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3/12

GSIA SSPI

Gesellschaft der Schweizerischen Industrie-Apotheker
Société Suisse des Pharmaciens d'Industrie
Swiss Society of Industrial Pharmacists

www.gsia.ch

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GSIA SSPI

GSIA in a nutshell

The Swiss Society of Industrial Pharmacists is an association of primarily pharmacists and other academic life-science professionals working in the Swiss pharmaceutical industry. To its members, the society is providing services and opportunities for networking and contacts within the pharmaceutical industry. Moreover, the society supports and rewards young academics, particularly in industrial pharmacy.

GSIA auf einen Blick

Die Gesellschaft der Schweizerischen Industrie-Apotheker ist eine Vereinigung von über 600 Pharmazeuten und anderen in der pharmazeutischen Industrie tätigen Life Science Akademikern. Wir bieten unseren Mitgliedern den Aufbau eines Netzwerkes in der pharmazeutischen Industrie sowie interessante Fortbildungen im pharmazeutischen Umfeld. Zudem unterstützen und fördern wir den Nachwuchs.

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Jürgen Werani

Pharma 2020: Strategic Perspectives

The 2011 GSIA Educational Event of the Swiss Society of Industrial Pharmacists (SSIP)*

Dr. Jürgen Werani, Schuh & Co. Complexity Management Ltd., St. Gallen, Switzerland

The pharmaceutical industry grew by 7 to 10% over the past decade resulting in a high return on investment for shareholders. At that time, the industry focused on an accelerated market introduction of new and innovative products, thereby gaining market shares in an already crowded place. The situation dramatically changed when the innovation pipeline dried out, most of best-selling drugs lost their patent protection, generic business took over, and public bodies asked for significant cost reduction in the healthcare business, particularly of cost for medical treatment. To further meet shareholder expectations and keep an attractive level of profitability, the pharmaceutical industry needs to fundamentally change and adapt its strategies.

The Swiss Association of Industrial Pharmacists has a continuous commitment to provide its members with high level education, and consequently topics for the annual programs are carefully selected. The 2011 educational program was dedicated to the topic of strategic perspectives which have an impact on future business. A number of these strategic perspectives provide opportunities for further development in the pharmaceutical industry. All lectures of last year's program are published in this special issue of SWISS PHARMA.

Before we take a look at pharma's future, it is important to understand how society will develop as well as the key trends that shape our future. Research organizations have developed a picture of a society based on megatrends which will certainly change the healthcare business. They have identified and evaluated the impact of demographic change, urbanization, individualization, health awareness, new waves of globalization and climate change to name but a few. These megatrends give guidance to articulate the strategic direction for several business areas, including the pharmaceutical industry.

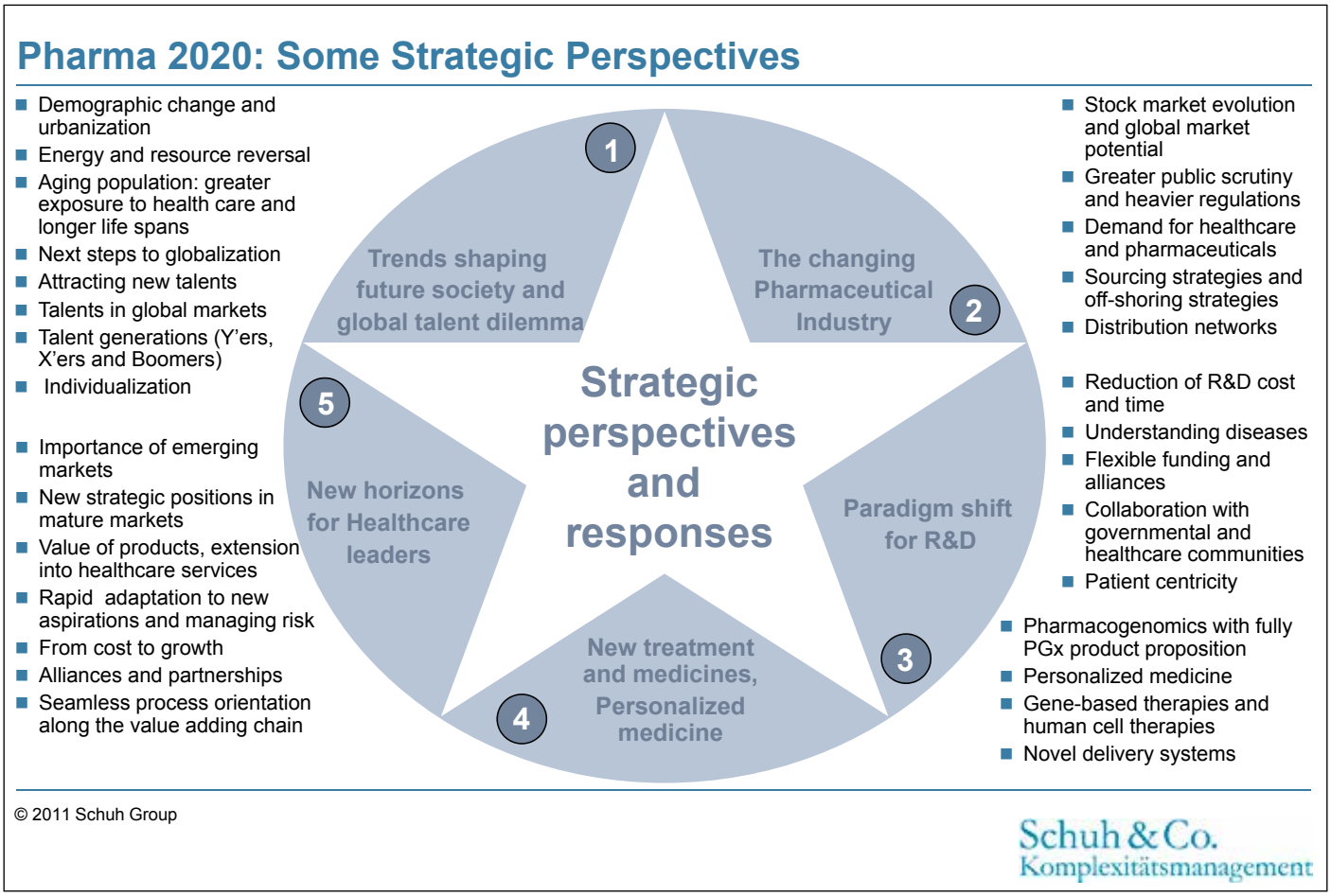
One key question to be addressed relates to sourcing the right talent and to prepare for the challenges the global talent dilemma poses. Who will be the winner in the competitive search for talent? Who are the talents in the new global markets that will drive business? What is the best mix of talent supply as mature and growth markets obviously require different strategies? How could talents be attracted if demand and supply are off balance? What are the preferences across different generations? And finally what are the drivers for talent retention? Is the healthcare business ready to address these challenges and can it meet these expectations?

Despite negative impacts the pharmaceutical industry is still growing; due to developments in emerging markets and the aging population, there is still an increasing demand for healthcare and pharmaceutical products. Changes in business and operating models need to address productivity and efficiency. The focus on core business has become a critical success factor. Near- and off-shoring as well as outsourcing have become considerations of key importance for the next generation of pharmaceutical business. Strategies and tactics to tackle cost pressure have become much more comprehensive and now include functions such as Information Technology, Finance, Human Resources, Customer Care and knowledge processes such as market research.

New types of products will require a higher level of complexity in manufacturing and distribution processes as different supply chains are needed for various products. The era of blockbusters will give way to multibusters integrated into new models of healthcare delivery, with wider distribution networks, demand-driven manufacturing and distribution. Boundaries between primary, specialty and emergency care will be increasingly blurred.

Closing the gap in the research and development pipeline continues to be one of the biggest challenges for the research-driven pharmaceutical industry. Most of the therapeutic areas already feature a large array of effective and safe medicines, and replacing the gold standards with new innovative products has become extremely challenging. Then what are the changes in the R&D strategy? Flexible funding models and research collaboration amongst companies will need to be considered as measures to control the rising R&D expenditure. In the past, research focused on investigating new molecules. The future-oriented approach, however, is to

* Gesellschaft der Schweizerischen Industrieapotheker(innen) (GSIA); Société suisse des pharmacien(nes) d'industrie (SSPI) www.gsia.ch



better understand the diseases and the role of the human genome. Thanks to scientific progress in sequencing the human genome, we will be able to develop targeted therapies. These personalized medicines will make treatments more effective, better tolerable, and can help to allocate healthcare spending in an efficient way. A fruitful dialogue amongst researchers and an interesting and challenging collaboration with regulatory bodies, governmental and healthcare communities, has begun.

In consequence of the outlined megatrends, challenges and opportunities, pharmaceutical companies must take a significant step to further change and improve business performance in order to keep up with the profitability of the past and to deliver innovative new drugs. The companies that will achieve this are the ones that are agile enough to be successful in emerging markets and capable of developing new strategic positions in mature markets. They foster and retain talent, anticipate new aspirations and rapidly adapt operating models. They will only succeed if they move from cost to growth, break down silos, manage risk differently, build alliances between research organizations, and enhance the value of products by diagnostic- and therapy-supported monitoring.

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Key Trends Shaping Future Society

Cornelia Daheim, Managing Partner, Z_punkt The Foresight Company, Cologne (D)

The analysis of megatrends enables a high-level view of the strongest developments that are already shaping future markets and societies and can be expected to do even more so in the future. For Pharma 2020 and, first of all, future society, eight megatrends can be expected to play a crucial role: Demographic Change, Urbanization, Individualization Reaching a New Stage, Health Thrives, Globalization 2.0, Business Ecosystems, Climate Change and Environmental Impacts, Energy and Resource Reversal.

Introduction

How could future societies develop? What will be the shape of our industry in 20 years? What will the demands of our customers be, and what could be the technologies we use? Questions such as these are the motivation for corporate foresight activities. In the last years, we have witnessed that these activities – the systematic gathering and interpretation of knowledge about the future and the transfer of such insights into action – are becoming more and more widespread. Companies such as BASF, Shell or the Bayer are just among the most well-known examples of corporation active in systematic corporate foresight.

Next to general trend research, the analysis of potential disruptions and game changers such as so called "wild cards", the mapping of so-called weak signals and of course scenarios, working with megatrends is among the key approaches in corporate foresight.

On Megatrends

Megatrends are long-term processes of transformation with a broad scope and a dramatic impact. They are considered to be powerful factors which shape future markets. There are three characteristics in which megatrends differ from other trends:

- TIME HORIZON: Megatrends can be observed over decades. Quantitative, empirically unambiguous indicators are available for the present. They can be projected – with high probabilities – at least 15 years into the future.
- REACH: Megatrends impact comprehensively on all regions, and result in multidimensional transformations of all societal subsystems, whether in politics, society, or economy. Their precise features vary according to the region in question.
- INTENSITY OF IMPACT: Megatrends impact powerfully and extensively on all actors, whether it is governments, individuals and their consumption patterns, or corporations and their strategies.

The term "Megatrends" was coined by John Naisbitt, who, 25 years ago, published a book of the same title. "Megatrends" presented 10 far-reaching developments which painted a picture of our future at the turn of the millennium. The book became a best-seller and made Naisbitt a trailblazer for social and economic trend research. With hindsight, one has to acknowledge graciously that his analyses did not lack the necessary vision. He coined, e. g., the expression "Globalization", recognized every individual's increasing responsibility for his own life, envisioned the information and multi-option society, and realized how decentral, networking structures would dominate the new millennium.

Today, megatrends have become a relevant strategic issue in many corporate headquarters. Siemens, to name a significant example, has stressed the importance of megatrends for its business on various occasions. Experience also shows, however, that businesses differ in their evaluation of specific megatrends – their relative stra-

SOCIETY
- Demographic Change
- Women on the Rise
- Cultural Diversity
- New Mobility Patterns

TECHNOLOGY
- Digital Lifestyle
- Convergence of Technologies
- Learning from Nature
- Ubiquitous Intelligence

CONSUMER
- Individualization Reaches a New Stage
- New Consumption Patterns
- Health Thrives

POLITICS
- Globalization 2.0
- Urbanization
- New Political World Order
- Growing Threats to International Security

ECONOMY
- Knowledge–based Economy
- Changes in the Work World
- Business Ecosystems

ECOLOGY
- Energy and Resource Reversal
- Climate Change and Environmental Impacts

Overview of Z_punkt's 20 megatrends

tegic significance being determined by a company's focus on specific markets, products, and customers. With its global maxim "The Consumer Decides", Nike is recognizing a megatrend which we describe as a new phase of individualization. General Electric, on the other hand, focuses on similar issues as its competitor Siemens, showcased by its "Ecomagination" advertising campaign.
In the following, an overview of the eight key megatrends for future society and Pharma 2020 will be presented – however, one has to be aware that this is a first introduction only, that strong regional differences exist, and that strategic implications will differ for each company depending on its markets and areas of activity. Furthermore, this is only a selection of those trends with the closest relation to Pharma 2020 – Z_punkt's full set of megatrends encompasses 20 trends in full. Still, the trends below can be expected to have a strong impact on future society, will shape the world we live in and the markets we operate in, and thus provide a solid starting point for looking at more details of the future face of Pharma in 2020.

Megatrend: Demographic Change

Over the next decades, the global population will continue to grow and age. In fact, only developing countries will experience a population boom, with populations in industrial countries stagnating or shrinking. Global migration movements will increase, while shifts in the current population structure will result in demographic upheavals.
Global population growth is predominately the result of high, and only slowly falling birth rates, and growing life expectancies in the developing countries. Even though life expectancies continue to grow in industrial countries, low birth rates mean that populations stagnate. The trend is characterized by these key aspects:
- Ageing and Shrinking of Western Populations
- Population Boom in the Developing Countries
- Growing Migration Movements
- Demographic Shifts (War for talents / youth bulge and "missing girls" phenomenon)

Megatrend: Urbanization

The size and number of cities will continue to grow, in particular in developing countries, as the promise of better living conditions lets rural inhabitants move to the urban areas in ever greater numbers. As a result, the number of large metropolises and megacities will rise continuously. This worldwide boom in urbanization will make higher demands on mobility, environmental protection, and investments in infrastructure solutions.
Booming urban development in developing countries is responsible for the largest part of the global increase in urbanization. In the industrial nations, high urbanization rates mean that total city populations have almost stopped growing. The trend is characterized by these key aspects:
- Urbanization of Emerging and Developing Countries
- Megacities Grow Strongly
- Development of Adapted Infrastructure Solutions

Background information about the author

Cornelia Daheim is Managing Partner at Z_punkt The Foresight Company, one of the leading international foresight consultancies. She supervises projects for key customers from several industries and within the framework of European research networks, and is the founder and head of the Millennium Project's German Node.

Megatrend: Individualization Reaches a New Stage

Individualization refers to the growing freedom of choice granted to individuals within society. Individuals' career plans and aspirations increasingly question traditional family structures, typical biographies, and conventional role models. The myriad options available for self-expression on the Internet have ushered in an entirely new level of individualization.
Platforms for social networking on the Internet have become market places of a new individuality. The number of active users of the world's preeminent virtual community, Facebook, is evidence of the growing significance of self-expression and individual networking in a (semi-)public space.
As a cultural process, measuring individualization is difficult. To be able to compare developments, social scientists rely on indexes which express socio-structural characteristics and value systems. In these terms, countries in Western Europe, the US, and Canada have the highest degree of individualization worldwide. In Western Europe, the Netherlands, the United Kingdom, and Switzerland as well as the Scandinavian nations lead the table. In Asia, Japan holds the leading position, but is only in a mid-table position globally.
This process mirrors extensive societal upheavals. A surge of individualization is currently evident in Asia, in particular in China and Japan, comparable to developments in Eastern European states after the collapse of communism.
Experts consider access to education and media as well as growing affluence as primary drivers behind the global trend towards individualization. The trend is characterized by these key aspects:
- Changing Relationship Patterns
- Changed Biographies
- From Mass Markets to Micro Markets
- Customization and Do-It-Yourself Economy

Health Thrives

The health care market is turning into one of the most important future markets overall. The reasons are manifold. Rapid progress in medical technology and pharmaceuticals makes radically new procedures possible. Growing life expectancies and greater personal responsibility in health issues are both behind the strongly increased demand for health products and services, as is a gradual shift of focus towards aspects of general well-being.
Looking at the development of health expenditure as a share of GDP, we can see that in the United States, overall costs have increased most dramatically, while public expenditure is only slightly above OECD average. Germany, on the other hand, has a public share far above OECD median which remains relatively constant as a share of overall expenditure. The OECD has calculated that the share of health expenditure will rise by 3.5% to more than 6% until 2050, depending on the scenario. This development increases pressure on public services. The trend is characterized by these key aspects:
- Increasing Health Care Costs and Higher Personal Responsibility
- Health Style (Health Lifestyles / Re-definition of Understanding of Health)
- New Foodstuffs
- Health Tech

Megatrend: Globalization 2.0

For two decades, global economic integration has been growing strongly and will continue to do so. In doing so, globalization will change in style and become more regional, more Asian, and come under increased governmental influence.
The steadily growing volume of trade prior to and following the banking crisis is evidence of globalization, with Asian emerging

countries gaining market shares. The trend is characterized by these key aspects:
- Shift to Asia
- Global Strategies, Customized to Places and Regions
- Emergence of a Global Middle Class
- Globalized Flow of Capital

Megatrend: Business Ecosystems

Increased competitive pressure forces businesses to focus on their core competencies and unlock new innovation potential. Collaborations with the business environment and the virtualization of business processes take centre stage.
In some industries, a significant share of innovation potential already comes from users rather than manufacturers. In addition to the increased division of labor in these pioneering industries, the growing number of ideas competitions and 'innovation communities' on the Internet is proof of the rising significance of user integration in new product development. The trend is characterized by these key aspects:
- New Value Nets
- Platform-Based Economy
- Business Mashups

Megatrend: Climate Change and Environmental Impacts

Population growth and increasing industrialization have made anthropogenic (man-made) climate change the biggest global threat. Clean technologies will become highly significant for avoiding the pollution of air and water, rise of sea levels, and future natural disasters. Regulation and changing consumer behavior will increase corporate responsibility for a sustainable global development.
Future rises in temperature will result in significantly higher sea levels, a result of higher water temperatures and the melting of the icecaps. Most directly affected are the 40% of the global population which live less than 100 km away from the coast. The trend is characterized by these key aspects:
- CO_2 Emissions and Global Rise of Temperatures
- Increase of Environmental Problems in Emerging and Developing Countries
- Clean Technologies
- Corporate Responsibility Increases

Megatrend: Energy and Resource Reversal

Global consumption of water and energy is rising, driven by population growth and economic development. Even though fossile resources will continue to play a major role in future energy supply, their increased scarcity will mean that use of renewable resources, improved energy efficiencies, and decentralized power supplies will become more important.
Global demand for energy will grow until 2030. Above all, absolute use of limited fossil (coal, oil, gas) and nuclear (uranium) fuels will increase. The trend is characterized by these key aspects:
- Strategic Resource Scarcities
- Use of Alternative Sources of Energy and Renewable Resources
- Revolution in Energy Efficiency
- Decentralized Energy Supply

Conclusion
The eight megatrends presented here will have strong impacts on all, but specifically the Pharma businesses by 2020 and probably beyond. They will change e. g. how companies operate, what customers demand, and where growth markers lie.

How can companies create value from knowledge about megatrends? Valuable insights will only be gained if information on a megatrend is translated into a company's very own context, and into future innovation fields, markets, and products. Not the trend as such is of interest, but its strategic implications. In addition to the fact that the knowledge about any trend only becomes worthwile when it is translated into strategic insights, one also has to be aware that all of these trends do not only interact, but are also much more complex than can be conveyed in such an overview – e. g. with respect to regional differences. Therefore, every company will need to be aware of these megatrends, and draw conclusions on what they mean for the company – in terms of new markets, implications for shifts in existing business fields and markets regionally, and changes in customer demands.

SOURCES

A brochure on Z_punkt's set of 20 megatrends is available here: http://www.z-punkt.de/fileadmin/be_user/englisch/D_Downloads/2007_20_most_important_megatrends.pdf

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The Global Talent Paradox

Recruiting and developing talent in today's global world poses many challenges and opportunities which result in a Global Talent Dilemma.

Maureen Solero and Claudia Bidwell, Novartis AG, Basel

A crowded, stretched world recently welcomed our 7th billion baby… the world might seem to be filled with people, but organizations continue to struggle with finding, retaining and motivating great talent. How does the growth of the emerging economies drive our recruitment and development practices… how does the new talent "mosaic" – of multiple generations and cultures working closely together provide challenges and opportunities for employers and employees alike… are we ready for the Global Talent Dilemma?

Global Talent Supply versus Demand

Planet Earth recently welcomed the world's 7th billion baby and by 2050 we will have a world of 9.2 billion and counting, but despite this a global talent shortage continues to challenge us, the supply versus demand sides are far from balanced in terms of talent quality. The paradox is about how we can ensure that we have enough supply of the RIGHT talent to meet our current and future hiring needs? In considering these challenges it is important to consider some facts:

- For the first time in history, Asia, not the US, will lead the world out of a recession back to global growth *(World Economic Outlook, IMF, April 2010)*
- High end, knowledge intensive jobs will move to growth markets, including Brazil, Russia and India, faster than labor-intensive back room jobs *(The Economist, April 2010)*
- Globalization will be increasingly linked to "Asian-ization" and de-linked from "Western-ization" *(National Intelligence Council, 2004)*

How do we organize our talent acquisition strategies in light of these changes? How do hiring managers in Africa, the Middle East, Asia and other growth markets meet organizations hiring needs? How do the mature markets sustain their workforce with several different generations working alongside each other, including Baby Boomers who wish to remain in the workforce?

Each of us who are in the market on behalf of our firms need to consider this increasingly complex, crowded world and recognize that increased populations do not directly translate into robust talent pools to meet our hiring needs. In attracting and hiring talent, we need to reflect complex factors more than ever before, including not just supply and demand issues – other considerations include cultural, generational, dual career, global mobility and work life balance challenges to name just a few. Understanding these trends and applying them to global hiring and talent management practices are key to managing and solving this dilemma.

Taking China as an example – despite its explosive population growth, by 2030, China is going to have an acute domestic shortage of available talent to meet its hiring needs. Specific age groups will be shrinking and supply will outstrip demand. As China seeks talent to meet its growing supply needs, increased immigration will be required, requiring Chinese firms to manage multi-cultural talent across its continent. Clearly this talent dilemma is not only felt in China. Many emerging and growth markets are importing talent from mature or other markets to meet their growing needs.

Approaches to Managing the Global Talent Dilemma

We need to recognize that there is not one market or type of talent we need to address. Each country has a different driver in terms of what is important to be mapped, and the key is to have enough of a grasp and understanding of the particular markets that one is operating in to understand the different drivers of talent supply and demand, what the key differences and nuances are as we seek to hire, for example, in North Africa versus Brazil versus India. We need to be smart enough to understand exactly how the market trends drive our strategy for recruitment and talent development in these markets, driving projected time and costs per hire, development drivers, compensation and other regional and country specific trends.

Insights from the Global Market

One study that is helpful in understanding more about this dilemma is the Talent 2015 study recently produced by Heidrick & Struggles. This study included a survey of sixty countries and more than 400 executives. *(Global Talent Index, 2015 – Heidrick & Struggles)*

The study highlighted several important points:

- Companies are generally confident of securing in the short term the talent they need. But they have significant reservations in both the developing and the emerging markets and growth markets about being able to retain the talent in those countries.

- Organizations are increasingly relying on developing and internally promoting employees, rather than hiring from the external market, particularly in Asia. Some of this trend has to do with localisation requirements but there is also a lot of focus on managing hiring costs.
- Severe scarcity of skills and competencies exist from entry level to executives in all markets in:
  - creativity and innovation in overcoming challenges
  - resiliency and problem solving
  - adaptability, intellectual agility and versatility

The 400 executives cited in this study feel this is a real issue and as we start to consider solutions for managing and preparing for projected talent challenges, perhaps it will help to focus on some of the areas highlighted in this study. We can start today by identifying those employees in our organization with strengths in innovation, problem solving, adaptability, strong change management, intellectual agility and adaptability. And in turn perhaps they and their networks can help us to source, recruit and develop talent with these traits to help us manage more effectively in the global world.

Technology – Enabling Talent Relationships

Clearly technology continues to invade every aspect of our life and is particularly active in the sphere of relationship building across the globe. Integrating technology as a tool in solving our global talent dilemma is therefore essential these days – technology is not just a channel, but it is a tool to proactively use.

Technology tools such as social media provide us with a unique channel to connect and leverage relationships with those highly skilled talents we need to attract to our organizations for current and future hiring needs. If you are not already integrating tools such as *LinkedIn, Twitter, YouTube and Facebook* into your talent strategies you are losing market advantage.

These tools provide an opportunity to connect alumni from organizations, from key universities, from scientific and research associations, from professional networks and connect them to each other and to your organization! Talent from the emerging and mature markets are increasingly using these social media sites to leverage global relationships for themselves as individuals and so should we as organizations. The scarcity of the talent skills we are seeking require innovation in recruitment and development, and leveraging technology to accelerate these global relationships will help us to increase talent pools in each of our markets to allow us more opportunities to attract, recruit and retain good talent.

Different Generations of Talent

There is a new world out there: demographics are changing, the economic buying power is shifting. It is a much more volatile world – managing complexity and change is now the norm. To add even more complexity to the overall puzzle – let us consider the different generations working alongside each other. This is probably one of the first times since the industrial revolution where 3 and sometimes even 4 generations will be working together in organizations. Each generation has different assumptions, working styles, communications styles – each of these are based on their experiences and their upbringing.

Concentrating on the three that are currently most predominant in the work force i. e. the Boomers, the Xers and the Yers,

- The Boomers – currently make up around 27% of the workforce – they are between 47–65 years old, they tend to be at the top levels of organizations, i. e. they are often leading them, they are in the senior ranks. The Boomers like face-to-face dialogue, they tend to be loyal to organizations and they are not necessarily technologically savvy or dependent.
- The Xers – make up 40% of the global workforce, they are between 32–46 years old. They tend to be in the mid-levels of organizations. They will question authority, they are more individualistic, they value families and they are information/technology savvy.
- Then you have the Yers/Millenials – who currently make up around 33% of the global workforce – they are 22–31 and tend to be in the lower levels of organizations. They are confident, have high self-esteem, and they want it now – immediacy and speed are important to them, and they are technologically agile and dependent.

Now why is this important in organizations? Each of them, each of us, are basically products of our own background, what happened in the world when we were growing-up, the social values prevalent where we were brought up. We have therefore different assumptions, we have different working styles, we have different communication styles. And now you put that together in a mix in an organization, and you get an interesting melting pot.

With the current economic and financial crisis, it has been noted that a large number of the Boomers are more likely to want to stay in the workforce longer, so overlaying the above mix, an important challenge is how do we keep them engaged, how do we tap into their vast wealth of knowledge?

Similarly, a recent study with students showed that they believe that they will have no offices, they will have floating desks, they will work wherever we want to, they will have lots of leisure time and lots of flexibility – one can argue that they are being naive – but those are their expectations and their current view of reality?

How will managers who are structured and have been brought up in a certain way of working in organizations, going to effectively manage and motivate groups of people who want to have fun at work, who have a less delineated kind of structure and way of working?

Different Cultures and a Virtual Reality

All of this is now very relevant for organizations because these generations are all working together in teams now. And in the not too distant future even a fourth generation will be coming into this mix. Added to the challenge of having different generations working together in a team, we can add further complexity that the future will see different cultures in different locations with different generations working together real time.

What does this mean? You are going to be either managing or part of the team which will have potentially 3 to 4 different generations working together – and in addition there will also be people in the team from many different cultures and countries.

Plus you will probably be a virtual team, with several of you in different locations, you will be using technology to communicate, and everything will be instant. People are now connected instantly– there is real time feedback about actions, social media is used. Face-to-face meetings and co-location will not necessarily be the norm in the future – they will be the exception in global organizations.

Given this how do you manage people and teams? The answer is not clear yet but it is certainly one of the dilemmas we are going to face. Clearly organizations are not set up to deal with this at this point in time. Managers and team members have in most case not been trained to deal with this kind of complexity. Organizational processes do not make working together like this easy. So how do organizations deal with this and what is going to happen?

The Tension between Employees and Employers

Looking into the crystal ball, how do we develop and retain talent? A contradiction has been created of a global talent imbalance –

- Mature markets face high unemployment and economic malaise
- Whilst emerging markets experience talent scarcity amid more rapid growth

Building and managing a talent base across multiple geographies, including mature and emerging markets, is a continuing challenge for global corporations. Each market has unique requirements.
A recent survey asked people how organizations could engage them, how would they get the best innovation and creativity out of them, and how to retain them? Training and development seemed to be still a very strong driver for people to want to stay in organizations and continue to be engaged. Employees realise that if they do not continue to keep their skills up to date, they will not survive and they certainly will not thrive. Leaders of organizations need to ensure that training and development continues to be offered and valued as being important in organizations, and not scaled back as part of cost-cutting.
Individualisation is more important to people. They want more freedom, they want self-expression on the job, they want work-life balance, they want recognition, and of course, pay and promotion too. These are some of the things organizations need to keep in mind in terms of trying to retain their talents.
Surveys show that the intent to stay with organizations and loyalty is actually declining. And that is despite the current economic climate. Just because people are not moving from the organizations does not mean that they are not wanting to. Although they might want to move, they don't feel they can right now given the economic conditions. So potentially what you have is employees who are not engaged and not really wanting to work in their current jobs. So how do we engage them given that intent to stay and loyalty is declining around the world in organizations?
Having looked at it from the employee side and established what they want, what about the employer side? Looking at this, it becomes very clear that there exists a clear tension and conflict between employee and employee expectations – it is built into the system of commercial organizations, of profit and loss, and it's going to become more acute in the future. Employers are focusing on productivity – they tend to be reacting to the economic conditions – short-term fixes versus long-term strategies. This conflict has always been there.
A modern example which shows this very well is the appearance and use of the mobile phone, i-phone or blackberry at work as one of the day-to-day tools of the knowledge worker – pretty much everyone has one now. When they first became common in the workplace 10 or so years ago, employees mostly were very pleased to have these time saving devices – one could do one's email when commuting – one could respond much quicker. And yes, it has made communications much faster. What many however did not realise at the time, was that employees are now on call 24 hours, 7 days a week. They can be reached any time, any place. And unless they put very strict boundaries around their personal life versus professional life, things are now blurred. In the past when an employee came into the office, that is when they would log-on and start working. Now employees can do their e-mail, all the time, wherever they are, if they chose to. How many of us look at our e-mails before we actually get physically to the offices in the morning (assuming we have an office) – most people we suspect.
The reality is that organizations are designed to extract more and more productivity out of employees, and historically have done so. But employees going forward want more life balance, more flexibility etc. This is where the conflict lies. What the organization of the future which wants to be successful in managing talent has to figure out is how does one pull this all together, how does it help move employee and employer expectations to come closer together?

What does the Future look like?

To summarize, organizations have multicultural, demanding and diverse employees, there will be complex markets to manage, virtual teams, networks that are immediate and vast as well as global, the world is now transparent. There is a relentless pace of globalization, the shift of balance and power is to Asia, there is a re-regionalization happening and volatility is huge. Employees will be distributed differently, people will be working differently, and new media will and has already conquered our professional and private lives.
This will mean a new breed of leadership is required. Those that execute a global approach that can accommodate diverse cultures and perspectives of doing business will be successful. Talent is now a truly global pursuit, to succeed one will need to have an engaged and creative organization. The future is clearly changing, managing talent is going to be complex and increasingly global.
Going forward talent will need to be managed in a more strategic way with customizable programs – carefully designed internal leadership development programs – and these will need to incorporate people's different preferences to learning and working.
To be successful in managing talent of the future we need to redefine how we work together because we are going to have people working in different locations from different geographies, from different cultures, from different generations working virtually, and they will have never met each other. Plus employees want to have time off, flexibility, etc. So how do we do that? Managers will need to be taught how to lead these types of teams effectively and our employees will need to be enabled to work within these constructively.

In Closing

The UN population fund reported that every twelve years we could add a billion people to the world, and the biggest growth will be in Sub Saharan Africa and South East Asia. Conversely in Germany, Russia, Italy and Japan, the populations are clearly going down. But a baby born today in the US has a fifty percent chance of living to be a hundred years of age.
This has massive implications as we know on resources, water, food, energy, etc. And if, in life science the employees are really the most important assets an organization has, then they really need to think about how they manage their talent globally. Given that there is a global pool now to tap into, organizations will need well informed and well thought out talent strategies which are aligned very closely to their business strategy to manage talent going forward. It's going to be much more complex than it has ever been before.
Talent is really a global pursuit and we hope we have left you with some food for thought and some tools to think about as you help make this change happen.

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Outsourcing as key success factor for the future of the pharmaceutical industry?

The urgently-needed increase in efficiency and productivity requires new business and operating models.

Antonio M. Russo, Head of Shared Services and Outsourcing Advisory, KPMG Switzerland, Zurich

The global pharmaceutical industry is in an accelerated state of transition. Shifting demographic trends in both western and emerging markets are driving the demand for more and better pharmaceuticals. Global healthcare spending levels have never been higher.
Yet pharmaceutical firms face a growing and daunting array of competitive, regulatory, price and operational challenges. The industry has been facing disappointing business and share price performance. There are growing threats to intellectual property protection and a general demonization of pharmaceutical firms by some mainstream media, politicians and influencers.
Major changes to business models are needed, including more consolidation to gain greater economies of scale, and better and more efficient ways to bring new drugs to market. Excelling at the core business of pharmaceuticals is more critical than ever. Also, outsourcing plays a growing and increasingly important role in defining next-generation pharmaceutical business and operating models.

All the factors actually favor a stable and sustainable thriving market with a golden future. The pharmaceutical industry is benefiting from a growing and, at the same time, aging world population. New emerging markets are opening up; and whole subcontinents are able to access pharmaceuticals and medical care thanks to higher living standards and increased prosperity.
Global spending on healthcare and pharmaceuticals has never been higher. Yet the pharmaceutical industry is coming under ever more pressure; many investors are disappointed with the performance of their stocks, and industry representatives are predicting new restrictive regulations, falling margins and menacing risks of a legal, political, scientific and personnel nature in the near future.

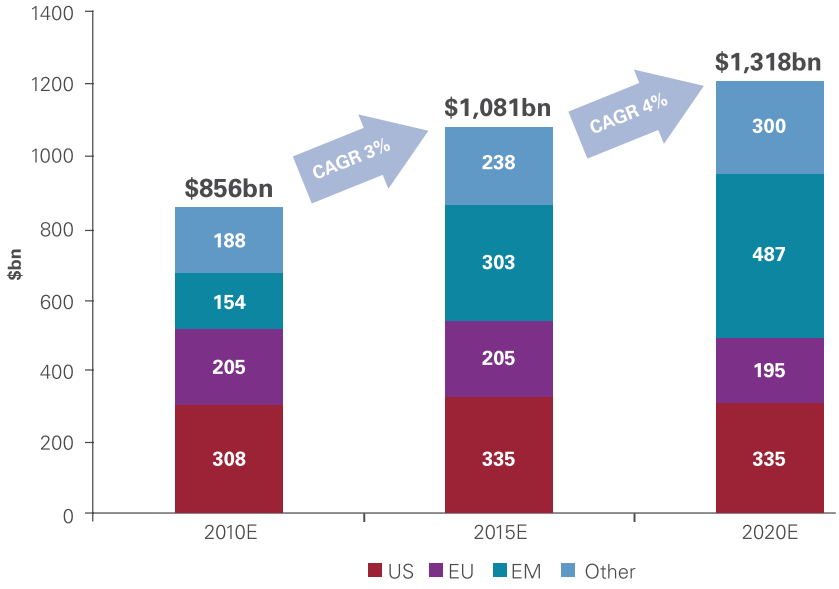
The fast growing emerging markets, such as Asia and South America, are certainly rapidly increasing demand for pharmaceuticals. However, operating margins are peaking and the impact of emerging market growth on the current cost base will bring margins down. Businesses need to ensure investment in these markets reflects the new industry and is not a template from the past.

Winning back confidence

Western markets are saturated and stagnating. Competition and an extremely actively controlled generic drugs market are, to some extent, repressing growth potential. In addition, companies are required to monitor their governance standards and in many instances win back the confidence of the authorities as well as that of the general public. The pharmaceutical industry is accused of disregarding the needs of patients, and the various intermediaries in healthcare and healthcare policy of being in favor of their own economic interests. A detailed examination and reevaluation of the business culture in the industry, a proactive discussion of values, and improved internal and external corporate communications are required to move forward here. The way risks and compliance regulations are handled is becoming a key factor in the strategic success of pharmaceutical companies. This aspect has been underestimated and neglected for many years.
In addition to these cultural and regulatory challenges, the pharmaceutical industry must evaluate new business models at an operational level to win back the confidence of investors and industry observers. Only those companies among the large pharmaceutical groups who manage to find new and innovative ways of developing truly global business models will benefit from the globalization of the value chain and dominate the market. Increasing efficiency is the driving force that promises success.
Pharmaceutical companies should focus on their core business and maximize efficiencies in non-core functions such as finance back office, personnel administration and information technology. The processes for discovering, developing and manufacturing new drugs are so complex and costly that in order to achieve the return demanded by the capital market, a critical examination of the current ways of doing R&D is required. These have become critical success factors which will lead to a sustainable competitive advantage in the future.

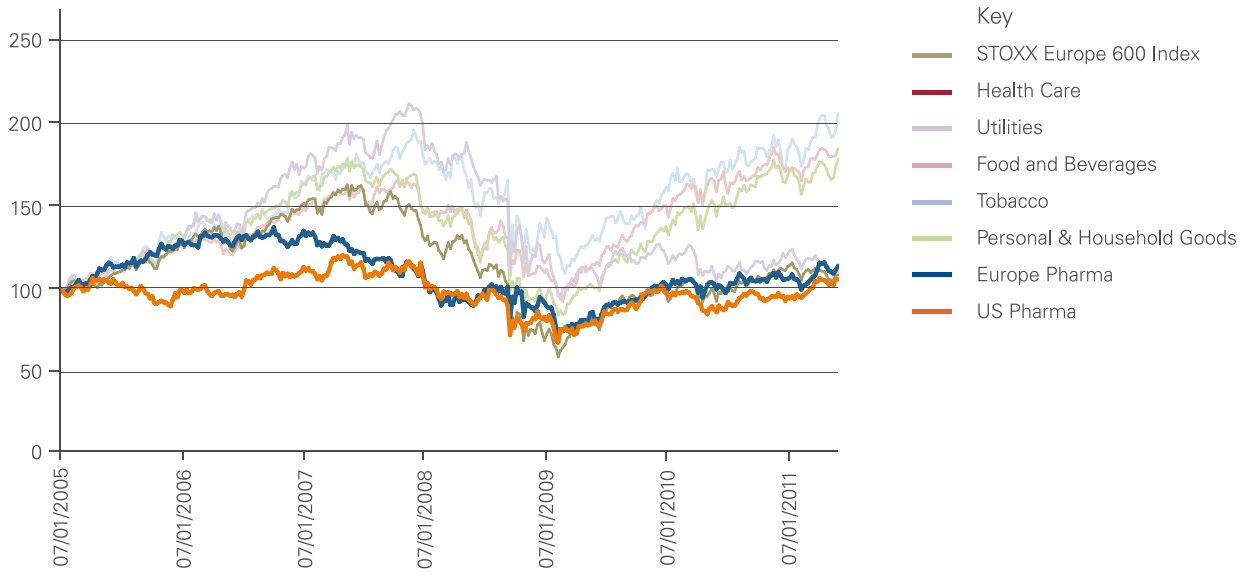
Pharmaceutical Industry 2010 to 2020 by Major Geographic Market

Source: 2010, 2015 IMS Health; 2020 KPMG estimates



Relative Share Price Performance from 2005

Source: Bloomberg



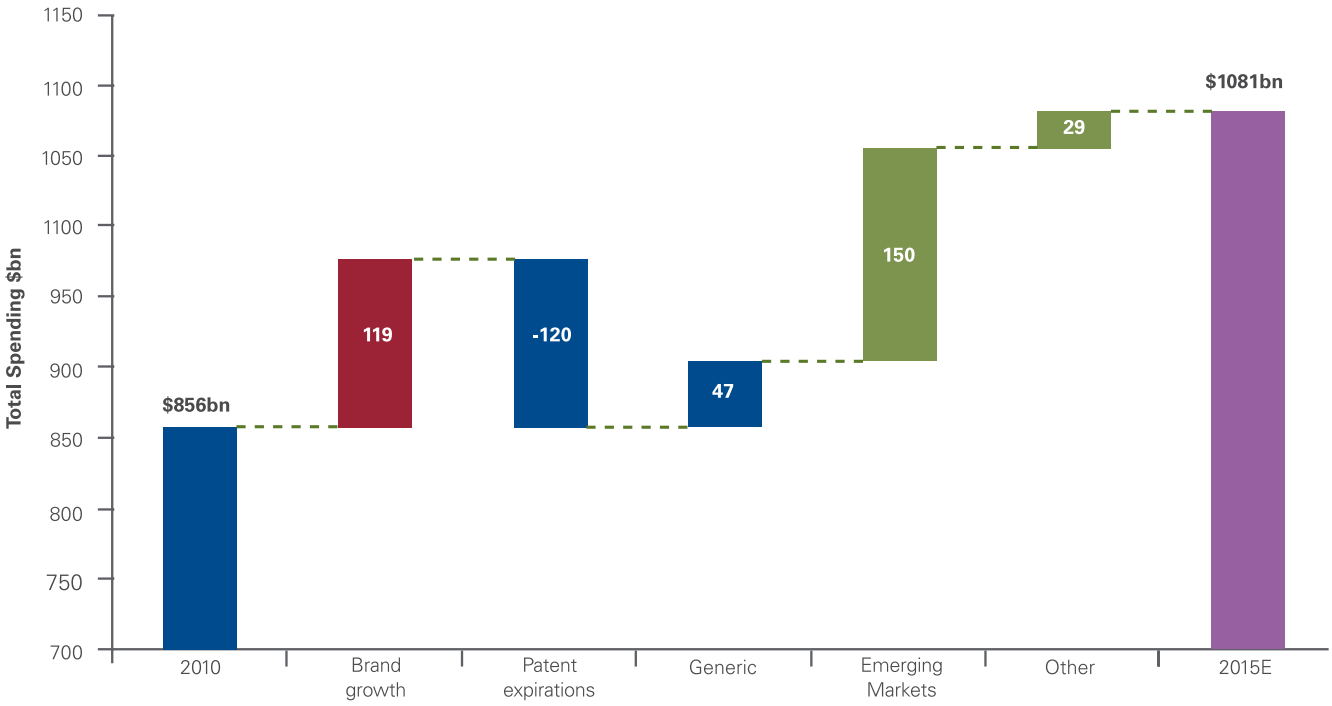
The productivity of research and development is sub-optimal in many firms

A further damper for future profit expectations of many large groups is the fact that many patents for internationally successful drugs will soon expire. Between 2010 and 2015 some USD 120 billion in sales will be lost in the global pharmaceutical industry due to expiring patents. The industry will grow in the future, though, thanks to opportunities in emerging markets, where an increase in sales of USD 150 billion can be expected in the same period.

The discovery and development of the next blockbuster, which would give a company a monopoly profit for years under patent protection, is becoming increasingly expensive and costly. Pharmaceutical companies have reviewed their strategies and refocused their R&D portfolio. We have observed that the number of newly approved drugs has remained more or less stable in the past years, but research and development costs have increased disproportionately. R&D productivity has been sub-optimal and poorly measured and we observe that returns on capitalized R&D spending have been steadily falling.

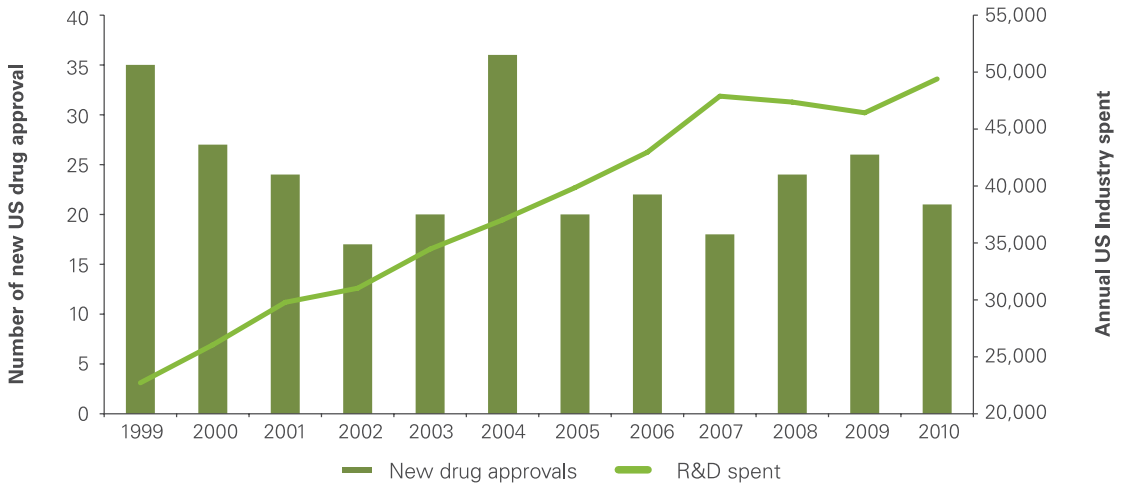
Emerging Markets are the Key Drivers of Total Spending

Source: IMS Market Prognosis; KPMG



New Medical Entity Approvals and Annual R&D Spending 1999-2010

Source: PhRMA and FDA



New strategic routes: outsourcing

Pressure on margins and the return on R&D puts pressure on pharmaceutical firms and forces them to look for new strategic ways of optimizing return. Through M&A, which have become frequent in the industry in recent years, companies have strived to drive economies of scale by leveraging synergies in sales channels, marketing, production, product pipelines and more efficient, common support functions. M&A in the pharmaceutical industry is nothing new but the scale occurring today is unprecedented. There is also greater focus than in the past on ensuring that the benefits and synergies projected from M&A efforts are fully realized. While mergers have enabled pharmaceutical firms to reduce costs, for example, by consolidating operations, they have also resulted in sprawling, costly and often duplicative back office and support operations. Significant investments in information technology (IT), applications and systems creates complex operating environments require extensive care and feeding and often need to be rationalized. The challenge in the current round of M&A activity is to lessen these negative side-effects while gaining the expected cost savings.

In addition, the pharmaceutical industry is increasingly implementing, with mixed success, operating models which were rare in the industry in the past, by better leveraging regional and global shared services and business process outsourcing. Companies with their headquarters in the US were the first movers in adopting such models followed by European-based companies. However, unlike other industries – for example oil and gas – the pharmaceutical industry still largely lacks experience and expertise in implementing globally integrated operating and governance models for shared services and outsourcing. The focus has mainly been on back office transformation, in some cases leveraging off-shoring labor arbitrage, and only a few companies have started moving up the value chain and bringing more knowledge-based activities in shared services and/or in the scope of their outsourcing arrangements. New areas have emerged strongly on a global scale such as Facilities Management and Legal Process Outsourcing.

The strategic goals of implementing shared services and outsourcing in the pharmaceutical industry are more than just reducing costs. First of all, the need to reduce costs, often significantly, is a given. However, greater emphasis is now being placed on redirecting highly skilled employees to more valuable and strategic work while eliminating the lower value and commoditized work through outsourcing. Increasingly, pharmaceutical firms are recognizing that performing lower value work internally does little to create differentiation, and the work performed is largely irrelevant to their strategic competitiveness. There is growing acceptance of standardized processes, models and IT systems to support and perform back office work and recognition of the diminishing value of maintaining highly customized operations.

What has started out to be widely in place in the administrative and support functions, such as IT, personnel administration and Finance & Accounting, will in future be the order of the day in many key R&D activities of the pharmaceutical industry. The optimal structuring and sourcing of processes in R&D and production will play an increasingly important role in the efficiency of the pharmaceutical industry value chain. Speed and efficiency in developing and bringing new drugs to market are the dominant issues for the future.

While administrative services can be handled efficiently through regionally or globally centralized captive or outsourced shared services centers, the knowledge-sensitive process of R&D is more complex in nature and not all the phases are equally suited to outsourcing. Pharmaceutical firms are redefining their strategies relative to diversification vs. specialization. This includes reassessing what work is so strategic that it leads to competitive differentiation, and therefore, must remain as internal operations, and what work, while still strategic, a third party can viably perform. The pre-clinical and clinical trial phases and the development of basic chemical substances are very well suited to being managed through new outsourcing models. However, the specialized processes of chemical manufacturing (functional genomics, discovery chemistry) and the areas of internal and market analysis are primarily best managed internally.

A wide market for specialized providers has now established itself for specific operating processes in the R&D value chain.

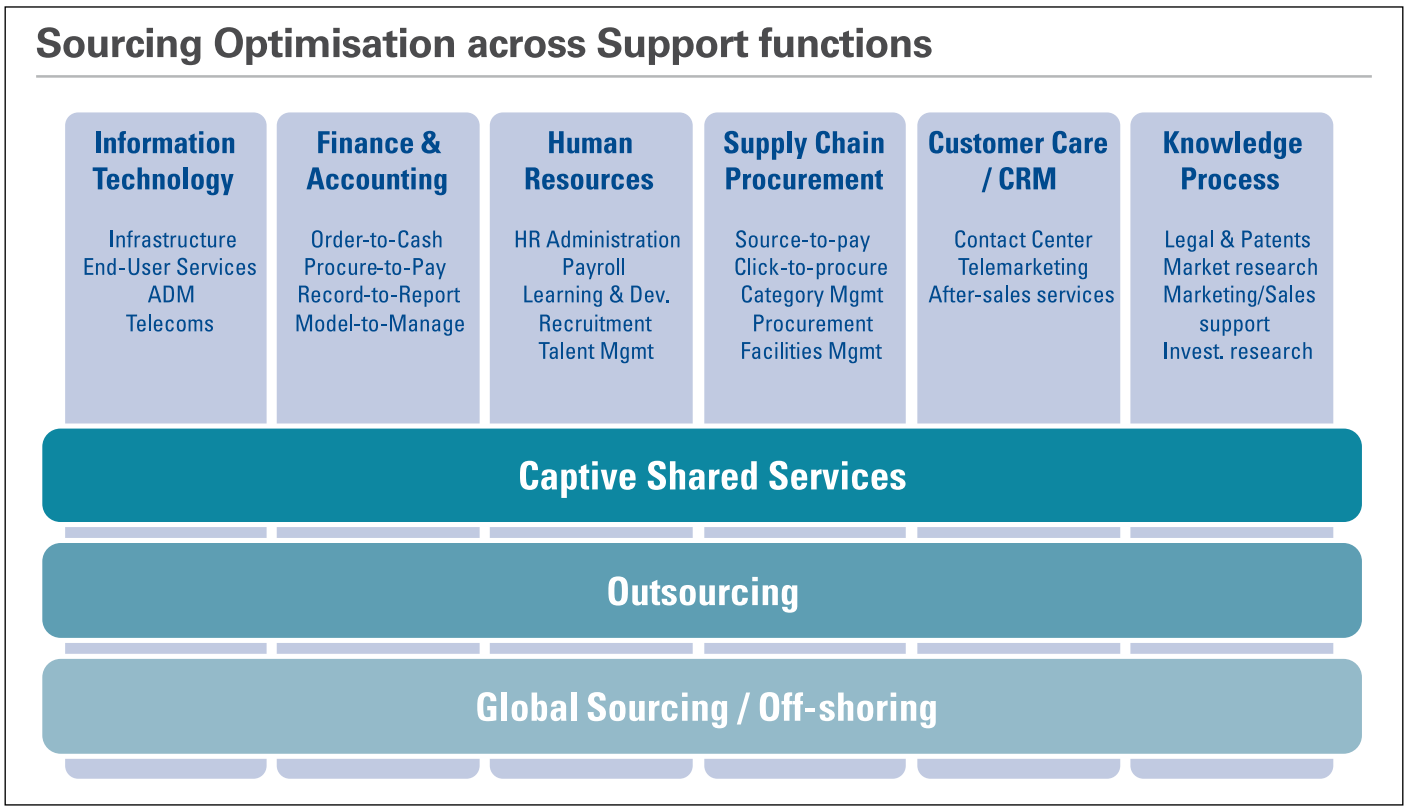
Critical points to consider

There are important directional trends in the global sourcing market that the pharmaceutical industry should consider when assessing its sourcing strategy:

1 The ongoing globalization of the business and IT services market will continue largely unabated. Protection policies will have little tangible impact on global sourcing in the long run, especially for global firms like many in the pharmaceutical industry. On the plus side, outsourcing providers will get better at designing, optimizing and delivering a broader range of services globally in a more integrated and coordinated manner.

2 Market consolidation within the pharmaceutical industry and between pharmaceutical and other life science industry segments will continue to accelerate. Relative to global sourcing, this creates both challenges and opportunities to expand efforts, rationalize, streamline and improve the efficiency of existing arrangements. Buyers can take advantage of change efforts to overhaul service delivery models in order to take greater advantage of global sourcing opportunities.

3 Pharmaceutical firms have great opportunities via divestitures and spin-offs to recreate their service delivery models and opera-



Pharma R&D Outsourcing

	Opportunity Analysis	Drug Research	Discovery	Developement	Registration	Launch/ Marketing
Extend of Outsourcing						
Activities Offshored	**Competitive Intelligence** • Pipeline analysis • Clinical trial mapping **Business Intelligence** • Product/ performance tracking **Market research** • Survey design • Therapy area research	**Functional Genomics** • Specialized chemistry • Bioinformatics support **Lead identification**	**Discovery Chemistry** • Lead verification • Lead optimization • Chemical synthesis • Hit/lead optimization	**Preclinical** • Bio analytics • Pharmaco-kinetics • Toxicology studies **Clinical Trials** • Programming/ scheduling • Data management • Site management • Clinical statistics	**Material Preparation** • Dossier production • CD production	**Analytics** • Commercial analytics • Sales force analytics • Brand modeling and forecasting
Operating Model	Captive + Outsourced	Only Captive	Captive + Outsourced	Captive + Outsourced	Captive	Outsourced
	Regulation	**Regulation**	**Regulation**	**Regulation**	**Regulation**	**Regulation**

 Most Outsourced Least Outsourced

tions. New opportunities exist to maximize the use of third-party specialists to manage and deliver these services and enable the new corporate entity to focus more intently on differentiating activities over back office or lower value-add operations.

4 Cost-saving programs will have to be carried out much more rigorously and consistently in future. The pharmaceutical industry is admittedly also affected by cyclical movements in the market, but not as greatly as other sectors. Many pharmaceutical firms are making use of the difficult times to implement long-overdue cost-cutting measures.

5 Pharmaceutical companies must improve their skills and increase the emphasis on becoming better at shared services and outsourcing governance. As more services are performed in regional shared services and/or by outsourcing providers, the required skills to manage this service chain must become a core competency just like those used to manage drug development, manufacturing and distribution supply chains.

Conclusion

The global pharmaceutical industry is facing difficult and challenging times with loss of intellectual property rights, increasing regulatory requirements, new global competition, pressure from the capital markets and the need to shift bloated legacy operating models to more efficient ones that shake core industry operating principles. Major changes to existing operating models will accelerate. Improved ways of doing both the strategic and operational pharmaceutical work are required. Outsourcing efforts to date in the pharmaceutical industry have been largely successful at reducing costs and shifting focus away from lower value-added activities. These trends will not only continue but will accelerate and broaden in scope.

Pharmaceutical companies today should seriously rethink how they deliver both back-office and administrative services as well as more strategic activities like drug development, sales and marketing, and regulatory compliance services. Increasingly, third-party outsourcing service providers will play a greater role in supporting and managing the delivery of these key business functions. The key challenge for pharmaceutical firms is to determine which services they should seek from third parties and then how to best execute efforts to source, transition and manage those service relationships successfully.

Background information about the author

Antonio M. Russo heads the KPMG Shared Services and Outsourcing Advisory practice for Switzerland. Prior to joining KPMG, he was the European Shared Service Practice Lead and Managing Director for EquaTerra in Switzerland.
Antonio has advised companies on shared services, Business Process Outsourcing, Program Management and supported a multitude of transformation and change projects. He helped organizations review operating models and develop multi-tower sourcing strategies for support functions (HR, F&A, Procurement and IT), and to design and implement captive shared services and outsourcing arrangements. Before joining EquaTerra, he was the CEO of a startup company developing brand protection technology, worked for IBM in the Advisory and Outsourcing space and for PwC Consulting advising clients in HR transformation and Organization & Change strategies.

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Research & Development driven pharmaceutical industry – How will the future look like?

Dr. Sven Schreder, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss (D)

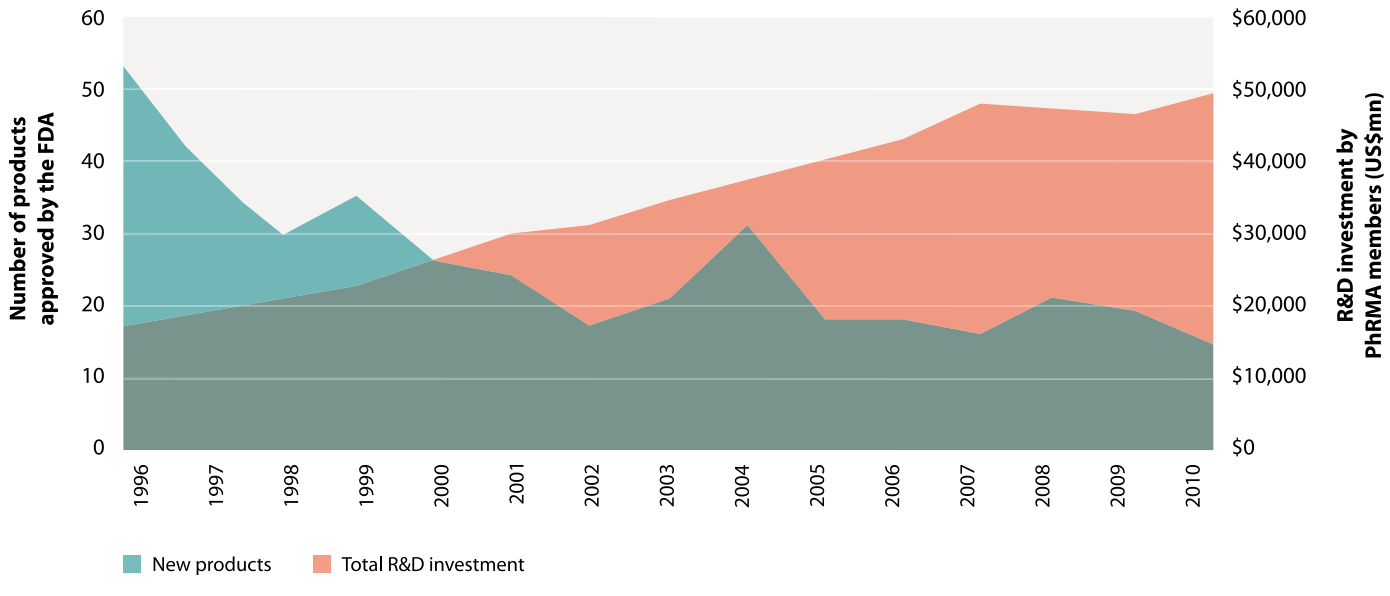
Nowadays, news for the research driven pharmaceutical industry is less often positive. A gap in the research and development pipeline is cited in many articles and the confidence of the stock market in the business model is modest. Over the last years, stocks of most of the Big Pharma have suffered.

The patent cliff is a fact and more than 100 billion USD in sales are at risk in the upcoming years. At the end of November 2011, the world's largest selling product Lipitor lost patent protection and will be facing tough competition, although Pfizer is trying to keep parts of the market share e. g. by offering special discounts and patient access programs. Therefore, it is obvious that most companies have started initiatives to change R&D strategies and to increase the productivity of their R&D organizations in order to bring attractive new products to the market. Among many other measures, there are also restructuring announcements and as an example, Novartis just announced to restructure their business which will result in the loss of 2000 jobs, however, countermeasured by the increase of 700 jobs in low-cost countries. This happened despite a double-digit increase in net profit for 3Q 2011. Obviously, this has caused some irritation among co-workers and the public, however, critizising the companies for the adjustment in the cost structure might not be appropriate, though. All that is currently in their pipeline won't be sufficient to replace the losses which are expected due to the individual company patent situation. Due to the long development timelines the companies have to adapt their organisations now. Based on the development timelines of 12–15 years from the initial idea to the launch of a drug product, the current product portfolio and sales reflect the research & development productivity of the late 90s. In the meantime, the competitive landscape has become much harder. With very effective products in broad indication fields going off-patent it is continuously getting more difficult to show a clear benefit over these products. In some of these fields, such as cardiovascular diseases, there is an increasing saturation as good generic products have become available.

It might even happen that these generic products are translating from former gold standards to the ultimate standard for a certain disease state. For a number of years, there was hope that research output could be enhanced by investing money in New Biological

The drug development process

Graph shows declining product approval despite increasing R&D investment. R&D investment figures only include company-financed R&D. *Source: PhRMA member survey 2011 and Nature Drug Discovery* [1]



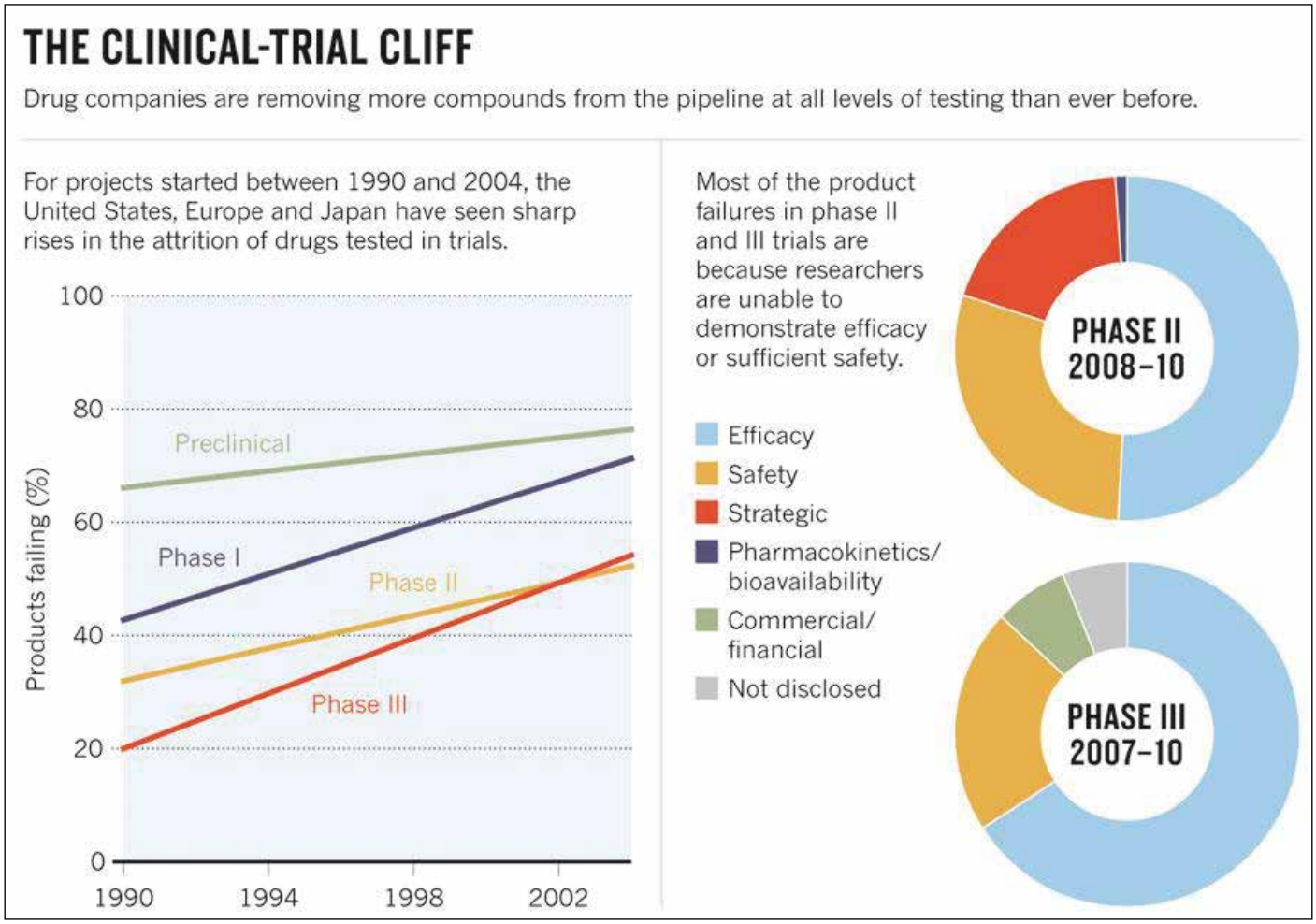
[1] **Mullard**, A, *Nature Reviews Drug Discovery 10*, 82-85 (February 2011)

Entity (NBE) development. However, the number of NBE approvals has remained flat over the last 15 years. In the past, the focus of new product development was creating products which were safe, efficacious and highly qualitative. This was and remains necessary and will stay the basis in the future to pass the regulatory hurdle to get approval by the authorities. However, while regulatory approval is a significant first step, pharmaceutical industry is nowadays facing the next hurdle which is reimbursement by the health care providers. More and more countries and agencies request further studies before an adequate price for the product is reimbursed. In many European countries austerity measures are being taken and although the Pharmaceutical Industry has understood the expectations of the respective regulatory agencies this reimbursement process is still not fully clear and also differs from country to country. However, it is clear that the health care providers will ask for further and different clinical studies and large and long outcome studies. These requirements will further increase the costs and the timelines for the development of new products and if reimbursement is delayed, it will further reduce the remaining time to utilize patent life of a new product once being introduced in the market. Overall, it will become more unlikely that a new product can generate enough profit to cover the development costs. Due to the high costs to develop a new product, the pressure on R&D units to reduce specifically the high costs associated with failures during the late stages of clinical development will significantly increase in the near future.

If we look at the attrition rate in every phase of development, whether it is preclinical, clinical Phase I, II or III [Nature, Vol 477, 29. 2011] the trend goes towards a higher overall attrition. All these negative trends would result in a non-sustainable business if no countermeasures were taken and the productivity could not be increased.

What are possible countermeasures?

It is obvious that the increasing hurdles for approval of new drug producs and their declining probability of commercial success cannot be solved with a single countermeasure but only with a combination of multiple individual approaches. It is of highest importance to increase the success rates during development, or at least, to have the unavoidable attrition of the portfolio in very early stages, ideally already during the research phase. Only very good drug candidates should achieve the "go ahead" to enter the preclinical development phase. Money needs to be spent on the few winners rather than being diluted among many losers. Clear cut go/no-go criteria need to be prospectively defined and applied, though many companies might still continue with programs for portfolio cosmetic reasons to impress analysts. Development costs are high and based on the large clinical trials mentioned earlier are not likely to be reduced. Some countermeasures are utilizing capabilities in low cost countries. It is clear that the volatility in sales will increase as it will become more and more unlikely that a company can launch the next blockbuster exactly at a time when the current big sellers go off patent. Therefore, companies may need to develop flexible funding models for development and launch. In order to get the best ideas and research targets creative ways need to be identified. Historically, many ideas used to come from the own research, whereas nowadays the number of research collaborations with small start-up companies and academia has increased and has become an important source of innovation. Once the right molecule is identified and moves forward to market, new ways to exploit the value of the product need to be followed, e.g. by increasing compliance of the patient to the medication. As a result, pharmaceutical companies need to be flexible in all areas of the business, be creative, be cost conscious, make fast decisions to terminate



projects to achieve early attrition and be able to react to volatility. In addition they also need to have the mindset to exploit the product by showing and proving an existing benefit over current treatment alternatives. The requirement for every possible future economical success is that a truly unmet medical need is addressed.

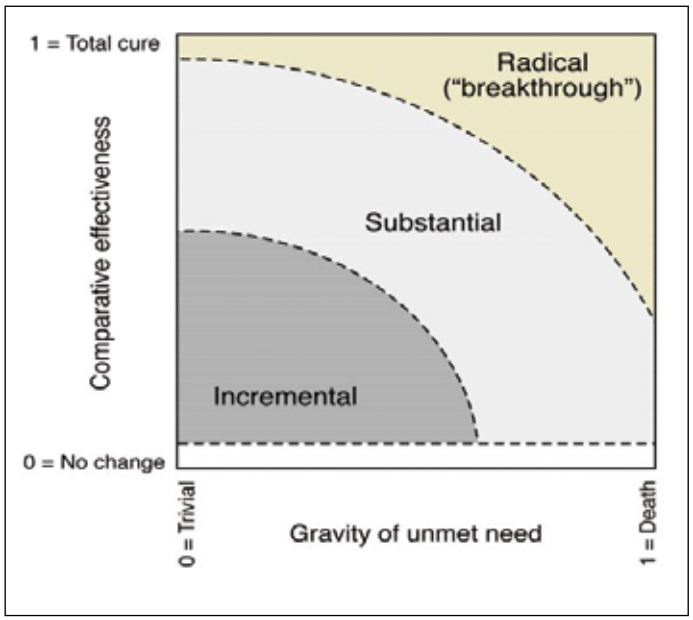


Figure 1: A model of pharmacological innovation

A medical innovation [Morgan, Open Medicine, Vol 2, No1, 2008] can be defined as incremental, substantial or radical. The two relevant dimensions are comparative effectiveness (0 = no change, 1 = cure) and gravity of unmet need (0 = trivial, 1 = death). Whereas it was rather easy to be better than the standard therapy (often none available at all) at the beginning of the last century it has been getting increasingly difficult to improve over the standard medication which is available nowadays. As discussed earlier, health care providers and patients are more and more asking for radical improvements in drug products to be willing to pay an adequate price for the medication. Given this relationship, the likelihood of success by utilizing current research and development tools is relatively low. This can be seen by the reduced number of new products approved in spite of the increasing expenditure in R&D [Mullard, Nature Reviews Drug Discovery, 10, 82–85, 2011].

Which are the avenues the pharmaceutical industry is going?

1. Open innovation

For decades, the in-house researchers have felt to have the privilege to be the only Think Tank of the companies and the success of their companies supported this mindset. However, in any given pharmaceutical research unit, the number of co-workers is limited to a few thousand or less whereas there are probably millions of good scientists around the globe working in the biological or other relevant research areas. It would be arrogant not to try to connect to these groups and not to try to identify the best ideas which then could be followed up in house or together with these research groups. It is worthwhile to mention that these partners may come from academia as well as public or biotech organizations. It will be a key success factor if companies are able to use these partners and can effectively manage them. And as always, the collaborations need to be based on a fair win-win situation so that both partners can profit from the strength and know-how of the other one. Many of these small companies are very fast in their decision making and committed and it needs to be ensured that the true value of these collaborations is not blocked through very slow internal decision making processes in Big Pharma. Therefore, apart from the heads of Research or Development, also Legal, Sourcing and other enabling functions need to find effective ways to work with these research partners. Still, the challenge will always be to be both very quick and to maintain an appropriate IP for both partners. People managing these interfaces might not necessarily be the best scientists but need to be able to build bridges and be able to collaborate openly even in times of failure (or success).

2. New business models

Apart from the standard model of doing own research, development, production and marketing of your product many different collaboration models are used nowadays. As described [Progressions Pharma 3.0, Ernst & Young, Global pharmaceutical industry report 2010], collaborations could take place in various area. One example is a community which is built by UCB and PatientsLikeMe with the aim to create an open and online epilepsy community that captures patients' real world experiences. Collaborations can also jointly develop new technologies, e. g. Novartis and Proteus who are creating a sensor-embedded pill that transmits data to a receiver in order to monitor vital signs of patients and boost patient compliance. Another example is the collaboration in precompetitive R&D where BG Medicine and Big Pharma jointly develop novel blood tests and imaging methods to find individuals with high-risk plaque disease before the occurrence of the first cardiovascular event. Other business models include partnerships with payers, creative financing, public-private partnerships, R&D risk sharing, expanding products, developing technologies, innovating distribution, leveraging data, optimizing R&D and collaborations in Orphan drugs diseases. Again, considering these kinds of collaborations, it will be the key to success that the companies will have strategies and the right people to manage these diverse and more complex operative collaborations in an efficient manner. Apart from the "Drug Hunters" in the companies, in addition a new type of researcher is needed eventually, a person that can be described as a complexity manager and enabler.

3. Translational medicine

The key to successfully reduce the costly failures in clinical studies lies in a better understanding of the disease and very smart clinical study protocols. Biology of a certain disease needs to be better understood and a very clear target-disease relationship needs to be established as well as a relationship between the human genetics and the physiology of the disease. In order to facilitate this approach access to human tissue related to a certain disease state is needed. Key questions to reduce the clinical attrition is to provide a better insight into gene expression in human tissue and better insight into the function of the targets by use of in vitro/in vivo knock-downs. One needs to ask if there are any interactions with the target in the tissue sample via Imaging technologies (PET), if there are even more relevant and predictive animal models, if we have early non-invasive efficacy markers, e. g. biomarkers or further imaging techniques. So far, animal studies focused mainly on safety readouts, however, recently mice have often been treated on top of standard of care in order to get additional early relevant efficacy readouts. To fix the low success rates in clinical trials [Nature, Vol 477, September 2011] more studies are using patient stratification tools so that the failure rate due to poor efficacy can be reduced by using personalized medicine. The question which patient will respond best should be evaluated by using pharmacogenetic techniques.

4. Personalized medicine

With the advances in sequencing the human genome it is expected that within the next 3–4 years the costs for genome analysis will come down to 1000 Euros and sequencing can be done within one day. Therefore, theoretically within a few years, everybody

could have the information regarding their genome and could get the most appropriate medication according to their genetic status and the respective disease. For a number of genetic defects and their impact on diseases this is about to be understood especially with research in Oncology. For many people it might be an uneasy feeling that their genetic state is known, however, those patients who benefited from targeted and specific therapies the advantages were obvious. Still, it will be extremely important to take data protection very seriously and the data should only be used to identify the best medication. Companies are more and more applying patient stratification tools and AstraZeneca claims that by now about 50% of the drug candidates are being associated and developed alongside with biomarkers [Scrip, October 12, 2011]. Recently, Zelboraf from Roche was approved for the treatment of patients with unresectable or metastatic melanoma with BRAFV600E mutation as detected by an FDA-approved test. The advantages of personalized medicines are manifold. For patients as they get the best personal treatment, for the prescribers as they can expect the best patient outcome, for the payers as they get the right value and the Pharma Industry as their product development has the highest chance of success.

5. Collaboration in the pre-competitive field

There are a number of areas where companies need to spend a lot of money in order to understand safety sciences, animal models, develop biomarkers, increase the understanding of certain diseases, develop diagnostic tools, improve preclinical models, understand factors which have an impact on a disease state and many more. However, most of these topics enable the development of a new treatment option rather than be the treatment option by themselves. Therefore, if companies develop these models on their own huge amounts of money might be spent without a direct relation to their new products to be investigated. Thus, it is necessary to collaborate in the pre-competitive field in order to improve science and tools but not to spend too much money outside the core business. Within Europe, there is a Public-Private Partnership between the European Commission and the European Federation of Pharmaceutical Industry and Associations (EFPIA) which is called the Innovative Medicines Initiative (IMI). There are annual calls with the aim to identify consortia which try to improve the science in the pre-competitive field regarding Safety, Efficacy and Education. As an example, a consortium was established in the field of development of personalized medicine approaches in diabetes in 2010. A European databank regarding phenotypical data will be generated, biomarker assays will be developed and prospective clinical trials will be set up. This should later on enable pharmaceutical companies to develop better drugs to treat diabetes more effectively.

6. Regulatory interactions

As new technologies and new methods are evolving, it is mandatory that these follow the respective guidelines in order to meet the expectations of the regulators all over the world. Some of the new approaches obviously have not yet found their way into recognized methods or into guidelines. The key to success is therefore an early dialogue with the regulators so that implementation happens in close collaboration with the competent agencies. Transparency of the innovator´s intention, early communication with the agencies and obtaining their agreement to the way forward is necessary. However, regulators also have to change their way of thinking and have to open up to the dialogue with the pharmaceutical companies. It is very positive to note that agencies have recognized this and meanwhile allow access to them to discuss such development activities. As an example, the US FDA's critical path initiative should be mentioned here. The initiative was articulated as a vision statement to improve the efficiency of product development industry-wide and to identify and prioritize the most pressing development problems for new drugs and other therapeutic agents and the areas that provide the greatest opportunity for rapid improvement in public health benefits. The Biomarkers' Consortium can be used as an example of a public-private partnership involving the National Institute of Health and the FDA. The aim is to discover, develop and qualify biological markers to support new drug development, preventive medicine and medical diagnostics. In addition, to further improve the safety and efficacy evaluations the Agencies further foster the interest in optimizing the quality of the new products. Basically, the quality of a product should be built in during the development phase, rather than tested into the product. Therefore, the ICH Q8 guideline was launched and in 2008 the FDA initiated a Quality by Design (QbD) pilot to foster the idea. For both agencies and industry the QbD approach had some challenges and there is still no common consensus across the industry and agencies how to deal with it.

The assessment of MAAs/NDAs which are including enhanced QbD approaches require a good understanding of statistical, analytical and risk assessment methods that have not been systematically used by pharmaceutical industry or regulators in the past. Therefore, such applications challenge the established regulatory experience. Generally, it is a good sign that industry and agencies use these pilots to improve understanding of their mutual expectations and the need to develop highly qualitative products is undoubted.

7. Conclusion:

The research driven pharmaceutical industry is facing an unprecedented challenge to their business model with an increasing number of blockbuster products going off patent which will result in a tremendous loss of revenues. The number of generic products that already address many of the main diseases properly is increasing. Thus, research targets with a clearly visible benefit are getting more and more difficult and therefore, attrition rates of projects in development are likely to increase further. Based on the ever increasing hurdles regarding safety, efficacy and quality aspects which need to be matched by any new product, it will be more and more difficult to achieve approval for a new molecule and it is getting more challenging to identify the right replacement candidates for the patent losses ahead of the industry. Additionally, reimbursement questions challenge the business model further.

The research driven industry will not be sustainable if the right countermeasures are not taken in due time. Open innovation, new business models, translational and personalized medicine, collaborations in the pre-competitive field as well as appropriate interactions with the agencies are potential measures among others which need to be taken.

On the other hand, given the fact that there is still a large number of diseases without any appropriate medication and available treatment there is still a lot to do for the research driven pharmaceutical industry.

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Personalized medicine

A change of strategies

Prof. Dr. Theodor Dingermann, Goethe University, Frankfurt (D)

In recent days, the vigilant observer of health related topics will encounter overproportionally often the phrase «personalized medicine». Wasn't medicine always "personalized", one might naively ask? It wasn't since it couldn't be – at least not to an extent which will be described here. Since till recently the technical background for this approach was not available. But what exactly is "personalized medicine"? An attempt to approach a difficult topic.

It may indeed seem odd that in today's highly sophisticated and technologically overloaded "conventional medicine" there should be hardly any "personalized" ways of treatment? But in fact, this is the case. Taking a closer look, one will see that first and foremost illnesses are being treated, whereas sick patients always come in second place. As we all know, we talk about treating high blood pressure, type 2 diabetes, breast cancer and so on. The individual patient plays a minor role in that. The current paradigm of evidence-based medicine relies on "double blind" and not at all on personalized criteria. It is assumed that standard treatments are applicable to all patients suffering from a particular disease.

This statement is not meant to put blame on doctors who are responsible for the therapy. Up to now, there were hardly any possibilities to include – in addition to disease related factors – also patient relevant factors in the decision-making on therapies. This is bound to be a deficit since, after all, no human being is like another. Time, however, is ready for a change. We just celebrated the 10th anniversary of the publication of the human genome. Today it is possible to analyze individual differences in human genomes within days and at affordable costs. From these analyses, deviations from the "average" can easily be derived and taken into consideration in order to avoid problems which can be anticipated. And on closer inspection, there are also hardly identical clinical syndromes, even if the name of an illness, e. g. a particular tumor, might suggest so. These differences can be characterized on the molecular level as well – not from every body cell but from cells of the affected tissue.

Up to date drugs had to be evaluated statistically in regards to their effectiveness and tolerability. The agents were studied first in several biochemical/pharmacological models in the test tube or in an organ bath, then in various animal test runs and finally on healthy human subjects and patients. This graded approach allowed to judge effectiveness and tolerability of the medicine, and only if a benefit/risk consideration turned out clearly in favor of the benefits, the drug was granted market access by national or international authorities.

For an individual, though, these statements exhibit a certain lack of reliability as the outcome of such studies appears in the shape of a more or less expansive Gaussian distribution (Fig. 1). Swings towards "ineffectiveness" are possible, just as well as swings towards overdosing in individual cases in spite of basically correct application, which may manifest itself in forms of intolerability or even a relevant toxicity. We got used to this because there was no acceptable alternative.

But how can a doctor know if a patient who is supposed to receive a medication which, according to a statistic evaluation, helps most but definitely not all patients who suffer from a certain illness, will actually benefit from said drug and will also tolerate it well?

Reasons for such individual deviations from the norm are differences in the genetic makeup of humans (Fig. 2). In order to be able to identify and interpret them, a doctor has to check into the genomes – meaning the immediate genetic information – of the patients. And this indeed is possible today. These new methods are summarized as "molecular diagnostics". They form the base for a personalized or stratified medicine which aims to divide a group of patients who all suffer from the same illness into at least three sub-groups: A first group of patients who actually benefit from the medication; a second group of patients who cannot benefit from the medication due to genetic circumstances; and a third group of patients who encounter significant side effects when receiving the drug in the generally accepted standard dose. The consequences that will result if this technical potential is systematically implemented could mark a change of paradigms. Instead of treating (just) diseases we will move towards the treatment of a patient suffering from a disease based on knowledge of his or her individual genetic repertoire.

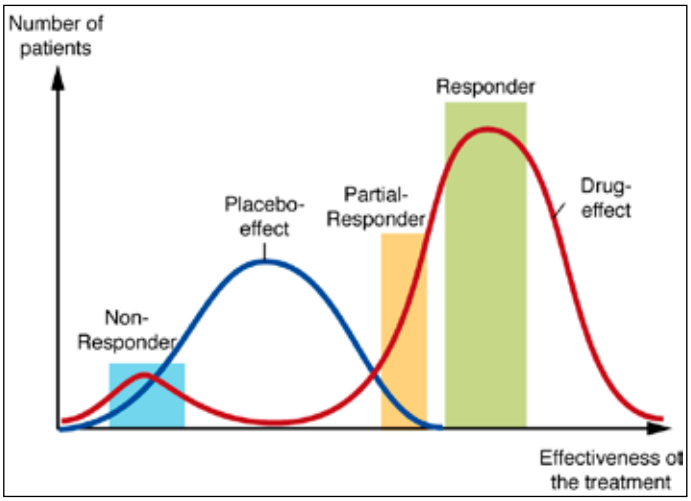

Fig.1
Example for a drug evaluation (prospective/double blind): When testing a drug in clinical studies, no Yes/No answers are obtained. If the test population is large enough two more or less expansive Gaussian distribution are obtained, one of which contains the "responders" (those persons for which the medication works), and the smaller other group of "non-responders" (those persons for which the medication does not work). Within the group of responders, another subgroup can be defined on the left flank, which only responds partially to the medication. Normally also patients receiving a placebo will respond to a certain degree. (Illustrations by Dr. Ilse Zündorf)

I want to illustrate this by two examples and, by that, I will point out clearly how important it would be to implement the appropriate steps as swiftly and comprehensively as possible.
The first example described has already reached the bedside because authorities reacted promptly and adjusted the approved indications for two innovative drugs after underlying problems and principles were identified.
This concerns the two recombinant antibodies Cetuximab (Erbitux®) and Panitumumab (Vectibix®) which had been approved for the treatment of colo-rectal carcinomas. Both antibodies block the epidermal growth factor receptor (EGFR) which is expressed on the surface of a relevant portion of these tumors. By binding to the receptor they prevent the corresponding growth factor from binding and thus interrupting the firing of replication signals into the cell's nucleus and as a consequence cell division. A prerequisite for the use of these two antibodies is, of course, that the tumor cells indeed express this growth factor receptor, thus screening for this biomarker is mandatory before applying these antibodies for therapy.
As plausible as this concept was and still is: The therapeutic results that could be achieved with these antibodies were pretty disappointing. Problems imminent in nearly all tumors arise from their highly genetically altered genomes. And this all the more so, the more advanced the tumor is before it was diagnosed.
A particular change that can be spotted quite often, and especially so with colon carcinomas, is the activation of a member of the signal transducing chain which is located downstream of the said growth factor receptor. This mutation renders the well-known proto-oncogene Kras constitutively active. If this is the case for a particular tumor, it obviously makes no longer sense to hinder the growth factor from binding to its receptor by one of the two antibodies.
To check this hypothesis, the two antibodies were tested with two groups of patients both suffering from colon carcinomas. The one group of patients carried no mutation in the Kras gene (wild-type Kras), whereas the second group carried an activating mutation in the Kras gene (mutant Kras). As predicted, the treatment with the antibodies proved much more effective in patients with colorectal carcinomas without activating mutations in the Kras gene, compared to those whose tumors had acquired the activating Kras mutation. Authorities reacted very swiftly and restricted the use of such antibodies only to those patients whose tumor cells carry a wild-type Kras gene.
This is by far not the end of the story. There are many more members along the various signal transduction chains which, when activated by mutations, uncouple the receptor signals from driving tumor growth. Once validated, such mutations will also restrict the use of the antibodies for therapy. This might sound like bad news

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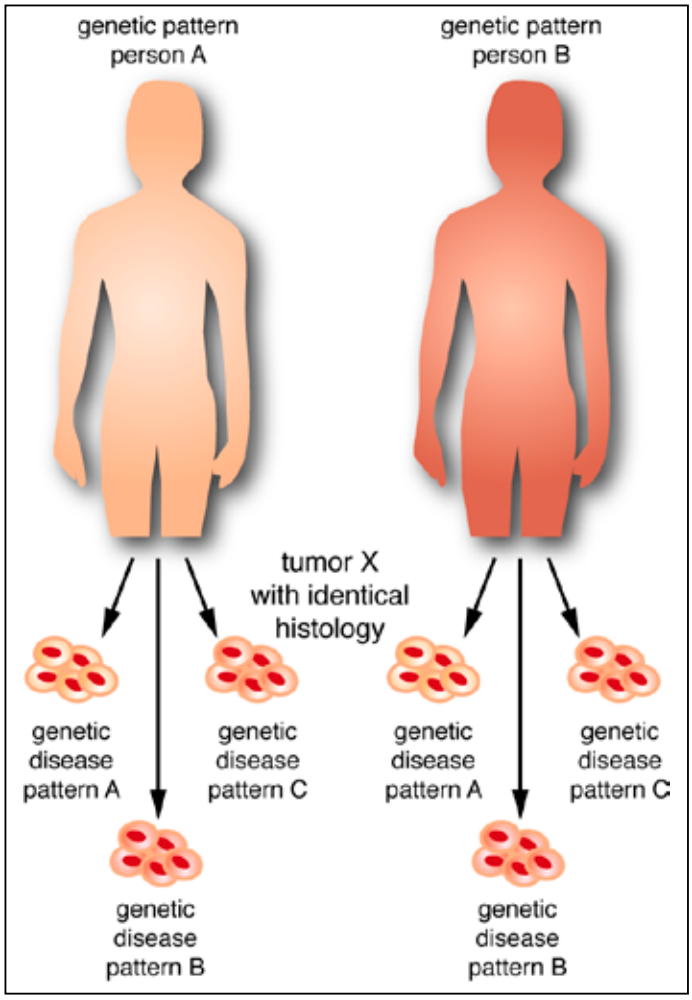

Fig.2
Every human being has completely individual genetic traits that can influence the effectiveness and tolerability of drug therapy. These traits are being passed on from generation to generation. They are present in every cell in an identical form, and they can be characterized at any point in the life of the individual.
In addition to that, there are for example genetic variations (mutations) present in a tumor that have been acquired by the tumor cells. They can have massive influence on a therapy decision. Since these mutations have been acquired sometime during life, they can only be detected in the affected cells (e. g. tumor cells).

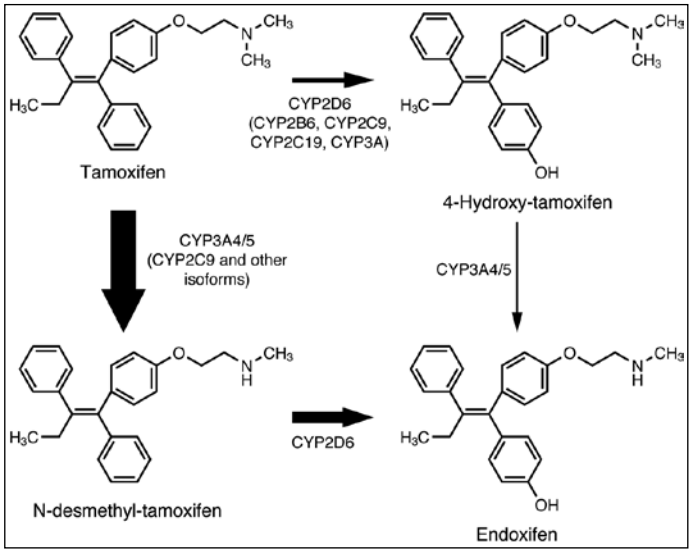

Fig.3
As it is known today, Tamoxifen is a pro-drug. It is being activated to Endoxifen by the cytochrome isoenzyme CYP2D6. Women who are poor metabolizers for CYP2D6 due to the absence of an active gene copy will receive basically no treatment, even when taking Tamoxifen on a daily basis – which has drastic consequences (see Fig.4).

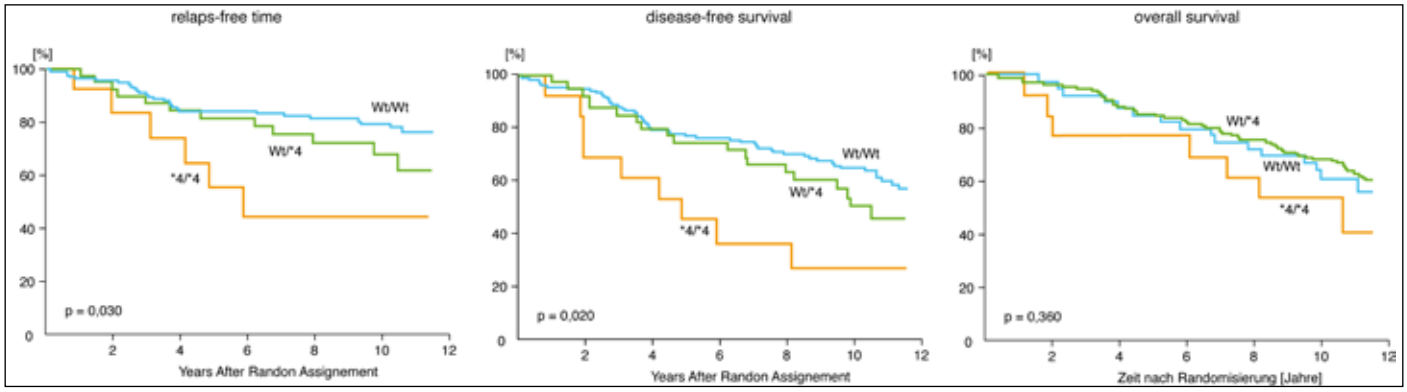

Fig.4
Kaplan-Meyer curves of female patients who were being treated with Tamoxifen in a chemo-preventive setting after resection of a receptor-positive mammarial carcinoma. Kaplan-Meyer curves are depicted for extensive metabolizers (Wt/Wt = two active copies of the CYP2D6 gene), for intermediate metabolizers (Wt/*4 = one active and one inactive copy of the CYP2D6 gene) and for poor metabolizers (*4/*4 = no active copy of the CYP2D6 gene).

for the respective companies which developed the antibodies. But in fact this is not the case. Only a highly responsive patient population can demonstrate the true value of these antibodies. Applying these fantastic molecules to patients who cannot respond due to particular individual mutations will heavily underscore the antibodies' therapeutic potential. This is a significant threat for the drugs today, where demonstrating "just" efficacy is not sufficient any more. Added value has to be demonstrated in addition, which is the new challenge in these days.

This example described a situation where disease relevant mutation had been acquired. To detect such mutations, the affected tissue has to be analyzed, for example the cells of a tumor.

There are, however, also therapy relevant mutations that are inherited. These are therefore present in all cells of the body, and in order to characterize them any cell can be examined at any time during life. Such mutations occur for example in genes coding for proteins, which participate in the chemical modification drugs. These modifications serve two purposes: they may be necessary to prepare the molecules for secretion. Or they may be necessary in order to render an inactive drug – a so called pro-drug – active. An example:

It has not been known for long that the old familiar and very well studied drug Tamoxifen is in fact a pro-drug. In the liver, this compound is chemically modified by cytochrome P450 isoenzymes, most importantly by CYP2D6, in order to obtain its active form Endoxifen. Endoxifen blocks the estrogen receptors thus preventing estrogen from binding. Therefore tumor cells which rely on estrogen for proliferation will stop dividing, which is why chemoprevention with Tamoxifen has been proven a very effective intervention for patients suffering from receptor positive mammarial and ovarian carcinomas. Yet its use is not as successful as it should be expected theoretically.

As it is known by now, the reason for this lies in the fact that up to 15% of the Caucasian patients are poor metabolizers for CYP2D6 and consequently not able to alter the inactive Tamoxifen into the active form Endoxifen (Fig. 3). Comprehensive retrospective studies have shown that this is a critical factor for these women. Unlike patients who are extensive metabolizers for CYP2D6, poor metabolizers for this enzyme cannot respond to the treatment and are therefore not treated at all – with dramatic consequences (Fig.4). Therefore, although the tumors of those women express the estrogen receptor, they need to be treated like patients carrying tumors that do not express the estrogen receptor. Based on these data, the FDA recommends now to test patients genetically before the decision of administering Tamoxifen is being made.

Many examples could be listed already today where therapies could be decisively optimized if in addition to parameters relevant for the illness, also patient-relevant, genetic parameters were included in an intervention decision. Based on molecular techniques the relevance of diagnostics has entered a whole new field: In addition to the classic terrain of defining diseases, diagnostics now extends its importance also towards biomarkers which allow drug related predictions whether a patient is likely to respond to a certain medication or whether the therapy will be tolerated.

In view of all this, personalized/stratified medicine will not only make necessary therapies for certain illnesses more effective and more tolerable. It will also contribute to allocate the enormous spendings in our healthcare system more effectively.

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Operations for the executive suite: Opening new horizons for current and future healthcare leaders

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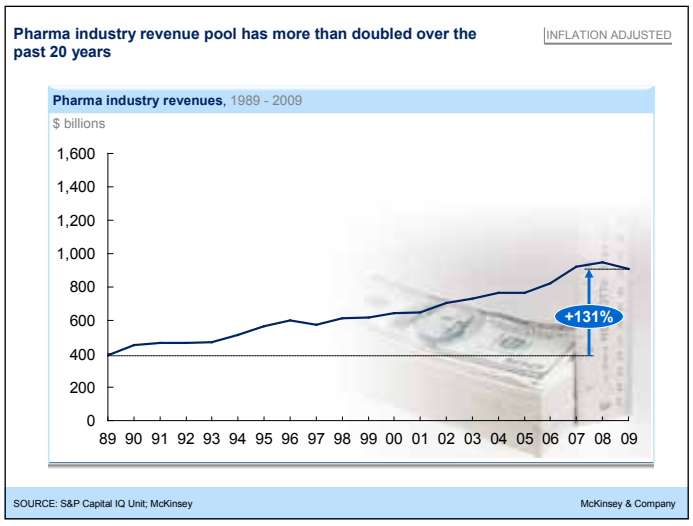
Traditionally, Operations topics have not always been prioritized or well understood by healthcare CEOs and their senior leadership teams, but the past should not be a blueprint for the future. The healthcare industry is in the midst of significant changes; and operations have been a pivotal success factor in other sectors that have experienced similar phases of maturation, declining innovation and commoditization.

Historically, pharma has been among the best-performing industries. In the last half-century, it has generated better returns than the S&P 500 for more years than have most other sectors – certainly better than telecommunications, semiconductors, computers, oil, defense, chemicals, and paper. Overall, the industry's revenue pool has more than doubled over the past 20 years, and its profit pool has expanded more than threefold.[1]



What trends are shaping the future path of the Pharma industry?

In recent years, the industry has found itself at a crossroads. Pharma revenues for 2010 were essentially flat – just 0.4 percent growth over 2009.[2] The industry's base of revenue and profit renewal has been eroding fast in the face of several major challenges.

- Portfolios and pipelines have weakened significantly. Returns on R&D have fallen by more than half, suppressed by reduced value creation and rising R&D costs. Drugs worth more than US$250 billion will lose patent protection between 2013 and 2017, putting 60 percent of the revenues of top 10 pharma companies at risk.[3] Periods of exclusivity have dropped from 13.8 to 11.2 years on average over the last 15 years.[4] Pharmaceutical and medical device companies (thereafter called "pharmacos") have slowed their R&D spending too, which is cause for concern given the challenges of maintaining, let alone improving, R&D productivity in the labs. The consequences are worrisome: Of the drugs launched between 1997 and 2007, 60 percent failed due to lack of differentiation.[5] Whatever innovation there is often focuses on secondary product features.
- Pharmacos are facing higher complexity everywhere. Generating fewer blockbusters, their success now rides more on niche products, usually produced in smaller batches. Their supply chains are becoming far more fragmented as they work to establish a presence in new markets and develop global networks of suppliers and distributors.
- The pharma industry is being transformed by an unprecedented shift to generics, including the emergence of a small but growing biosimilars market. Generics currently represent more than a quarter of all pharma sales worldwide, and are growing at twice the rate of branded drugs, meaning that they are expected to account for about 40 percent of aggregate pharma revenues by 2015.[6] Penetration differs among developed countries but overall generic sales have increased in most countries. Most future generic growth is expected to come from emerging markets.
- Healthcare systems are increasingly challenging the status of pharma prices through radical reforms of structure, funding, or organization as well as through reactive cuts linked to recent economic conditions. For example, the government of the Netherlands recently capped the amount it is willing to pay for many popular drugs. Germany has introduced a tender system in which payors ask pharmacos to bid for contracts to supply specific molecules or portfolios of products. In the United States, where healthcare costs as a percentage of GDP are the world's highest, the system is shifting from fee-for-service payments to outcome-based reimbursement.
- Healthcare systems are also looking to improve quality and increase safety and access. The United Kingdom's National Health Service, for example, has expanded its oversight on quality and has restructured hospital providers. Regulators worldwide increasingly emphasize safety and compliance. Part of the challenge for both companies and authorities is the increased globalization of both clinical and commercial supply chains. Adding to the challenge is the greater complexity of products to be evaluated, often without precedent or clear legislative framework.
- Risks for pharmacos are on the rise. In the United States, warning letters from the federal Food and Drug Administration have proliferated by more than 300 percent over the last five years. Between one and three consent decrees are issued every year, resulting in millions of dollars in fines, lost revenues, and increased expenses. In some new markets, counterfeit drugs represent anywhere from 10 percent to 30 percent of all sales. Unexpected risks, including political crises and natural disasters, can trigger

global consequences such as significant supply disruptions and lost revenue.

The news is not all bad, however. New opportunities are emerging for pharmacos, including new markets and consumers, new technologies, and more efficient operations:

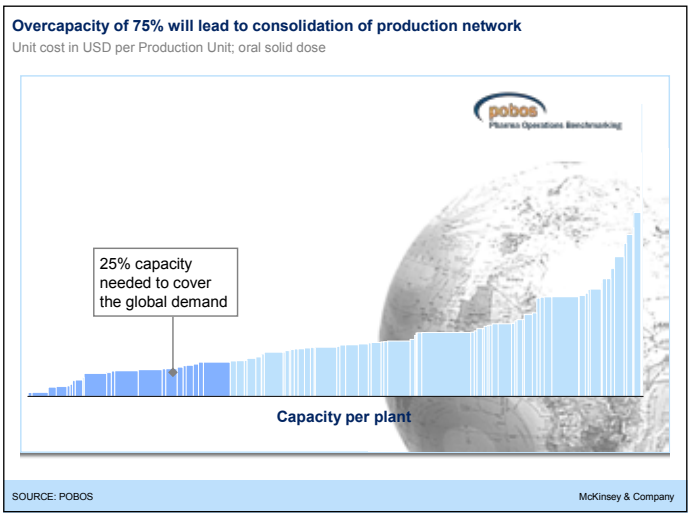
- Emerging markets are poised to bring in a billion new consumers, almost all of them currently underserved or unserved. Collectively, emerging markets will represent approximately 45 percent of global GDP by 2018 and are expected to grow twice as fast as developed markets in the 2008–2018 period.[7] Pharma sales growth at 10 to 20 percent annually in the largest emerging markets already eclipses the 2 to 3 percent growth found in developed markets.[8] While the largest new markets are in the BRIC countries (China alone will soon represent nearly a third of the world's pharma sales), there is great potential in the next wave of emerging markets in Africa, Asia, and Latin America.
- The increased healthcare needs of an aging population will be a factor in all developed markets as well as in key emerging markets such as China. For example, according to the Organisation for Economic Co-operation and Development (OECD), the population aged 65 years and older will be 240 million in 2020 – up from 98 million in 1980. And the OECD estimates that the current annual healthcare cost of a 75-year-old is 10 times that of a 35-year-old. Lifestyle and chronic illnesses are also on the rise. According to the World Health Organization (WHO), in 2008, 63 percent of all deaths were due to chronic noncommunicable diseases (NCDs), a fourth of them occurring before the age of 60. Annual NCD deaths are projected to increase by 15 percent globally between 2010 and 2020, with the greatest increase expected in low- and middle-income regions.[9]
- Biotechnologies will continue to flourish and provide an innovation engine for the industry – especially important as product differentiation becomes more valuable. The large-molecule market is expected to grow at twice the rate of small molecules, driven by major scientific advances – such as protein biology/complex molecules, large molecule synthesis, and genomics/personalized medicine – and by the need for more specialized and integrated approaches to treatment.
- Pharmacos continue to emphasize operational improvements and to redress operational inefficiencies. Most big pharmacos have announced and implemented aggressive cost reduction programs. Lean transformations and continuous improvement initiatives are now common in the industry – a huge shift in thinking compared to 10 years ago.

Pharma and medical device companies are already considering the implications of these trends

These challenges and opportunities add up to a mandate for fundamental change in the pharma industry. Many in the industry recognize this imperative, but companies are only beginning to take the large and difficult steps they will need to make in order to survive and prosper in the coming years.

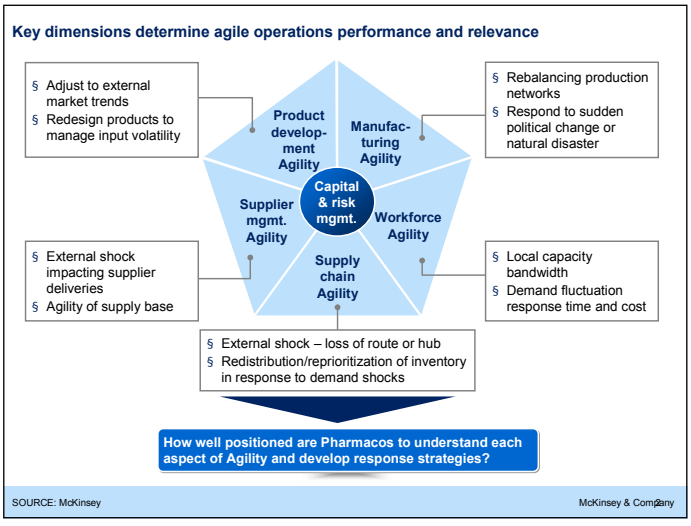
Reduce overcapacity

The industry today is facing overcapacity of 75 percent or more – a situation that is already driving a wave of network consolidations and rationalizations. This has arisen for a variety of reasons: volume shifts from originators to generic competitors (which often build highly cost-effective assets), "once-daily" and combination medications, shifts in technologies, deliberate over-investments to create safety buffers, and increasing productivity. A McKinsey study of over 30 global pharmacos shows average annual productivity increases of 7 percent over the past four years, which implies that productivity would double in a decade.



Build flexibility in their supply chains

In a "hot, flat, and crowded" world pharmaceutical supply chains are increasingly at risk. Since supply chains have become more global and interconnected, natural disasters such as the recent Japanese earthquake and Tsunami, or political upheavals in the Middle East, can wreak havoc on the business. When the 2010 volcanic eruption in Iceland stopped European air traffic, many pharmacos struggled to find alternative transport, leaving some lifesaving drugs out of supply for two weeks. The Japanese Tsunami damaged numerous pharmaceutical plants, some of which may never reopen. Other changes in the environment have combined to raise the pace and complexity of competition, which puts a premium on the ability to rapidly and efficiently adapt operations.



Master external supply management

With a few exceptions, pharmacos have moved away from the belief that they should produce products in-house by default. Today, the dominant model is a balance of in-house and contracted production, with most pharmaceutical production in-house and API outsourced. On average, a global pharmaco works with 100 to 200 contract manufacturing organizations (CMOs) – probably too many. A more proactive approach to external partnerships is a powerful way to optimize utilization and reduce risk – and it can accelerate innovation. Partners can bring new formulations to the table, along with packaging ideas or devices. As breakthrough research becomes more difficult, these can become key differentiators.

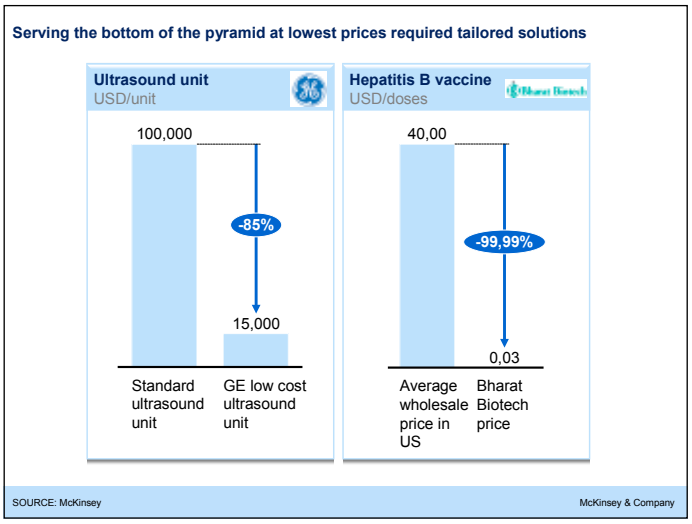
Catch the train to emerging markets

In the years ahead, most pharmacos' output will be destined for emerging markets. Many of these markets will also require that production be local or in a low-cost region, and that products address the unique requirements of the local customers. The emerging market supply chain will become the core of pharma operations.

While the opportunity is huge, so is the challenge, especially from an operations point of view. In India, for example, prices are 85 to 90 percent lower than in the US and they continue to fall. Some Indian companies produce tablets at a cost of $2 per thousand, compared to the roughly $60 that multinational corporations spend on average. This has major implications for business models, especially for pharmacos selling into markets with cost-plus pricing structures. Achieving low cost is not just a matter of raising margins – it is a prerequisite to entry.

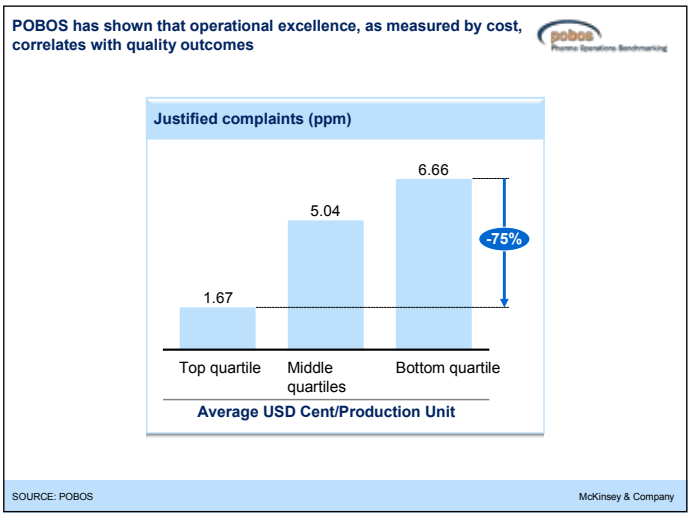
The next billion customers in emerging markets will also need tailored solutions to meet their unique requirements. Companies will rapidly exhaust approaches that merely attempt to cut cost from their existing processes and supply chains– success will come from holistic re-design that considers the entire value chain, with a blend of technical, consumer and business model insight. Radically redesigned products could also expand the markets back in developed countries.

In distribution, models vary widely across countries and pose different challenges. In China, for example, companies face over 1,000 wholesalers in a multi-layer structure; in Mexico, retailers expect pharmacos to provide category management skills; and in other countries, pharmacos such as Sanofi Aventis in Brazil have forward-integrated to ensure distribution and create strategic advantages.



Excel in quality

In an environment of increased quality scrutiny and more sophisticated regulatory supervision companies will need to move away from mere "risk avoidance" – an impossible goal in any case – to a more structured risk assessment and prioritization of resources to focus more closely on what matters. Modern practices in quality assurance could improve patient safety, reduce risk and also capture significant earnings improvement. Most operational excellence efforts in quality and compliance have delivered unexpectedly high savings.



Operations can open significant value creation opportunities

Many of the changes the industry must now make will depend on dramatically improved operational capabilities. The experience of other industries demonstrates the importance of operational excellence to companies squeezed as innovation rates drop, sectors mature and new markets and competitors drive prices down. Consider the exceptional supply chain efficiencies of Walmart and Dell, how Apple and Unilever have developed new talent, and the success of Procter & Gamble in breaking down silos within Operations and other functions in order to capture value.

Many pharma CEOs and executive teams have already started to spend a lot more time on operations. But all too often, their attention has been in reaction to serious regulatory issues. We believe that it is time for pharma CEOs to proactively examine how their organizations can capture even more value from operations – indeed, how they might be able to harness operations to create competitive advantage. Other industries have proved that it is possible to leverage operations to spur innovation, help open new market opportunities, and shift cost and risk paradigms.

We have identified a number of specific operations topics, grouped into five themes, that could create billions of dollars in value upside for pharmacos.

New aspirations and operations models

Leaders in other maturing industries have found new sources of growth by setting aggressive aspirations for their operations. Apple operates at two days of finished-goods inventory. Nucor can build a mill at 10 percent of the cost of a traditional integrated mill. Walmart's focus on operational cost-efficiency has driven 17 percent annual sales growth and 20 percent EBIT annual growth over the last decade. The pharma executive suite must challenge Operations to more aggressively question the company's operations model and develop a transformational strategy – delivering breakaway performance rather than incremental improvements.

- Could we launch products in half the current time, at best-in-class costs right from the start? Could we deliver small-scale personalized drugs immediately – and on demand? Could we track patient behavior in real time to improve efficacy and patient compliance?
- Could a fundamental challenge to the manufacturing ownership-and-control model gain us billions of dollars in market capitalization and newly freed working capital? Apple and Intel provide examples of the spectrum of this discussion.
- Structural industry changes are pushing manufacturing questions to the center of biopharma companies' agendas too.

What's the right technology to invest in? Should we manufacture internally or externally? How could we push back against the low-cost players? Placing the right bets in biopharma will make the difference between failure and success in the swiftly changing biopharma landscape.

Developing talent

The former head of Operations at Apple is the company's new CEO – and that is an organization where few of us think that operations is the core. Pharmaco executive suites can help Operations organizations to develop their talent and shift their mindsets in step with their evolving responsibilities. That applies both to Operations' global leadership team and to shop floor personnel.

- Operations leaders of the future should be able to turn operations into a competitive advantage for their companies. For this they would need new skills and competencies – boldness in vision, ambition, creativity, and commitment; a mindset and skills that extend beyond operations; and the ability to lead fundamental transformation at scale. Do our operations leaders have those characteristics? If not, what can we do about it?
- How could we develop our front-line transformation leaders and ensure strong and sustained support for driving change? With the right levels of ambition and support, transformational change initiatives can capture 20 to 30 percent in productivity gains within a year, as well as improve quality, flexibility, and employee morale.

Moving from cost to growth

Operations has the potential to open up new opportunities just as a new treatment or a blockbuster drug would do. Volkswagen's platforming and modularization strategy has allowed the company to serve niche markets at 25 to 40 percent lower cost and with significantly faster time-to-market. Nestlé and Unilever have reached large and underserved emerging market populations through novel distribution models. GE, Coca-Cola, and Deere, among others, have leveraged low-cost designs for emerging markets to win new customers back in their developed markets. But to achieve this type of success, the pharma executive teams have to coach and challenge their companies' Operations groups and shape their roles toward delivering growth.

- Could we leverage our operations capabilities to boost revenues? Other industries did that a long time ago – using products and platforms from emerging markets for global strategic advantage; making niche products profitable; or reacting nimbly to shifts in demand.
- Technology has already transformed many industries, and healthcare is ripe for a similar change. Could hundreds of billions in healthcare costs and sales losses be avoided through improvements in patient compliance and with more effective management of chronic diseases? Could our company develop the technological skills to succeed against the new competitors in this field?
- The biggest unexplored opportunities in developing markets lie in the fast growing, emerging middle-class population. What will it take to unlock these opportunities? Do we have the operations capabilities to reach and serve a lower-income population in economically viable ways?

Managing risk

Risk exposure and value at stake are higher than ever before in the healthcare industry. Supply chain risk events are the second-largest contributors of large monthly declines in share price, resulting in drops of 10 percent or more when compared to the S&P 500 over the same time period. Pharmaco leadership teams must have a deeper understanding of this and work to embed agile mindsets in their organizations, while helping them to manage risk systematically, proactively, and cost-effectively. Taking a lesson from other industries, Hewlett-Packard's supply chain risk-management program delivered incremental value in excess of $500 million during its first six years.

- Could we substantially reduce or eliminate our supply chain risk exposure? A systematic and structured risk-management approach will cost-effectively mitigate risk and proactively reduce the likelihood and negative consequences of disruptive events. By taking advantage of upside opportunities, this approach could potentially deliver millions of dollars in reduced supply chain costs and higher supply assurance.
- The industry's current dynamics and volatility require lean initiatives to be supplemented with agility as a central focus for operations. How could we set up a system of structural agility that goes beyond issue resolution and firefighting, improves operating margins significantly without major investments, and drives profitable growth thanks to faster product launches and fewer stock-outs?
- Is our organization prepared for the evolving regulatory environment? Regulators worldwide are transforming themselves – developing smarter and leaner ways of working, and becoming more collaborative and increasingly sophisticated in their use of standards, best practices, and proven methods. Pharma executives must be vigilant about regulators' new mindset and new strategies in order to sustain financial performance, brand image, and long-term competitiveness.
- Do we still rely on "compliance by inspection" in an increasingly complex and competitive medical devices sector? Could we achieve a 10 to 15 percent increase in earnings by adopting modern quality approaches and tools? Through cross-industry best practices in quality assurance, the medical products sector could improve patient outcomes, capture $5 to $6 billion in incremental EBITA, and reduce risk.

Breaking down the silos

Operations needs sufficient cross-functional support to step into its new role and deliver to its full potential. The CEO and the executive team are the only ones who can break down the organizational silos and align Operations, R&D, and Commercial leaders behind common goals and strategy.

- What happens when the product and customer value that are driven by pure science innovation start to slow down? Could we combine customer insight, engineering innovation, and manufacturing best practices to create products with distinctive value for customers? Design-to-value is finally finding its way into healthcare to drive growth and profits. Getting it right could mean 15 to 25 percent higher margins and increased sales, plus improvements in speed-to-market.
- Consumer goods supply chain champions achieve 4 percent or higher operating margins, better service levels, and greater capital effectiveness than their peers. Could we follow the same path within the pharma industry to transform our supply chains?

Conclusion

The healthcare industry is facing significant changes – as it is reaching a more mature stage and innovation declines, new risks and opportunities are shaping the landscape for pharma and medical device companies. In this environment, operational capabilities will continue to be a growing source of risk for pharma players, but they will also be a powerful driver of growth and profits. Capturing these opportunities will require sustained executive suite involvement and repeated challenges to the organization. While there are no definite answers or off-the-shelf solutions, just increasing awareness of the operations potential for value creation, of specific opportunities and lessons from other industries, could put a company on the path to success.

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On future challenges of global Pharma

What are the core issues, role models and how to find or educate people with the right competencies? A synopsis of the panel discussion.

Prof. Dr. Gerd Folkers, Department of Chemistry and Applied Biosciences, ETH Zurich and Collegium Helveticum, Zurich

A lively panel discussion focused on the concern about the future role of the European pharmaceutical industry in global markets. Shifts in values and markets, diverse consumer behavior and needs and distinct education traditions may enforce a rethinking of Europe's claim for leadership.

Where are talents in today's world and what are the core requirements?

First, one needs to understand what you are buying. Talent is not to be commoditized, but one of the core issues is just making sure to understand the skills that are really needed. In a second step you can determine whether there are multiple markets that have these skills.
Project management is certainly a core requirement, and it can mean different things depending on how it is applied, there are certain skills in terms of process management, analytical skills, KPIs, etc. These can be found in multiple markets. But the challenges are not so much in those kinds of skill selection but rather the highly specialized medical scientific clinical areas where there is only a very small restricted supply, which may require moving locations.
Another challenge is global brand teams, just taking it into Marketing for example, versus technical development skills. To build global brand teams in Shanghai or in Hyderabad can be an interesting opportunity and a challenge to really get people to understand brands across the globe.

Is there a hypothesis on what is differentiating joint ventures in Pharma which work well from those which we may have seen fail?

For any kind of joint venture collaboration, both parties need to be enthusiastic with the joint venture. It is a classical win-win situation, and only if both parties share the same commitment then everybody thinks this will benefit my company or my organization to the same level. But very often, big Pharma is trying to be the dominant partner. The dedication to a certain topic, however, is usually much stronger in the small companies because for them it is often the question of the company's survival. Hence small companies are really strongly motivated, whereas for big Pharma the project is just one among many. Especially lawyers and business people tend to dominate the interaction too much, which will not result in a positive outcome. We need to address these joint ventures in a really collaborative approach.

What are the tools of prediction, and which role plays the understanding of genetics and evolutional biology?

There are several tools around, such as trend analysis, mapping data, qualitative as well as quantitative ones. We are still in the beginning in terms of really mapping out and making sense of large amounts of data. The same is true for scenarios, and other tools including Delphi methods, which means approaching experts in a specific way that encourages them to show where there is consensus about the future and also non-agreement. So the important future areas can be detected, but also those where many questions are still open. The latter are among the most interesting areas. This is where assumptions are scrutinized as to where we take things for granted about how our business works. At the moment, there are lots of ideas about modeling assumptions about the future around biology principles but it is hard to transform them into a strategic outcome which can be implemented. Many people are looking at biological processes but it turns out that it is hard to translate them into a strategic tool.

This opens a hot debate on human cultural co-evolution or a cultural parallel evolution, and its interfacing and interferences with genome-based technologies. We have this cultural interference, into the society, by using sophisticated drug therapy to cure people. Is this justified in terms of ethics? How do we know that this is "good" ethics and who decides upon it?

Being a human has to do with "humanity". If it is just for the strict perspective of genomes, we kind of dilute the gene pool and may lose superiority. Medical treatment and welfare tries to save life at all cost and will consequently facilitate the survival of less adaptive mutations. But this is the cultural achievement of moral behavior and we feel obliged to act along these principles. On the other hand cultural behavior and introducing culture technology is again

based on genetic inheritance. As long as we have not understood how the genotype and the phenotype are really related and whether this is a one way street or not in topics like epigenetics, we stay unable to predict evolutionary outcomes and might not use this as a strategy.

Will Western Europe societies all be losers in this megatrend game because of their different value patterns?

There is a high risk at the moment that we would be losing out if one looks at, to borrow a term, the agility, the flexibility. Considering the sheer numbers of people that are in the eastern hemisphere, how the spending power is shifting, how the number of people entering into any kind of consumer role is shifting, we are at a high risk. The question is whether we manage to reinvent ourselves somehow in a new role, and maybe redefine what we see as a positive kind of growth. It is not only about counting the numbers but also about the whole discussion of redefining quality of life along indicators which are not only quantitative in kind. There may be the opportunity to regain a leadership role which is oriented more around sustainability. The key question, however, is whether we reinvent the role that we have and find a productive role that is beyond any kind of arrogance and to find our place in an actually completely shifting power game.

So that relates directly to the suggestion that we heard from the experts. Do we have to shift to the Asian way of thinking?

The question is: are there losers in this new change, or do we all win? That is a very different perspective in terms of thinking about it, increasingly in terms of looking at talent acquisition for global multinational firms. We need to realize that, increasingly, we are all part of a global community, and that comes with some confusion and great change. Actually one may enjoy working with people that are eastern or from some of the emerging markets because it may tell us more about ourselves. Our challenge will be the dilemma we spoke about: We need to expect and understand that the new world is global and that there are going to be changes. We will have to understand whether we really expect these to be losses or gains, and some of it will be individual. But the world at large is what is going to benefit, and there is going to be a map change and we have to decide amongst ourselves whether we accept that or not because it is obviously inevitable.

I asked myself what is the concept behind all of what you have taught us. Is it the good human being? Is it the autonomous human being?

This question has created a controversy. While there was some agreement in the panel, others objected. There was the conviction that autonomous acting is not a reality but an assumption or a belief. And although there may be nothing like a completely rational decision in many cases, one has to stick to the belief because it is the only way to proceed. That may be true for how all organizations work.

Being a teacher at university, how would relocation and shift affect our education at university level? Do we still need chemists, biologists, pharmacists if there is no, in central Europe, no need for research and development anymore. Would we just train people to become retail pharmacists, and that's it?

The question again caused controversy. The major concern of science teachers at the university was that the goal of education shifts more and more to "simple" technical skills. They argued that this focus may also responsible for the lack of innovation that we see at the moment and just foster incremental improvement.
Furthermore it was criticized that in decision making more and more scientists are replaced by lawyers and economists or accountants. So teaching young scientists to follow and exploit fundamentally novel ideas and directions was felt to be a misfit in the system.
The counter argument doubted the development described and in contrast pointed out that in emerging economies people with the same technical skills as been acquired in Europe normally show a completely different attitude in terms of appetite for growth. The suggestion was to think about how to adapt the attitudes that can be seen in emerging economies in order to stay competitive.
A third vote completely disagreed with that argument. Technical skill and being hungry may be not enough to achieve sustainable economic success. While it may be right to be dedicated to the scientific topic, a certain broadness and overview is needed to do successful research in Pharma. The actual development and recruiting policy was thought not be sensitive enough for these questions. It has been suggested to establish a platform where people with a solely focus on technical skills and others with overview and broadness can meet to learn from each other. If this became a success, industry would benefit tremendously.
Another vote pointed to the importance of volatility and agility. Twenty years ago, McKinsey, for example, was mainly driven by economists, but not by very many scientists. Today more than 50 percent of the consultants are scientists or physicians or pharmacists or engineers, a very broad range of people coming from a variety of disciplines and leading the company. It was emphasized that the champions will embrace this agility and volatility and make use of the pool of scientists in China and India.

What is the future in R&D? Research in the pharmaceutical industry is not comparable to e.g. the automotive industry. While in the automotive industry fundamental parts of the car such as the engine, the wheels, etc., have stayed the same for 100 years, every new mechanism of action in drug development is a completely new challenge, as would be the construction of a completely new type of engine. Can this be made more efficient?

One dimension is that today's Pharma companies very much segment in high price blockbuster products and for those, the majority is in-house. Production, launches, everything is made in-house.
However, there are also first very big products that are mainly manufactured at third party sites. This is not driven solely by the question of capabilities, but rather by the question of how much to invest in biologics production, trying to assess the chances whether a product will make it to the market or not. It raises the question whether risk can be split and how to test a new situation where both in-house and third party share the development, but the majority comes from the third party. It is believed that this atomization approach will become more and more relevant but by far slower than in other industries. Which means that even in research, surely in development, surely in launch and operations, the question of composing your value chain with the right players will become more important.
We need an ongoing reinvention. If the analogy to the automotive industry is taken up again, Mercedes defined three components as being core: The engine, the axle and the gear box. And they said we will never give this to a third party, because this is where the quality comes from, and this is the in-house core competence.
Now we see the advent all these electronic vehicles. And the electro-engine, this is a standard, nobody cares, whether it's from Mercedes or not, because electro-engines are all the same. So the intelligence is in the battery and the way of compressing and keeping energy in the battery, and making sure the battery does not explode and does not burn. Things have changed dramatically from

one day to another. The paradigm has changed. One should stay very alert about what might be the future paradigm.

What is a core function in Pharma in 2020?

Certainly developing products and research are still the core of your business, but with the growing importance of the emerging markets, the distribution network will become more and more key. Understanding the local markets, the individualization, is vital, as we learned from the McKinsey presentation as well. To bring the right products to the right markets and understand the needs locally will remain core. What will not remain core are things that can be atomized or consolidated and can bring a competitive advantage to your company, so certainly a big portion of support functions, finance, HR, and certainly IT; also certainly pieces of legal, certainly pieces of operations and production.

Well it is interesting to hear whether the colleagues from HR would consider this non-core?

Organizations have actually outsourced all of this in fact. But it is the individualization and the customization what products are going to hit in particular populations. What populations are they needed for, what populations, emerging markets populations, Western type populations that are going to make the difference. Functions like HR to a great extent can be outsourced.
In a different comment, it is always core to have a new molecule. Without a new molecule all is nothing. In order to really be efficient and flexible on the way to a new molecule, it is necessary to efficiently manage networks. To manage networks with whatever research function, academia, whatever. It is needed to effectively manage a whole bunch of partners inside and outside the company, and in order to do this, people should have done at least the research part and the development part, as well as the medical part also in operations. Core people should have the real understanding of what is going on. Because the other parties, they can tell you everything. Probably 10, 15, 20 percent, maybe 30 percent of research and development and medicine should stay in-house, to keep the knowledge of the necessary. Then it is key, and a crucial task for HR, to identify people who are able to manage in complex networks.
Another vote guessed that basic research will no longer be a core competence because this is already done better and more efficiently in other places. Development and developing the product including the combination of service, product and maybe device will remain a core competence but possibly not in a traditional commercial sales force. However understanding of customer insights and understanding of different segments and requirements of segments is considered be a very big in-house competence, with a lot of learnings from fast moving consumer goods. In operations, chemical production will be no longer a core competence, since every chemical molecule of this world can be sourced from China now, whereas formulation as a core competence will remain. Packaging might not survive as a core competence, but definitely talent will be an important core competence of the future. Finally, it will be a core competence to have a consistent, understandable, meaningful logic for the company. And referring again to the automotive industry, a company like Porsche which is extremely successful in the market has a very low element of in-house competence and very deep level of involvement on the whole value chain. So it is expected that also in Pharma there will be very different models for success with more and less in-house competence.

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