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Management

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IN THE QUEST OF TRUE FREEDOM

As India gears up to celebrate its 72nd Independence Day, we examine a few factors which are crucial to liberating the true potential of our pharma industry

Revolutionising India Pharma Inc with indigenisation, innovation and information

With a strong R&D base and academic talent, India has the potential to become a leading innovation player in biotechnology and pharma

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Indigenisation in Indian pharma industry will boost the economy and generate huge numbers of employment in the country as well

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Innovation generally refers to changing processes or creating more effective processes, products and ideas. Innovation is pragmatic in discovering drugs, developing therapeutics and delivering healthcare as per Indian needs. It is only by creating innovation in technology, strategies, practices and policies that Industry can take on global healthcare challenges.

The decade 2010-20 has been declared in India as the Decade of Innovation. We have formulated a science, technology and innovation policy, aimed at an innovation-led development. This policy calls for creating an ecosystem for innovation activity to thrive in our country. It highlights the need to encourage and recognise grass roots innovators.

With a strong R&D base and academic talent, India has the potential to become a leading innovation player in biotechnology and pharma.

India's contribution to affordable healthcare goes much beyond being a pharmacy of the world. GE's Research Centre in India has developed a number of low-cost bio-medical equipment from scanners to portable electrocardiograms as has Bristol-Myers Squibb developed a number of promising novel drugs at its partnered research centre in Bangalore. Biocon, on the other hand, has not only developed insulins in India indigenously through a proprietary technology in the early 2000s, but has also developed and delivered two affordable novel biologics for the benefit of cancer and psoriasis patients in India. India is therefore proving its mettle as a "laboratory for the world" that can deliver affordable innovation and a growing number of collaborative efforts are succeeding in delivering products and services that can go a long way in ensuring that the right to healthcare becomes truly universal.

India is a large diversified territory driven by volume consumption as compares to value, and is dependent on in-licensing the technologies. Fostering innovation can also support Make in India initiative, augment employment, support the Start-up India mission etc.

Indigenisation in the Indian pharma industry is very much supported by the available resources in India i.e. large educated population, scientists' pool, technologies and initiatives taken by the government to drive the concept.

For instance, 100 per cent Foreign Direct Investment (FDI) is allowed under the automatic route for greenfield pharma and 74 per cent FDI through brownfield pharma under the automatic route. Under the Pharmaceutical Promotion Development Scheme (PPDS), the government extends financial support to conduct seminars, conferences, exhibitions, and mounting delegations to and from India for promotion of exports as well as investments, conducting studies for facilitating growth, exports as well as to discuss on critical issues affecting pharma sector.

Other measures to support indigenisation of the sector include training/knowledge improvement activities on issues relevant to growth of pharma industry; pharma technology upgradation; strengthening of existing infrastructure facilities to make Indian pharma industry a global leader in pharma exports; enhancing the quality, productivity and innovative capabilities of the SME pharma sector in the country; helping industry meet the requirements of standards of environment at a reduced cost through innovative methods of common waste management system etc.

Financial incentives such as market exclusivity, reduced R&D cost including tax credit on R&D cost; R&D grant for Phase I to Phase III clinical trials and the User or Registration Fee Waiver Act for biologicals and orphan drug cases to promote their maximum use in India would also prove to be very beneficial.

Indigenisation in Indian pharma industry will boost the economy and generate huge numbers of employment in the country as well.

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Considering the success Indian industry has shown to create copy-cat drug products, the ecosystem is ripe to create hybrid NDAs, which have been sporadic and serendipitous in nature

People with knowledge combined with the availability of tools, technologies and ingredients are essential part of the innovation ecosystem to foster new drug development leading to improved convenience, compliance, efficacy and safety. Interestingly, there exists great possibility to innovate and address unmet medical needs by unique solutions built on smart strategy of relying on information available from previously approved drugs, essentially with novel approaches leading to improvement in delivery and clinical use. Several regulatory agencies, recognising pressing needs and immense benefits of innovation in healthcare, have made available, well-defined pathways of review, approval and market exclusivity of these hybrid new drug applications. In 2012, Generating Antibiotic Incentives Now (GAIN) was passed as part of US Food and Drug Administration Safety and Innovation act (FDASIA) to address public health threat of antibacterial drug resistance by stimulating the development and approval of new antibacterial and antifungal drugs. The US Food and Drug Administration (FDA) has already approved 12 drug products with Qualified Infectious Disease Product (QIDP) designation, each receiving a priority review apart from granting 147 QIDP designations, including approximately 74 designations for novel drugs in a short span of approximately five years.

It is important to note that in 2017, more than 50 per cent of all NDAs approved have been 505(b)(2) drugs. This percentage is expected to rise to more than 80% over the next few years due to obvious low risk, relatively small program budget, accelerated development and approval and extended market exclusivity. A few examples of such success stories are briefed below:

- PROCARDIA XL is a zero-order release tablet of Nifedipine that not only reduces dosing frequency from thrice a day to once a day but also significantly improves the efficacy to safety ratio.
- Cipro XR not only resulted in reduction of dosing from 2/3 times a day to once a day thus improving patient compliance but also extended the usage of the molecule for resistant UTI which otherwise could not be treated with the immediate release tablets.
- ABSORICA, a semisolid filled hard gelatin capsule formulation of isotretinoin has improved efficacy and patient compliance over soft gelatin capsule formulation of this drug.

Considering the success Indian industry has shown to create copy-cat drug products, the ecosystem is ripe to create hybrid NDAs, which have been sporadic and serendipitous in nature. The time of entry of the innovative new product is very critical to ensure market success. Preferably, such products, need to be introduced well before generic competition to create maximum value. To start off with, a focused and concerted effort by a few players to achieve repeated success would act as an impetus for many more players to join in the path of innovation, growth and sustainable business.

At least on critical APIs which are required for essential medicines, India needs to be self-reliant. Indian pharma majors need to look at backward integration at least for their flagship brands and develop a long term business continuity plan

DR AJIT DANGI
President & CEO, Danssen Consulting

Although we have achieved the distinction of being the 'Pharmacy of the World', our over dependence on APIs imported from China is a major geopolitical risk.

Independence with APIs

Blood pressure drug Valsartan, manufactured in China by Zhejiang Huahi Co., contaminated by an impurity NDMA (Nitrosodimethylamine) which has a potential carcinogenic risk and banned in 22 countries including India, is another example of the risk involved in such dependence. Recently, after closing down over 145 API manufacturing facilities in China for non-compliance of environmental laws, there has been shortages of many products in India such as Vitamin C based formulations. At least on critical APIs which are required for essential medicines, India needs to be self-reliant. Indian pharma majors need to look at backward integration at least for their flagship brands and develop a long term business continuity plan. The trade war between China and the US, Brexit in UK are some of the indications of shape of things to come where India can suffer a collateral damage. As in the words of Ruchir Sharma, Chief Global Strategist of Morgan Stanley, one of the major trends in 2018 onwards is 'Deglobalisation', India needs to be prepared for this mega trend.

From imitation to innovation

While India is proud of being the third largest manufacturer of pharma products in terms of volume in the world, we need to transit from imitation to innovation. The strategy of reverse engineering has paid us rich dividends, time has now come to move up the value chain from cost arbitrage to intellectual arbitrage by using innovation as a platform. For this, we need to foster an ecosystem of strong Intellectual Property protection, human capital of talent with requisite skill set and policy initiatives to incentivise innovation.

Another important issue is of economies of scale and scope and optimum utilisation of capacity. According to IMS report, 95 per cent of our domestic sales revenue of about ₹1.2 lakh crores comes from top 150 companies. We have today over 9000 manufacturing pharma companies. Time has now come for consolidation which is also required from the point of view of meeting global quality compliance standards as the manufacturing infrastructure required for this is increasingly becoming sophisticated and expensive.

Government of India is promoting indigenisation of goods and services through 'Made in India' campaign. This can be used as a key strategy to help indigenisation of the Indian pharma industry as well

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The industry is not devoid of attempts to engage in NCE development. However, success is glaringly elusive. This calls for deeper introspection and policy measures

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Promoting indigenisation

As we have seen, the government of India is promoting the indigenisation of goods and services available in the country through the 'Made in India campaign.' This can be used as a key strategy and advantage to help the indigenisation of the Indian pharma industry as well. Today, the pharma industry in India is rapidly growing and so is its dependence on APIs from foreign countries. Even if we look at other industries such as the defence industry, India is the world's largest importer of defence equipment and is dependent on other countries to fulfil its requirement. Hence, the government has decided to try and boost jobs and FDIs in India through the indigenisation of the defence industry. The Indian pharma industry too can adopt similar strategies either through tech transfers or through the development of high quality sources for key APIs in India itself.

Building an innovative ecosystem

Innovation should not only be looked at from a point of developing new products, but should be used for the improvement or evolution of existing products as well. Temperature sensitive products can be made to resist higher temperatures which leads to better stability in poor or uncontrolled conditions such as transportation. Painful injections can be made to be painless and aseptically filled products can be made to withstand terminal sterilisation to ensure sterility of the product. Such innovation can be advantageous to several existing products, as this finally impacts the end consumers by promoting patient safety. It also creates confidence with doctors which finally results in the product gaining a key position in the market by becoming the preferred choice.

Healthy exchange of information

In India, we have a large number of pharma companies working on several products for many years. Each company has generated large amounts of data, based on their scale, relating to their product portfolio. If this data is shared between these companies, each of which have their own area of expertise, there could be several advantages. This healthy exchange of information could strengthen the position of these companies in the Indian market itself, further promoting the indigenisation of the Indian pharma industry.

Twenty years after the product patent regime commenced, we still cannot boast of a robust drug discovery engine or a notable level of novel drug pipeline in the country. We have nurtured a solid foundation of generics with revenues north of $35 billion and substantial export success. Investment capability is then not the constraint in an industry with an aggregate balance sheet of substantial size. The industry is also not devoid of attempts to engage in NCE research or development. However, success is glaringly elusive. This calls for deeper introspection and policy measures that can trigger sustainable innovation engagement.

Foremost, it is critical to appreciate the risk level and gestation period in discovery and development and resultant reticence in industry investments. While industry is not averse to the idea of investing in higher risk R&D, the level of binary risk has always been an impediment to investments stepping up to an optimal level. With sub-optimal level of investments, the cycle of investment and value realisation is never set in motion. Only when initial investments lead to fruition on commercialisation and monetisation milestones, are additional investments likely to follow.

Here is where extra-mural government funding could play a catalytic role. Government grant funding accessible to ventures has substantially gone up in the last decade and has in fact been a major driver for the current entrepreneurial wave. However, the extra-mural funding allocation of about $150 million has been insufficient for drug discovery ventures given the scattered support to more than 400 ventures and relatively sub-optimal level of programmatic investment per venture.

To nurture an indigenous drug discovery engine, we need to redesign our funding programmes for novel drug development and ensure tenor and quantum of foundational support stretches through a while cycle for the initial pipeline. It is also critical to take cognisance of weak pipeline of globally benchmarkable translational solutions in domestic institutions.

Combining pragmatism and considerations for sustainability, we should ensure funding for technology access from global sources while simultaneously channelling intra-mural funding in a manner that our institutional backbone can rev up the engine in the decades to come. The India discovered drug shouldn't be a one-off wonder, we have to make it the order of the day in the future.