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Abstract:

We are witnessing a changing paradigm of healthcare sector in view increasing pressure on governments to provide free healthcare to citizens and increasing cost-consciousness of governments/payers to address this public issue. This changing paradigm in healthcare requirements requires a holistic review of the legislative framework in which industry operates. All stakeholders and all applicable regulatory and legal frameworks need to be appraised in order to address the requirements of 21st century healthcare. Drug development is very risky, costly and lengthy process and inventors and investor deserve financial gains for their efforts. Pharmaceutical industry requires the money to keep investing back in the R&D to develop innovative and effective medicines for the patients, keep the workforce engaged and keep playing a vital role in the economy. We cannot let this industry stifle – as without it we cannot have new medicines and a healthier world. Saving money is important but saving life is much more important. All stakeholders – governments, policy makers, and industry should work with this ultimate objective in mind. This article tries to initiate a discussion as to how we can meet the requirements of each stakeholder without compromising and create a win:win situation.
We are witnessing a changing paradigm of healthcare sector in view increasing pressure on governments to provide free healthcare to citizens and increasing cost-consciousness of governments/payers to address this public issue. However, what we have not seen is any corresponding development in the legislative and business framework in which these pharmaceuticals operate in order to accommodate these changing requirements and keep flourishing and playing important role in the economy. Instead, the framework in which pharmaceuticals operate is becoming more complex, lengthy and costly. 10-15 years ago it used to cost half of the amount industry spends now to develop a new drug and it was quicker to bring the product to the market than it is now. So, for the industry it is more costly to develop a new product now and the other hand governments are asking to reduce the prices and not allowing the new drugs onto the market. It seems quite logical that the framework in which industry operates needs to align with this changing paradigm to ensure that we are not stifling the industry to save the cost. We need a holistic approach to look into this issue and define a framework, which is acceptable to all stakeholders – industry, government/payers and patients. This article tries to initiate a discussion as to how we can meet the requirements of each stakeholder without compromising and create a win:win situation.

Pharmaceutical industry is one of the largest contributor to global economy and the largest contributor to research and development (R&D). Around 20% of global business expenditure on R&D is accounted by the pharmaceutical industry worldwide and it generates revenue of more than $700 billion. It invests an average of 16.1% of net sales in R&D - more than any other industry. Another not as well known fact is the important role the pharmaceutical industry plays in the global efforts to fight diseases and improve public health in the developing world. It is estimated that industry’s contributions are over $ 2 billions. Industry’s partnerships with academic, governmental, non-governmental, multilateral, and community-based organization exceed or rival in total size the annual budgets of the World Health Organization and World’s Bank’s health programs. Donations of medicinal products, education to healthcare providers and patients, infrastructure improvements – to name a few – are the contribution made by the pharmaceutical industry in developing world to improve the public health of those nations. All these contributions by pharmaceutical industry in developing world cannot be sustained if the industry cannot generate sufficient revenues from developed world. Therefore, in order to maintain and further develop these philanthropic contributions by the pharmaceutical industry in
developing world, the governments/payers/policy makers in developed world need to work in close collaboration with the industry to design a framework which creates a conducive environment for the industry.

WAY FORWARD:

As mentioned above, the changing paradigm in healthcare requirements requires a holistic review of the complete healthcare sector in which industry operates. Pharmaceutical industry needs the money to keep investing in R&D to develop innovative and effective medicines for the patients and keep the workforce engaged and play a vital role in the economy and keep helping people in the developing world. Government/payers needs to save cost and design cost effective methods for the healthcare systems to ensure appropriate use of taxpayer’s money and the patients needs innovative medicines to save their lives or improve their quality of life. So, what can be done in order to keep all these stakeholders happy?

It seems that the decision makers agree that we needs to preserve a vibrant pharmaceutical sector as an essential pre-condition for the well-being and high level of public health of citizens and a competitive knowledge-based economy. Pharmaceutical legislative framework needs to be compared against other industry sectors to create a level-playing field which fosters the pharmaceutical industry and innovation. We cannot let this industry stifle – as without it we cannot have new medicines and a healthier world. Following are few ideas that can be explored to address industry’s need, which will also benefit other stakeholders.

We need to design procedures whereby extended exclusivity can be offered subject to certain conditions, which are in line with other stakeholder’s requirement – pricing for instance. By the time a patented medicinal product reaches the market a maximum of 10 years of patent protection is left. So, pharmaceuticals lose 10 years of patent exclusivity, while developing the product. Currently, a 6-month extension of patent can be obtained as per EU paediatric regulations. However, given not all products are generating billions, it seems unfair that research based pharmaceutical industry is by law obliged to conduct paediatric studies for all products costing billions and in return they get a very limited extension, which in most cases would not
even generate the cost of conducting those paediatric studies. Therefore, a scheme of patent extension or commercial extension certificates can be introduced. Additional fee/renewal applications for these extension certificates can generate revenue for governments. Additionally, these extension certificates could be subjected to certain conditions – for instance, for the first year of extension, the manufacturer will bring down the commercial price at least 10% as compared to the price of product during the normal patent protection period and then for second year, a further 5-10% as compared to last year’s price. This way, the companies can choose which product they want to take through this procedure, which would be beneficial for them and for other stakeholders too.

The conventional drug development process consumes time and money. – currently estimated to take 10-12 year costing over 1 billion Euros. Out of 10,000 compounds investigated, only one or two can be expected to reach the market as a medicine after extensive R&D. Of these few marketed medicines, only one in five will produce revenues that match or exceed the costs of R&D before losing patent protection. Moreover, almost same amount of money (€ 1 billion.) if not more, is spent on post-marketing activities. So, can we look at this whole drug development process and design a framework, by which we can bring the products to the markets within 5-6 years from discovery to patients? It will reduce the cost by half at least, and will offer longer exclusivity to the pharmaceutical companies and in turn the government/payer can work out an acceptable price in return of these expedited drugs. We can have an adaptive trial with 3 phases in a single continuous trial starting as a conventional phase I/II, and those subjects meeting the objectives would be moved in next stage of the trial – phase III. So, at a given time, there would be patients on a trial at various phases ranging from I to III. This will reduce the cost and time associated with approval, initiation and maintenance of the conventional separate trials. These types of trials can then be monitored by a central body, which will also keep the regulators informed of the status and issues at a regular basis. So the regulators are aware of the history of the product, when it is filed as a new MAA/NDA. This will help reduce the review time to grant approvals.

Additionally, the regulators can grant ‘limited licenses’ for use in selective patient population to observe performance in real clinical setting outside of clinical trails. In this way, upon demonstrating effectiveness – both clinical and economical – the ‘limited licenses’ can be extended into full licenses. These types of trials and development methodology can be started as
pilot projects on limited scales and later on can be developed as standard models. Products going through this expedited route could be made subject to price negotiations and pharmaceuticals would be happy to do that, given they are reducing the cost and gaining some additional years of exclusivity. And the patients would be happy too to get innovative medicines quickly onto the market and accessible.

Moreover, why not look at the improving the healthcare system itself? Ironically the cost of administration of certain cancer drugs via infusion to the patients is equal to the cost of that drug itself (so much fuss about cancer drugs being expensive). If the intention is to save cost, then the bill shouldn’t be picked up by the pharmaceutical industry only and all the stake-holders should contribute towards that. A vast amount of tax-payer’s money is consumed by the administration and bureaucracy in the healthcare systems. Apparently £1.5 billion can be saved by just looking at the administrative/bureaucracy redesign in the NHS. We need to bring corporate culture into healthcare providers, whereby performance is measured against set targets and we need to make it a lean and efficient organization. Healthcare organizations and industry can work in close collaboration to workout a better aligned system of providing healthcare to our citizens in order to reduce the overall cost of providing healthcare. This government-industry collaboration should not be just limited to cost of medicines (which is about upto 20% of the healthcare budget) and should encompass other aspects where 80% of the budget is spent. Pharmaceutical industry can provide much more than just the medicines – patient education, compliance, administration of medicines, supply chain and even can help bring corporate values and performance measurement in healthcare systems – both for the drug itself and the outcomes and the associated cost.

The industry itself is at a central stage of this evolving healthcare needs/system and it is vital for its survival to revamp the way they operate, in view of the expectation of all other stakeholders. The pharmaceutical industry is like any other industry – controlled by the shareholders/investors. And they have some expectations too – return on investment. It is very important for the pharmaceutical industry to satisfy its core stakeholders – patients/society and the investors. There is increasing pressure from the investor to reduce the cost and generate reasonable return on investments – fair enough – otherwise they can invest in any other sector. Therefore, the pharmaceutical industry needs to find and design innovative ways of doing the
business in order to satisfy the core stakeholders – patients (by developing innovative, safer, effective medicines) and investor (generating reasonable revenues). Additionally, the industry needs to satisfy the other stakeholders – payers/governments and healthcare professionals (by providing cost effective solutions of providing healthcare) too.

So, what can be changed or improved in the way industry operates in order to satisfy these stakeholders? It has to become more agile and innovative and design strategies to reduce the cost and time it currently spends bringing new medicines to the market. To start with, the first and foremost is to work in close collaboration with these stakeholders to understand their needs. What exactly patients want, how to reduce the burden of chronic diseases, what exactly payers want, how pharmaceutical can work in close collaboration with the hospitals and care centres to reduce the cost of providing the healthcare, how to establish a better and close professional relationship with the healthcare professionals. Industry also needs to look at the way they develop the drug. The industry needs to create a culture of fast and robust early development mechanisms to screen potential medicines. Industry also needs to look outside of its boundaries/functions to streamline the process in order to improve the speed and reduce the bureaucracy and cost. Industry needs greater collaboration to design innovative R&D. So, it boils down to how the business model of the industry can be improved and how the operations can be streamlined to fulfil the needs of all these stakeholders? Keep the patients first in mind - develop the right drug that fulfils unmet need or provides a safer and more effective solution to the patients and also look at the costs – how it will affect the payer/government and healthcare system – is it a cost-effective solution?

Additionally and importantly, the pharmaceutical sector needs to improve its image by bringing its social contributions into public domain. Unfortunately, the pharmaceutical industry currently suffers from a poor reputation in public. The work carried out by the pharmaceutical industry in developing countries needs highlighting – the time, efforts, energy, costs and associated risks in developing new medicines need to be highlighted. Currently this type of information is only limited to healthcare related publications and forums and not very visible to general public. Industry should bring these facts into general public domain using various available media – TV, Newspaper etc. In this way, the industry can secure the support of the key stakeholders – the
patients. Industry should work in a very open environment while conducting business with governments, payers and healthcare providers so everyone understand the situation and can work together to move forward. I cannot see if governments can work directly with the banks to save them from collapsing then why they cannot work with pharmaceutical industry to ensure that it keep providing the vital input into our society and economy. If there is no healthy pharmaceutical industry, there won’t be any new drugs.

CONCLUSION:

_Innovation, creativity, public health and a better healthier world_

This article is intended to start a holistic discussion at a wider forum where all stakeholders can get involved and come up with a solution in view of new developments in healthcare sector and requirements of 21st century. We need to design a framework which addresses all stakeholders’ needs, i.e., manufacturers (return on investment to spend it back in development), payers (cost) and patients (superior quality, innovative and effective products). We also need to keep helping the industry to continue the work being done in developing countries to improve the health and quality of life of millions of people. At the end of the day, we are talking about patients – to save lives or improve quality of lives is the ultimate objective. _Saving money is important but saving life is much more important._ All stakeholders – governments, policy makers, and industry should work with this ultimate objective in mind.

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Views expressed in this article are purely personal and do not represent views of any affiliation author might have.