cover the broad spectrum of therapies that value added medicines represent, including future digital ventures. After all, it is the breadth of these therapies that gives it the power to improve the lives of the many forgotten patients.

Figure 12: Sources of value



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Aurelio is a global thought leader based in IQVIA's London office. The European Thought Leadership team creates topical and forward-looking strategic content relevant to pharma executives worldwide and publishes articles, blogs and white papers on a regular basis.

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Prior to IQVIA, Aurelio has worked in Discovery R&D and as a strategy consultant in Life Sciences. He holds an MSci in Chemistry from Imperial College London.

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