

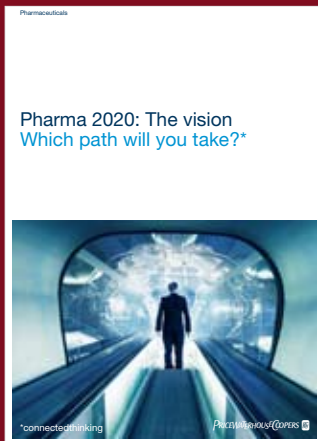
Pharma 2020: Supplying the future

Which path will you take?

*Pharmaceuticals and
Life Sciences*



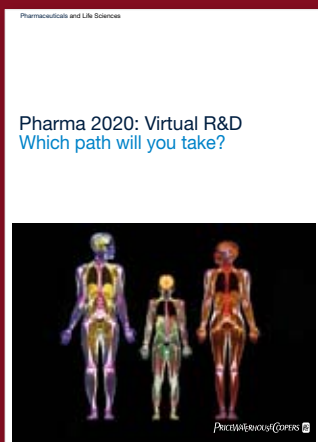
Previous publications in this series include:



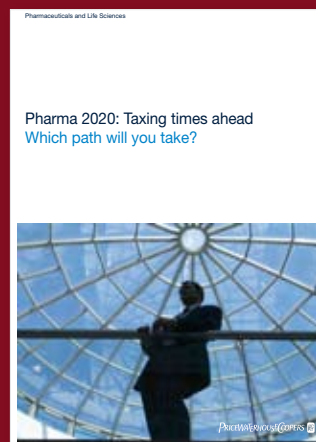
Published in June 2007, this paper highlights a number of issues that will have a major bearing on the industry by 2020. The publication outlines the changes we believe will best help pharmaceutical companies realise the potential the future holds to enhance the value they provide to shareholders and society alike.



Fourth in the Pharma 2020 series and published in April 2009, this report highlights how Pharma's fully integrated business models may not be the best option for the pharma industry in 2020; more creative collaboration models may be more attractive. This paper also evaluates the advantages and disadvantages of the alternative business models and how each stands up against the challenges facing the industry.



This report, published in June 2008, explores opportunities to improve the R&D process. It proposes that new technologies will enable the adoption of virtual R&D; and by operating in a more connected world the industry, in collaboration with researchers, governments, healthcare payers and providers, can address the changing needs of society more effectively.



The fifth report in our series, published in December 2009, focuses on the opportunities and challenges from a tax perspective. It discusses how the political, economic, scientific and social trends currently shaping the commercial environment, together with the development of new, more collaborative business models, will exert increasing pressure on effective tax rates within the industry. It also shows how companies can adapt their tax strategies to support the provision of outcomes-based healthcare and remain competitive.



Published in February 2009, this paper discusses the key forces reshaping the pharmaceutical marketplace, including the growing power of healthcare payers, providers and patients, and the changes required to create a marketing and sales model that is fit for the 21st century. These changes will enable the industry to market and sell its products more cost-effectively, to create new opportunities and to generate greater customer loyalty across the healthcare spectrum.

All these publications are available to download at: www.pwc.com/pharma2020

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Introduction

The pharmaceutical industry is experiencing major upheavals, as PwC* noted in earlier Pharma 2020 papers. Many companies have responded by trying to discover, develop and market medicines more efficiently, but they've invested relatively little effort in reconfiguring their manufacturing and distribution operations to date. Yet the supply chain is just as important; it's the link between the laboratory and the marketplace.

Unfortunately, it's a link that frequently doesn't work very well. Most pharma companies have complex supply chains that are under-utilised and inefficient. Worse still, they are ill-equipped to cope with the sort of products that are coming down the pipeline. By 2020, many of the medicines the industry makes will be specialist therapies that require totally different manufacturing and distribution techniques from those used to produce small molecules.

In short, the pharmaceutical supply chain needs a radical overhaul, and we predict that it will undergo three key changes over the next decade:

- It will fragment, with different models for different product types and patient segments
- It will become a means of market differentiation and source of economic value; and
- It will become a two-way street, with information flowing upstream to drive the downstream flow of products and services.

We've identified four potential supply-chain options from which pharma companies can choose. Those that focus on specialist medicines can either delegate all their manufacturing and distribution to trusted contractors or build service-oriented supply chains to enhance their brands. Those that focus on mass-market medicines can either become low-cost providers or build supply chains that generate a profit by servicing both internal and external customers.

We'll discuss the main trends dictating the need for a new approach to the manufacturing and distribution of medicines, together with some of the techniques and technologies that will help the industry make the necessary changes, in more detail in the following pages. We'll also look at the key characteristics of each of the four routes we've identified, and the implications they carry.

* "PwC" refers to the network of member firms of PricewaterhouseCoopers International Limited (PwCIL), or, as the context requires, individual member firms of the PwC network.

The times they are a-changin’

A supply chain is the means by which a company transfers its products from development to the marketplace in order to sell them and generate a profit. It includes all the organisational, operational and value-adding activities needed to manufacture those products and get them to the customer. So, for a pharma company, it covers everything from new product development through to delivery to the hospital, retail pharmacy or patient (see **Figure 1**).

Some companies have superb supply chains. Fashion retailer Zara is renowned for the speed and agility of its supply chain, for example.¹ Apple, Procter & Gamble, Cisco Systems and Wal-Mart also rank among those regarded as leading examples.² However, most pharma companies have supply chains that are neither flexible nor cost-effective.

When the ‘blockbuster’ paradigm prevailed, this wasn’t a serious problem, but the situation is now changing dramatically. Generic competition has already dented Big Pharma’s revenues – a trend that will continue, as the patents on products with sales of more than US\$267 billion expire over the next six years.³ So the economies of scale the industry leaders have traditionally enjoyed are rapidly diminishing.

Many pharma companies have as a result started refining their supply chains. But most of the changes they’ve introduced have been short-term measures to address immediate challenges like the rationalisation of larger manufacturing networks as a result of acquisitions. This is reflected in the progress – or, rather, lack of it – they’ve made in recent years.

Asset utilisation rates have improved. Between 2004 and 2009, overall equipment effectiveness in packaging increased from 36% to 51%, for example. Quality has also risen, with the percentage of rejected batches falling from 1.00% to 0.74% over the same period. But average set-up times have increased from 79 minutes to 93 minutes, and the vast majority of pharma companies are still far from having any kind of ‘continuous flow’, smooth production scheduling or make-to-order manufacturing. Instead of producing on demand, they must hold large quantities of inventory, which drives up their working capital and overheads.⁴

Figure 1: The supply chain is the backbone of a pharma company

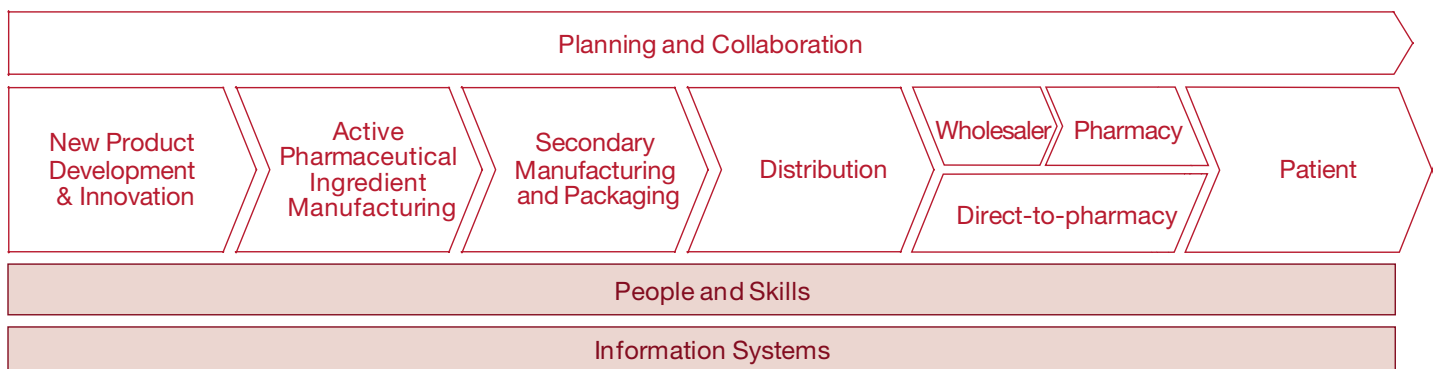


Figure 2: Numerous forces are dictating the need for a different sort of supply chain

1 New product types

- More complex manufacturing and distribution processes
- Different supply chains for different product types
- Shorter product lifecycles

2 Live licensing

- Incremental launch of new medicines
- Ability to scale up and down very rapidly
- Step changes in the revenue curve

3 Increasing emphasis on outcomes

- Expansion into health management service
- Leaner and more adaptable cost structure that preserves gross margins at every stage of the product lifecycle

4 New modes of healthcare delivery

- Blurring of the boundaries between primary and acute care
- Much wider distribution network
- Demand-driven manufacturing and distribution processes

5 Growing importance of emerging markets

- Offerings designed for patients in emerging markets
- More widely dispersed and more robust supply chain

6 Greater public scrutiny

- Heavier regulation
- Robust risk assessment and risk-management capabilities across the extended supply chain

7 Environmental pressures

- Sustainable eco-friendly processes
- Relocation of plant to less vulnerable regions

Even more importantly, few, if any, pharma companies have supply chains capable of meeting tomorrow's needs. Numerous forces – both internal and external – are reshaping the environment in which the industry operates, with profound consequences for the way in which it manufactures and distributes its products (see **Figure 2**).

Source: PwC

1. New product types

Pharma's portfolio is changing substantially. Industry analysts predict that, by 2016, bioengineered vaccines and biologics will account for 23% of the global market (measured by value), up from 17% in 2009.⁵ The product base will become even more diverse, as advances in nanotechnology, tissue re-engineering, stem cell research and other such disciplines start to yield fruit (see **Figure 3**).

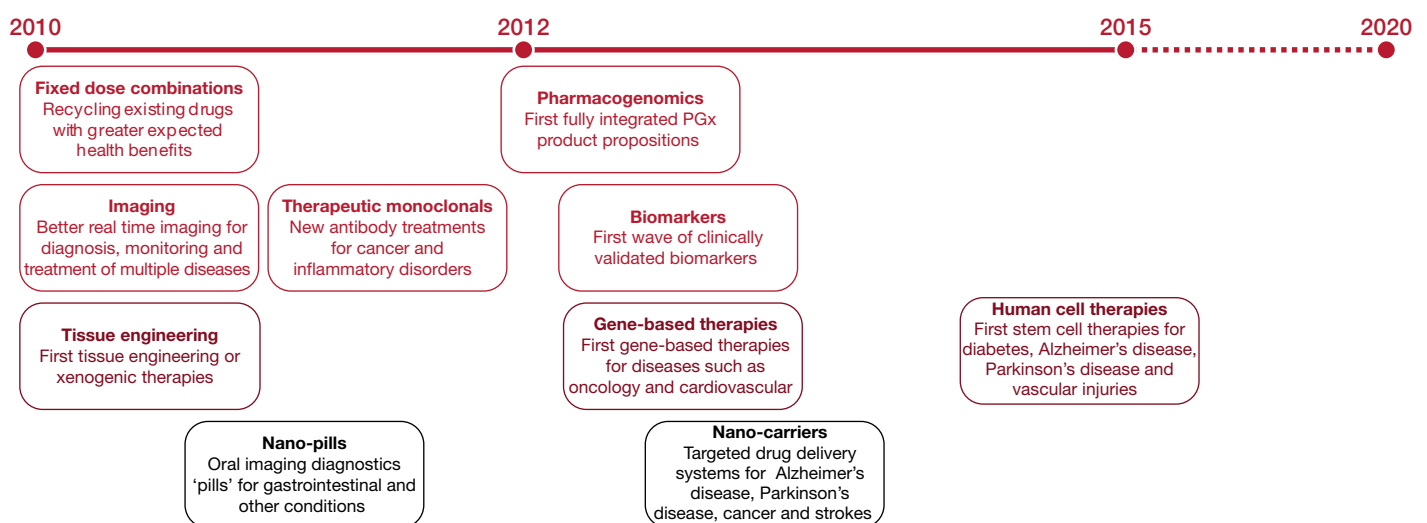
However, many of these new therapies and the devices used to deliver them will require more complex manufacturing and distribution processes than conventional chemical entities. Indeed, some personalised medicines and poly-pills will have to be 'finished' at the pharmacy or point-of-care (see sidebar, **New drugs and devices**). Such challenges will not be enough to prevent product lifecycles getting shorter, though; greater competition both from similar new products and from totally different product types will reduce the period of exclusivity all but the most personalised therapies enjoy, as it has in the case of conventional medicines.

New drugs and devices

Biologics are in general more susceptible to impurities in the production process and damage during shipping than chemical entities. Making gene- and tissue-based therapies is even more difficult. Each sample must be individually extracted, propagated, prepared and tested before it can be administered, so it must be treated as a separate manufacturing lot and finished at a location near the patient.

Many of these specialist treatments will also need novel delivery devices, since it is difficult to produce oral formulations of large molecules. Micro needles, magnetically targeted carriers, nanoparticles, polymer capsules and multi-layered medicated patches are likely to predominate, but such devices are much more complex than those that are used today.

Figure 3: By 2020, Pharma will be making a much more diverse range of products



KEY

Mainstream technologies already happening Gene/Cell/Tissue technologies Nanotech-related technologies

Source: PwC

2. Live licensing

The launch process will also become much more incremental, as new methods for assessing, approving and monitoring medicines emerge. At present, the marketing applications for most new medicines are either approved or rejected; the supply chains for manufacturing and distributing them are designed to support peak sales volumes; and the revenues they generate climb in a relatively simple curve.

But the binary system of authorising new medicines is becoming more graduated. The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) introduced conditional approvals for certain products some years ago.⁶ Both agencies are also placing much more emphasis on post-marketing surveillance, and we believe that the current system will eventually be replaced by a system in which new therapies are granted 'live licences' contingent on further testing to confirm their safety and efficacy in different patient populations.⁷

Once this happens, the 'big bang' launch will give way to a phased approach in which demand for a new product rises as the licence is extended. The interval between the initial launch and peak sales point will thus be much longer; the revenue curve will climb more slowly; and the payback period for capital expenditure on plant and equipment will be more protracted (see **Figure 4**). So, rather than making a large upfront investment in a supply chain designed to cope with peak volumes, any company launching a new medicine will need to build a supply chain that can be rapidly adjusted as the licence alters.

Option 1

Build one facility to accommodate peak sales

Advantages:

- Low scale-up risks.
- Big site drives operational efficiencies.

Disadvantages:

- Large capital outlay for un-proven demand.
- Low utilisation during growth of the product.

Option 2

Adopt a modular manufacturing platform scaling up to support each volume plateau

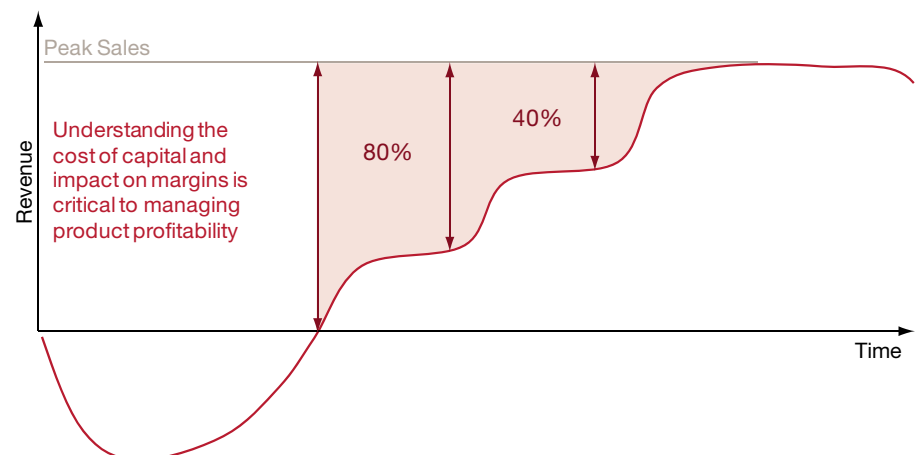
Advantages:

- Capex linked to known market demands.
- High site utilisation.

Disadvantages:

- Cost and risk of commissioning more sites.
- Many small sites increases cost base.

Figure 4: The revenue curve will climb more slowly, when 'live licences' replace the binary system of approving new products



Source: PwC

3. The increasing emphasis on outcomes

Financially stretched governments and health insurers are simultaneously becoming much more demanding; they now want clear evidence that the medicines they buy are really effective. This has huge implications for Pharma. The industry will not only have to manage the manufacturing and distribution of medicines and companion diagnostics, it will also have to ensure that patients get the most from the therapies they receive by supplementing its products with a wide range of supporting services.

The ability to provide demonstrable value for money will thus become a critical differentiating factor, and the supply chain will play a key part in providing that value by commissioning and supervising aspects of the services patients need to manage their health.

4. New modes of healthcare delivery

The drive to cut costs and improve outcomes underlies several other changes taking place in healthcare delivery, with equally momentous consequences for the industry. Most of the OECD countries have been trying to reduce reliance on hospitals and specialists since the 1980s.⁸ Self-administration of medicines is also on the rise, as patients are encouraged to take a more active role in managing their own care. Both these trends will continue as clinical advances provide better medicines for acute conditions and patients become more empowered. Many diseases which must at present be treated in hospital will then be treated at home.

But migrating from a system in which care is provided in a relatively small number of hospitals, clinics and surgeries to one in which care is provided through a diffuse network of nurses and community carers has enormous ramifications. Pharma will need to distribute its products to many more locations, including patients' homes. It will therefore have to harness the most efficient 'final mile' distribution networks in order to deliver medicines to the door as economically as possible.

The digitalisation of healthcare delivery, with greater use of electronic health records, e-prescribing and remote monitoring, will reinforce the drive to push healthcare into the community. However, it will also provide Pharma with one of the key components needed to make the transition. E-prescriptions are effectively point-of-sale data. Access to this data will enable pharma companies to build demand-driven supply chains in which healthcare packages for different patients are assembled at 'super hubs' before being delivered to their homes. By 2020, information about patients and the medicines they need will thus be as important as the products themselves.

5. The growing importance of the emerging markets

The growing importance of the emerging markets will accentuate these challenges. Although patients in the developing economies are becoming more prosperous, they typically pay more than half the cost of their medicines themselves – and few can afford to pay as much as patients in the mature economies.⁹ Moreover, the choices they make are often based on different values from those that influence the design of products and services intended for consumption in the developed world. Cost and the ability to buy on a daily or weekly basis are more important than convenience, for example.

If Pharma is to market its products effectively in the developing economies, it will have to understand the needs of patients living in these countries and tailor its offerings accordingly; and it can learn from the medical device industry in this regard (see sidebar, **Designs for the developing economies**).¹⁰ It will also have to build a supply chain that is both more geographically dispersed and more secure. The number of recorded cases of counterfeit, stolen or illegally diverted medicines has already soared nearly nine-fold since 2002.¹¹

Designs for the developing economies

Several medical device companies are already designing and manufacturing products specifically for people living in the developing economies. Freeplay Energy has, for example, developed foetal heart rate monitors and pulse oximeters that are driven by human power and designed to cope with harsh conditions. Mindray Medical International, one of China's biggest medical equipment manufacturers, also specialises in making inexpensive patient monitoring and life support devices. And cardiologists at India's Care Hospitals have designed cheap heart valve replacements, minimising the number of disposable parts to keep costs down. Pharma can learn from such role models. It can, for instance, develop economical formulations and stripped-down services for patients who can't afford its most expensive offerings.

6. Greater public scrutiny

In fact, by 2020, the ability to manage risk and compliance throughout the supply chain will be more crucial than ever before. While globalisation is increasing the risks, greater public awareness and more diligent enforcement are raising the bar. In 2009, for example, the FDA recalled a record 1,742 medicines. A single company accounted for more than 1,000 recalls but, even when these are stripped out of the picture, the number of recalls still rose by 50% year on year.¹²

Other administrations are also tightening the rules. The Indian government recently passed a law mandating the use of track-and-trace barcodes on all drugs meant for export, with effect from July 2011, following reports that Chinese counterfeiters were selling fake medicines labelled 'Made in India' in several African countries.¹⁴

7. Environmental pressures

The Green agenda presents other difficulties. All pharma companies already operate under strict environmental controls, for obvious reasons. But these regulations are likely to become even tougher, given the international drive to curb carbon emissions. Taxes on water consumption are also likely to rise, as population growth, increased farming, rapid urbanisation and climate change exacerbate the shortage of fresh water (see sidebar, **Water is the new gold**).¹⁵

However, many of the assets pharma companies own are designed to support specific manufacturing processes – processes that typically consume considerable amounts of energy and water. If the industry is to reduce its environmental footprint, it will have to adopt new, more eco-friendly processes and that will require a substantial investment in new equipment.

Indeed, some companies may have to relocate some of their production facilities to completely different places. Global warming is changing the world's weather patterns and many of the traditional centres of pharmaceutical manufacturing, such as Singapore, lie in regions that will become more vulnerable to extreme weather events. Even if it proves possible to engineer a better climate – e.g., by locking up the ice caps or using plants to suck up excess carbon dioxide – geoengineering experts widely agree that the effects would be limited. Such measures would, at best, reduce peak temperatures during the transition to a low-carbon world.¹⁶ But relocating a plant to a new country or region is a complex business; numerous political, financial and commercial factors must be looked at, as we indicated in “Pharma 2020: Taxing times ahead.”¹⁷

Water is the new gold

About 20% of people live in countries that don't have enough fresh water, but the situation will get much worse over the next decade. The global population is projected to rise from 6.8 billion to 7.6 billion by 2020. The amount of food needed to sustain mankind is thus increasing – and farming already accounts for about 70% of the world's total fresh water consumption. Rapid urbanisation is also driving up demand for safe drinking water and sanitation facilities, and environmental changes like deforestation and global warming are exacerbating these pressures.

Water shortages will have a serious impact everywhere. The United Nations predicts that, by 2025, 1.8 billion people will be living in regions where water is very scarce, while 5 billion could be living in ‘water stress’ conditions. The problem will be particularly acute in China, India, sub-Saharan Africa, South Asia and some parts of Latin America. But even countries in more temperate zones will suffer. One recent study suggests, for example, that large swathes of the south-western US will be at risk of water shortages by mid-century.

The collective impact of these trends

To sum up, the current model for manufacturing and distributing medicines isn't fit for Pharma's future needs, as many industry executives recognise. The high margins that made it feasible to tie up capital in large stocks of raw materials and finished goods are ending. Most companies also have asset bases that are ill-suited to produce the sort of therapies that are now in the pipeline or to cope with new environmental regulations, so they'll have to sell or re-engineer much of their existing plant.

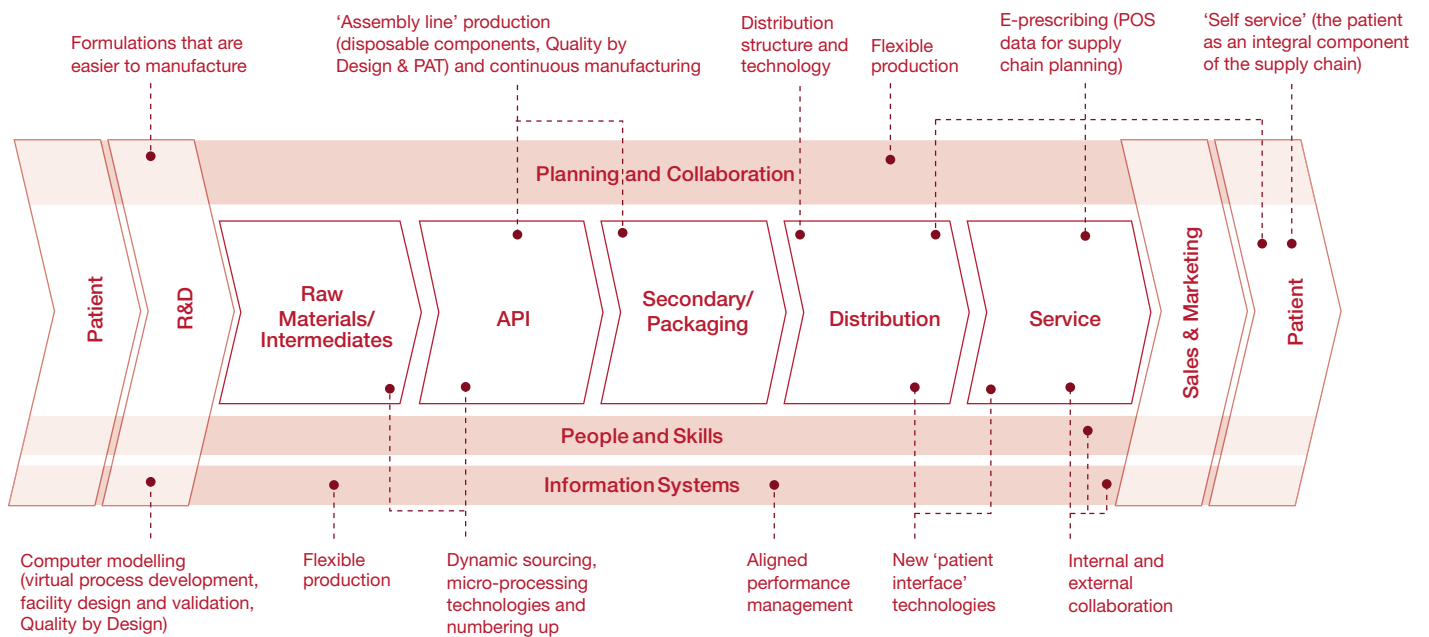
The change in the industry's remit has even more fundamental implications. Pharma companies will have to manage a vast network of service providers, as well as manufacturing and distributing their own products. They will also have to acquire a much deeper understanding of patients. In a world where outcomes count for everything, it's not molecules that create value but, rather, the ability to integrate data, products and services in a coherent business offering. Understanding this shift of emphasis from products to patient outcomes is critical; those firms that can develop and supply integrated product-service packages will be able to deliver significant benefits to every stakeholder in the healthcare value chain.

Removing the roadblocks



Timely access to various emerging technologies will help Pharma manufacture and distribute its products more efficiently. Some of these technologies will enable it to build quality into its manufacturing processes, while others will enhance its throughput or facilitate collaboration to realise economies of scale (see **Figure 5**).

Figure 5: Significant opportunities for improving the supply chain exist



Source: PwC

1. New development technologies

Formulations that are easier to manufacture

During the past 60 years, audio technology has evolved from the vinyl record to the iPod, but the way in which medicines are delivered has stayed much the same. Compressed tablets containing a mixture of active ingredients and excipients are still the most common dosage form.

However, more sophisticated drug delivery techniques will provide the means with which to create formulations that are easier to manufacture – e.g., powder in vials and liquid droplets on blank tablets.

Researchers are also working on the ‘holy grail’ of oral biologics, and industry experts believe it will eventually be possible to produce stable, pill-based versions of some proteins (see sidebar, **Biologics in a bottle**).¹⁸

Using formulations that can be more easily manufactured will enable Pharma to minimise its investment in product and process development until the later stages of the product development lifecycle, when it’s easier to estimate the potential value of new products. And the development of oral biologics will eliminate the need for cold-chain distribution of such therapies.

Biologics in a bottle

One of the main obstacles in developing oral biologics is the fact that proteins break down in the gastrointestinal tract and cease to be active. Some proteins also have a very narrow therapeutic index and must be delivered in doses too precise to be orally administered. Nevertheless, numerous companies are trying to create pill-based proteins.

Bangalore-based Biocon is testing an insulin pill in the US and India, for example, with promising preliminary results. Meanwhile, Novo Nordisk is conducting a Phase I study of an oral insulin pill formulated using Merrion Pharmaceuticals’ gastrointestinal permeation enhancement technology. Several oral biologics for the treatment of autoimmune diseases are also in the pipeline, including a new class of drugs called JAK inhibitors. One such instance is *tasocitinib*, which was developed by Pfizer and is now in Phase III trials.

Virtual process design and validation

Meanwhile, computational modelling will enable Pharma to design and validate manufacturing processes virtually, using Quality by Design (QbD) principles. In-line process monitoring via process analytical technologies (PAT) will generate the data needed to validate these models and secure regulatory approval.

The FDA has already published a draft guidance in which it proposes replacing ‘three-batch validation’ with a three-stage methodology that involves designing a suitable process, using the knowledge gained in development and scale-up; ensuring the process is capable of reproducibly manufacturing commercial batches; and validating it continuously during routine production.¹⁹ By 2020, this approach is likely to be the norm.

The conventional process of scaling up will also be replaced by ‘numbering up’ – i.e., using microreactors in parallel arrays. Numbering up has several significant advantages over traditional techniques. It dispenses with the need for costly and time-consuming studies to devise a process for scaling up chemical reactions, since the process that was used to produce a few grams of product in the laboratory is the same one that is used to synthesise larger quantities. In addition, using microreactors makes it much easier to control key parameters and thus improve yields.

2. New manufacturing technologies

Flexible production

Virtual engineering will not only accelerate the validation of new processes, it will facilitate the rapid reconfiguration of existing manufacturing lines for different products. With flexible processes and miniaturised, modular components that can be quickly connected or disconnected like pieces of ‘Lego’, it will be relatively easy to alter the order in which specific unit operations are performed. Widespread use of disposable technologies will likewise reduce changeover times (and the consumption of clean water).

Collectively, these improvements will allow pharma companies to create different supply chains for different product types and markets, manage sudden shifts in demand such as the step changes associated with live licensing and reduce their manufacturing costs. They should simultaneously help the industry fulfil its social responsibilities, including the need both to pioneer more sustainable manufacturing processes and to produce medicines the entire world can afford.

Continuous processing and automation

By 2020, most medicines will also be manufactured continuously. Process tomography and other such technologies will enable companies to capture real-time data on critical processes, develop complex multivariate models and automatically compensate for unexpected process disturbances. Process data generated during the development phase will be used to ‘teach’ process control systems to respond to process disturbances even before commercial manufacturing begins.

Meanwhile, advances in colloidal and foam systems will facilitate the micro-processing of active pharmaceutical ingredients (APIs).

Micro-containers with embedded superparamagnetic nano-particles can be treated with an alternating magnetic field to release materials encapsulated in bubbles within the material and thus converted into micro-reactors for the efficient production of thousands of individual doses of tailored biological products.²⁰

Micro-processing will even make it possible to formulate some medicines and poly-pills at the point at which they are dispensed. Several companies have already started providing pharmaceutical compounding services, one such instance being Fagron, a subsidiary of the Belgian Arseus.²¹ But, by 2020, the pharmacist will be able to ‘mix’ medicines individually on the premises, using validated formulation equipment – much as DIY stores mix paints to produce customised colours.

Transgenic production

Simulation and automation aren't the only tools to hand; transgenic engineering offers a fundamentally different way of producing many therapeutic proteins. The process involves inserting foreign genes into host animals or plants so that they express proteins they wouldn't otherwise express and then using them to 'manufacture' large quantities of these proteins.

GTC Biotherapeutics has already demonstrated the commercial viability of transgenic production techniques with its recombinant human antithrombin ATryn, which is extracted from the milk of genetically modified goats.²²

Other examples include the Netherlands-based Pharming, which uses transgenic rabbits to make the C1 inhibitor protein.²³

Transgenic production has several significant advantages over more traditional methods for producing therapeutic proteins, such as mammalian cell culture and bacterial systems. It requires substantially less capital expenditure, is easy to scale up or down in line with demand (by increasing or decreasing the size of the herd) and can be undertaken in rural environments where the infrastructure for more high-tech manufacturing techniques may not be available.

3. New distribution technologies

Just as new technologies are emerging to help pharma companies manufacture a wider and more complex range of medicines, so new technologies are emerging to help them distribute those medicines. Cloud computing will provide the information platforms they need to share data securely and economically with suppliers around the world, analyse the data very rapidly and respond to sudden changes in supply and demand, while advanced tracking technologies will enable them to monitor products from the factory gate to the patient – an increasingly important feature, as the industry manufactures more biologics with high unit values and specialist delivery requirements (see sidebar, **Fingering the fakes**).²⁴

Fingering the fakes

Various new tracking technologies are in the works. One such example is the 'bokode' – a kind of data tag that can hold far more information than a conventional barcode and be read from much further away. DNA labelling could also provide a way of fingerprinting proteins and determining where they have been manufactured, if the problems with selecting a DNA fraction that doesn't affect a protein's performance can be overcome. DNA fingerprinting has already been used to identify 'counterfeit' foods; researchers in Spain recently used a technique called forensically informative nucleotide sequencing to test nine commercial seafood samples containing shark meat and isolate those that were incorrectly labelled.

4. New patient interface technologies

New 'patient interface' technologies are likewise being developed, some of which will bring pharma companies closer to patients than ever before. One instance is the prototype chip and receiver devised by Proteus Biomedical, which records exactly when a tablet is metabolised (see sidebar, **Tablets go high-tech**).²⁵

By 2020, there will be many such patient interface technologies on the market and the information they generate will help patients manage their health more effectively, as well as allowing healthcare providers to monitor their compliance in real time. But they will also provide pharma companies with information they can use both to design more robust products and services, and to develop more accurate production and distribution plans.

Tablets go high-tech

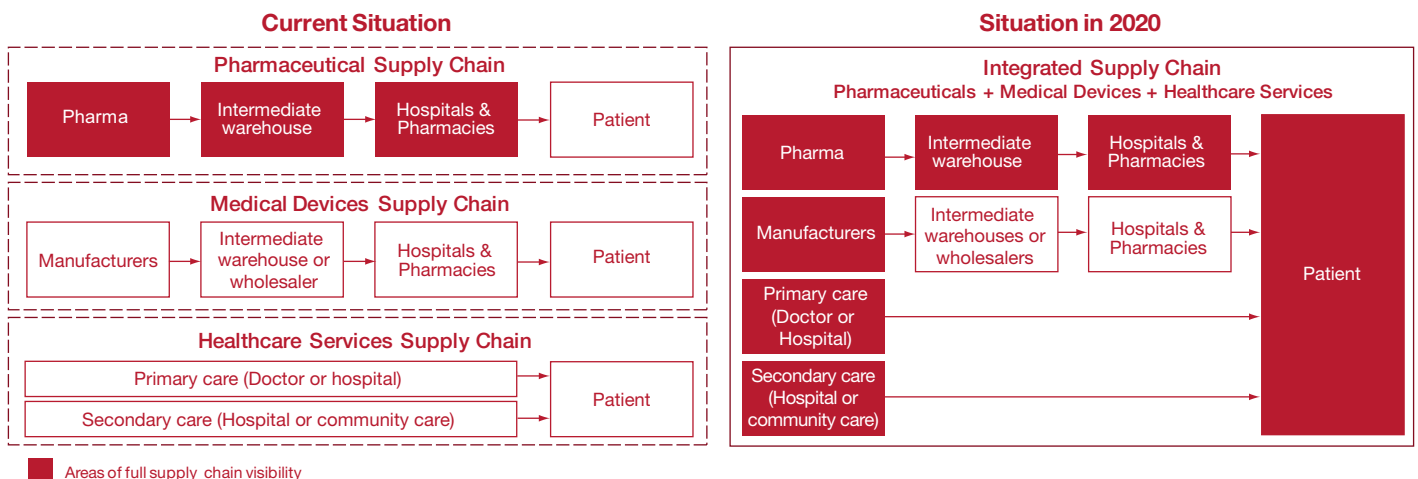
Proteus Biomedical has developed a miniature digestible chip which can be attached to a conventional medicine and used to monitor patient compliance. The chip sends a signal to a sensing device worn on the skin, which records the time and date at which the medicine has been ingested as well as measuring certain vital signs. The information is then forwarded, via wireless technology, to the patient's doctor. Novartis has previously tested the chip on 20 patients who are taking its blood pressure treatment Diovan, with impressive results; the company reported that compliance could be improved from 30% to 80% in six months.

5. Greater collaboration

Technology isn't the only answer to Pharma's problems, though; greater collaboration with the other parties involved in healthcare provision will also help the industry become more efficient.

At present, there are three distinct supply chains for designing, manufacturing and distributing pharmaceuticals; designing, manufacturing and distributing medical devices; and providing healthcare services (including laboratory work and pathology). Integrating these supply chains so that all the upstream and downstream partners can see the full picture would enable them to plan ahead more accurately and manage demand more cost-effectively (see **Figure 6**).

Figure 6: By 2020, the pharmaceuticals, medical devices and healthcare services supply chains will be fully integrated

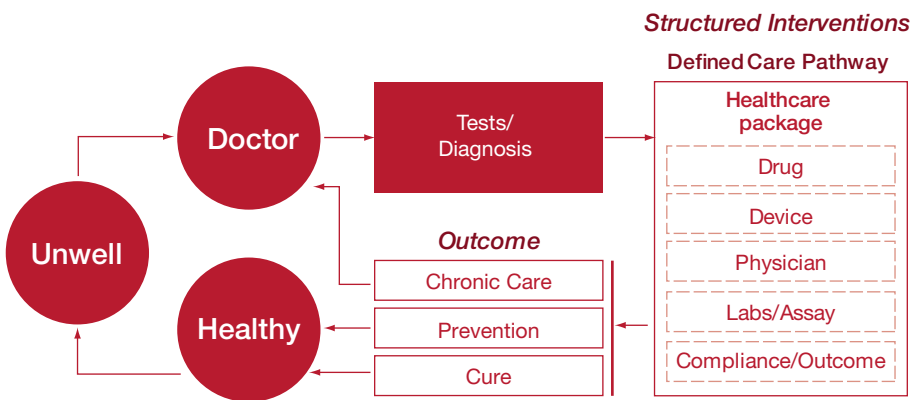


Source: PwC

Creating an integrated healthcare products and services supply chain would not be easy. But one of the main tools used to manage healthcare quality could prove invaluable here. Healthcare providers in many parts of the world are developing defined care pathways to standardise the treatment of patients with the same illnesses and thus improve outcomes. This will ultimately result in the creation of defined healthcare packages for each care pathway.

With access to each roadmap for each illness, and data on the incidence of each illness in a given population, pharma companies and medical device manufacturers will be able to predict demand for their products much more accurately. They will also be able to define a supply pathway for each product, depending on whether it's a one-off treatment (such as a prophylactic vaccine, gene therapy or anti-infective) or a recurring treatment for a chronic condition, which must be supplied on an ongoing basis (see **Figure 7**).

Figure 7: The development of care pathways will provide greater supply chain predictability



Source: PwC

There is potential for collaboration in other ways, too. Most pharma companies at the moment manufacture and distribute their own products, for example, but this reduces asset utilisation rates and drives up distribution costs, as well as causing unnecessary environmental damage. Conversely, sharing manufacturing and distribution resources would be much more economical. A few pharma companies have started experimenting with 'shared services', primarily to support joint product development initiatives. However, the vast majority of companies still build, own and operate their own supply chain infrastructure.

Some companies may choose to establish joint ventures, while others turn to third parties. Abbott Laboratories and Boehringer Ingelheim already manufacture for other organisations, for example.²⁶ And the contract manufacturing sector is expanding very rapidly. In fact, market research firm BCC Research estimates that the bulk- and dosage-form drugs segment will be worth about \$73 billion by 2014, more than double the \$36 billion it was worth in 2007.²⁷



Collaborating to cut the kilometres

In September 2009, confectionery giants Nestlé and Mars joined forces with a leading British supermarket chain to synchronise deliveries of their products over the busy Christmas period and reduce their environmental footprint. The two manufacturers worked closely together to coordinate their deliveries to three regional distribution centres so that any part load order that either company received could be combined in one truck load. By dint of collaborating, they eliminated over 12,000 kilometres of duplicate journeys.

Experience in other industries has also demonstrated the benefits of managing distribution collectively (see sidebar, **Collaborating to cut the kilometres**).²⁸ And increasing demand for biologics has stimulated the development of specialist logistics providers capable of handling very sensitive pharmaceutical freight. Many provide specialised service where each shipment is transported in temperature – and humidity – controlled conditions, monitored from a dedicated call centre using web-based tracking and reporting, and delivered directly to the customer's door.²⁹

Moreover, some of the most sophisticated third-party logistics (3PL) providers – i.e., companies that offer freight management and warehousing – are expanding into supply chain management and coordination services. And it is arguably these fourth-party logistics (4PL) providers, as they are known, that can deliver the greatest improvements. When telecommunications equipment manufacturer Alcatel turned to a 4PL to manage the supply chain for its e-business networking division, for example, its supply chain costs fell from 5.8% to 5.1% of revenues within two years in that division.³⁰

In other words, the contract manufacturing and logistics industries are both maturing and, by 2020, some of the biggest providers will offer integrated supply chain services. This will enable pharma companies to share resources and capitalise on economies of scale throughout the value chain.

Choosing among the options

We've discussed why the vast majority of pharma companies will have to build supply chains with new manufacturing, distribution and service-management techniques, and some of the developments that can help them. But what route should they take?

There are two options for companies focusing on specialist therapies and treatments for orphan diseases, and two options for companies focusing on mass-market medicines. We believe that most companies will fall into one of these two categories by 2020, although the very largest companies may cover both ends of the spectrum. But they will still have to develop different supply chains for different product types.

More specifically, companies that concentrate on specialist therapies can either exit from manufacturing and operate virtual supply chains or become service innovators.

Companies that concentrate on mass-market medicines, including generics and over-the-counter (OTC) products, can either become low-cost manufacturers or build supply chains that service other organisations and create a profit in their own right (see **Figure 8**).

Companies with a broad range of products that present different characteristics and therefore supply chain needs, will in the future need to segment their supply chain operation, aligning to the unique demands of the product group. Pharma companies that operate more than one supply chain option will increase with the breadth and demand of the portfolio.

Figure 8: Four options exist for restructuring the pharmaceutical supply chain

Operations Strategy			
Specialist Therapies		Mass-Market Medicines	
Virtual Manufacturer	Service Innovator	Low-Cost Provider	Profit Centre
Create a virtual network of integrated supply partners	Build a service-oriented supply chain to enhance brands and differentiate company from its competitors	Build a reliable, 'no-frills' supply chain to deliver products as economically as possible	Combine agile, economic manufacturing and distribution with the provision of satellite services to generate profits

Source: PwC

Recommendations for becoming a virtual manufacturer

Our experience suggests that there are several key steps a would-be virtual manufacturer should take. It should start by defining what it is and does, including its business strategy, aspirations and corporate culture. Then it should identify the financial and technical demands its portfolio presents, and how those demands are likely to change over time. Once it's looked in the mirror and analysed its requirements, it can crunch the numbers, with a detailed study of its internal capabilities, product flows and costs, and compare its own capabilities and costs with those of potential suppliers.

Any company planning to become a virtual manufacturer should also hire good negotiators, because it's the deal – not the science – that will ultimately determine whether it succeeds. So it needs people who can forge strong commercial contracts. And it should make sure it retains enough know-how both to evaluate its suppliers properly and to track their performance, including any changes in the materials suppliers and processes they use and any problems maintaining quality control or yield rates.

After that, the company can concentrate on choosing the contractors it wants to work with, and here the secret is to be selective. Focusing on a small set of contractors and working closely with them during the tender process ensures they have a clear grasp of the company's business, and the complexities of the products or processes that are being outsourced. But it's also essential to maintain a close relationship with those suppliers after they've been appointed. Lifecycle management of contracts is crucial in realising value and minimising contract 'leakage' through off-contract buying or poorly aligned service levels.

1. The virtual manufacturer

The first option for companies making specialist therapies is to outsource the entire supply chain from production of the earliest clinical batches to full-scale manufacturing, packaging and distribution, and become virtual manufacturers. This is very different from engaging in the sort of tactical outsourcing most pharma companies now employ currently. Becoming a virtual manufacturer isn't a short-term fix to address cash, capacity or capability constraints but, rather, a deliberate strategy. And executing that strategy successfully involves building a network of fully integrated supply partners.

A number of small firms have already taken the virtual route, but several large companies have recently announced plans to outsource a bigger share of their manufacturing. AstraZeneca intends to outsource all its API production over the next five to seven years, for example, while Bristol-Myers Squibb, GlaxoSmithKline, Merck and Pfizer aim to outsource as much as 40% of their API needs.³¹

The business case for virtualisation is clear. It enables a company to shift to a flexible cost base, reduce the risks associated with investing in new assets and access new technologies and skills. It also helps it align its supply chain network with its demand forecasts, transfer the risk of primary and back-up supply to a third party and drive costs down by switching products and processes between competing suppliers in its network.

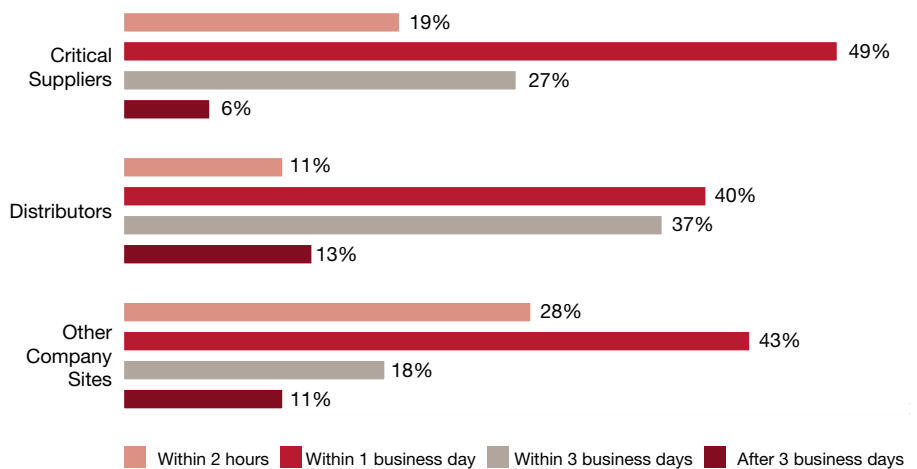
However, despite these advantages, no Big Pharma company has virtualised its whole network yet. Concerns about the calibre of the contract manufacturing sector, supply integrity, quality and compliance persist. In one recent survey, for example, 91% of the firms that relied on outsourcing reported experiencing a 'significant incident' as a result of quality problems or delays, compared with only 59% of those that performed most of their manufacturing in-house.³²

The consolidation of the contract manufacturing sector will alleviate some of these difficulties. A small cadre of global players will replace the multitude of local providers that currently exist. The evolution of the logistics industry will likewise result in the emergence of strong 4PLs capable of distributing healthcare packages directly to patients or their healthcare providers efficiently and economically. But any company that decides to operate a virtual supply chain will still have to maintain sufficient in-house expertise to choose the right partners and monitor them constantly. Baxter has first-hand experience of a serious breach in the integrity of its supply chain, for example. In February 2008, two Chinese plants were found responsible for producing contaminated supplies of chondroitin sulphate, the raw material used to make its blood thinner Heparin, and Baxter is now facing a spate of law suits.³³

In order to manage the risks associated with collaboration, virtual manufacturers will need to ensure they have access to real-time data from every stakeholder in their supply chains. At present, most pharma companies rely on periodic audits, but these only produce snapshots in time. And most companies can't get vital supply-chain data very rapidly. In one recent study, only a small percentage of respondents said they could get information from critical suppliers and distributors within two hours. Indeed, a number struggled to get the information within three days (see **Figure 9**).³⁴

Some of these difficulties can be resolved by using interoperable systems and common practices, requiring suppliers to provide a complete history for every batch of raw materials or components they produce and replacing periodic audits with constant surveillance. But any company that takes the virtual manufacturing route will also have to encourage its suppliers to collaborate in developing a better understanding of key parameters and implementing process controls to produce greater supply chain visibility. In effect, it will need to treat its suppliers as extensions of itself, rather than as separate manufacturing and distribution islands.

Figure 9: Most pharma companies struggle to get supply chain data promptly from critical suppliers, distributors and other company sites



Source: Axendia

Recommendations for becoming a service innovator

Becoming a service innovator entails developing an intimate understanding of patients, by linking up with patient groups, participating in online patient communities and social networks (e.g., PatientsLikeMe) and giving patients a forum in which to provide feedback. Any company that wants to take the service innovation route should also analyse the care pathway for every disease for which it has medicines, including the clinical and economic implications of different forms of intervention, since diet, exercise, compliance support and counselling also play a role in managing many illnesses.

Thereafter, the company should aim to get as close as possible to its customers. In other words, it should invest as much and as passionately in understanding the current and future needs of healthcare providers as it's traditionally invested in R&D. It should also look for partners – be they contract manufacturers, logistics companies, hospitals, clinics, data analysis firms, technology suppliers or lifestyle service providers – with a similar corporate culture and ethos.

The next step is to start building networks for patients with different diseases. That's partly a process of negotiation; the participants in each network will need to agree on their goals, as well as defining what they'll do to realise those goals and how they'll be rewarded for their efforts. But it's also essential to create a common supporting infrastructure, robust performance indicators, proper governance structure and clear audit trail.

And it's important not to underestimate the cultural adjustment that's needed. The task of the service provider is to commission and manage a huge network of contractors around the globe, and ensure they provide a truly integrated product-service offering. That's a very different job from manufacturing and distributing its own products.

2. The service innovator

Alternatively, companies making specialist therapies can become service innovators – i.e., build supply chains that are capable both of manufacturing and distributing complex treatments, and of commissioning and managing a multitude of suppliers to provide supporting health management services. German healthcare group Fresenius has already expanded into services very successfully; it's now the world's leading provider of dialysis machines and dialysis care.³⁵ Other companies, such as Baxter and Novo Nordisk, are adopting a similar approach.³⁶

However, becoming a service innovator isn't easy. Any company that chooses this option will have to make major cultural changes. It will, for example, have to understand its role in every care pathway and concentrate on helping patients manage the disease lifecycle, as distinct from trying to stimulate demand for its products. And it will have to look at the supply chain through the eyes of the patient as the ultimate customer.

It will also have to restructure its asset base and invest in new capabilities, both internal and external. It will have to build a supply chain that's sufficiently mature to manage a vast network of suppliers and yet sufficiently nimble to respond rapidly to the demands of numerous different customers. And it will have to develop a new financial structure. Much of the economic value it creates will depend on the activities it performs in its local markets, rather than the medicines that constitute its underlying intellectual property – a change that carries huge tax implications.³⁷

That said, the provision of integrated product-service packages has many advantages. It enables a company to differentiate its offerings, reach new markets and create new sources of revenue. It also creates opportunities to enhance the customer relationship and improve customer loyalty, because services are more dependent on skill and more difficult to imitate than products.

3. The low-cost provider

Mass-market manufacturers, including generics producers, likewise have two options, the first being to borrow from best practice in other sectors and become a low-cost provider. The consumer products industry has, for example, developed various lean manufacturing techniques from which Pharma can learn.

Indeed, Johnson & Johnson has already done so. It's no accident that the firm is the only pharma company to feature routinely on AMR Research's annual list of the organisations with leading supply chains.³⁸ Johnson & Johnson makes and distributes a wide range of OTC medicines and beauty and baby care products. It has drawn on this expertise in managing the supply chain for its prescription pharmaceuticals business.

One of the prerequisites for becoming a low-cost provider is a clear understanding of a company's operating costs, so that it can allocate those costs accurately among the different products and services in its portfolio. It's also essential to ensure that the cost of each product or service corresponds with the 'value' it provides. The days when a new medicine could command a premium price merely because it was new are well and truly over, as healthcare policy-makers and payers compare the pharmacoeconomic performance of different therapies.

However, most pharma companies don't really understand their product costs. There are many reasons for this, including the fact that they incur significant hidden R&D and manufacturing costs (e.g., depreciation associated with idle equipment and expenditure on investigations or re-work). The systems they use to allocate overhead and management costs are also based on what's easy to measure, which isn't always what's right. So they don't fully account for such costs at product level – and that, in turn, results in invisible cross-subsidies.

In addition to acquiring a detailed picture of its operating costs, any company that wants to be a low-cost provider will have to adopt the principles of 'design for supply' – i.e., optimising the fit between a product's design and the efficiency with which it can be made. Again, this is something many firms are likely to find difficult.

Most pharma companies at the moment develop new products and then scale up the supply chains they've established for manufacturing and distributing clinical trial supplies. But this locks in expenses that would otherwise be unnecessary and creates problems further down the line. Conversely, if the development and manufacturing functions work closely together, the manufacturing function can advise on any issues that have implications for production and develop a supply chain as early as possible.

In fact, a lot of the basic data needed to industrialise a new medicine is ascertained in discovery and early clinical studies. Information about how a drug candidate behaves in the body is essential in establishing its safety and efficacy in early human trials, for example, but it's equally important in designing the route of administration, dosage form and processes used to manufacture the product. Information about a product's likely cost of goods sold (COGS) – and thus its commercial viability – should also play a role in determining the business case for any development programme.

Recommendations for becoming a low-cost provider

How do you become a low-cost provider? The first thing to do is to turn on the spotlight. A company can only allocate a fair share of its costs to each product or service in its portfolio when it's analysed its end-to-end supply chain and compiled an accurate picture of all its costs. And only then can it accurately forecast the profit it expects each product or service to create throughout its lifecycle.

The next task is to integrate the product development and manufacturing functions, and start cutting the fat. The design of a product, the materials and components it uses and the technology platforms that are used to produce it all have a significant impact on its manufacturing costs, so it's vital to get early input from plant management. It's also important to design operational procedures that comply with the regulatory requirements while supporting continuous improvement and to define work flows for each product or service in order to uncover any opportunities for reducing cycle times and costs, or improving compliance.

Of course, the best way of sourcing the materials and services that are needed may change over time. The low-cost provider will as a result need to review its sourcing decisions on a regular basis. It will also need to adopt a different management and workforce philosophy, and allocate cost centres to the shop floor to facilitate pragmatic, cost-effective decision making.

Recommendations for becoming a profit-centred supply chain

The first step in building a profit-centred supply chain is to check out the competition. A company that takes this path should start by measuring itself against its rivals, identifying its unique capabilities and focusing on the features that set it apart from the crowd. It should also analyse all its supply chain costs, so that it knows how much to charge internal and external customers for every product it manufactures.

Once management has a clear sense of the strengths and weaknesses of the supply chain, together with the cost base, it can begin promoting the business – but selling a service is very different from providing that service for a ‘captive’ market. The most successful contract manufacturers familiarise themselves with the expectations, attitudes and terminology of their customers, and position their business as an external extension of their customers’ organisations. They also work hard to allay any fears that contract services are inferior, recognising that customers want a trusted partner who’ll manage the manufacturing of their products as responsibly as they would manage it themselves.

Turning the supply chain from a cost centre into a profit centre entails adopting a fundamentally different mindset then, but it requires financial investment, too. If it’s to attract new customers in an intensely competitive environment, the profit-centred supply chain needs to invest in improving its manufacturing base with better, more flexible facilities, higher levels of automation and Quality by Design engineering. It also needs to establish a robust knowledge management system so that it can use the data it collects – including insights gained from manufacturing other products – to continuously improve its performance. And it needs to look for opportunities to add value (e.g., by offering new services or using data more effectively).

4. The profit centre

Alternatively, mass-market manufacturers can combine agile, economic manufacturing and distribution with the provision of satellite services for patients – and do this as a service for both internal and external customers. Turning the supply chain from a cost centre into a profit centre has several advantages, not least that it encourages greater commercial discipline and makes additional cash to fund the development of new skills.

A number of pharma companies are restructuring their R&D functions to promote innovation and splitting their development functions into separate therapeutic franchises with the power to make sourcing decisions themselves. So the viability of their supply chains already hinges on the ability to satisfy internal customers by providing the technical capabilities, geographic reach and customer service they require at competitive prices.

However, the journey from cost centre to profit centre is a very difficult one indeed. It requires a flexible asset base to support multiple methods of manufacturing; substantial investment in infrastructure and management resources to build a global network of service providers; and robust demand and capacity forecasting. It also entails the development of clearly defined service levels and rigorous governance to ensure that internal and external customers are treated fairly, since they must now compete for finite resources.

Moreover, any supply chain management team that takes this route shouldn’t simply assume it will retain its internal customers. On the contrary, it will have to compete on an equal footing with external manufacturers – and the competition could be fierce. Several in-house manufacturing functions have ended up in head-to-head battles with contract manufacturers for manufacturing volume.

If an in-house provider loses much of its internal custom to external contract manufacturers, this could obviously create a problem with stranded costs. The parent organisation might then permit the in-house provider to charge internal customers a small premium. But the board of any company in which this was a clear trend would soon be questioning whether it should be in the manufacturing business at all.

Different skills for different routes

The four models we've described all entail a much more sophisticated approach to the development and introduction of new products or services, then, but thereafter they raise different challenges and require different forms of expertise (see **Table 2**). The virtual manufacturer needs first-rate planning and collaboration skills to coordinate a huge array of suppliers. The service innovator also needs superb organisational skills, together with a massive distribution network, to orchestrate the delivery of complex product-service offerings directly to patients.

The low-cost provider needs excellent manufacturing skills to make its assets work as efficiently as possible. And the profit centre needs all-round proficiency to survive as a standalone business.

But whichever route – or routes – an individual company takes, it will require conscious planning. In other words, the industry can't continue to rely on reactive supply chain management.

Table 2: Each option demands a different set of core skills

Key Skills Needed	Virtual Manufacturer	Service Innovator	Low-Cost Provider	Profit Centre
Collaborative planning and coordination	✓	✓		✓
New product development and innovation	✓	✓	✓	✓
Active pharmaceutical ingredient manufacturing			✓	✓
Secondary manufacturing and packaging			✓	✓
Distribution to hospitals and pharmacies		✓		✓
Direct-to-patient delivery		✓		✓

Source: PwC



Managing the movement of information

The options we've outlined have several overarching implications. One of them is the increasing importance of information – and hence the need for robust information management systems. If Pharma is to manufacture and distribute pharmaceuticals on demand, and oversee the provision of health management services for patients with specific diseases, it will require accurate information about which products and services patients want, and when and where they want them.

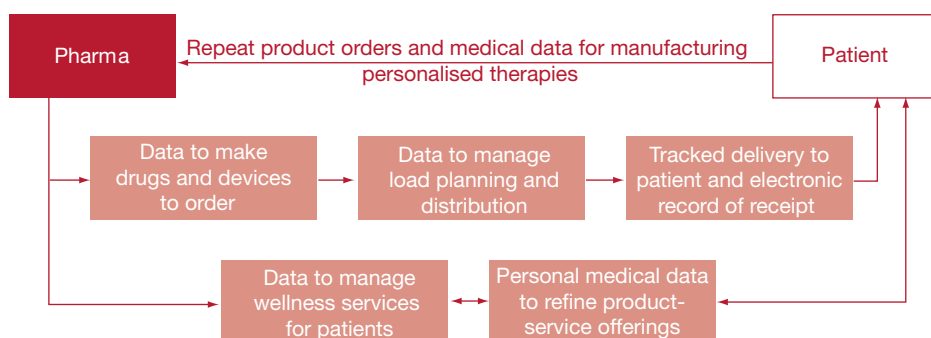
The more customised the offering, the more detailed the data the industry will need. In order to make individually formulated therapies, for example, it will require information about the age, gender, weight and genetic profile of every patient for whom these therapies are intended – information that's very sensitive indeed.

Widespread use of e-prescriptions will provide the point-of-sale data Pharma needs to make and distribute medicines to order. Outcomes data will likewise enable it to refine its offerings. It will be able to develop different formulations, delivery mechanisms and product labels for different patient cohorts. It will also be able to take a more proactive role in helping individual patients manage their health, with follow-up tests, long-term monitoring and the like, where appropriate.

But if the industry is to get access to this data, it will have to establish reliable information management systems with appropriate security and privacy measures. It will have to satisfy some formidable regulatory hurdles, too. Healthcare providers in the US are required to follow stringent rules for protecting information that can be used to identify a patient either directly or indirectly, for example – and there's no reason to suppose pharma companies would be subject to less rigorous terms.³⁹ Managing and extracting meaning from the reverse flow of information will also present a major challenge, one that requires extensive use of sophisticated analytical tools.

Moreover, Pharma will not only need access to much more – and more confidential – information, it will need to share more information with more organisations. It will, for instance, have to share data on orders and product flows with contract manufacturers, data on load planning with distributors and data on patients' health with service providers (see **Figure 10**). In short, it will have to control the management and transfer of information as carefully as it controls the physical movement of its products.

Figure 10: By 2020, the management of information will be as important as the management of products



Source: PwC

Restructuring the asset base

A second key implication of the vision we've articulated is that most pharma companies will have to restructure their asset bases. The contract manufacturing industry will probably pick up some of the plant and equipment they no longer want. Between 2007 and 2009, for example, contract manufacturers acquired 15 factories originally owned by Big Pharma companies (see **Table 3**). But this is not a guaranteed exit route. Many contract manufacturers are becoming more wary, after several spectacular failures. Keata Pharma, which initially acquired Pfizer's factory in Amprior, Ontario, subsequently went bankrupt, for example.⁴⁰ Those that want to produce specialist therapies will also be more interested in building modern facilities than in snapping up old plans.

The nature and location of the redundant assets individual pharma companies own, together with the level of demand for specialist plant and equipment, will obviously have a bearing on how easily, and for how much, they can dispose of these assets. However, some companies could incur considerable costs in the form of one-off charges or accelerated depreciation. Any firm that decides to restructure its asset base will also need to evaluate the financial impact of changing its business model, including the tax implications.

Table 3: Contract manufacturers have picked up Big Pharma's old plant

<i>Seller</i>	<i>Buyer</i>	<i>Site Location</i>
2007		
Abbott Laboratories	Aesica Pharmaceuticals	Queenborough, England
AstraZeneca	Corden Pharma	Plankstadt, Germany
Abbott Laboratories	Famar Healthcare Services	Saint Rémy, France
Boehringer Ingelheim	Haupt Pharma	Toride, Japan
2008		
Pfizer	Actavis	Nerviano, Italy
Wyeth	Akrimax Pharmaceuticals	Rouses Point, New York
Pfizer ¹	Pillar5 Pharma	Arnrior, Ontario
2009		
AstraZeneca	Corden Pharma	Caponago, Italy
Eli Lilly	Evonik Industries	Tippecanoe, Indiana
Pfizer	Haupt Pharma	Latina, Italy
Pfizer	Hovione	Cork, Ireland
AstraZeneca	Minakem	Dunkirk, France
GlaxoSmithKline ²	Phoenix Chemicals	Annan, Scotland
Bristol-Myers Squibb	Sigma Pharmaceuticals	Noble Park, Australia

Notes: 1 Original owner; acquired from Keata Pharma.

2 Original owner; acquired from Shasun Pharma Solutions.

Source: Chemical & Engineering News

Conclusion

So, what's the bottom line? The sort of medicines Pharma makes is changing and the financial pressures it faces are increasing. Specialist therapies can't generate the same economies of scale as mass manufacturing. Cash-strapped healthcare payers are also scrutinising outcomes much more rigorously and exploring new reimbursement mechanisms, while healthcare providers are developing care pathways to standardise and improve the treatment of disease.

The supply chain is simultaneously becoming more important, as the medicines the industry makes get more complex and the opportunities for generating value from pure product offerings diminish. Biologics and personalised treatments are more difficult to manufacture and distribute than small molecules, and services will comprise a greater share of the economic value many companies create.

We believe that, by 2020, most pharma companies will therefore have different supply chains for different product types. The precise routes they pursue will vary, depending on their portfolios, pipelines and expertise. But whichever road they take, they will need to get closer to patients, since reliable demand data is a prerequisite for making to order and intimate personal details are a prerequisite for making customised therapies.

They will also have to provide a wide range of services to help patients comply with their medical regimens and monitor the effectiveness of their interventions – activities that have traditionally been the province of healthcare providers and payers. And they will have to ensure the healthcare packages they develop are fully integrated with the care pathways for every disease they address.

The most successful pharma companies will be those that seize the initiative and start building agile, efficient supply chains – either virtual or physical – to support this vision. They will be those that use their supply chains to differentiate their brands and 'go the final mile', those that recognise information is the currency of the future.



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