



Convergence of Health and Pharma

As the biggest industry sector in most European economies, healthcare is already given a big chunk of the gross domestic product (GDP). This portion is expected to become even bigger and have a huge impact on employment, the opportunities to grow businesses and economies in general.

There are challenges to be addressed, however. Globally, all health economies face similar challenges - shortage of clinicians, quality, costs, easy and uniform access, regulatory compliance and safety. In addition, new consumer technologies have led to fresh challenges, promoting greater patient power.

Action is required at all levels to change the way healthcare is delivered. New healthcare IT systems must offer software that supports the core medical processes, hardware that allows easy access to information at the point of care, and standards that make the integration of different systems easier.

Governments' financial incentives and regulations will make automation in healthcare practices a must-do. There's an increasing need for hospitals to attain cost efficiencies and provide evidence of effective use of IT in healthcare practices. These will drive market growth.

What's the road-block, then?

The deepening financial crisis is limiting governments' ability to pay for healthcare. This is a situation that in turn, presents one of the biggest challenges to the pharmaceuticals industry. For it is highly likely under these circumstances that governments would introduce cost containment measures such as a freeze on new drug reimbursement and so on.





HEALTHCARE SPECIFIC CHALLENGES

Healthcare faces many significant challenges in the near future. In the first paper of this series, Healthcare Challenges and Trends, we present these challenges in greater depth.

Let's recapture some key points, such as:

Cost

Factors such as ageing populations and insufficient public funding are affecting both receivers and providers of healthcare.

When it comes to funding, the number (and size) of buyers of IT varies from country to country. It does not necessarily depend on the size of the country but rather on the structure of the healthcare system.

Looking at buying patterns, we find that investment in IT healthcare purchases is shifting towards a more coordinated, joint model. Here hospital chains within a region or doctors' associations identify a set of 'preferred suppliers'.

Demographics

Europe is steadily greying. In the face of unprecedented demographic changes (an ageing population, low birth rates, changing family structures and migration), it is important, both at the European Union (EU) and national level, to review and adapt existing policies, and ensure sustainable public finances to guarantee adequate pensions, healthcare and long-term care.

The European Commission predicts that healthcare spending will rise by two percent of GDP by 2050. This will also be in part due to a change in expectations rather than just demographics. What is significant in the EU is that there is a rather steady increase in life expectancy but there is no parallel increase in healthier lifestyles.

Some EU states, particularly Nordic countries, but also France, Germany, Austria and UK have moved towards a long-term view on health care, including focusing on illness prevention and providing community care. It emphasises health promotion and prevention of illness, suggesting that tackling obesity, promoting exercise, and disease screening will have its economic benefits in the long run.

Quality

Healthcare systems are under close scrutiny by society.

Good quality healthcare is one of the most important factors in how individuals perceive their quality of life. In most countries it is a major political issue and in some cases, the healthcare delivery organisation is a part of the national identity.

The quality of care is increasingly important – as patients begin to exercise their right to choose how and with whom they engage for their healthcare. They demand transparency of data and care processes. As a consequence, healthcare organisations will need to focus on how quality outcomes can be published in a meaningful way for patients. Patient safety is the major focus of patient advocacy groups and healthcare leaders. They will enforce deeper investigations of medication errors, hospital acquired infections, wrong site surgery or pressure sores, like never before.

This whitepaper, part of a series from CGI, discusses the challenges faced by healthcare and pharma, the close association between the two and the need for them to converge to find common workable solutions that would benefit both.





PHARMA-SPECIFIC CHALLENGES

Pharma 1.0, the traditional business model that relies on high value blockbuster drugs, is coming to an end. IMS Health forecast a maximum CAGR of 6%, some way below the usual level. It's a time when blockbuster drugs are few and far between and generics are competing for a greater share of the market. What does all this imply for Pharma?

Demonstrating benefits and cost-effectiveness is in demand

The cost of developing new drugs is increasing. From the scientifically intense discovery of new compounds, early stage development, pre-license clinical trials to data capture, submission to regulatory bodies and even late stage development – every related activity is proving more expensive. To add to the pressure, regulatory bodies insist on 'seeing' the benefits and cost-effectiveness, more than ever.

Reducing spend at the national level is in focus

Health economies and insurance companies, themselves under financial pressure, are driving cost savings in their drugs bills.

Faced with budget pressures and evidence of cost inefficiency, all OECD countries have introduced healthcare reforms or are planning to do so in the near future. While the direction of reforms has not always been the same in all countries, these reforms aim to provide better means of dealing with such issues as the evaluation of new technologies, ageing populations, pharmaceuticals, and cost-sharing by health consumers.

With continued growth in other components of health spending, pharmaceutical reforms are directed at restraining overall spending. Pharmaceutical products are restricted through the use of 'negative' and 'positive' lists. Prices or profits in this sector have been tightly controlled, incentives to use cheaper generic products increased, and attempts made to change the prescribing practices of doctors (e.g. peer comparisons).

Pipeline assets under scrutiny - seeking to address unmet needs

What are the assets in the pipeline and how are they faring? Under the current economic circumstances, pharmaceutical companies are taking a close look at these assets with a critical eye. They are also looking at the decreasing productivity of research and development.

They are all arriving at the same conclusion: only by building an ecosystem based on collaboration with competitors, the healthcare provider community, and an increasingly well-informed society, can they continue to drive good returns for their shareholders.

Ernst & Young call the new era Pharma 3.0, the health outcome ecosystem¹. To reach it, pharmaceutical companies need advanced capabilities to:

- connect and share information for competitive advantage; information is the currency of Pharma 3.0
- drive business model innovation through radical collaboration
- operate multiple business models opportunities as well?

1 Ernst & Young. Progressions: Building Pharma 3.0. Global pharmaceutical industry report 2011.



WHY CONVERGE?

Traditionally, the healthcare and pharmaceutical industries have followed a conventional supplier-consumer relationship. However, both industries face the same core challenge: how to deliver better health outcomes at lower cost.

At the drug discovery level

Working together on pre-license activities – the sensible way forward Pharmaceutical organisations want to understand the causes of diseases and to develop compounds that can be tested in the lab for their effectiveness in treating a disease. Once these targets are identified by the research and development team, they are usually passed to a team responsible for turning these targets into medicines that can be submitted for clinical trials. Once the complex clinical trials process is completed, the medicines can be submitted for regulatory approval, and if granted, sold to healthcare providers. End to end, this process of discovering and developing a new molecular entity (NME) takes in average 13.5 years, and (capitalized) costs of \$1.8 billion². The number of targets that hit the market as medicines is a small percentage that is fast diminishing. During target identification, scientists work to understand the cause of disease by looking at pathways, for example, of how the disease begins and spreads. They investigate gene expression³, protein mechanisms and many other highly complex aspects of the causes of disease. Advances in genomics⁴, proteonomics⁵ and protein modelling are transforming the discovery process. At the same time, the sheer volume and structure of the data is challenging the leaders in the field to develop shared ontologies⁶ to express the meaning of the data.

It is in this area of intensive scientific research that collaboration and transformative partnerships between the pharmaceutical companies themselves can take place. A common ontology allows a shared understanding of the semantics of the original data. The cloud offers to host large volumes of complex data in collaborative platform and at relatively low cost. This is an area where CGI and our partner ecosystem have a definite, key role to play.

At the end of the discovery process, the object is to turn target compounds into medicines. This is a costly part of the process, and the later a target falls out of the process, the greater the loss incurred by the company. It is therefore vital that those medicines entering the later-stage clinical trials, with live patients, are targeted at a narrow, highly specific cohort⁷.

² Paul SM, Mytelka DS, Dunwiddie CT. How to improve R&D productivity: the pharmaceutical industry's grand challenge. Nature Reviews Drug Discovery 2010; 9: 203-214 http://www.imshealth.com/deployedfiles/ims/Global/Content/Insights/IMS%20Institute%20for%20He althcare%20Informatics/Global_Use_of_Medicines_Report.pdf (Executive Summary).

³ Gene expression is the process by which information from a gene is used in the synthesis of a functional gene product.

⁴ The study of genes and their function.

⁵ Proteomics is the large-scale study of proteins, particularly their structures and functions.

⁶ An ontology is structured hierarchy of knowledge.

⁷ In clinical trials: A group of persons with a common characteristic, set of characteristics or exposure, who are followed for the incidence of new diseases or events, as in a cohort for a prospective study.



Post-marketing surveillance and translational research

All drugs have to be monitored even after they are licensed. Now it is slow, uncertain and expensive. In addition, while it may not be traditionally included in pharma R&D phases, it is evident that phase V of translational analysis and evaluation is increasing in importance for both society and the pharma industry.

Access to adverse reaction reporting in primary and secondary care can be made automatic, continuous and accurate. These streams of rich information also provide an opportunity to analyse the effectiveness that compounds currently in the market may have for other diseases. With data already in electronic form we can easily do it. Obviously those results won't be enough for officials to justify a claim for new indication, but it can tell us, where to look, and how. Many older drugs may have uses we are not at all aware of. An extension in indication of an 'old' drug would be an optimal scenario for patients, healthcare and pharma since that way it would get a new 'life' without the need to undertake costly studies for safety.

We can help you. From early stage development, to data capture, submission to regulatory bodies and even late stage development. In the process you'll not only reduce costs but will stay on top of compliance demands.

At the patient level

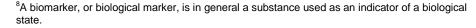
Fidelity of patient cohorts - needs everyone to be involved

Effective drugs coming to market sooner at lower cost would benefit everyone. Healthcare providers are therefore keen to ensure the patients enrolled onto clinical trials are the best possible candidates for the drug under test.

Healthcare providers have a wealth of information within their 'walls' that could help pharmaceutical companies improve the fidelity of their patient cohorts for trials. More often than before, academic hospitals are carrying out genetic sequencing for their own research purposes, using the latest machines from Illumina and others. Many health authorities have substantial, longitudinal patient records collected over years. These may include records for members of the same family. And finally, some organisations are starting to collect phenotype (or lifestyle) data as part of various Citizen Scientist initiatives. This treasure trove of information presents a great opportunity to improve the quality of the cohort of patients invited onto clinical trials, and bring effective drugs to market quicker and more efficiently. We believe this is an opportunity for everyone involved in the process – pharma companies, healthcare providers and for us, their IT partner.

During clinical trials, issues associated with compliance management are common. For instance patients may stop taking the medicines. It could be because they felt the drug does not have a positive effect on their condition, they experienced side-effects or they simply lost interest. Advances in mobile technology provide the industry interesting ways to address such issues. Firstly, there are multiple solutions for smart packaging that inform people managing the trials when a patient has opened a blister pack and retrieved a pill or a syringe. There are smart pills that can even communicate when they have been swallowed. There are a growing number of smart devices that can monitor physiological signs as evidence of compliance and monitor adverse side-effects if they should appear. It is this latter type of development that could see another collaborative model evolving between healthcare and pharma.

A great example of this type of collaboration is in prostate cancer. There is a specific biomarker⁸ for this cancer type (PCADM-1, present in urine). In fact, several companies have already developed near-field capable devices to measure the level of the biomarker. Such real-time monitoring of the progress of disease when being targeted by a new drug is of immense value to the healthcare provider, the pharmaceutical company







and to the patient. It is arguable that a patient witnessing a real-time reduction in the biomarker levels would continue with the treatment, thus assuring compliance with the trial and providing accurate and the most current information for all stakeholders. Suppose this was combined with a real-time monitoring solution for previously identified adverse side-effects like raised blood pressure levels or increased heart rate. We would then be able to identify safety issues before a patient approaches his or her healthcare provider. Using such remote monitoring devices requires a secure platform for managing this Internet of Things. We have developed the world's leading Machine2Machine platform expressly for this purpose.

Close collaboration between healthcare providers and pharma for cohort identification and compliance management will dramatically improve the efficiency of the regulatory process, and only a partner like us can help with these challenges.

WORKING TOGETHER FOR AN ENLIGHTENED HEALTHCARE ECOSYSTEM

Within this paper we have highlighted the challenges facing the medical and pharmaceutical communities, but also the huge opportunities that inevitably come are born of necessity.

For us and our partner ecosystems, these emerging opportunities would mean working with the academic medical community and pharmaceutical industries towards a more holistic approach to patient care. It's a chance to be a part of a new enlightenment for each player in the healthcare ecosystem, from governments to enterprises to individuals - an opportunity we wouldn't miss for anything in the world.

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About CGI

With over 68,000 professionals in 40 countries, CGI fosters local accountability for client success while bringing global delivery capabilities to clients' front doors. Founded in 1976, CGI applies a disciplined delivery approach that has achieved an industry-leading track record of on-time, on-budget projects. Our high-quality business consulting, systems integration and outsourcing services help clients leverage current investments while adopting new technology and business strategies that achieve top and bottom line results. As a demonstration of our commitment, our average client satisfaction score for the past 10 years has measured consistently higher than 9 out of 10.