6.1 The future and post WTO scenario

Stand on the crossroads of a new world of pharmaceuticals. Doctors and scientists are aware of the fact that whether or not a patient benefits from a prescription drug is a function of the individual’s genetics, the drug and the disorder or condition for which the drug was prescribed. Changes in science, technology and clinical medicine afford a better understanding of these determining characteristics at a molecular or sub-molecular level. This holds a great promise: the discovery of more effective and better-tolerated therapies means more efficient use of healthcare resources. From a business perspective, this changes everything. If the future is one in which correlation of drug response with individual genotype is the norm, it will mean that drugs that would be unsafe or ineffective for a given patient will not be prescribed. It would also open the possibility of marketing the drug-lets.

An article in a recent issue of Health Affairs describes this new environment as well as we could have: “In the long run, [this] could undermine the current focus on blockbuster drugs that bring in large annual revenues for the life of a drug patent. Although this pattern is likely to continue for some time, and segmented markets already exist for many drugs, the emergence of large variation in the genetics of drug response could divide demand for pharmaceuticals into increasingly smaller subgroups, each with its own unique (pharmacogenomic) needs.\[105\]

Prescribing drugs according to genotype could reduce demand for particular drugs, thus lessening the stream of revenue and the profits available to invest in research and development.
Unless more new drugs coming on the market offset that reduction, [this] could increase market differentiation, reduce profits and perhaps effect change in investment patterns and the scope of industry-funded research."

6.2 Impact on consumers

The standard argument advanced for deregulating drug prices is that market mechanism and competition will help check and stabilize drug prices. Such a dubious argument seems to be originating from the failure of the government to evolve an effective mechanism to monitor the pharmaceutical industry’s adherence to the DPCO, and, more importantly, the process of liberalization being pursued by the government. As has often been argued, the pharmaceutical sector is peculiar in the sense that it is a seller’s market; the consumer, the public, has no choice in the matter because the interface between the product and the patient is through the doctor for whom the issues of price and affordability are secondary or the chemist who has no interest in selling cheaper drugs (Ramachandran, 2002).

As mentioned earlier, the deregulation of the drugs market in 1995 was soon followed by prices of drugs going up and similar consequences may be expected as a result of the Pharmaceutical policy, 2002. The Indian government seems to forget that even in developed countries like the United States and the U.K. there are effective price control mechanisms and bodies to monitor drug prices.

In a developing country like India, what is most disturbing about this policy is that it does away with the control over the prices of a large proportion of the drugs just when the country is moving towards a stricter patent regime which,

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106 This will give rise to stiffer competition and survival of many small and medium scale companies
107 According to (Ramachandran, 2002) it has often been argued, the pharmaceutical sector is peculiar in the sense that it is a seller’s market; the consumer, the public, has no choice in the matter because the interface between the product and the patient is through the doctor for whom the issues of price and affordability are secondary or the chemist who has no interest in selling cheaper drugs.
it is feared, will further promote monopolistic practices in the pharmaceutical sector.

6.2.1 Access to essential drugs in India (2000).

Based on the statistical estimates received from WHO's country and regional offices and through the world drug situation survey carried out in 1998-1999, the department of essential drugs and medicines policy of the WHO divided countries into four categories.

1. Good access to essential drugs - Countries in which 95-100 percent of the population had access to essential drugs.
2. Medium access to essential drugs - Countries in which 80-94 percent of the population had access to essential drugs.
3. Low access to essential drugs - Countries in which 50-79 percent of the population had access to essential drugs.
4. Very low access to essential drugs - Countries in which 0-49 percent of the population had access to essential drugs.

While countries like US, UK, Australia and even Sri Lanka fell under the best (95-100%) categories; China, Indonesia etc. fell under the (80-94%) category; and even Pakistan, Myanmar and Bangladesh were in the (50-79%) category; India fell in the last (0-49%) category\(^{108}\). Some key indicators of India's Health Report Card. On the basis of data received over the period from 1995 to 2000, the Human Development Report - 2002 (UNDP) states that in India - less than 50 percent of the population has access to essential drugs, only 31 percent of the population is using adequate sanitation facilities, 47 percent of children under the age of five years are underweight, 46 percent of children under the age five are under height for age and only 42 percent of the births are attended by skilled health staff.

\(^{108}\) According to HDR 2002, UNDP (Human Development Report) in case of availability of essential drugs countries like US, UK, Australia and even Sri Lanka fell under the best (95-100%) categories; China, Indonesia etc. fell under the (80-94%) category; and even Pakistan, Myanmar and Bangladesh were in the (50-79%) category; India fell in the last (0-49%) category.
6.2.2 Poverty and its correlates
As is well-known, conceptualizing poverty is a difficult and controversial subject. At one level, it would appear reasonable to hold that poverty is essentially the non-fulfillment of certain basic needs and the threshold of such needs consists of being able to meet minimum nutritional, clothing and shelter requirements, escape avoidable morbidity, and be literate. However, what constitutes a basic needs package is itself a controversial subject. Should one focus only on a narrow set of economic and social criteria? What about political and cultural deprivations? There are no easy answers, and they have a whole range of conceptual constructions associated with the notion of poverty, some of which do have operational counterparts.

In the narrowest sense, poverty is pegged to a nutritional norm, and most of the poverty discussions in India are based on such a norm. It is based on the view that it is possible to have a nutritional norm such that the probability of a person being undernourished at that norm is minimum. Taking this norm as an anchor, it is then possible to apply the known nutritional contents of different foods and work out the expenditure required for the cheapest food basket. This is what economists call a poverty line.

Using such a poverty line, economists generally agree that from the 1950s to the mid-1970s, there was no trend change in the percentage of people below the poverty line in India, but during the next decade and a half there was a clear trend decline. As regards the period of economic reforms, there are conflicting assessments. As is well-known, poverty estimates in India are based on surveys on consumer expenditure conducted by the National Sample Survey Organisation (NSSO). Based on these surveys, the official position of the government of India is that the incidence of poverty in the country declined by nearly ten percentage points in the five year period between 1993-94 to reach 26.1 percent in 1999-2000, even though there were wide inter-state disparities both in terms of the poverty ratios at the latter date as well as in their rates of decline during the decade of the 1990s.
However, many experts have questioned the government's claim, mainly on the ground that the methodology of the NSSO survey on consumer expenditure in 1999-2000 was different from the earlier surveys, and have argued that the incidence of poverty could be substantially higher than the official estimates. The claims and counter-claims have been widely discussed in the recent months by experts. However, it may be noted here that the critics of the official estimates appear to be on a firmer ground.

Even the calorie-based narrow notion of poverty has complex causal connections, but its obvious major structural correlates are as follows: (a) assets, both tangible (e.g. land) and intangible or embodied (e.g. skill); (b) employment availability; and at rate of return to labour power. Efficacy of economic processes and policies towards poverty reduction depends on their impacts on these correlates, a lesson from economic history that one can hardly afford to ignore. During the first four decades after Independence, particularly during 1970s and '80s, Indian economic policymakers appeared to show relatively more respect to this lesson compared to what seems to be the case in the reform period.

On account of the quick liberalization leading to easy import of all types of products, there is a scenario shift from a 'sellers market' to a 'buyers market'. As a result, the Indian consumer is witnessing an increased choice of products of superior quality at lower prices. As an immediate reaction, consumers are jubilant. It was always a dream of all Indian consumers, excepting a microscopic minority, to touch, feel and use imported goods. But, very few could actually fulfil it. They can enjoy foreign grown exotic fruits. All these goods are available to them with more value for money due to their perceived better quality, attractive packaging and uniform appearance.
However, a large majority of Indian consumers are wise enough to understand the risk of rejecting Indian products. They are, therefore, cautious in their jubilation. While they wish to purchase high quality low price goods, they would be happier to have this goal fulfilled by the Indian manufacturers and farmers.

If Indian businesses do not survive global competition, there will be an overall recession leading to a sharp decline in the purchasing power of the Indian consumers. Businesses may close by their own if their goods are not lifted in the market. Employees will lose their jobs consequently. Unemployed persons cannot continue to be competent consumers. Further, once the dependence on imported goods reaches an irreversible level, there is an imminent risk of unchecked price escalation by exporting countries. Thus, although initially the reaction of the Indian consumers is positive, it may turn negative if proper steps are not taken for arresting the closure of Indian businesses leading to total dependence on imported goods. To avoid negative impact attracting foreign direct investment (FDI) and obtaining contract manufacturing becomes very important.

6.3 Impact on manufacturers

Indian as well as MNCs in India, are generally pleased with the emerging scenario because they now have access to more sources of raw materials. They enjoy an option to import raw materials of better quality at lower prices. Many manufacturing companies can import uniform quality contamination-free raw material from anywhere at attractive landed price. Worldwide sourcing also makes it possible for them to overcome seasonality problem. They can carry out-processing operations throughout the year.

A natural corollary of this freedom is the worldwide competition for their finished goods. They can face a tough competition in case of imported finished goods. Imported pure cotton yarn, fabric and garments, processed foods, edible oils can land from the world's best-known manufacturers. The
MNCs active in this area are of finished products. The processors in India have, therefore, started tightening their belt through reduction in costs, improvement in technology and enhancement in quality.

The most important qualitative and intrinsic implication of this competitive paradigm is the need felt by Indian processors to change their mindset from being a mere supplier to a serious market developer. They have realized that they can no longer take the customer for granted by making goods available for them to consume. No more monopolies and no more protections mean altogether new roles and responsibilities.

Demand driven production will be the *mantra* of tomorrow. In fact, this is where the typically Indian companies can score over their more resourceful competitors of foreign origin. Understanding evolving customer needs and creating custom made products to please consumers will help win the race of the new millennium; contemplating direct import.

### 6.4 Impact on public sector

With the reduced role of the state under globalisation the public sector drug companies are faced with serious problems including imminent closures. Public sector drug companies like Indian Drugs and Pharmaceuticals Ltd. (IDPL), Hindustan Antibiotics Ltd. (HAL), Bengal Chemicals and Pharmaceuticals Ltd. (BCPL), Bengal Immunity (BI) and Smith Stanistreet Pharmaceuticals Ltd. (SSPL) played an important role in the production of essential drugs at affordable prices. Under the globalisation process the role of the public sector has been marginalised and they have become sick. Attempts have been made to either privatise or close them. The Penicillin Plant in HAL, the biggest in the country, has been handed over to private hands. Its Streptomycin plant also has been leased to a private company for manufacture of other drugs. IDPL which is having the biggest pharmaceutical

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110 If Indian businesses do not survive global competition, there will be an overall recession leading to a sharp decline in the purchasing power of the Indian consumers. Demand driven production will be the mantra of tomorrow. In fact, this is where the typically Indian companies can score over their more resourceful competitors of foreign origin.
plant in Asia is closed from 1996 for want of proper financial assistance from the government.

The public sector drug companies used to supply raw materials to the small scale sector companies. Now, these companies are facing difficulties in procuring raw materials\(^{111}\). Similar is the fate of BCPL, B.I. and SSPL. These three units were taken over by the government after they were made sick by the private owners. Proper utilisation of their capacity could not be made due to lack of will on the part of the government, mismanagement at the administrative level and high level corruption.

It is not because of any inherent weakness but due to the lack of political will, deliberate efforts to destroy them, corruption and mismanagement that these public sector units have been rendered commercially unviable. Strategic management has become most important aspect for such companies\(^{112}\).

Moreover, the number of workers engaged in these units have been reduced drastically. When IDPL was established it had a strength of more than 15,000 workers.

Today, it has been reduced to less than 7,000. With the pharmaceutical industry taking a leap towards biotechnology development world-wide, only the public sector drug companies, with the backing of the central government, could have faced the challenge effectively from the MNCs in the new situation.

### 6.5 Mergers and acquisitions

International and national level mergers, acquisitions and takeovers have now become a common phenomenon in the pharmaceutical industry. Intern-

\(^{111}\) The public sector drug companies used to supply raw materials to the small scale sector companies. Now, these companies are facing difficulties in procuring raw materials. Many medium and large scale manufacturing companies pay higher prices for not availability of product and building brand equity.

\(^{112}\) To design strategies has become easy with help of books like The mind of the strategist, Blue ocean strategy, but companies should have better options if strategy stalls what should be next step.
ationally Acclaimed, Home Product merged with Cyanamid, SKB with Sterling, Rhone Poulenc took over Fashions, BSF with Boots, Glaxo with Burroughs Welcome, Ciba Geigy with Sandoz, Warner Hindustan with Parke Davis, Hoechst with Rhone Poulenc etc. are some of the examples of big takeovers. By mergers and acquisitions these companies became even larger with more financial power at their disposal over their competitors.

In coming days, with the help of international financial companies the MNCs are likely to capture and take control of Indian companies to control the Indian market.

To match the situation created by international mergers and takeovers, Indian companies are adopting the same path. For example Wockhardt took over Merind and Tata pharma, Ranbaxy took over Croslands, Nicholas Piramal took over Roche, Boehringer, Sumitra pharma. The inevitable results are job loss of workers. Because of overlapping of jobs large numbers of workers are declared surplus. After merger Glaxo-Welcome and Ciba-Sandoz announced a reduction of fifteen thousand and ten thousand of their work force respectively world-wide. Upjohn and Pharmacia decided to close 24 of their 57 plants in different countries after their merger.

Some countries are adopting the 'buy and grow' method. They are taking over some popular brands and increasing their business. SKB took over Crocin from Duphar, Ranbaxy took over seven leading brands from Gufic, Dr. Reddy's Lab purchased six products of Dolphin and two each from Pfizer and SOL pharma. Sun pharma purchased all leading brands of NATCO, after selling the popular brands the companies are becoming sick and closing their shutters throwing the workers on the street.

113 This is a classic example where Indian companies those have adapted new strategic movements those will help Indian companies to crate their presence in more and more foreign markets and acquire those markets through building brand equity even in case of generic drugs as well as formulations.
114 Ranbaxy, Dr. Reddy's Lab, Sun pharma, etc are changing their strategy to acquire strategic marketing assets. This strategy brings more funds and sales for the companies.
The government's permission to the MNCs to come to India with 100 percent equity have threatened the existing companies with the same origin and their workers.

Through the process of mergers, acquisitions and takeovers MNCs will gradually perpetuate their grip on the Indian industry by the creation of a limited number of mega companies having monopoly control and domination world wide. In the absence of competition people will have to pay any price as it happens in the sellers market.

6.6 Impact on allied industries
In total contrast is the behaviour of Indian companies engaged in manufacturing and distributing a majority of businesses of typically Indian origin and ownership did not prepare themselves to face stiff competition from superior players. They were almost in slumber and the post-WTO circumstances awakened them, shaken them and stirred them.

The reality in its full seriousness dawned on them too late, as an immediate reaction, they are upset with the government of India and the WTO for spoiling the game that they were familiar with far so long,

They have realised that their costs, quality parameters and services are under attack on account of global competition. Many of these companies have actually earned lower profits’ or have incurred losses in the last year for the first time. Their survival is at stake.

Some of these businesses have panicked and have embarked upon an instant damage control exercise. Some have downsized their organization overnight; some have opted for a merger; some have initiated dialogue for entering into a joint venture whereas some others have planned to stop manufacturing and resort to only marketing of imported goods.
6.7 Impact on traders
The Indian trading community has shown mixed reactions. There is no panic. They are happy with more opportunities coming their way, mainly in the area of imports. However, they are also worried on account of emerging global competition, resulting in thinner trading margin.

Traders all over the world are a sharp lot. They sense hostility quicker than the smartest animal in the forest. Indian traders are no exception. They are quick enough to realise the implications of the changing rules of the game and have started reorienting themselves to the new era.

In addition to various 'unwelcome concepts' under WTO, new technological advances such as Internet and e-commerce have challenged the age-old practices followed by Indian traders. This sort of double trouble has actually transformed the working style of some of them. For instance, they have decided to adopt international trading norms that are characterized by transparency, grading, service orientation and credibility, 'Stick together' is one of the survival strategies of the trade. In line with this thinking, some Indian traders have started checking out the feasibility of defensive measures such as formation of consortium, local mergers and global partnership.

6.8 Impact on service providers
Financial institutions, insurance companies, consultancy organizations and Information Technology organizations. There is a tremendous scope for new services to businesses in the changing environment.

However, it is observed that the banks, financial institutions and insurance companies have been indifferent so far. Most of these organizations are in the domain of public sector. Any innovative services from these organizations although all of them have their physical presence overwhelmingly visible in rural as much as in urban India.
It will immensely benefit all concerned if the Indian public sector organizations shade off their existing notions and get busy with innovation of commercially beneficial banking and insurance products. Business potential being truly enormous, foreign organizations with vast experience in this field will lose no time in swamping the Indian terrain under the sleepy eyes of the public sector natives. MNC invasion is, therefore, imminent.

On the other hand, organizations providing paid consultancy services and information technology services are pro-active. Their visibility is clearly noticeable in all businesses and also in rural India. If computer education is the need of the future, is eagerly encouraging the young generation to get it. It is amazing to see massive proliferation of computer training schools and cyber cafes in district towns and taluka places. In fact this growing network is actually paving the way of e-commerce.

6.9 An old business model for new science is not suitable

Today's pharmaceutical firms employ a business model that has served them quite well for decades. At every major firm, the straightforward formula essentially is the same: develop a highly successful blockbuster drug (at a cost estimated between $450 and $800 million), reap enormous profits (justified by the tremendous investment made in R&D) and reinvest a good portion of those profits to fuel the discovery and development of new (ideally, also blockbuster) drugs.

Putting aside for now whether or not that's an appropriate model, and consider the cost. Why does it cost so much to develop drugs and bring them to the market? The answer has everything to do with why the paradigm shift is coming. The pharmaceutical industry speaks of drugs as being "in the pipeline."
During the first stage, drug development, the costs, scientific complexity and time requirements involved are staggering. Applied research — including synthesis, biological testing and pharmacological screening of up to 10,000 compounds takes around four years.

The number of compounds is narrowed down to perhaps three, and clinical development takes another eight years, including Phase I, II, and III clinical trials. It can take two or three years to register a drug and plan for the market launch. The product is then ready for market, but the cost has been borne and the complexity has symbolically been reduced from 10,000 compounds to one useful drug. But were those 14 years a prelude to market success? Alas, the fun is only beginning. As Ned McCulloch of IBM Life Sciences asks, “Can life sciences products get remedy to patients has become a big question.”

At the other end of the pipeline, the new drug — approved and ready for market faces a set of hurdles that add new costs and additional complexity. There’s the issue of coverage and reimbursement. Who will pay to buy the new product? Physician acceptance and training must also be considered.

The health system infrastructure must be addressed to ensure that there is clinical decision support for diagnosis and prescribing. And finally, will patients accept and use the new drug? The prospect of success would appear daunting under this traditional scenario, but with blockbuster drugs and the billions of dollars in sales that such drugs represent, the pharmaceutical industry has done well for itself. And in doing so, patients have been assured of R&D that keeps leading to “better” therapies.

Researcher struggles to see any way in which the old business model has much of a chance with the new science. As one of experts has so poignantly put it, “The easy drugs have been done.” On top of this, “precise diagnoses leading to universal specific treatments are, for many illnesses, myths.”
"Many of the “easy” drugs, have are about, come off patent. And the next generation of drugs might not be anything like blockbusters, but more like “drug-lets” that address, with better effectiveness, the unmet medical needs of ever smaller segments of the population. And therein is the change being ushered in by the new science.

The role of retail market
The 32 leading grocery retailers account for 34 percent of the total global food retail market, estimated at $2.8 trillion. The top 10 grocery retailers account for $513.7 billion – or 54 percent of total sales for the top 32 retailers.

6.10.1 Pharmaceutical sector and subsidiary industries

1. Publicly - held biotechnology companies
2. Genomics
3. Veterinary pharmaceuticals
4. Agrochemical sector
5. Ag biotech
6. Seeds
7. Food and beverage industry
8. Global grocery retailers
9. Pharmaceutical sector

The pharmaceutical sector delivered a whopping 17 percent return on both revenues and assets outpacing any other industry. “Bottling money” is the way Fortune magazine describes big pharma’s performance. All of the top 10 drug companies had pharma profit margins exceeding 18 percent in 2000. Glaxo-Wellcome, before merging with Smith Kline Beecham recorded a profit margin over 30 percent; Hoffman-La Roche’s topped with 44 percent. The value of the pharmaceutical market has grown from an estimated $70 billion in 1981 to $317 billion in 2000. In 1981, the top 10 companies held just over 20 percent of the global pharmaceutical market. Today, the top 10 drug companies control an estimated 48 percent of the $317 billion world market.
Industry analysts predict that big pharma's future profits may be less spectacular. Blockbuster drugs (generating revenues in excess of $1 billion) are clogged in the pipeline, patents on current ones are expiring, and citizens worldwide are painfully aware that only the wealthiest can afford to get "healthy" on prescription drugs.

According to the UN Development Report, 1,223 new commercial drugs were released worldwide between 1975 and 1996, but only 13 were developed to treat tropical diseases and only four were the direct result of pharmaceutical industry research. In 1998 global spending on health research was $70 billion, but just 0.42 percent was dedicated to vaccines for HIV/AIDS ($300 million) and about 0.14 percent ($100 million) was devoted to malaria research.

Each year, millions of people in low- and middle-income (LMI) countries die from preventable and treatable diseases. AIDS provides one of the starkest examples: it killed more than three million people in 2004 and has become the world’s leading cause of death for adults aged fifteen to fifty-nine. These deaths continue despite the fact that we have known for years that antiretroviral combination therapy (ARVs) can substantially improve the lives of those living with HIV / AIDS, and even reverse the tide of death associated with the disease. But the drugs that we take for granted in the United States have long been out of reach for most of those living with HIV/AIDS around the world. One crucial reason has been their cost. In 2000, the average worldwide price for patented ARVs was more than $10,000 per patient per year. Today, the same medicine is sold in generic form for as little as $168 per year. This drastic reduction in price has enabled governments and international agencies to initiate programs designed to bring these medicines to millions of HIV-positive individuals around the world who otherwise lack access to them. These programs still have a long way to go before they meet the existing

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need, but they would not have begun at all if prices had not come down so dramatically.

Bloated profits and monopoly patents have become a high-profile political issue in the North and the South. In the United States, the elderly have seen annual spending for prescriptions soar 116 percent since 1992. US spending on prescription drugs shot up 18.8 percent last year, an increase of $20.8 billion. Big Pharma’s image took a beating earlier this year when it charged that South Africa was infringing monopoly patents by attempting to import cheaper anti-AIDS drugs for poor people. Stung by the negative publicity, the industry was forced to withdraw its high-profile lawsuit in April 2001. Analysts suggest that the future of Big Pharma will radically change with the field of pharma cogenomics and “personalized medicine.” Sophisticated genetic tests capable of detecting minute variations in human DNA will someday enable doctors to predict not only the presence of a genetic disease (or the likelihood of getting it), but how an individual would respond to a given drug, or avoid severe side effects. Kenneth Conway, president of Millennium Predictive Medicine told Chemical and Engineering News: “We think we’re going to subdivide diseases. Once we get people with the right disease diagnosis, the disease definitions are going to change from ‘You have breast cancer’ to ‘You have molecular profile A,B,C, or D.’ The treatments of those diseases are going to be different.”

Corporate hegemony is overwhelming governments and subverting national sovereignty. When governments become subservient to corporations instead of citizens, democracy is undermined, diversity is destroyed, and human rights are jeopardized. The trend in corporate consolidation is mirrored by growing disparities between rich and poor, both within and between OECD nations and the south.

Concentration in corporate-power is perhaps the defining feature of the global economy at the dawn of the new millennium. Extraordinarily powerful new
corporate configurations are replacing governments and engineering new mechanisms of monopoly control over resources and technology. RAFI has been monitoring corporate concentration in food, agriculture, and the “life industry” for several decades.

Corporations are wielding economic might to gain enormous political power. A comparison of corporate sales and country GDPs reveals that General Motors is bigger than Denmark, Wal-Mart is bigger than Norway, General Electric is bigger than Portugal.

Combined sales of the world’s 200 largest corporations accounted for 28 percent of the world economic activity but the top 200 corporations provide only a tiny fraction of the world’s jobs. The top 200 employed less than 1 percent of the world’s workforce. Combined sales of the world’s top 500 corporations in 2000 were equivalent to 47 percent of the world’s gross national income. These companies collectively employed only 1.59 percent of the world’s workforce.

Critical talent refers to the groups and individuals that drive a disproportionate share of their company’s business performance and generate greater-than-average value for customers and shareholders.

A company’s critical talent possesses highly developed skills and deep knowledge not just of the work itself but also of “how to make things happen” in the organization. Without these people, organizations could not achieve their strategies.

The nature of critical talent varies by industry or organization. In large pharmaceutical organizations, for example, “blockbuster drugs” are the engine to fuel growth. In 2004, Pfizer’s top 10 products each generated more than $1
billion in sales. So Pfizer pays particular attention to the researchers and clinicians who drive this development.

6.11 Building talent: A shift in mindset

A growing number of successful companies are taking more than their fair share of the talent marketplace and cultivating high performers in key positions through a very different method. Rather than starting with recruiters, they first look inside to match employee experience and aspirations to the company’s evolving strategic needs.

This doesn’t mean that they ignore external talent. They take recruiting seriously, in large part to achieve ambitious growth targets. But their historically low turnover rates let them spend much less time battling churn and a lot more time outmanoeuvring the competition.

As the competition for critical talent heats up, organizations must rethink the ways they manage these people. To begin, they must identify the segments of the workforce that drive their current and future growth rather than focus on metrics and outcomes (“acquisition” and “retention”), they must concentrate on the things that employees care about most: developing in ways that stretch their capabilities, deploying onto work that engages their heads and hearts, and connecting to the people who will help them achieve their objectives.

By focusing on these three things, attraction and retention largely take care of themselves. The three sections, describe how this model of ‘develop’, ‘deploy’, and ‘connect’ really works, and why it helps companies generate superior performance.

117 Rather than starting with recruiters, they first look inside to match employee experience and aspirations to the company’s evolving strategic needs.

Note: This has become the most important aspect for any company that want to create its identity in the international market. Many companies do not analyse the strengths of various employees working in various departments. Many of these employees have multiple capabilities to work for various departments for cooperation, co-ordination and analysis of data so as to help the senior management and decision makers to design effective and efficient business models and strategies.
Companies need a mix of highly analytical people technologically savvy with creativity, global know-how, adaptability, and great communication skills to collaboratively solve complex and rapidly changing issues. Developing such skills is rarely achieved by spending more on training. Formal training programs are important, especially when employees lack key skills or knowledge. But even online courses that provide access to coursework 24 hours a day, 7 days a week can fall short when it comes to resolving complicated, time-sensitive issues.

A well-known MIT study found that people are five times more likely to ask a co-worker for information than to consult an intranet, database, or company computer system. Other studies also suggest that "who" you know is increasingly more important than "what" you know. Rather than push more information onto employees through conventional training, it is more important that they "learn how to learn." The sales executive who must know the customer's business backwards and forwards, as well as his own, and those of his alliance partners can no longer be a deep specialist in a single product or service. It is more important that they knows where to go for information and whom to ask.

When people need to solve a problem, they tend to turn to others—not to their computers. Solving complex problems requires that critical talent focus on their relationships with others.

Research suggests that people who cultivate broad and diverse networks are more successful than those who rely strictly on their inner circles. The best way to develop critical talent is through the collaborative resolution of real-life issues ("action learning").
A well-known study conducted over a decade by the highly respected Center for Creative Leadership finds that “stretch” assignments and daily interactions with others are far more important to the development of successful executives than the formal training they received. Not surprisingly, the hardships people endure provide the richest learning experiences of all. When asked to identify the key events that made a difference in how they manage today, only 3 percent of executives cited formal coursework. On the other hand, 12 percent pointed to business mistakes as their most potent learning experience. Another 12 percent cited a change in project scope as a key event in their development. Interactions with others also commanded high responses.

The situations in which people learn most:

- 67 percent When working together with a colleague on a task
- 22 percent When doing own research
- 10 percent When a colleague explains something personally
- 2 percent Through a manual or textbook

People learn the most in situations that stretch them—the “trial by fire” experiences that put them slightly outside of their comfort zones. They learn not by pondering over a hypothetical problem, but by directly tackling real issues. Today in many top performing MNCs very limited educational and training opportunities are available to managers. But thinking is to create absolutely developed leaders.

Companies can get people having to move from managing ten people to managing 200 overnight. That kind of stretch in the job will either create growth or death. Such great people that most of them grows just by leaps and bounds. People also learn from those they trust: bosses, subordinates, peers, and mentors, both internal and external. At its heart, learning is social in nature.
In this way, content acknowledges the crucial role that the quality of interactions has on the financial performance of the company.

6.12 Deploy

If people learn the most in jobs that stretch them, they perform best when they can actively discover and define the role that will tap their deepest passions and skills and the conditions required to succeed. For some, the key to feeling more committed is flexible work arrangements. Others love most aspects of their job but detest the 30 percent of it that causes them to look elsewhere. Still others are simply mismatched. That is, their performance is compromised because they haven't either the motivation or ability they need to succeed.

Organizations cannot make everyone happy; in some situations, turnover is the price to be paid. However, voluntary turnover within critical segments of the workforce can put a company’s strategies at risk.

Deployment is about matching the correct candidate to a critical job or project\(^{119}\). But it doesn't stop when people are assigned. Companies must continuously focus on their critical talent to ensure that their skills, interests, and capabilities evolve in line with strategic objectives.

At times, this may mean re-evaluating the design of the job or it may mean redefining the conditions of the job through virtual arrangements and flexible schedules.

6.13. Call for greater workforce mobility

The traditional career ladder is shrinking as organizations become flatter. Without vertical mobility, employees need lateral experiences that promise challenge and growth. To fulfill this need, firms must expand their definitions of advancement and offer diverse sets of career paths.

\(^{119}\) Deployment is about matching the correct candidate to a critical job or project. This is one of the most important aspect where Indian companies have to redesign their employment structures.
This means providing opportunities across divisions, business units, geographies, and even professions establishing a transparent and fluid internal job marketplace. By encouraging greater mobility, organizations inspire a more engaged workforce and promote greater strategic flexibility.

Deploying talent also means helping those who are mismatched in their jobs. By mismatched, it does not just mean lack of capability, although this is often the case. People are also mismatched when they have the skills, but not the burning interest. It isn’t surprising that most organizations hold people to the confines of their resumes. It is risky to hire or reassign people based on their potential, rather than their experience. But inviting talented people to explore their options is not as risky or costly as paying them when they’re disengaged, or losing them altogether to the competition.

By and large, people are capable of doing many things. With the proper experiences, support, and connections, they are apt to gravitate to roles that unleash their passions. Indeed, some of the most successful business people were never educated or trained for the roles they mastered.

People often need to try several roles before they find their best fit. Self-introspection is crucial. If a mutually satisfactory solution can be struck, then they win it immediately. If an arrangement can’t be struck, then they may win it in the future even if a valued employee chooses to leave. Successful talent management includes strategies to stay engaged with alumni. Individuals granted latitude by their employers to explore new territory often make their way back with renewed vigor and insights.


Few jobs are accomplished in isolation. Most require the backing, decision-making help, and knowledge of key individuals, both inside and outside an
organization. As problems become more complex and collaboration more common, who you know is increasingly becoming more important than what you know. People have always relied on informal networks to get their work done. Many studies clearly show that social capital determines one’s ability to gain access to information, solve problems collaboratively, and achieve goals. Work largely happens “off the organizational chart” through our informal networks. The glue that binds people together in these networks is trust.

It is often suggested that one can learn 70 percent of what they know about their jobs through our informal networks. Engineers and researchers were five times more likely to turn to another person for information rather than to search an impersonal source such as a file or database. People with rich networks tend to solve problems faster, and with better results.

Rich networks don’t mean that everyone needs to be connected with everyone else. People are likely to rebel against requests to attend more meetings or answer more e-mails. Instead, a targeted approach is required to connect people with the right people and knowledge. Rather than leave such connections to chance, organizations can do a lot to help individuals to increase the quality of their interactions and knowledge flows. Encouraging “communities of practice,” the self-organized groups that form around a common mission or interest, is one such means.

Peer assisted programs are another, as SAAC has found. The quality of a person’s informal networks also has a substantial impact on their performance. Many studies say that the energy we send to each other in our interactions is four times a greater predictor of performance as the information that is brought to the table. Positive energy gets created when one listens carefully, respects others’ needs and perspectives, and promptly answers questions. One has to reflect on personal experience to know the impact of toxic interactions on their ability to perform.
This focus on networks and connections is one with which few organizations have deep experience. But emerging software is changing that picture. Social Network Analysis (SNA) tools are one of the hottest areas of investment for venture capitalists. This doesn’t refer to the software that drives dating Web sites, but to the technology that identifies the connections between people and their knowledge. By mapping such connections, leaders can gain important insights on how work really gets done in critical parts of the organization: who knows whom, who knows what, who trusts whom, who energizes others, and who creates bottlenecks. The tool is not meant to point fingers, but to create healthy flows of knowledge and relationships.

When properly used, Social Network Analysis can help leaders increase the success of an important merger, locate expertise for a crucial project, or strengthen executive team performance. It can reveal gaps in knowledge and highlight the difference in the personal networks of high and low performers. As such, it can be a powerful tool in the development and deployment of key individuals.

The Develop-Deploy-Connect model is interconnected and virtuous. An improvement in one area naturally leads to an improvement in another. Done right, a balanced strategy that integrates all three dimensions leads to increased capability, alignment, and commitment, which in turn drives business results and performance.

6.14 The so what? approach

The Develop-Deploy-Connect model is interconnected and virtuous. An improvement in one area naturally leads to an improvement in another. For example, people develop better skills when they are deployed in stretch assignments and connected with others from whom they can learn and grow.

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121 Balanced strategy in many Indian companies with learn and grow methodology is required to increase capability, alignment, and commitment, which in turn drives business results and performance.
Likewise, effective deployment occurs when people have the knowledge, skills, networks, and relationships they need to succeed. Finally, effective connection happens when people are deployed in work that engages their curiosity. In these circumstances, they are more likely to learn from and teach (i.e., develop) others.

Important benefits result from this virtuous circle. One is capability. When highly capable individuals work together, they build organizational capability. The second is the alignment that occurs when the right people are in the right jobs.

A third result is commitment. People are more likely to master work that engages them, fosters their growth, and encourages productive relationships. When people feel the organization takes a keen interest in their interests, skills, and connections, they are far less tempted to look for challenges outside.

6.16. Going forward: taking the first steps in building talent
The first step is defining exactly which jobs are critical. This is a central exercise, but it is not as straightforward as it might appear. It requires a clear vision of the range of current and future strategies that will drive organizational success. This doesn't mean banking on a single outlook, but may instead require alternative scenarios that acknowledge the uncertainty of business. It then requires a firm understanding of the talent supply and demand patterns outside and inside the organization. Within core business units, identifying critical workforce segments requires determining which jobs make or break organizational performance. Companies must also identify the skills that will drive future growth. When combined with projections of skills needed for future projects, these data help the company plan the deployment and development of key individuals.
Once leaders identify their company’s critical talent and skills, they must next match people, skills, and knowledge to company needs. Decisions to re-deploy, develop, and stimulate connections evolve from this analysis. It is important that this not be a top-down process. People are likely to underperform if they are deployed against their will. The same is true of the professional who is forced into a mentoring relationship as part of his development.

The role of the organization is to communicate needs and create support mechanisms (e.g., electronic job boards, coaching, and strategic networking events) that people need to grow in line with organizational goals. Many times the strategy is communicated, but decisions are made on an individual basis. It’s the responsibility of the line leader to be sure that individual and organizational goals are aligned.

As the competition for critical talent heats up, organizations must better understand the supply and demand of critical workforce segments. A pharmaceutical giant such as Pfizer must monitor (and try to influence) the availability of researchers and clinicians as part of its talent strategy. Such analyses help organizations understand the supply and demand of talent at the professional, or job level.

A next layer of analysis involves determining the skills required to achieve important strategies. A complex software project, for example, may require a business unit to ramp up the quantity and quality of its programming skills. Many organizations are beginning to develop skills databases that provide an inventory of currently available skills. When properly designed, skills databases can be modeled to analyze the gap between what is currently available and what will be needed to execute shifts in strategy.

When a company manages critical talent in strategic manner, it must guard against unwittingly creating a culture of ‘haves’ and ‘have-nots.’ A focus on
critical talent and the people who support them doesn’t mean other employees should be blocked out of the development process or kept in unsatisfying jobs. Managers must keep their eyes out for employees in less critical roles who possess the talent to succeed in critical roles. There are countless stories like the one of Southwest’s chief operating officer, Colleen Barrett, who rose from being a legal secretary to a top position. In the coming years, most companies will have no choice but to seriously rethink their approaches to talent strategies. But shifting demographics should not be the only reason. Improving the performance of critical employees directly improves organizational performance. Furthermore, focusing on critical talent is relatively new territory for most companies and, thus, offers a new way to compete. Compared to more popular investments in customer, technological, and financial strategies (which have been refined over decades), a well-designed talent strategy could truly differentiate an organization.

Companies will be reluctant to go back to the stopgap measures of recruiting and retention. Managers may be amazed by how often the talent they need resides right under their noses or the noses of colleagues a continent away.

Rather than fight a futile war for talent, leaders should look within for the critical skills and knowledge required to execute the company’s most important jobs. By developing, deploying, and connecting these people the right way, leaders can raise their performance and the performance of the entire organization to a whole new level.

6.17 Access to information regarding new drugs
According to the World Health Organization (WHO), roughly ten million lives around the world could be saved every year by improving access to essential medicines and vaccines that already exist. Approximately thirty percent of people around the world do not have regular access to essential medicines, and in the poorest parts of Africa and Asia this figure rises to over 50 percent. This is what we term the access gap, and it has many determinants. One
important determinant is price. Unsurprisingly, there is considerable evidence that consumption of medicines is sensitive to price. In particular, price has disproportionately severe effects on patients in LMI countries. Not only are consumers in these countries poorer on average, but they also tend to pay a greater proportion of their own medical costs than consumers in wealthy countries. While patients in wealthy countries are often insulated from the high cost of medicines by third party payers (for example, insurance companies or government funded programs), in LMI countries, public medicine expenditure does not cover the basic medicine needs of the majority of the population and private health insurance is rare. In both low- and middle-income countries, the public sector pays less than thirty percent of drug costs.\textsuperscript{67} Price, in turn, is affected by patent status. Empirical studies focused on developing countries predict, for example, that the introduction of patent regimes has, or is predicted to have, the effect of raising prices. The estimates range widely depending on the drugs and countries being considered from 12 percent to over 200 percent, but even the lower estimates imply very substantial costs for consumers. Development and aid agencies working in the field confirm these theoretical predictions. MSF has concluded that the most significant factor in lowering prices is the introduction of generic sources in a country, and Oxfam International has called generic competition the single most important tool to remedy the access gap.

Some have argued that pharmaceutical companies are unlikely to patent in LMI countries, and therefore that we ought not focus on patents as a barrier to access. This position has been widely discredited based on evidence of patenting, particularly in key supplier markets. Pharmaceutical companies have been willing to patent widely, and cling to the exclusivity that their patents provide, even where the public health implications are dire.

Although, as we might expect, gross national income, market size, and relative income inequality are generally important determinants of patenting strategy, patenting still occurs in low-income countries. Furthermore, the
absence of patents in a given country is not the *sine qua non* of effective access to generics. A supply of medicines must also exist, but developing countries differ substantially in terms of their existing pharmaceutical production capacity." In the poorest countries, even when medicines are locally formulated, they may be unaffordable because of inefficiencies in production and limited market size.

As a result, patents in a variety of countries can matter a great deal to the shape of the supply curve. Patents may obstruct production and export from certain countries, namely middle-income supplier countries such as India which play a critical role in the global market for generics. They may also limit the available markets to those that are too small to justify the costs of reverse engineering specific medicines, retooling production facilities to make them, or establishing distribution networks. For example, while many poor and low-prevalence countries in Africa have few or no patents on ARV medicines, it was not until late 2003 that the first African company began to locally produce ARVs.

While patents are not the only factor blocking access to medicines, exclusive rights in one LMI country can create serious, preliminary obstacles to access in that country and prevent the emergence of a competitive market to supply medicines to another country that has no such barriers. Finally, the aspects of this problem that are visible today are only the tip of the iceberg. It is easy, but shortsighted, to ignore the value of medicines that have not yet been developed. Obviously we expect and need new medicines. As they come into being, as TRIPS takes hold in supplier countries such as India, and as TRIPS-plus provisions take effect in more and more countries, the role of exclusive rights in the access crisis will grow more important. Though sobering, this is only half of the problem.
6.18 Production

Two models that avoid roadblocks set up by governments and industry and that have the potential to catalyze wider change. These approaches draw on recent literature and experience with commons-based production modalities. The term "commons-based" signifies forms of production and coordination that rely on a mechanism other than proprietary exclusion and that treat all actors symmetrically vis-à-vis the resource in question.

Commons-based initiatives offer a model by which a network of independent but interconnected participants can choose to act not to change the legal system, but to change their practices within it. In so doing, they can circumvent barriers posed by standard applications of exclusive rights, such as patents and copyrights, and by rent-seeking lobbying that blocks statutory and regulatory change. These efforts do not rely on government action or private-sector, price-driven, market-mediated solutions, but on collaborative practices buttressed by contractual tools that apply property like rights to ensure access and distribution rather than control and exclusion.

This part describes the commons-based projects that have proliferated in recent years in the area of the production and distribution of information. It also discusses the innovative contractual forms that sustain many of these initiatives. Finally, this part shows that universities and other public sector institutions are already beginning, in fragmentary and preliminary ways, to adapt some of these models to the biomedical domain.

6.19 Commons-based production models

The wide range of open source and free software created by programmers who freely contribute their time and talent to collaborative efforts confounds the historic presumptions of property law. These presumptions say that property rights, price signals, and managers are necessary to organize and incentivize efficient production. Free and open source projects, ranging in size from projects with merely two or three programmers to large-scale projects
like the Linux kernel, use none of these presumptions and yet produce high-quality software that has come to occupy an increasingly prominent place in the information technology economy. Free and open source software could not have flourished in this way without the legal innovation embodied in the GNU General Public License (GPL). The GPL was developed in the 1980s by Richard Stallman, a programmer from MIT who sought a way to protect the historically collaborative mode of software development from the encroachment of firms that wanted to make software proprietary.

The GPL has two key components. First, it gives users the right to copy, alter, and distribute the software source code, as modified or in its original form. Second, it includes a "copy left" requirement, obliging those who create derivative code to grant the same rights to those who receive the derivative software. Thus, the GPL not only shares but also requires others who benefit from the license to share their own contributions. The GPL turns copyright on its head, by guaranteeing rights to use, learn, freely distribute, and modify, but not the right to exclude. This legal jiu-jitsu is well-suited to the cooperative nature of peer-produced software and its reliance on reciprocal sharing of innovation. It has also been a model for other commons-based initiatives seeking to arm themselves against the rapid expansion of exclusive rights to information and culture over the past few decades.

Creative commons is one of the most rapidly growing of these initiatives. It offers authors and artists a series of simple licenses that allow them to contract around the default in copyright law that reserves for them “all rights” in their creative works. Using the Creative Commons website, individuals can choose between a menu of eleven licenses. The Attribution License, for example, permits content to be freely shared, modified, and commercially used, as long as the original author is given credit. The noncommercial license allows the same activities, but only for noncommercial purposes. There is also a share alike license, which requires that any derivative works be distributed under the same terms as the original work. In the academy,
commons-based production has become an important model for scientific publishing. The recently-created Public Library of Science (PLoS) offers peer-reviewed Internet-based content free to readers.

It covers the production costs of its journals with philanthropic donations and per-page-fees paid by authors and ensures the free distribution of articles by applying the creative commons attribution license to them. The National Institutes of Health (NIH) has recently adopted a policy intended to improve the public's access to publications resulting from NIH-funded research.

The policy calls upon scientists to submit the final-version-accepted-for-publication manuscripts to the NIH, and provides that the manuscripts will be made freely available on the Internet through the NIH's digital archive, PubMed central, within twelve months of their final publication. Genomics research has been another major area for commons-based initiatives. The most prominent of such efforts is the Human Genome Project (HGP), a publicly funded, international research project that committed itself to releasing its data and not claiming patent rights in the mapped genome. Many of the follow-on projects which seek to functionally specify genomic sequences and create maps useful for applied research have also adopted commons-based structures.

The Ensemble Genome Browser uses open source software to create free, annotated maps of primarily mammalian genomes. The HapMap project, which seeks to identify haplotypes (shared genetic variations) to help researchers better understand and address diseases with a genetic component, is also commons based.

Biological Innovation for Open Society (BIOS) project is perhaps the most self-conscious inheritor of both the lessons and tools of the free software movement. A nonprofit created by the Australian organization CAMBIA, BIOS
seeks to catalyze the creation of a new, self-sustaining commons for researchers in the field of agricultural biotechnology.

It aims to do this by creating portfolios of essential biotech research tools and licensing them under a GPL-style license. The scientist behind the initiative, Richard Jefferson, has already created two technologies that engineer around proprietary tools critical for biotechnology-based crop improvement. Licensees who want access to these technologies must accept the terms of the BIOS license, which requires them to share and make available to other participants in the initiative any improvements they make to the core licensed technology. Licensees are permitted to patent and license any products they develop as distinguished from improvements on the tools licensed by BIOS in whatever way they wish, and uses of the licensed technology are not limited by territory or field.

6.20 Enhancing technological capacity in the developing world

If an overview is taken of the problems faced by poor countries in doing research; lack of funding is a result of low GDP, which in sub-Saharan Africa is about US$ 300. Less than one percent of this is allocated to research.

There is a need for research funding to motivate scientists. In India there is a brain drain because researchers are poorly paid. Those who remain may not be able to compete for funding. Poor communications systems also limit the ability to research and write proposals.

Here is a need to collaborate through regional and international networks to facilitate research. Transfer of appropriate technology is essential, adding that all needed is a little bit of transfer of technology and some funding.

Some have the technology but are unable to make use of it. There is a strong need to collaborate also in vaccine development. The political will is present, but it is the outside boost that is lacking.
One of the assumptions of TRIPS is that IP will facilitate technology transfer. It is indicated that a large percentage of exchanges take place within corporate structures. International firms should ensure that their activities fit into the scientific and technological policies of host countries and contribute to the development of national scientific and technological capacities, including their capacity to innovate.

The challenge for developing countries is to enlarge the capacity to benefit from science and technology. This implies increased investment in basic sciences, R&D and technological innovation. It is only when each country clearly understands the issues and develops a national capacity that we can hope for developing countries playing their proper role in R&D agenda setting.

Developing countries should have the long-term intention to work at technology development as opposed to transfer. Simple transfer implies a continued dependency on the West. It is only when indigenous technological capacity is built that we hope in the long run to have an effect on R&D for neglected diseases.

Effective global health research is anchored and based in strong national health research systems, said Tikki Pang from WHO's Research Policy and Cooperation. "Whether or not knowledge is global, the use of knowledge is local. This is a very important reality."

The health is about development. Improved health requires not just R&D on health but rising living standards, and better service provision for the poor. The more successful developing countries developed an indigenous capacity for scientific and technological innovation. Health R&D in developing countries depends on contributions from a multiplicity of scientific disciplines.

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122 This will offer many Indian companies an opportunity to grow faster with indigenous talent and technology has become a vital part of growth and profits Indian companies.
6.21 Do patents help or hinder research?

At the World Health Organization / Special programme for research and training in tropical diseases (WHO-TDR) current R&D for neglected diseases has been focused on opportunities emerging from non-patent protected products. But making use of patent-protected technologies will be necessary.

Intellectual Property Rights secure a territory, and exclude others from doing R&D. This includes, by default, R&D for neglected diseases. The most difficult thing is to have access to compound libraries, because these libraries are proprietary. Of course one can generate money to buy libraries but this is not the most effective way. A mechanism of sharing needs to be promoted. Funding R&D for neglected diseases is being increasingly recognized as one of the major challenges facing the international community today. The intellectual property system itself may not be sufficient to provide incentives for research and development into the diseases which mainly afflict the poor in developing countries.

TRIPS represent an effort to find an appropriate balance between the need to promote research and development and the need to ensure affordable access to the fruits of these activities. Many consultants say in their articles that IPR should be looked at as an incentive.

The fact that not everybody is getting access to antiretrovirals in India does not at all mean that IP is not a barrier for access. India has never had an equitable public health policy; there has been no serious move to introduce one since the Hathi Committee report more than twenty years ago. The blame for inequity of access to medicines cannot therefore be laid at the door of the generics companies.

The TRIPS Agreement should not be implemented until the developing countries are ready for it. People are not taking advantages of safeguards in
TRIPS - this is because bilateral agreements by US and EU are being used to bully countries not to use them.

TRIPS is a social contract, ensuring profits in return for R&D. However, the profits were not all going back into R&D. Some go into R&D, more goes to the shareholders, more again to marketing, making the process more and more expensive. The development of our medicines had been privatized, it is a very expensive way of doing R&D, there is no guarantee that developing country needs will be met, there is lot of me - too drugs.

A recent report by NIHCM, which stated that out of a total of 1,035 new drugs approved by the FDA in the USA between 1989 and 2000 only 35 percent were considered new molecular entities.

6.22 Towards a framework convention
The WHO constitution mandates WHO to work and promote international agreements between countries to promote public health. It has taken half a century, with the introduction of the tobacco convention, for that mandate to be executed.

There are two reasons why it took so long for a tobacco convention to be established; the first is the utter conservatism of the public health community and their deep mistrust of legal process. The second is the power of commercial interests. They tend to fight as strongly as they can against legal regulation, and when opposition fails they move to co-option. It was opposed by industry, front groups and other vested interests.

There are many health R&D needs ranging from vaccines, treatment, diagnostics, research into infrastructure, health systems, to prevention and health promotion. The idea of a global fund for R&D will get a lot of support from developing countries but it will probably fall apart at the last minute because rich countries won't put the money in.
There is a strong question why an R&D treaty was the best approach by WHO, both theoretically and politically. Very few, if any, governments will commit themselves to long term funding increases via an international treaty. The R&D treaty is called the TRIPS Agreement. But TRIPS is a limited and problematic framework for addressing global R&D. Love argued that R&D could be annexed to the WTO Agreements. The WTO got over the promises without action scenario, and maybe that’s why many want to tag on to it.

One of the problems with the current system is that the R&D process is paid for by sales, which limits access.\(^{123}\)

Even for a relatively wealthy country, the requirement that high price pays for R&D leads to these scenarios. So there are competing goals between access and paying for R&D. Private benefits are not equal to social benefits.

The experience shows that treatises and conventions work only if NGOs act as a very active watchdog and remind governments to meet their legal obligation and duty and put their words into action.

What needs to happen define a needs-driven international R&D priority agenda commit all countries to contribute to R&D for health outline an agreement and clear rationale for sharing the burden of the cost of this R&D define appropriate funding and incentive mechanisms for governments to fulfill their commitments to public sector.

Involvement in R&D to establish and strengthen international mechanisms for exchanging and transferring research results, knowledge, and technology ensure that developing country involvement in public R&D is central, including through North-South and South-South collaboration, and through the conduct of such R&D in disease-endemic countries.

\(^{123}\) One of the problems with the current system is that the R&D process is paid for by sales, which limits access. For R&D attracting foreign direct investment is essential.
Quoting an old adage - here, would be apt, if they get a fish they feed them self for a day. If they get a fishing rod then they can feed themselves for a lifetime and other generations get fed too.

This is not beating up on industry; industry is doing exactly what it is set up to do, and one of those things is to defend their products at all costs. It is up to our governments. In that way they are making the fishing lines.

6.23 Public health considerations
The current minimum standards in the TRIPS Agreement; historically derived from those of developed countries may not necessarily be appropriate for developing countries struggling to meet health and development needs. The new obligations have dramatically changed the legal framework for the production, supply and access to affordable medicines in developing countries.

6.24 Packaging and labelling
To give the overall summary, the data show that the US is the largest domestic market in the world. Mark-ups were highest, on average, in Japan and lowest in the UK; note that Japan was, until recently, an extremely regulated protected domestic market. There exist variations in health expenditure between countries. Health expenditure as a percentage of GDP is the highest in the US, and the gap is widening over time between the US and other nations. The US also has by far the lowest proportion of health expenditure funded by public sources. In 1989, the EU average for funding by public sources was 66 percent, so France lies below the average, with both Germany and the UK above the average.

The US pharmaceutical industry is the strongest. The US has the highest R&D expenditure, the largest introduction of NCEs, and also, the products from its firms dominate the Top 50. Although Japan substantially increased its
proportion of NCEs in the 1981-1990 period, evidence shows that if the number of breakthrough NCEs is considered, then between 1970-1983, US firms developed 42 percent whereas Japanese firms developed 4 percent only (Ballance et al, 1992; Thomas, 1996). The trends in patenting activities show that among the EU member states, there has been a slight decline over time in patenting activities in the US, with a slight rise for Japan. Thus, Japanese pharmaceutical firms, unlike in electronics, for example, are not competitive in the US market place.

Consider now the summary of the UK and German ‘national strength’ aggregate measures. The success story in the EU has been the rise of the UK in the 1980s. Its leading firm, Glaxo, for example, rose from 17th in the world in terms of sales in 1983, to 1st in the world in 1995. They have observed a relative increase in R&D expenditure in the UK, and furthermore, its companies are extremely good at developing NCEs that are commercially successful.

During the 1981-1990 period, only 28 new drugs were developed, but a relatively high percentage of these turned into blockbusters. Germany, on the other hand, has a much weaker position. It developed far more drugs (67 NCEs between 1981 and 1990), spends approximately the same amount on R&D, but has a very low number of blockbusters to account for this (only 5 in 1990). As a final measure of international competitiveness. Germany's share of the US market is only 4.6 percent, compared to 14.6 percent for the UK.

Having provided a brief summary of aggregate market characteristics in the pharmaceutical industry, this section now goes on to examine exogenous structural changes observed over the past two decades. Beginning in the late 1970s, competitive Industry dynamics has become more complex. This was due to radical changes in the nature of the innovation process and the introduction of new marketing and distribution techniques.
The linking differences in the performance of UK and German pharmaceutical firms, as highlighted above, to their ability to react to these changes in the competitive environment.

The nature of the technological process: over the last twenty years, the development of biotechnology has fundamentally changed how drugs are discovered. The traditional methodology, prevalent in the 1950s and 1960s when knowledge about the properties of the compounds that could be used to synthesise new drugs was still lacking, screened thousands of chemical compounds for efficacy against a given disease. In the 1970s, basic biomedical knowledge increased; the traditional methodology has been replaced by 'rational drug design', that is, the development of more precise models of how particular diseases function, and the design of molecules designed to target particular cells or cause particular biological interactions within the body. Biotechnology is beginning to displace traditional 'chemical' capabilities.

When such a new research methodology is adopted, it may be the case that organisational rigidity and inertia hinder incumbents’ ability to take advantage of new opportunities. However, although the discovery process is changing, the assets needed for development and commercialization are not, and these assets continue to be owned by the largest firms. As in any industry, the pharmaceutical industry comprises a value-chain of clusters of organizational, capital, and human resource competencies in areas such as research, development, production, marketing, distribution, etc. In pharmaceuticals, some processes in this value chain, such as manufacturing, are generic activities with low value-added. As research is one of the highly specialized and hence value-added processes, the fact that most biotechnological research is taking place within small start-up firms rather than large firms is an important change.
However, the vast majority of start-ups are crucially dependent on large pharmaceutical firms. This is leading to interesting networks of agreements being observed, where the biotech firms supply the ideas, etc., and the larger firms supply the complementary specialised assets such as development, financing, obtaining regulatory approval, and finally marketing, that allow them to appropriate most of the gains from innovation.

To develop this further, the cost of developing a single new drug is currently about $350 million; only a small proportion is spent in basic research (current estimates are approximately 10 percent). Once compounds are discovered / designed, most development and virtually all marketing and distribution is undertaken by large pharmaceutical firms. Basic research results are usually not known for several years, so securing finance is a crucial problem for most start-ups. As a result, many biotech firms license all or part of their results to the large pharmaceutical firm in return for working capital. The existence of hundreds of specialised research firms increases the flexibility of large firms, and as long as they can appropriate most of the commercial gains from biomedical research, then established firms have important reasons to support and engage independent third party research networks.

In the world of rational drug design, research in complex disease areas usually takes place along a number of distinct research trajectories. For example, Penan (1996) identifies fifteen distinct research programmes to fight Alzheimer's disease, each of which is supported by a different constellation of university departments, large pharmaceutical firms, and in some cases, biotech firms. Under these conditions, in which no one firm can monopolise a therapeutic field, the ability to scan research becomes crucial. Although it is still important to maintain in-house scientific and technological capabilities for monitoring and using external knowledge, developing licensing arrangements and research collaborations with biotech firms helps diversify the firm's 'bets' across a number of research programmes. Overall, these new research opportunities imply that firms may have an incentive to change the structure of
their internal R&D activities, to broaden their activities across a larger number of therapeutic areas.

Although knowledge is a public good, it is not a free public good, and internal scientific capabilities will still be necessary for knowledge exploitation. Substitute drugs are constantly being discovered; PhRMA, for example, estimates that the 'exclusivity period' before a substitute drug enters the market has decreased from six years in 1977 to one year in 1992.

Marketing and distribution networks: over recent years, large pharmaceutical firms have spent as much money on marketing and distribution as they have on development. Until recently, marketing was dominated by the labour intensive practice of sending thousands of 'retailers' to visit individual doctors, as well as some advertising in medical journals. However, recent pressure to increase the returns on individual drugs, coupled with important developments in the organisation of the US pharmaceutical market, have prompted leading firms to adopt new distribution and marketing strategies.

Redeveloping prescription drugs into ‘over the counter’ (OTC) versions is perhaps the simplest way to extend the life of a compound nearing the end of its patent life. This tactic requires direct to consumer advertising through the commercial media, as well as the development of distribution channels to retail outlets. Strategic movements like these will offer Indian companies an added advantage.

6.25 Trade promotions and market penetration
To provide a brief introduction to the competitive process in pharmaceuticals, first observe that this industry is characterised by dynamic competition. New products (and also processes) are continuously being introduced. Unlike basic chemicals, say, where innovation is rather more incremental and new products displace the old upon introduction, the pharmaceutical industry is better characterised as an example of a radically innovative industry. The
firm's main goal is to introduce a new chemical entity (NCE) in an existing or new therapeutic market. Second, and importantly, competition is truly global. The results from R&D are easily transferable across national borders, with perhaps some local modification necessary to comply with the standards/regulations. In other words, the results from R&D can be exploited anywhere in the world, although note that the generation of R&D remains far less international.

However, the competencies which firms must create in order to compete globally, and the rules by which markets are organised, may originate within national economies. In part because the generation of R&D currently remains relatively national, although this is changing, we argue that national institutional frameworks will still influence leading firms' competencies.

6.26 Transportation
Today the couriers have direct contact with the customer and must make continual decisions that impact the efficiency and effectiveness of the supply chain, such as how to reconfigure a route and how long to wait for a customer's packages. The marketing and distribution competencies differ dramatically from the more traditional 'detailing' activities. Pharmaceutical firms that choose the OTC route have two options.

First, they can establish costly relationships with advertising agencies and develop new distribution channels; or second, form marketing joint ventures (JVs) with firms who have already developed a competency in the areas required. The most important changes that have occurred in the US, however, have developed as a result of the reorganisation of links between doctors, distributors (pharmacies), and insurers. During the 1980s, health care and insurance functions began to merge into HMOs and other managed care organisations, encouraged by various reforms in the US health care system. This created networks of concentrated buyers.
Towards the end of the 1980s, a similar fusion of pharmacy, marketing, and distribution operations began to take place within so-called 'pharmaceutical benefits management' (PBM) firms. PBMs serve these concentrated buyer networks, partly by providing drug utilisation reviews and other information such as drug usage rates that pharmaceutical firms can feed back into their development and marketing activities, but more importantly, by using the concentrated purchasing power to negotiate strong price discounts. This is done through managing the 'formulary' (the list of drugs that each doctor within a certain health care organisation can prescribe).

In recent years, leading US pharmaceutical firms have acquired several of the largest PBMs, showing evidence of forward integration into health care markets.

Such forward integration complements an expansion of research across several therapeutic areas. While profits are still driven to a relatively large extent by the control of a few 'blockbusters', the new distribution and marketing capacities ensure that the life-cycle of each compound can be maximised, especially as drugs nearing patent end are transformed into OTC versions.

Having some guaranteed market access through controlling one or more PBMs allows leading firms to minimise the risk of not being first, that is, if a firm loses a 'race' to develop a particular treatment, it can usually produce a 'me-too' drug within a few years, and assure a fixed volume of sales through the PBM.

6.27 Doha declaration of WTO
Although the TRIPS Agreement affords considerable discretion on how its obligations are interpreted and implemented by governments, developing countries have faced obstacles when seeking to implement measures to promote access to affordable medicines. Thus, developing countries sought to
clarify through adoption of the Doha Declaration that the provisions in the TRIPS Agreement did provide sufficient flexibility and discretion to ensure access to medicines in the interests of public health.

The Doha declaration refers to several aspects of TRIPS, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights. These are briefly described below.

The TRIPS Agreement allows the use of compulsory licenses. Compulsory licensing enables a competent government authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder. Article 31 of the Agreement sets forth a number of conditions for the granting of compulsory licenses. These include a case-by-case determination of compulsory license applications, the need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary license and the payment of adequate remuneration to the patent holder. Where compulsory licenses are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived in order to hasten the process.

Although the Agreement refers to some of the possible grounds (such as emergency and anticompetitive practices) for issuing compulsory licenses, it leaves members full freedom to stipulate other grounds, such as those related to public health or public interest. The Doha declaration states that each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

Parallel importation is importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or
with the patent-holder’s consent. The principle of exhaustion states that once patent holders have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights in respect of that market have been exhausted by the act of selling the product.

Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.

Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical products sold in different markets.

**Para 6 of the Doha declaration**

Although existing provisions of the TRIPS Agreement permit the grant of compulsory licences to enable generic production of medicines, countries without domestic manufacturing capacity cannot avail themselves of this flexibility. The option of importing generic medicines is hampered by the restriction in the TRIPS Agreement that requires production under compulsory license to be predominantly for the supply of the domestic market.

This has raised concern that exporting countries may have difficulties exporting sufficient quantities to meet the needs of those countries with insufficient or no manufacturing capacity.

The WTO solution is essentially a waiver of the export restriction, thereby allowing the total amount of production under a compulsory licence to be
exported. Whether countries may export and import generic versions of patented medicines under the system adopted in the WTO decision will depend on the extent to which national laws allow for it.

A number of potential exporting countries have amended national laws to enable the production and export of generic medicines under compulsory license\textsuperscript{124}. Canada was the first country, followed subsequently by Norway. The European Union is currently considering its draft regulation. India has also included a provision on compulsory licenses for production and export in the amendment of the patent law. However, there has not been any notification by countries to the WTO in respect of their intention to use the system as an importer. There may be a number of possible reasons for this.

First, the threat of compulsory licensing for production of competing generics has led pharmaceutical companies to offer larger discounts. Secondly, the granting of compulsory licenses under the system may appear to be too complex and burdensome for developing countries.

In the post-2005 environment, when almost all countries are obliged to provide product patent protection, the effectiveness of the WTO decision may well be put to the test.

In the pre biotech days, big pharmaceutical companies supplemented their own research with that drawn from university research institutes and hospitals.

The new biotech companies offered not only a range of large molecule biologics as drug candidates for range of therapeutic areas, but also an array of new platform technologies that hasten the drug discovery and development process, ranging from high screening based on combinatorial chemistry to

\textsuperscript{124} A number of potential exporting countries this is very important aspect for exports of generic and OTC drugs.
genomics and proteomics (Granberg and Stankiewicz 2002). This range of specialisations has vastly complicated the lives of pharmaceutical companies.

Pharmaceutical companies have actively pursued biotech companies to form alliances for the development of new drugs. Biotech companies have benefited from the funding available from the pharmaceutical companies.

It is rare for biotechs to be able to afford to complete the clinical trial process without significant external assistance. Often the pharmaceutical company in return for a revenue stream to be paid to the biotech acquires the development and marketing rights.

The structure of these alliances depends on the relative positions of the two companies. Lerner and Merges (1997) have undertaken a detailed analysis of a small number of biotech alliances to determine the balance of control between the biotech and established pharmaceutical company.

The study also examined which party was likely to control particular aspects of the alliances. This indicated that the pharmaceutical company was most likely to control the marketing and manufacturing aspects as well as the power to terminate the alliance. The biotech was more likely to retain control over the patents and related litigation.

Strategic alliances encompass a wide range of inter-firm linkages, including joint ventures, minority equity investments, equity swaps, joint R&D, joint manufacturing, joint marketing, long-term sourcing agreements, shared distribution/services and standards setting\(^{125}\). (OECD 2001)

Alliances have not only been formed in pursuit of new drug candidates but have also been with platform companies, which provide the specialist

\(^{125}\) This is the most vital aspect for the success of fast growing Indian companies to crate their identity
technologies to improve both the drug search process as well as speed up development.

6.28 Post marketing experience
AIDS is a disease that disproportionately affects the developing world, but also has a market in the West. The debate in recent years has focused on the high price of AIDS drugs, but lessons can also be learnt from the R&D of AIDS drugs.

AIDS is one of the success stories; In 1987 Pfizer developed one medicine. By 1999 there were more than 60, and more than 102 in 2001. It proves it can be done if the need is there. Although the R&D situation for HIV drugs is not as crucial as for other illnesses, the drugs aren’t perfect. Efficacy not optimal, toxicity can be worrisome, tolerability is a problem, costs are significant.

India need, better drugs. R&D gaps remain when drug development is well supported and industry is able to do this work. However, the research on cheap diagnostics and how the drugs are best used is woefully under-supported.

If everything is scaled up now; still there are around 1.5 million infections a year. Vaccine development is too urgent a problem to do in a serial fashion and there is a need for several things in the pipeline at once. This increases investment risks and one is trying to invest large amounts of money before all the data is in. Flexibility is important, as is the willingness to take risks.

Strategies suitable for Indian pharma companies under WTO regime
Relationship building
Relationship building cuts across the different lobbying areas and must be considered a basic principle of an integrated model. A best practice would aim to build and maintain strategic relationships with all stakeholders that is politicians, regulators, scientists, media, patients and healthcare professionals. Relationships would be put in place and close ties established
well before a crisis arose. In addition, a coordinated approach would be key; R&D and marketing would have distinctive roles to play in this context. Senior executives would drive relationship building from the global to the regional to the national levels, with relationship building a part of job expectations and appraisals for certain staff.

**Therapeutical reputation building**

This concept stands at the core of an ideal lobbying model. The assumption is that direct lobbying, supported by a specific therapeutical reputation, will create additional goodwill, provide for opportunities of indirect influencing, and improve the marketing position of products. Overall, it will facilitate and improve lobbying efforts, both in relation to influencing the external environment (policy in a particular area) and with product approvals / pricing / reimbursement decisions. Therapeutical reputation building may be applied by different types of companies, ranging from a therapeutical niche business model to a company with a widespread product portfolio.

A best practice company would focus its reputation and communication efforts and build a strong position in just a few therapeutic areas e.g. oncology, cardiovascular. A clear and focused reputation building programme would enable the company to position itself on ‘excellence’ in a particular therapeutical area.

![Diagram showing levels of reputation building](image)

- Scientific Conferences, WHO Initiatives, Global Compa
- Research Institutes
- Public Health Strategy, Health Forum, 6th Research
- Framework Programme, Awareness Raising,
- Scientific Platforms
- Scientific Future Forum,
- National Advisory boards for Therapeutical area,
- co-operation and support of patient groups, national expert congress, scientific presentations with media reporting, road shows, Promotion Material On Therapeutical area for patient groups, Doctors, Disease Awareness Raising,, activities with specific patient sub-groups, activities in political context
This enables the company to build up both reputation and goodwill, and to reach key stakeholders of all types without being seen as directly intervening in the product approval / pricing process.

Corporate communication
An ideal type approach would ensure consistency of messages and actively pursue corporate reputation building at global, regional and local levels. Corporate reputation building would be aligned with therapeutical reputation building, to ensure mutual reinforcement. In Europe, reputation and image building would be undertaken at EU, EMEA and national levels. Investors relations and crisis communications would form an integrated part of the reputation building effort. A strategic approach would be employed to define the overall corporate communication direction and to leverage corporate image building for product approvals and drug launches.

Policy
The goal of the company would be to promote a favourable regulatory environment at EU and national levels. The company would have policy functions to cover both these levels that is a Brussels office and national public affairs functions. This would not only efficiently lobby at different political and institutional levels but would link policy lobbying with other corporate and regulatory issues to leverage influence and increase impact in specific areas of interest.

Regulatory product approvals
The goal obviously would be to ensure that products get to market quickly, with a favourable data package (facilitating good market access) and at a satisfactory price. In addition, life cycle management of the product would be crucial.

Regulatory product approvals would view its function not solely as support for product approvals but as a hub to build reputation (on a corporate as well as
therapeutical dimension) with regulatory authorities and their indirect influencers (scientists, evaluators, administrators).

The pre-launch strategy for a product would involve the regulatory, clinical, commercial, product development and manufacturing experts and would target non traditional as well as traditional customers in terms of product approvals that is moving beyond the scientific community and healthcare professionals to politicians, patient groups in order to optimise the outcome for the product.

Regarding the key lobbying area of therapeutic reputation building - good regulatory practice will enable a company to leverage itself in an area even before a product is made available and indirectly promote good practice to key stakeholders.

**Pricing / reimbursement**

Pricing functions should work closely with relevant departments in order to achieve such goals as optimum pricing and profitability strategies, effective pricing models, development of data packages supporting reimbursement objectives and the protection of patented drugs against generics. Pricing and reimbursement must be organised by the country, even if the product is centrally approved.

Matters such as price sensitivity, pricing externalities and investor relations should all be taken into account in order for a best practice company to fully demonstrate the added value of its products.

Given how pricing and funding decisions are made by state-authorised committees and processes, improving the chances for a favourable pricing and funding review will often depend on longer-term influence on policy-making, rather than particular advocacy around a single product. This should
also be taken into account by the lobbying strategy of the company as a whole.

**The therapeutically reputation model for the big pharma company**

The therapeutical reputation lobbying model would be mainly driven by excellence in a particular therapeutical area. Pro-active therapeutical reputation building (e.g. by targeting the scientific community and healthcare professionals) would be at the core of the approach and this would be reflected through innovative structures (e.g. business units on therapeutic areas, horizontal integration of the concept across departments). The pharmaceutical company in question may not pursue a very high profile lobbying approach, as it would avoid all general policy lobbying outside the main area(s) of it therapeutically focus. By targeting those who will have the most influence on the regulatory bodies, the company would be seen as a major but focused lobbying player. An integrated lobbying approach would be in evidence - corporate communication functions supporting the product approvals process in terms of global branding and effective partnerships being created across departments. The pharmaceutical company would also leverage its commitment through working closely with the scientific community to support its pre-approval market preparation activities and communication with pricing authorities. This focused lobbying approach would allow the pharmaceutical company to pursue an innovative and scientific communications strategy.

The strength of the therapeutically reputation lobbying model is also its weakness. As it tends to focus expertise in a specific lobbying area, other crucial areas, for example, policy and relationship building with other stakeholders can be sidelined.
The niche lobbying model of a large biotech company

The innovative technology driven lobbying model is based on the lobbying approach of major biotechnology companies. The biotechnology industry enjoys a generally favourable image as a collection of innovative young companies, and they make extensive use of this entrepreneurial and innovative reputation.

Biotechnology companies are trying to distance themselves from the big pharmaceutical companies, which have become public villains in the debate over rising drug prices. Biotechnology companies therefore put an emphasis on being truly innovative, pushing the boundaries of science and this for the benefit of mankind not for financial interests in the first place.