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THE AWARE CONSUMER

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QUALITY OF DRUGS

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Abyss Or Bridge ?

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QUALITY IN PATIENT CARE

VIEWPOINT

BEJON KUMAR MISRA | bejonmisra@theawareconsumer.in

Need For Scientific Investigation

Legal accountability of marketing companies is absolutely essential for protecting patients interests especially given a situation where large pharma companies are making healthy profits from the sale of medicines that they themselves are not involved in manufacturing.

IF WE WERE to believe every word of the book "Bottle of Lies", it would be easy to label India the scamster of the world as far as the pharmaceutical industry is concerned. While much of it is true, however, to paint the entire industry bad because of a few rotten eggs would be wrong. It is not for nothing that India is billed as the 'pharmacy of the world' and has the distinction of supplying 40% of the world's generics. This reputation is built on years of hard work, meticulous research and stringent regulatory compliance.

The Nation Drug Survey 2014-16 was aimed at getting beyond the layers of data lying in public domain that seem determined to pronounce India guilty of a web of deceits and frauds. We wanted to conduct a scientific survey, unbiased and totally consumer-oriented to come out with credible data on what is the truth.

There is such lack of trust in the system that even good work done by the government draws skeptical reaction. Therefore, we felt that establishing credibility in the system is important and the Survey should be conducted in a transparent manner to gain consumers' trust. Towards this end we achieved a robust sampling system, involved trusted government agencies and used accredited or government labs. The results were not surprising. Only 0.04% of the samples were found to be spurious on a pan India basis, and about 3% of was not of quality standards. There are pockets in the country that are indulging in malpractices and by no stretch of imagination is the malady a pan Indian one.

What does it prove? For one, that media has a way of hyping incidents in bits and parts – the bits and parts that will grab the most eyeballs. Further, in the era of social media and maximalism, things have a tendency of snowballing out of all proportion.

While Katherine Eban's book has investigative vigor and journalistic artistry, it can in no way be an indictment of Indian pharmaceutical industry's manufacturing and marketing practices. To establish the credentials or lack of it of an industry the size of India's pharmaceutical sector, you need more than a book. You need a thoroughly scientific investigation into the entire industry and its stakeholders. The Nation Drug Survey is just a beginning.

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Message from the Editor-in-Chief

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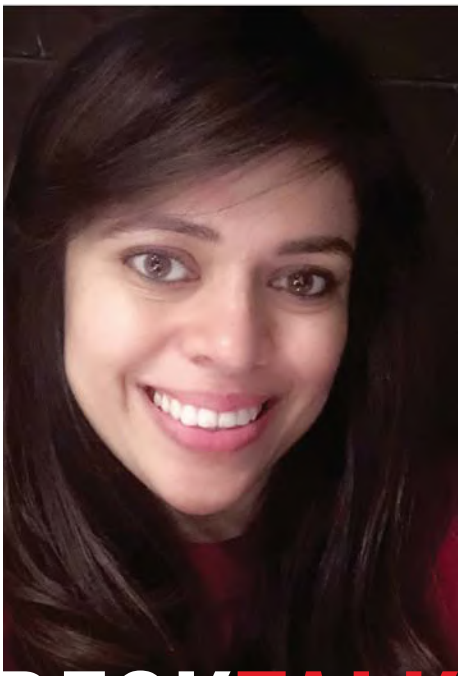

DESKTALK

IT IS THE MORAL DUTY OF PHARMA FIRMS TO DELIVER QUALITY DRUGS AND DEVICES

INDIA'S PHARMACEUTICAL INDUSTRY is vast. If we talk in numbers, the country's pharmaceutical industry is expected to expand at a CAGR of 22.4 per cent over 2015–20 to reach US$ 55 billion. India's pharmaceutical exports stood at US$ 17.27 billion in FY18 and have reached US$ 19.14 billion in FY19. In short, it is huge and promising.

To expect an industry of this size and diversity to be without issues and challenges would be naive. Not surprisingly then, it is the same industry where you have an ethics-immune Ranbaxy and a pioneer like the 82-year-old chairman of pharmaceutical major Cipla, Yusuf Hamied, who was recently made an Honorary Fellow of the prestigious body, The Royal Society of UK.

Pharmaceuticals is an industry that needs must be high on quality – it concerns human life. And human life is precious. Look around you in hospitals and private clinics, what do you find on the faces of patients and their families – hope. It is that hope which keeps even those battling terminal diseases cheerful – hope of a cure, a succor or a miracle. Much of this hope hinges on the medication that the doctor prescribes. Families willingly stake their all in the hope of a cure. They are not bothered about the price of the medicines; they are putting their faith in its efficacy irrespective of cost. Out of pocket expenses may turn them to paupers, but no patient or their kin would stop a line of treatment as long as there is hope.

To play with this hope is inhuman and unethical. Consumers deserve quality medicines. It is the moral duty of pharmaceutical companies to ensure that they deliver on this. Whether it be medicines or medical devices, for the consumer a subpar one could obliterate the fine line between life and death.

Yet, as long as companies are blinded by the profit motive no amount of regulation and laws will make them honest. They will still find loopholes to twist around the rules or flout it.

What would the doctor prescribe for such a patients? A high dose of corporate ethics and personal morality, most likely, apart from rules, laws and regulations to keep them in control. And, perhaps the same Hippocratic oath of ethics that keeps the doctor in check?

INSIDE

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KATHERINE EBAN

INVESTIGATIVE JOURNALIST. AUTHOR, NYT BESTSELLER, BOTTLE OF LIES

"One drug investigator said to me that he thinks the concern is higher for people on maintenance medications who are taking these drugs day in and day out. Those drugs may have toxic impurities. Those can build up in your liver, you may not know it, or you may be having side effects that you didn't think about before, and then you realize, "Wait a second I was switched to a different generic" or "I was switched from a brand to a generic."

ROUNDUP

IMAGE: PIXABAY

Docs Can't Accept Freebies From PHARMA COMPANIES

The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, prohibits doctors from taking gifts, travel facilities, hospitality and cash or monetary grants from pharmaceutical and allied health sector industry.

DATA BRIEFING

USD 380.60 Billion – Size & Share of global market for generic drug by 2021

The pharmaceutical industry spends about $12 billion every year on gifts and payments to physicians (Studdert DM, Mello MM, Brennan TA, 2004). The goal of spending all this money is to get physicians write more prescriptions for a particular company's product.

Changes Proposed To Make Marketers Liable For Quality Of Drugs Outsourced To Third Parties

IN A MOVE aimed at ensuring quality of drugs available to consumers, the health ministry has proposed changes in regulations that would hold marketing companies accountable for drug product quality.

The impact of this regulation would be on both domestic and multinational pharmaceutical companies. Many of these companies also outsource production to third-party units primarily due to capacity constraints at plants or to use facilities for export purposes.

Currently, under the Drugs and Cosmetics Rules, the onus of ensuring quality of drugs falls on the manufacturer. In case of any defects or substandard quality of product, it is the manufacturer who is liable for action and there is no liability on the marketing company.

Through amendments to the rule, the ministry wants to make marketing companies responsible for quality. It has invited comments from the industry on proposed rule amendment.

"Legal accountability of marketing companies is absolutely essential for protecting patients interests especially given a situation where large pharma companies are making healthy profits from the sale of medicines that they themselves are not involved in manufacturing," a media report quoted Malini Aisola of All India Drugs Action Network.

It is common knowledge as to how larger pharmaceutical companies pass on the buck to smaller contract manufacturers whenever a product is found to be substandard. The rules are proposed to be changed to ensure that the guilty do not escape the noose.

Under the current rules, it is the drug manufacturer who is responsible for product quality and labelling. The marketing companies only require a license to sell and stock goods. As the amendments in rules would make compliance on quality the responsibility of the companies, it is being hoped that they would become more accountable under increased scrutiny. ◗

THE GOVERNMENT OF India seems to be on a path to administer the bitter pill of discipline to its pharmaceutical industry and errant doctors. While it is common knowledge that pharma drug makers push large benefits along with sample medicines to doctors in a bid to influence their decision on drugs; it took a hard rap on the knuckle from Union Health Minister Harsh Vardhan, to bring the spotlight on this practice.

Vardhan said in the Lok Sabha that there had been complaints received about the unethical marketing practices adopted by pharmaceutical companies. Emphasizing its illegality, the minister said that the code of conduct for medical practitioners prohibits doctors from taking gifts, availing travel facilities, enjoying free hospitality or taking cash gifts from pharmaceutical and allied health sector industry. The minister sounded a warning that the managing director or CEO of errant companies would be held responsible for such malpractices.

Notably, this code of conduct for doctors regarding their relationship with pharmaceutical and allied sector industry is detailed under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, prohibits doctors from taking gifts, travel facilities, hospitality and cash or monetary grants from pharmaceutical and allied health sector industry, as ultimately they are responsible for ensuring adherence to the code.

This regulation also empowers the Medical Council of India and respective State Medical Councils to award punishment to a doctor who acts in violation of the code of ethics. The MCI is an Appellate Authority.

The minister said the complaints received by the Department of Pharmaceuticals are forwarded to Pharma Associations concerned for necessary action as per provisions of Uniform Code for Pharmaceutical Marketing Practices (UCPMP), as prepared by Department of Pharmaceuticals.

Currently, under the Drugs and Cosmetics Rules, the onus of quality and labelling is with drug maker. Marketers just need license to sell.

New Rules Mooted To Make It Mandatory For Doctors To Dispense Generics Only

Experts point out government needs to work on availability and pricing too

IMAGE: FREEIMAGES.COM

THE GOVERNMENT OF India is likely to bring in amendments to the Drugs and Cosmetic Rules, 1945, to make it mandatory for registered medical practitioners to dispense only generic medicines.

According to media reports, the proposal was recently tabled before the Drugs Consultative Committee (DCC) of the Central Drugs Standard Control Organisation (CDSCO).

The proposal wants to amend the rules to ensure that registered medical practitioners supply only generic medicines and that physicians' samples are supplied free of cost.

The Indian Medical Association (IMA) meanwhile is planning to meet the drug control authorities over the issue later this month. Media reports quoted a senior association member as saying: “While we welcome the move by the government to ensure that generic medicines are supplied, the government also has to ensure easy availability, unclogged supply chain, and strict quality control of generic medicines. We welcome the move to keep drugs affordable, but we have to ensure availability and effectiveness also of generic medicines.”

Dr. Babu K.V., an ophthalmologist from Kerala has written to the drug controller to reconsider the matter. In a media report he said: “If this amendment goes through, doctors would be violating the law by dispensing branded drugs. But this is not a simple issue. While I am not compelling my patients to get the drugs prescribed by me from my clinic, they can avail the brands/generics of their choice from anywhere. The main concern is to offer the best medicines which are most effective so we should not be forced to prescribe in a particular manner."

Explaining his reasons, Babu said that while many generic eyedrops are available at cheaper costs, they cause extreme irritation in the eye as compared to branded products that are a little costlier.

The Kerala ophthalmologist said that his views are based on the feedback from his patients and reasoned that since the well-being and comfort of the patients is a top priority, he was dispensing branded drugs mainly for this reason.

Delhi Medical Association member Dr. Anil Bansal echoed similar sentiments. In a report he said, “The government should keep strict price control on medicines and ensure that the highest quality medicines are given to the patients. All laws, checks and balances should be directed at giving the best possible treatment at the best cost. This differential treatment (in terms of medicines) does not work in the long run.”

Source: Secondary research & media reports

Consumers, Beware

For Pharma Companies Nothing Is Sacrosanct, Least Of All Consumers' Lives

Cases of fraud in India and abroad show why consumers need to be on their guard

IMAGE: FREEIMAGES.COM

From low quality to spurious, you never know what that bottle of pills contains.

WHEN IT COMES to healthcare, there is a lot that consumers need to be beware of – from spurious drugs, poor quality generics, hospitals that fleece mullah in the name of healing, doctors that are more concerned with pushing drugs that bring them quality freebies than prescribing quality and cost-effective treatment, scams in diagnostics, defective devices, quacks and charlatans to much more.

"Lives will be lost [if new drugs aren't developed], but lives are also lost by overpriced drugs when people don't have access to them."

–Mark Pauly

It is an irony then, that in India, those that heal are traditionally looked up to as angels of God. For scamsters nothing is inviolable. Take for instance the flagship Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). When you click open the website, the landing page is a prominently displayed public notice warning the general public about unauthorized and unscrupulous persons claiming to be representative of Bureau of Pharma PSUs of India (BPPI) and PMBJP.

In the month of June this year, media reported that the BPPI had found 25 batches of drugs of 18 pharma companies substandard since January 2018. The BPPI is the implementing authority for PMBJP, the Government of India's flagship affordable medicine scheme. Of the 18 companies involved, 17 were private and one was a public sector unit (PSU) – Indian Drugs and Pharmaceuticals Limited (IDPL).

In July, Strides Pharma Science Ltd.'s, a pharmaceutical player based in India, tried to dispose of quality-control records, but was caught. The company sells numerous drugs in the US, including ibuprofen. As per media reports, US Food and Drug Administration inspectors had found the records awaiting shredding at the company's manufacturing unit in Puducherry. In a warning letter to the company's Chief Executive Officer, which was made public, the agency revealed the matter. What's even more damning is that the agency found discarded records in a 55-gallon drum in the company's scrap yard! Ibuprofen is one of the drugs manufactured at the Puducherry plant.

While this has put a question mark on the effectiveness of the company's quality unit and the "integrity and accuracy" of its data; the incident is not an isolated one. Pharma companies across the world have been facing the heat over their quality control measures. In a damning indictment, most of the heart pills contaminated with probable carcinogens that have faced yearlong recall were manufactured in India and China.

According to a Bloomberg investigation, the problem is industrywide. Drug-makers routinely flout norms and ignore the red flags despite some of the drugs failing to pass US standards. Strides has the approval to make losartan for the US, one of the drugs, part of the wider recall.

From quality to pricing of drugs, nothing seems to be sacrosanct. In May, Teva Pharmaceuticals USA Inc was accused of orchestrating a sweeping scheme with 19 other drug-makers to inflate drug prices by more than

Caution against "Frauds"

It has been brought to our notice that some unauthorized and unscrupulous persons are attempting to falsely use the name / logo of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) in respect of their businesses and falsely representing BPPI / PMBJP, for implementing PMBJP with a malafide and dishonest intention to mislead and defraud innocent and unwary members of the public. The public in general is hereby cautioned against such unauthorized and unscrupulous persons claiming to be representing BPPI / PMBJP, and are advised to verify the details from the official website of Bureau of Pharma PSUs of India (BPPI): janaushadhi.gov.in. BPPI, shall not be liable to unwary individuals who fall victim to such unauthorized and unscrupulous persons claiming to be representing BPPI / PMBJP without confirming the authenticity of the clains of such persons.

Beware of fake websites

ıshadhi.org www.janaushadhi.org.in

Heart pills probably manufactured in India or China were laced with carcinogens.

IMAGE: PIXABAY

1,000% in some cases. Of these, seven were Indian drug manufacturers. A total of 44 US states had joined hands to file the lawsuit accusing these companies of indulging in illegal conspiracies to strangle competition for generic drugs and illegal profiteering in over 100 different drugs.

The seven Indian pharmas included big names as Wockhardt, Dr Reddy's Laboratories, Aurobindo Pharma, Glenmark Pharmaceuticals, Lupin, Zydus Pharma (Cadila Healthcare), and Taro Pharmaceutical Industries – a subsidiary of Sun Pharma. Five executives of the above firms were also named in the lawsuit. The lawsuit that runs into 500 pages accuses the executives of colluding over industry dinners, cocktail parties and golf outings and through text messages and telephone calls.

According to the case paper, the scam ran over a period of 19-months from 2013 to 2015. In this period, Teva raised prices on about 112 generic drugs and on at least 86 others, colluded with its competitors.

The list of drugs so influenced included tablets and capsules and creams and ointments to treat a wide range of conditions including diabetes, high cholesterol, high blood pressure, cancer, epilepsy, etc.

Though the Indian companies denied the allegation, many of the drug-makers are under the regulatory scanner at home on similar charges of profiteering.

According to the data of National Pharmaceutical Pricing Authority (NPPA), altogether 1,991 cases of overcharging customers have been registered under the Drug Prices Control Orders (DPCOs) between August 1997 and March 2019. They together account for nearly Rs 6,285 crore with interest. There are another 666 cases where pharma players have made excess profits by selling medicines at prices higher than that notified by the drug pricing regulator.

Wockhardt Limited and Medibios laboratories are the biggest case stuck in litigation under DPCO 2013. Other major drug companies on the list are Pfizer, Zydus Healthcare's and Sun Pharma Laboratories.

These cases are but the tip of the iceberg and the list is long.

Source: Secondary research & media reports

SUPPORT THE CAMPAIGN

LOOK OUT FOR THE RED LINE

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Medicines such as Antibiotics have a Red Vertical Line on their pack to indicate that these should be consumed only on doctor's prescription. Always complete the full course as prescribed by the doctor.

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HTTP://WWW.CAUSES.COM/CAMPAIGNS/106670-RAISE-AWARENESS-FOR-SALE-USE-OF-ANTIBIOTICS-TO-COMBAT-AMR

In Need Of A Growth Pill

IMAGE: FREEIMAGES.COM

Concerted effort, collaboration and regulation are the key to unlocking the potential of India's pharmaceutical industry.

THE LAST FIVE years certainly haven't been good to the "pharmacy of the world". From a high of around 15% per annum, the industry over the last year witnessed double digit growth once again at 11per cent per annum. It came after a period of lows where it went through single digit growth and even de-growth. Blame it on demonetization, implementation of GST or the setback in the US market over quality of generic drugs, it is time that the India pharmaceutical industry took a long hard look at itself and put its act together again. But more of that later.

As the largest provider of generic drugs globally, Indian pharmaceutical industry supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in the UK.

In 2017, companies in India received 304 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA). India accounts for around 30 percent (by volume) and about 10 percent (by value) in the USD 70-80 billion US generics market.

Growth Forecast

While the industry is forecast to grow by 9-11 per cent over the previous fiscal and is likely to touch $41.9 billion in FY20; it is aspiring to touch USD 120-130 billion by 2030 from the current USD 38 billion.

The country's biotechnology industry is expected to grow at an average growth rate of around 30 percent a year and reach US$ 100 billion by 2025. It comprises bio-pharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics.

According to a study by Care Ratings, on the domestic front the industry is likely to grow at around 12 per cent and reach $20.4-$20.8 billion during FY20. However, exports are likely to reach $21.1 billion in this fiscal with a growth rate of 8 to 10 per cent. According to the 'Manufacturing & Service Industries: Review FY19 & Outlook FY20', the branded generics export is set to see better growth due to the demand for affordable health care in emerging and developed nations as also the rising per capita income in emerging nations. The report

also sees the demand for export rising as many patents are set to expire as also brand exclusivity.

It is expected that Indian pharmaceutical companies will likely be focused on developing speciality medicines and complex generics in a bid to expand their portfolio and increase their share in the world export pie.

The other drivers of growth in the domestic market will be growth in presence of chronic diseases, increasing per capita income, improvement in access to health care facilities and penetration of health insurance. “These factors are expected to increase the volumes of Indian pharmaceutical industry and the volumes are likely to grow faster compared to total domestic market growth rate,” adds the report.

Indian Pharmaceutical Alliance (IPA) estimates that the Indian pharmaceutical industry, currently at USD 38 billion, could touch USD 120-130 billion by 2030. The report 'Indian Pharmaceutical Industry: The Way Forward – Vision 2030', is a research collaboration with McKinsey & Co. It also has inputs from IPA members and industry leaders.

According to the India Brand Equity Foundation (IBEF), the sector was valued at USD 33 billion in 2017 and is expected to expand at a CAGR of 22.4 per cent over 2015–20 to reach US$ 55 billion. The country's pharmaceutical exports stood at US$ 17.27 billion in FY18 and have reached US$ 19.14 billion in FY19. Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, Ayush and herbal products, and surgicals.

The report adds that to achieve this goal stakeholders would need to work together to accelerate the goal of universal healthcare for all across the country and the world by providing high quality drugs at affordable prices.

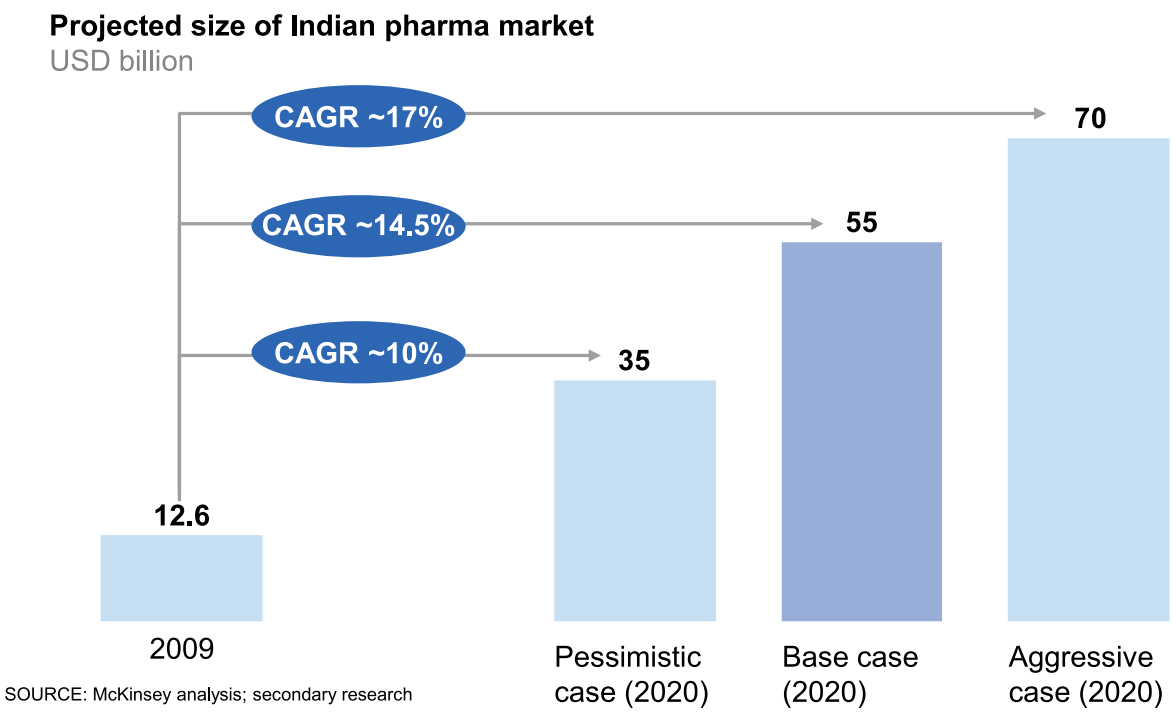
'India Pharma 2020: Propelling access and acceptance, realizing true potential', a McKinsey & Company report, had forecast that the Indian pharmaceuticals market would grow to USD 55 billion by 2020 on the back of steady increase in affordability and a steep jump in market access and would be comparable to all developed markets other than the US, Japan and China. It had also forecast an even more impressive level of penetration, with India dominating in terms of volumes and a close second only to the US market.

Varying estimates notwithstanding, the Indian pharmaceutical industry has a robust future, if it plays its cards right.

Growth Drivers & Roadblocks

As foreign direct investments (FDI) equity inflows into the country declined 1% to $44.4 billion in 2018-19 from a record $44.8 billion in the previous year (as per the data released by the Department for Promotion of Industry and Internal Trade in May), the government set about examining India's FDI policy. Notably, foreign investments fell 74% to $266 million in pharmaceuticals. This despite the fact that foreign investors can own up to 100% stake in pharmaceutical companies. In 2016, the government had allowed up to 74 per cent FDI in existing

Indian pharma market will grow to USD 55 billion by 2020



SOURCE: McKinsey analysis; secondary research

pharmaceutical companies through automatic route. Earlier, 100 per cent FDI was permitted through government approval route.

According to reports, the Union Cabinet has given its nod for the amendment of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector in order to allow FDI up to 100 per cent under the automatic route for manufacturing of medical devices subject to certain conditions.

The cumulative FDI inflows in the pharmaceuticals sector between April 2000 and March 2019 was USD 15.98 billion, according to DIPP data. Some of the notable developments in the pharmaceutical sector as noted by IBEF are as follows:

- Between July-September 2018, there were 39 PE investment deals worth USD 217 million.
- Investment (as % of sales) in research & development by Indian pharmaceutical companies increased from 5.3 per cent in FY12 to 8.5 per cent in FY18.
- In 2017, Indian pharmaceutical sector witnessed 46 mergers & acquisitions (M&A) deals worth USD 1.47 billion.
- The Indian pharmaceutical industry's exports to the US are set to get a boost, as branded drugs worth USD 55 billion will become off-patent during 2017-2019.

Pharma industry stakeholders will have to play a large role in order to tap the opportunities. As IPA report noted, they will have to work on becoming the world's largest and most reliable high drugs supplier.

While pharmaceutical companies need to make a concerted effort, the government too needs to pitch in with enabling policies and supportive ecosystem. The government seems to be already working in this direction as noted by IBEF. Some of the notable initiatives taken by the government to promote the pharmaceutical sector include:

- The announcement by the Uttar Pradesh Government in October 2018 that it will set up six pharmaceutical parks in the state. It has already received investment commitments of more than Rs 5,000-6,000 crore (USD 712-855 million) for the same.
- The National Health Protection Scheme, the largest government funded healthcare program in the world announced in Union Budget 2018-19. It is expected to benefit 100 million poor families in the country by providing a cover of up to Rs 5 lakh (USD 7,723.2) per family per year for secondary and tertiary care hospitalization.
- In March 2018, the Drug Controller General of India (DCGI) had announced its plans to start a single-window facility to provide consents, approvals and other information in a bid to boost the Make in India initiative.
- Last year, plans were announced to set up an electronic platform to regulate online pharmacies under a new policy in order to stop any misuse due to easy availability. This year, the new government is planning to roll out the e-pharmacy project in its first 100 days, having released the draft rules for it last year.
- The Government of India had unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. It also reduced the approval time for new facilities with the aim to boost investments. Under this vision, the government aims to provide support to Indian pharmaceutical sector through state of-the-art infrastructure, internationally competitive scientific research personnel for pharmaceutical R&D, and funding for research in the public and private sectors.
- Two important mechanisms introduced by the government to deal with the issue of affordability and availability of medicines are the Drug Price Control Order and the National Pharmaceutical Pricing Authority.

Innovation & Government Support

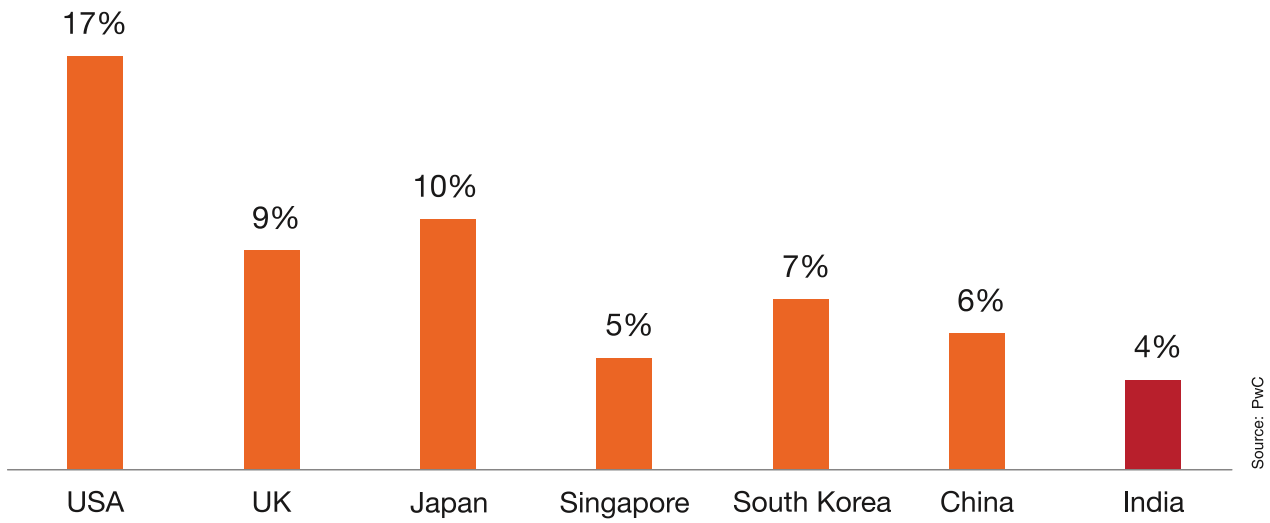
The IPA sees government as a key enabler to achieve its pharmaceutical industry vision and says that it can do so through strategic interventions like increasing expenditure on healthcare from about 1 per cent to 2.5 per cent by 2025 and to 5 per cent of GDP by 2030. This would be in line with the healthcare outlay of developed economies in Europe and North America.

The other ways that the government can promote the pharmaceutical sector include a stable pricing policy and supportive regulatory environment; focus on API (active pharmaceutical ingredient) manufacturing so as to reduce the reliance on imports through plug-and-play infrastructural support in dedicated zones; and efforts to promote innovation by creating a research ecosystem supported through competitive tax breaks on R&D investments, technology transfers and through targeted regulatory simplifications.

India already has a large pool of scientists and engineers who can steer the industry ahead to an even higher level. Notably, over 80 per cent of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms.

'Vision 2025 – Unlocking India's potential for leadership in pharmaceutical innovation', a report by PwC had pointed out that though India can build on its strengths in generics and move up the value chain by enabling innovations and new drug discovery; the Indian pharmaceutical industry lacks a strong record in innovation. India does not fare well when compared to pharmaceutical innovation leaders such as the US, UK, and Japan and countries that have recently moved up the innovation ladder like South Korea, China, and Singapore. The report points to many gaps in the Indian ecosystem, with India investing just 0.9% of its GDP (Gross Domestic Product) towards overall research and development compared to an investment of 1.6% in the UK, 1.9% in China, 2.8% in the US, and 3.3% and 4% in

India must increase its expenditure on healthcare



Japan and South Korea respectively. India's spend on pharmaceutical R&D at 0.08% of the GDP is just 1/8th of the amount the US spends (0.62% of GDP) and 1/4th the spend of the UK (0.3% of GDP).

The report suggested creating an innovative ecosystem to promote growth and development in the pharmaceutical research sector on the basis of four key pillars – infrastructure, financing, human resources, and a legal, IPR (Intellectual property rights) and regulatory framework. The report added that India can unlock the innovation potential by working on these four pillars, strengthening the ecosystem and addressing the roadblocks. Vision 2025 is an attempt to provide the country a roadmap to strengthen its innovation ecosystem and thereby emerge as a global leader in the world pharmaceutical space.

Hopes for the Rs 1,20,000 crore plus pharmaceutical sector to achieve its potential hinge on the steps the government would take in its second term. The first term of the government saw some heartening development with a series of measures being taken by the government that looked positive and beneficial to the end consumer. For example, the government pushed the case for lower prices of medicines (including anti-cancer drugs) and medical devices and laid greater emphasis on the sale of generic drugs.

However, the industry has been critical of these moves which it calls unilateral decisions at best. They feel that bringing new drugs under Drug Price Control Order (DPCO) and National List of Essential Medicines (NLEM), imposing price ceiling on drugs and the focus to make medicines affordable are likely to restrict the growth in prices of drugs and consequently constrain the rise in value of Indian pharmaceutical industry in this fiscal.

The industry calls the first term of the Modi government quite harsh on the sector. The tough measures taken by the government include ban on the sale of certain fixed-dose combination drugs, price ceilings on knee-cap and stents, invoking of extraordinary powers "in public interest", under Para 19 of the DPCO, not putting up a defense of Indian generics, to bring in certain anti-cancer drugs under price control, and little or no investments to strengthen the drug regulatory institution. The industry fears that the lack of strict regulations could very well mean that a top brand player is actually competing against the manufacturer of spurious drugs. Some measures that they feel could end up hurting the industry include:

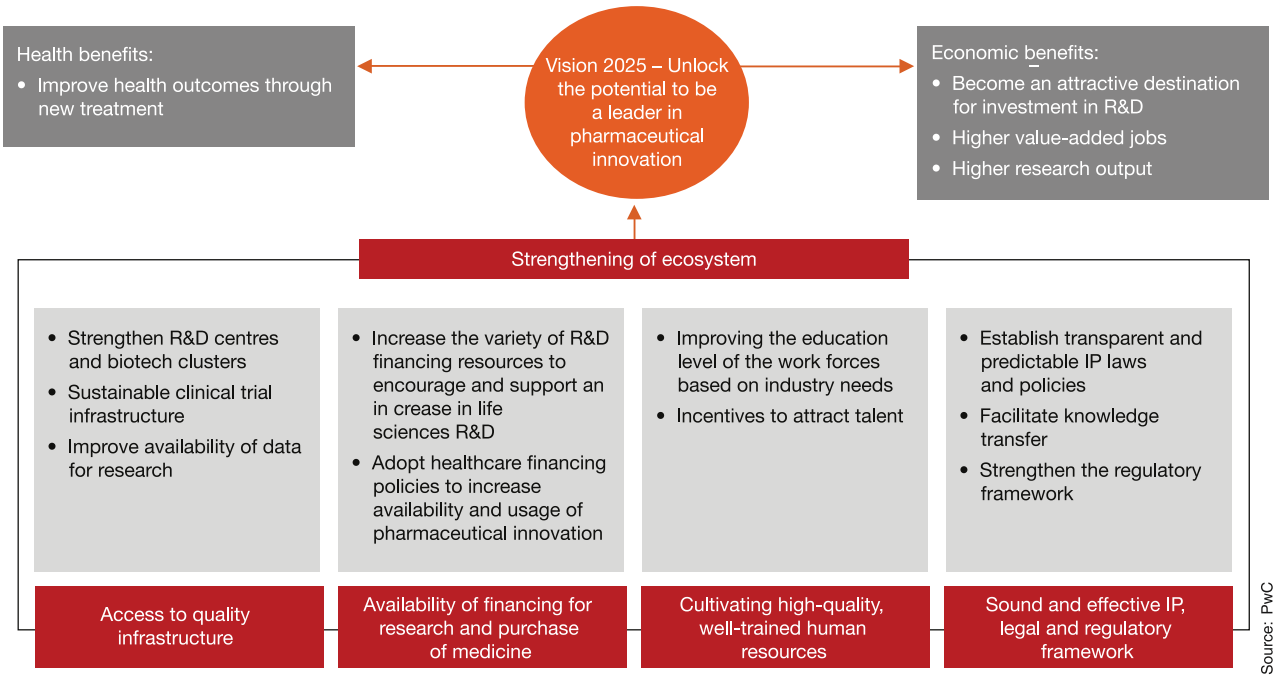
Despite the apparent discontent, the government is expected to roll out some other measures in its second term. These include:

- Price control regime becoming more broad-based.
- More FDCs can be banned. With over 1000 drug combinations available in the market, the industry expects the list of 344 could get expanded as recommended by the Kokate Committee.
- Generic drug sales to get a firm push from the Jan Aushadi route.
- More medical devices under the ambit of price control.
- Uniform Code of Pharmaceuticals Marketing Practices (UCPMP) guidelines may become a reality bringing in greater scrutiny of companies and their engagement with doctors.
- A pharmaceutical ministry that has been for long a key demand of the industry.

Road Ahead

The future of the Indian pharmaceutical industry would depend much on how the government manages to strengthen the regulatory ecosystem. While it is true that the domestic pharmaceuticals market would get a boost

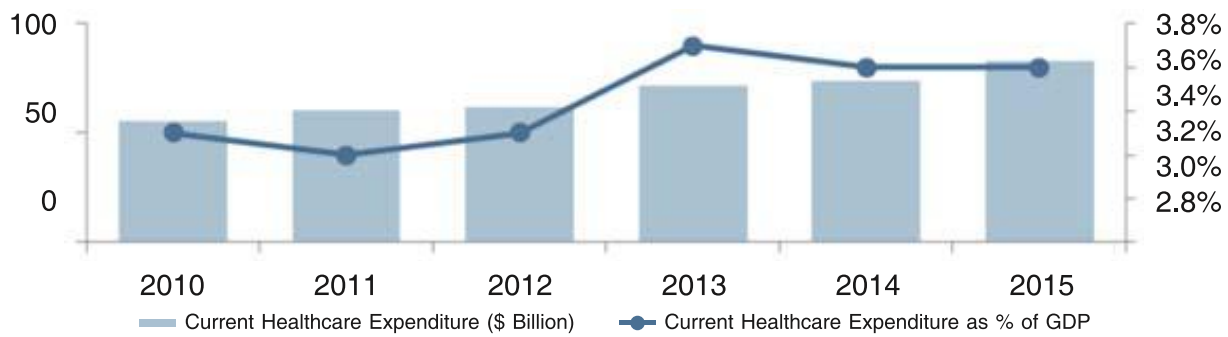
How India can unlock its potential



Source: PwC

India needs to steadily increase its expenditure on healthcare

India's Current Healthcare Expenditure and Healthcare Expenditure as a % of GDP (2000-2015)



Source: World Health Organization Global Health Expenditure database, October 2017

with government stepping up investments and schemes like Ayushman Bharat; the global growth would depend on how it manages to put in place a regulatory infrastructure to ensure quality and safety of drugs. As of now of the 12,000 manufacturing units in India, only 25 percent comply with WHO's good manufacturing practices (GMP) or good laboratory practices. There are few nationally accredited laboratories in India. There are 62,000 pharmaceutical products but only 47 drug testing facilities listed under the National GLP program of which, six Central laboratories sample around 8,000 drugs per annum, leaving a vast demand unmet. The low output, low-quality pharmaceuticals have given rise to another problem – drug-resistant diseases – an unintended consequence of the laxity.

Further, the good intentioned Jan Aushadhi centres have become an eyesore without supply and quality assurances, and without a substantial hike in the health budget, leading to frequent drug recalls from these centers. The government's policy of systemically sidelining branded drugs from entering the domestic space and the constant pushing of cheaper alternatives, has only added to the confusion all around.

Source: Secondary research & media reports

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IMAGE: PIXABAY

A CAN OF TROUBLES

The book Bottle of Lies exposed the dubious practices adopted by Indian generics makers and trained the spotlight on all that is wrong with the industry.

BY THE TIME (July) *Bottle of Lies: Ranbaxy and the Dark Side of Indian Pharma* by investigative journalist Katherine Eban made its appearance in India, it had already opened a can of troubles for the Indian pharmaceuticals industry with its US launch in May. An incriminating account of how the country's pharmaceutical industry works, it effectively blew the lid off a racket that was going on right under the noses of the regulatory authorities, allegedly in complicity with them.

The book chiefly is an expose of the culture of forging and fudging data and even destroying it to escape regulatory scrutiny. Eban's work is based on her decade long research into the industry's practices. The companies mentioned in the book including Ranbaxy were releasing substandard medicines in countries where the regulations were lax including in India. If Eban's account is to be believed, these companies not just did so with impunity but had no moral qualms doing it – for Ranbaxy it was just "blacks dying" in Africa with their substandard AIDS drugs. Lives of people in poor countries had no value. Therefore, generic substandard quality drugs were being routinely sold in these markets.

The sordid saga would have ended in 2013 itself when Ranbaxy pleaded guilty to seven charges of selling adulterated drugs in America and paid $500 million in fines. But it only brought to fore a nagging question – if Ranbaxy was doing it to America, how deep was the rot in India with lax rules?

If what Dinesh Thakur, the Ranbaxy whistleblower is believed to have told Eban is correct, Ranbaxy was just the tip of the iceberg: "Testing the drugs for India was just a waste of time … because no regulators ever looked at the data … (companies) just invented the dossiers on their own and sent them to the Drug Controller General of India (DCGI). What was needed for the DCGI was not real data but good connections."

Eban's book provides a hair-raising account of fungible documents, frauds, insanitary manufacturing conditions, fake laboratories and much else. A dangerous scenario.

Let us understand what exactly generic drugs are and why they are cheaper. Also, is cheap actually best in the case of generics? Opinion is divided on the efficacy of generics.

Generic vs Branded Drugs

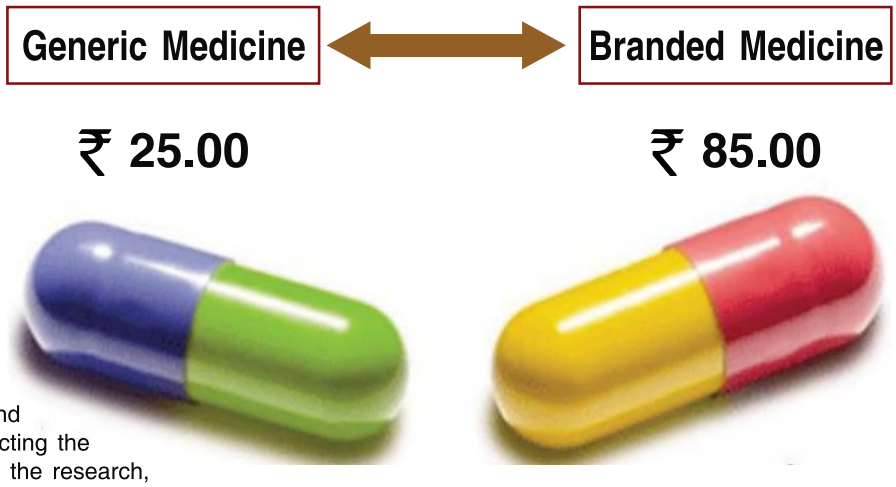
Simply put generics are copies of branded drugs and are formulated once patent and other exclusivity rights of brand-name drugs expire. These drugs are in the same dosage as the original, are intended for the same use, have the same effects and side effects, are administered in the same way, and have the same risks. In short, generic drugs have the same pharmacological effects as the branded drugs of which they are copies. According to a paper titled 'Pharma Regulations for Generic Drug Products in India and US: Case Studies and Future Prospectives', a generic drug must:

Generic drug, though a copy of brand drug, cannot look exactly like the brand-name drug

IMAGE: PIXABAY

- Contain the same active ingredients as the innovator drug
- Be identical in strength, dosage form, and route of administration
- Have the same use indications
- Be bioequivalent (as a marker for therapeutic interchangeability)
- Meet the same batch requirements for identity, strength, purity and quality
- Be manufactured under the same strict standards of GMP required for innovator products

Prescription Drug Cost Comparison



A generic drug cannot look exactly like the brand-name drug under the U.S. trademark laws. Patent protection of brand name is valid for around 17 years, protecting the pharmaceutical company that invested in the research, development, and marketing of the new drug. No other company can make and sell the drug. Once the patent expires, other pharmaceutical companies, approved by the FDA, can make and sell generic version of the drug.

As per estimates, about half of all generic drugs are being made by brand name companies. Most make copies of their own drugs or other company's branded drugs and sell them without as generics. Once a generic medication is approved, any number of companies can produce and sell it. This competition helps bring down prices of generic drugs. Generic medications are often priced 30% to 50% lower than brand name medications.

In India, though the quality of drugs imported, manufactured and sold in the country is regulated under the provisions of Drugs and Cosmetics Acts, 1940, and Drugs and Cosmetics Rules 1945, according to media reports, there is no definition of generic drugs in the Act or the Rules. All drugs, whether branded, generic or branded-generic, imported or manufactured for sale and distribution in the country must comply with the same standards as specified in the Second Schedule to the Drugs and Cosmetics Act, 1940.

"Public Health & Hospitals" is a state subject and hence the primary responsibility of ensuring adequate supply of free and quality drugs is that of the state governments. In keeping with these aims, under the National Health Mission, the central government supplements the state government in their efforts to strengthen the healthcare system including the provision of essential medicines (mostly generic) at the state healthcare facilities free of cost.

Apart from this, the Centre also provides financial and technical support to the states and UTs for strengthening and/or setting up of robust systems of procurement, quality assurance mechanism, warehousing, prescription audit, grievance redressal, dissemination of Standard Treatment Guidelines and IT backed supply chain management systems like Drugs and Vaccines Distribution Management Systems.

The US Food and Drug Administration also mandates that there should be no difference between generic and branded drugs, and they should be as effective and safe as branded ones. In order to ensure this, generic drugstore put through a rigorous review process that includes a review of scientific information about the generic drug's ingredients and performance. A generic drug manufacturing plant must also fulfill the same criteria of standards as a manufacturing plant of branded medicines. To ensure compliance with this rule, the FDA conducts approximately 3,500 on-site inspections each year.

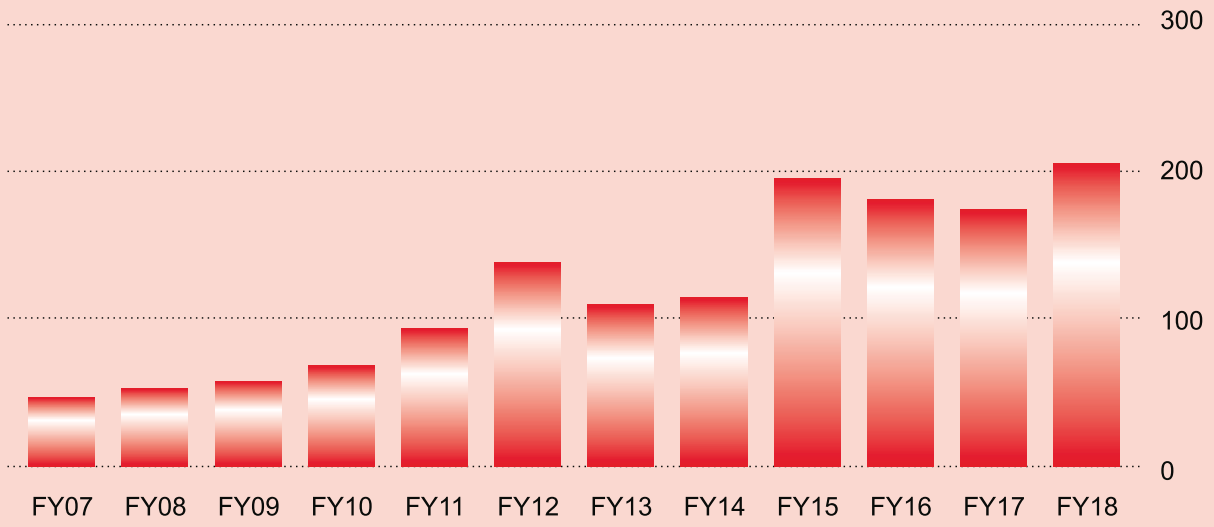
According to the U.S. Food & Drug Administration's official website, FDA opened the India Office in New Delhi in 2008, to ensure that food and medical products exported from India to the U.S. are safe, are of good quality, and are effective.

In 2014, US and Indian drug regulators had agreed to conduct joint audits and inspections of pharmaceutical manufacturing facilities in India. According to reports, the agreement was to understand global benchmarks and help Indian drug regulators meet international standards.

Once a generic medication is approved, any number of companies can produce and sell it. This competition helps bring down prices of generic drugs. Generic medications are often priced 30% to 50% lower than brand name medications.

India Inspections

FDA drug-quality checks increased 18 percent in fiscal 2018 to a new peak



*Fiscal years for the federal government run Oct. 1 to Sept. 30
Source: FDA data via public records request

Bloomberg

Loopholes in the law?

Notably, laws in India specify that all medical prescriptions should give generic medicines and all pharmacies must make them available to patients. According to reports, the Drugs Technical Advisory Board recommends that retailers maintain a separate rack/shelf solely for the storage of "generic medicines sold in proper name" in a part of the premises separated from other medicines. They shall display the following words in a conspicuous manner at a prominent place in their licensed premises "generic medicines in proper name are also available".

The Board also recommended including a definition for generic medicine under Drugs and Cosmetic Rules, 1945, since it is currently not defined.

Despite the central government aggressively marketing generic drugs by opening pharmacies and asking pharmacies to display availability of these medicines; in reality there is a rare chemist store that displays generics on its shelf. Manufacturers and marketers adopt aggressive marketing to ensure that it is branded drugs or branded-generics that are pushed through the neighborhood chemists. Weak enforcement of laws and the ignorance of consumers allows them to get away with this.

Government estimates say about 85% of total health expenditure in India is financed by household out-of-pocket expenditure and medicines constitute 20% to 60% of total healthcare expenditure. Understandably, there is considerable financial strain on the masses.

Conclusion

In their defense, these pharmaceutical players allege a conspiracy theory to defame India and that the Ranbaxy episode happened a decade or more back and since then thing have changed.

The world's largest exporter of generic drugs, India makes almost 40 percent of all new generics the FDA approved in 2018 through October. There have been enough red flags for the FDA to crack down on Indian factories around the country. According to media reports, drug inspections have revealed open toilet drains at a sterile facility owned by Mumbai-based Wockhardt Ltd to malfunctioning equipment at one of Dr. Reddy's Laboratories' plants in south India.

Across the globe, the major reason behind fudged data is bad laboratory practices adopted by companies as revealed in the course of investigations and inspections. However, in India apart from this, they have also uncovered high-profile cases of "overt and deliberate fraud". This has brought the global spotlight on the manufacturing culture.

The result of these discoveries has led the FDA to increase inspections in India by 18 percent last year after two years of declines. While for America, India may pose the FDA's biggest challenge in its efforts to ensure cheap and safe drugs; for Indian masses, given their ignorance and lax law enforcement, the challenges are deeper.

Source: Secondary research & media reports

Abyss Or Bridge?

The idea to create a cadre of quacks by allowing those "connected with modern scientific medical profession" to practice allopathy instead of being a bridge to healthcare shortage can proof to be a pitfall.

Shri Narendra Modi
Prime Minister of India is one of the star proponents of Yoga and India's traditional medicine system AYUSH.

IMAGE: PIXABAY

INDIA'S INDIGENOUS MEDICAL systems – Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy (AYUSH) – come under the Ministry of AYUSH. The ministry was formed in November 2014. Established as the Department of Indian System of Medicine and Homeopathy (ISM&H) in March 1995, it was renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003. The ministry's mandate is to ensure optimal development and propagation of AYUSH systems of health care.

Such is the renown of AYUSH system, that recently British MP David Tredinnick, Conservative MP from Bosworth in Leicestershire, asked Prime Minister Boris Johnson on his first day in the House of Commons about linking up with India's AYUSH. He asked Johnson if he would ensure that his new health secretary Matt Hancock interacts with the AYUSH ministry in New Delhi and possibly use its insights to solve Britain's health issues.

The popularity of alternative health sciences got a clinching backing when the UN General Assembly adopted an India-led resolution in 2014 declaring June 21 as 'International Day ofYoga'. Since then, Yoga Day is being practiced all over the world in large numbers. The purpose of recognizing Yoga is to promote its holistic approach to health and well-being. Prime Minister Narendra Modi is one of the star proponents of Yoga, and promotes AYUSH unabashedly. This year too at the the G20, he made a pitch for the practice of Yoga alongside other AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) treatments.

Wisdom vs Science

While promoting AYUSH as a safe alternative healthcare system has its merits, the recent move of the government to introduce a bridge course via the new National Medical Commission (NMC) Bill, 2019, backfired as it led to widespread protest from the medical fraternity. The bridge course would have allowed practitioners of alternative medicines such as homoeopathy and Ayurveda to practice allopathy. According to reports, the government has now replaced the contentious bridge course with "limited license to practice modern medicine" clause.

Prime Minister Shri Narendra Modi at the the G20, made a pitch for the practice of Yoga alongside other AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy) treatments.

PHOTO: PIXABAY

Allowing traditional medicine practitioners to practice allopathy would be a disservice to consumers.

However, this too has raised the hackles of the medical practitioners as they feel this would end up creating a cadre of 3.5 lakh registered, legal quacks in India. Section 32 of the NMC Bill 2019 that deals with the role of the community health provider states, ""The commission may grant limited license to practice medicine at mid-level as a community health provider to such person connected with modern scientific medical profession who qualify such criteria as specified by the regulations: provided that the limited license to be granted under this sub-section shall not exceed more than one-third of the total number of licensed medical practitioners registered under sub-section (1) of section 31."

The new clause has led to more questions as experts feel that community health providers like compounders, lab technicians, blood sample collectors, anyone even remotely connected with modern medicine, could get a licensed to practice medicine without the supervision of a qualified doctor.

Implications for Consumers

There has been a concerted effort to push AYUSH as alternative treatment in place of allopathy. In a country like India, where citizens in vast rural and semi urban stretches still repose blind faith in quacks, witchcraft and unproven methods of alternative treatment, where cow urine is promoted as an antidote to cancer, and all kinds of alternative therapies are sold for cure of sexually transmitted diseases even in urban cities, there is an urgent need to proceed with caution while pushing AYUSH. If consumers turn to these treatments ignoring proven allopathic treatment, it could have serious repercussion.

In May this year, an advisory note was issued by the AYUSH ministry which read that alternative and traditional medicine included under the AYUSH banner as an “integral part of the country's healthcare delivery work…not at all comparable to the modern medicine system.” AYUSH research has generally not provided conclusive evidence and the ministry's attempt to dissociate scientific research from AYUSH can only lead to its detriment.

Conclusion

For AYUSH to evolve from being India's relics of the past to an alternative scientific branch, it must be brought under the same standards and criteria that are applied to modern medicine. There is an urgent need to promote through research those alternative therapies that have been found to be effective from among the thousands that exist as a vague treatment currently.

By setting the bar low for AYUSH and going on the defensive, the government is doing more harm to its cause.

If the government's idea is to create a cadre of alternative healthcare practitioners to help bridge this shortfall, it is certainly a shortsighted one. Indian consumers certainly deserve qualified doctors, not quacks.

Source: Secondary research & media reports

PHOTO: PIXABAY

AYUSH system relies on India's indigenous ancient wisdom.

eHEALTH

Ushering A New Era In Citizen Healthcare

eHealth could be the answer to India's healthcare challenges.

IMAGE: FREEIMAGES.COM

Technology could revolutionize India's healthcare system and the government is keen to enlist its help.

TECHNOLOGY COULD PROVIDE better access to products, information and knowledge for the consumers. Once plugged in, the consumers could find a variety of useful information on health and update themselves. Technology could also open up avenues of health services hitherto unavailable. They could benefit from e-pharmacies, diagnostics and insurance, all at their doorstep. Digital footprint would mean easier tracking and records and help clean the system of frauds, spurious medicines and middlemen. But more than that through an online model across the country, the government could ensure citizens can procure health services and that everything is tracked, recorded, organized and operated in a professional manner. Citizens could get direct access to doctors and experts and telemedicine could open up the path for even a villager in a remote corner to access a top specialist sitting somewhere far. An online model also ensures that the patient has an overview of the whole process. This transparency ensures that consumers are not shortchanged.

Looking at these benefits and many others that an online model of healthcare would bring to India, in 2015, the government had proposed the setting up of the National eHealth Authority (NeHA). It was to function as a promotional, regulatory and standards-setting organization in Health Sector. The vision of this authority was the “attainment of high quality of health services for all Indians through the cost-effective and secure use of information and communication technologies in health and health-related fields”. The goal of the body was “to ensure development and promotion of eHealth ecosystem in India for enabling, the organization, management and provision of effective people centered health services to all in an efficient, cost-effective and transparent manner.

The objectives of the NeHA are:

- To formulate “National eHealth Policy and Strategy” for coordinated eHealth adoption in the country
- To oversee orderly evolution of eHealth initiatives (state and nationwide) and to guide adoption of eHealth at various levels and in different geographical and health system areas
- To promote setting up of state health records repositories and health information exchanges (HIEs) to facilitate interoperability
- To formulate and manage all health informatics standards for India
- To lay down data management, privacy and security policies, guidelines and health records of patients in accordance with statutory provisions
- To enforce the laws and regulations relating to the privacy, confidentiality, and security of the patient's health information and records
- To coordinate efforts across departments and ministries, and liaise with other related policy/regulatory groups to ensure consistency and coherence
- To help enable ecosystem that involves stakeholders to improve care delivery and health outcomes
- To map continuous evolution of the eHealth landscape and take on new functions as needed

The functions of the NeHA include:

1. Policy and Promotion

- To work out vision, strategy and adoption time plans, with timeframes, priorities, and road-map in respect of eHealth adoption by all stakeholders, both public and private providers, large scale hospitals and stand-alone clinics
- To formulate policies for eHealth adoption that are best suited to Indian context and enable accelerated health outcomes in terms of access, affordability, quality and reduction in disease mortality and morbidity
- To engage with stakeholders through various means so that eHealth plans ae adopted and other policy, regulatory and legal provisions are implemented by both the public and private stakeholders
- To provide thought leadership, in the areas of eHealth
- To effectively promote adoption of eHealth in the country, NeHA would have the mandate to set up an agency to provide oversight, handholding, capacity building, etc.

2. Stndards Development, Release, and Maintenance

- NeHA will oversee and actively work with all relevant stakeholders including SDOs for formulation and adoption of health informatics standards
- NeHA will act as a focal agency for participation or engagement with global SDOs in eHealth such as IHTSDO. It will undertake all activities leading to adoption and release of suitable standards and Indian profiles

3. Legal Aspects Including Regulation

- NeHA will act as an enforcement agency with suitable mandate and powers
- NeHA will be responsible for enforcement of standards and ensuring security, confidentiality, and privacy of patient's health information and records

IMAGE: PIXABAY

A centralized repository of patient information would make healthcare quick, accurate and timely.

4. Setting up Electronic Health Exchanges for Interoperability

NeHA will prepare technical and policy documents relating to architecture, standards, policies, and guidelines for eHealth record repositories and HIEs

- NeHA may also initiate Proof of Concept (PoCs), in close consultation with government – centre and states, industry, implementers and users
- NeHA would lay down operational guidelines and protocols, policies for sharing and exchange of data, audit guidelines and the like; these shall be guided by experience in operation and use of PoC, global best practices and consultations with stakeholders (MoHFW, State governments and other public and private providers, academia, R&D labs, and others)

5. Capacity Building

- NeHA would co-work with academic institutions to spread awareness on Health Informatics and eHealth to health care delivery professionals. NeHA would provide inputs, in terms of areas of need / requirement of different courses according to the background of the learners, to academic institutions

6. Certification Framework

- NeHA will collaborate and work with STQC, Department of Electronics and IT (DeitY) in creating a certification model for certification of HER products, STQC is envisaged to function as the certification body

7. Other Functions

- Incidental to the discharge of its functions or as assigned to NeHA by the government or parliament or as the situation warrants

Thus, the NeHA established to regulate the increasing usage of electronic records in healthcare, and for the maintenance of digital health information and e-Health records across the country. The goal, in short, is to promote development of eHealth ecosystem in India that would work to organize, manage, and provide effective people-centered cost-effective health services to Indian citizens in a transparent manner.

Electronic Health Record

Towards this end, electronic health records (EHRs) would enable uniform and smarter access to healthcare. The aim of EHR is to provide a uniform system for maintenance of Electronic Medical Records/Electronic Health Records

(EMR/EHR) by hospitals and healthcare providers in the country. Towards this purpose, the government set up an expert committee to develop EMR/EHR Standards for adoption/implementation in the country.

To provide interoperability of various EHR systems already implemented, an Integrated Health Information Platform (IHIP) is being setup by the Ministry of Health and Family Welfare (MoHFW).

The objective of IHIP is as follows:

To enable the creation of standards compliant Electronic Health Records (EHRs) of the citizens on a pan-India basis along with the integration and interoperability of the EHRs through a comprehensive Health Information Exchange (HIE) as part of this centralized accessible platform. IHIP is envisaged to enable better continuity of care, secure and confidential health data/records management, better diagnosis of diseases, reduction in patient re-visits and even prevention of medical errors, better affordability, optimal information exchange to support better health outcome, better decision support system, and thus eventually facilitating improvement in the reforms of treatment and care of public health at National-Level.

The government envisages the following benefits from IHIP:

- Provides a vehicle for improving quality and safety of patient care by reducing medication and medical errors
- Stimulates consumer education and patients' involvement in their own health care
- Increases efficiency by eliminating unnecessary paperwork
- Provides caregivers with clinical decision support tools for more effective care and treatment
- Eliminates redundant or unnecessary testing
- Improves public health reporting and monitoring
- Creates a potential loop for feedback between health-related research and actual practice
- Facilitates efficient deployment of emerging technology and health care services
- Provides the backbone of technical infrastructure for leverage by national and State level initiatives
- Provides a basic level of interoperability among electronic health records (EHRs) maintained by individual physicians and organizations
- Reduces health related cost

How will EHRs Help

EHR works with a cloud platform to store and make information available. This ensures higher quality and safer services. With accurate and complete, up to date and timely information about patients, the EHR can revolutionize the healthcare system in the country. Relevant information can be shared securely when required with with medical professionals and patients. Since all the past information is recorded, this tool can help with accurate diagnosis.

As a centralized repository of patient information, EHR promote legible and streamlined documentation, decreased paperwork and reduced duplication of testing. This would mean decreased healthcare cost.

If computerized systems are installed in ambulances, patient information can be continuously monitored and recorded on EHR.

As more than 75 and 65 per cent of outpatients and inpatients respectively are admitted to private facilities in India, EHRs will help improve diagnosis through the central repository of data of all hospitals and healthcare facilities in the country.

Conclusion

eHealth and EHR are the need of the hour in a country like India if it hopes to improve healthcare facilities to its citizens. From being a repository of citizens' health records, enabling accurate diagnosis, and facilitating easier and quicker access to blood bank, etc., the EHR can also track and record data like location, contacts, pictures, fingerprints, etc., that would help in locating accident victims, organ donors, blood donors etc., accurately. Habits can be tracked and used to improve communication between service provider and user.

As we can see, EHR has uses beyond registration and billing for patients at hospitals and can be utilized in various ways to ensure health for all in the country.

Source: Secondary research & media reports

eHealth: More than just an electronic record

"Good Intentions Are Not Enough When You Go Up Against Entrenched Interests Backed Up Endemic Corruption"

Dinesh S Thakur

Public Health Activist

better known in India as the Ranbaxy whistleblower, in a candid interview to The Aware Consumer, lets his views known on the state of Indian pharmaceutical sector.

About Dinesh S. Thakur: Dinesh S. Thakur is a public health activist focused on improving the quality of affordable medicines across the globe. He current focus is to improve health policy in the United States and in India. He is an expert and accomplished entrepreneur in pharmaceuticals, biomedical product development, drug regulation, and information technology. He was recognized with the Joe A. Callaway award for Civic Courage in 2014 and is the recipient of the ACFE's Cliff Robertson Sentinel Award. He was named Whistleblower of the Year by Taxpayers against Fraud in 2013. While at Ranbaxy, Mr. Thakur discovered that the company was falsifying drug data and violating current good manufacturing practices and good laboratory practices. He resigned in 2005 after reporting the fraud to company management and worked with authorities for eight years to unravel the complicated trail of falsified records and dangerous manufacturing practices. In May 2013, Ranbaxy pleaded guilty to multiple criminal felonies and agreed to pay $500 million to resolve criminal and civil allegations of falsified drug data and systemic manufacturing violations resulting in substandard and unapproved drugs.

Q The book Bottle of Lies: Ranbaxy and the dark side of Indian Pharma by author, Katherine Eban, seems to have opened a can of troubles for Indian Pharma companies. But while India is being singled out, there are other countries that have escaped the scrutiny, including US. For a global problem like this, what recourse do you suggest?

I don't think India is being singled out. The author tells a story and the fact that a vast majority of generic drugs consumed by patients in the US are manufactured in India gives this discussion a context. If for example, half of the US drug supply came from a different country, not India, then that country would have been the backdrop for this narrative. Fortunately, or not, I decided to go back and work for a Generic manufacturer in India based on my misguided belief that I would make a meaningful contribution to the country where I was born. I was mistaken. Good intentions are not enough when you go up against entrenched interests backed up endemic corruption. Lastly, if you have read the book, there is a full chapter on what happened at Mylan. This is a generic manufacturer based in West Virginia, US. I am not sure I agree with the premise of your question that India is being singled out unfairly.

Q Since Ranbaxy, several pharmaceutical companies have been implicated in similar or worse crimes. Don't you think the hyped expose has made the world take a myopic view of India made generic drugs?

So your question is conflicting. On one hand you say that there are other pharma companies which have been "implicated" of behavior similar to what I documented at Ranbaxy. And then you ask about "myopic view" of the world. If you acknowledge that there is behavior similar to what we found at Ranbaxy at other firms who make medicines for us today, how does that make the view myopic? The more wide-spread this behavior is, the more systemic the issue is. Do you agree? Now, to your point about "hyped expose", that is a matter of opinion and not fact. I am ill equipped to comment on your opinion, I can only comment on facts.

Q Why does it seem that while America is turning a blind eye to regulatory failures at home, it is running a vilification campaign against India and others?

This is a loaded question. You make a presumption about what the US is doing, namely vilifying India. I disagree. I have seen more prosecution of wrongdoing in the US in one year than I have seen for decades in India. In fact, if you spend a little time on Google, you will see that for the former US FDA commissioner spoke in favor of Generic Drugs (and they are all made in India). The US is protecting its public health. Whether we like it or not, a vast majority of our drug supply actually originates in India. You may well characterize what the US is doing as "vilification", I do not see it that way. Let's took at the facts. The 2018 Office of Compliance Report shows more than one third of the warning letters issued were for data integrity violations. Just let that fact sink in and then reflect the presumption you make in asking this question.

Q Quality failures are not just an Indian phenomenon. Third world countries have for long been the dumping yard for all kinds of substandard goods. What is your prescription for this?

It is true that third-world countries have been at the receiving end of poor quality medicines for a long time. But let's ask ourselves, why does that happen? There are three factors in my experience. First, the regulator in the country of origin is complicit with this. It allows or turns a blind eye toward this behavior of manufacturers it is supposed to police. Second, the regulators in these third-world countries are not often equipped or funded adequately to ensure the quality of their drug supply. Third, major donors and non-governmental organizations prioritize access over quality in their effort to help alleviate public health crises. To your question, let us start by making sure our regulator CDSCO stops colluding with the exporters and assisting them in shipping NSQ drugs to these third world countries.

Q What about the J&J faulty hip transplant case? A high-profile branded company that treated Indian consumers shabbly?

I have written and spoken extensively about this case. Any company that is implicated in this kind of behaviour should be prosecuted. Unfortunately, we don't the legal framework to hold JnJ to account in India. I tried to organize patients who were affected by this atrocity and help them pursue legal action. Unfortunately, for a number of reasons, I was unsuccessful. We need laws to hold wrongdoers accountable, immaterial of whether the company is Indian or a MNC. And we need the legal justice system to function and hold these wrongdoers accountable.

Q The manufacture and distribution of medicines is a complex, globalised affair and it is often hard to track where fake or substandard medicines come from and where they go. Also, a medicine may be manufactured

in one country, but the ingredients may have been sourced from multiple countries. Would labelling medicine's like say "made in India", help then? Is it even possible?

I am assuming you are asking this question in the context of the US drug supply. There is no law on our books today that requires the market authorization holder (the company that received approval to sell their product from the US FDA) to disclose where the product was made. We know where our food comes from, where our clothes are made and where all the gadgets we rely on are assembled. In the interest of transparency and empowerment of the consumer to make an informed decision, we need similar disclosure of the name and location of the manufacturing facility on the product insert that comes with our prescription drugs. This is an area I am working toward.

Q The Indian Pharma sector hasn't been in the pink of health these last few years and the latest expose and the campaign in the US could very well mean the end of cheap generic drugs from India. For poor consumers around the world it could be big blow. Your comments.

The US healthcare system relies heavily on generic drugs made in India. The US has lost majority of its manufacturing capacity to overseas facilities over the last decade. I do not see this situation change in the near future. What we need in the US is better enforcement of our quality standards immaterial of where the product is manufactured. Most generic drugs have co-pays between $5 and $15 for a 30-day supply and I don't see that changing either.

Q There are branded generics and non-branded ones, state owned pharma-made and private sector made and there are huge price differences even within the category. How is the consumer supposed to distinguish the good from the evil? Please advise.

I am assuming this question is being asked in the context of Indian market. It is immaterial whether a product is made by state-owned or a private sector company made. It has to meet one standard of quality. And the enforcement of this standard is up to the regulatory body. The consumer (patient) is ill-equipped to discern the difference in quality of drugs, especially at a time when she is the most vulnerable (sick). To your question, overhaul the Drugs and Cosmetics Act. Make it consistent with the current science. Introduce accountability provisions for intentionally manufacturing and selling NSQ drugs in the country. And prosecute those who are found guilty of his practice to the fullest extent under law immaterial of their wealth, political connections or influence. Can we agree to start there?

Q FDA seems to have positioned itself as a 'global regulator'. Don't you think it is a case of overreaching it's brief, when the American CGMP practices are not global standard?

I disagree with the premise of your question. Please point me to ONE instance where the US FDA has as you say "positioned" itself as a "global regulator". The US

Congress has specifically given the US FDA mandate under FDASIA to enforce US quality and compliance standards for drugs made for the US market. Perhaps you can find ONE instance where the US FDA inspected and penalized a generic manufacturer for not complying with Code of Federal Regulations for Drug Manufacture for a product NOT made for the US market or paid for by the US taxpayer. What the US FDA does and it is based in law and is limited to its remit of protecting public health in the US. Your question is a talking point by the industry in India which is baseless.

Q Are we not forgetting that India has also produced companies like Cipla that jolted the global pharmaceutical industry with an offer to sell anti-AIDS drugs at a fraction of the price charged by multinational drug makers in Africa?

I am sorry, who is forgetting what? Why are you conflating issues of quality with issue of access and price? By no means have I ever said that EVERY Indian company commits fraud. Yes, there are those who produce a quality product at a cheaper price and that is good. How is that even remotely related to the issue of substandard quality drugs? This again is a talking point by the industry which cannot counter facts and therefore indulges in whataboutery, plain and simple.

Q What can we expect from you next?

You can expect that I will do whatever I can to help improve the quality of drug supply not only in the US, but also in India. I am litigating in the Delhi High Court as we speak on three specific issues which go to the core of how the regulatory system functions in India and puts public health, including those of young children who are sold an unproven, potentially harmful drug as an appetite supplement in India with the full knowledge, consent and blessing of the regulatory system. I continue to fund research into how dysfunctional the regulatory system in India is, and how the State Drug Regulatory Authorities have no accountability at all for allowing NSQ drugs to enter our supply chain. I continue to advocate for better accountability and prosecution of wrongdoers who put profit over public health in India.

Pyush Misra
Director,
Consumer Online Foundation

Govt. Clips Wings Of Drug Price Regulaltor

But will it serve consumer interest better?

Medicines are essential for the health of human beings. Hence drugs have been declared as essential and put under the Essential Commodities Act. However not all drugs are considered to be essential and the National List of Essential Medicines (NLEM) 2011 is the primary basis for determining the essentiality of a drug. It constitutes the list of scheduled medicines for the purpose of price control.

In 1995, the Government of India issued the Drugs Prices Control Order, 1995 under Sec. 3 of Essential Commodities Act, 1955 with the purpose of regulating the drug prices. The Order provides the list of price-controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by government, penalties for contravention of provisions, etc. For the purpose of implementing provisions of DPCO, powers of government were vested in NPPA. Later, the Drugs (Prices Control) Order (DPCO) 2013 was notified containing 680 scheduled drug formulations spread across 27 therapeutic groups. However, prices of other drugs can be regulated in public interest.

The NPPA controls and regulates the prices of pharmaceutical drugs in India. However, it has limited authority to fix, review and justify pharmaceutical prices under the Drug Prices Control Order (DPCO), 1995. In order to fix and revise the prices of controlled drugs, the NPPA monitors the prices of decontrolled drugs in order to keep them at a reasonable level.

How Drug Prices are Controlled

Thus, the prices of all essential medicines in India are controlled under DPCO by fixing ceiling prices, limiting

the highest prices companies can charge. The National List of Essential Medicines (NLEM) includes essential medicines that satisfy the priority health needs of the population. Factors like safety, efficacy, disease prevalence and the comparative cost-effectiveness of medicines are considered when drawing up this list. An expert panel appointed for the purpose updates the NLEM list periodically. This panel works under the aegis of the Ministry of Health and Family Welfare.

The NLEM 2015 contains 376 medicines on the basis of which the National Pharmaceutical Pricing Authority (NPPA) has fixed prices of over 800 formulations using the provisions of the DPCO. However, these formulations cover less than 10% of the total pharmaceutical market.

The current DPCO 2013 has three primary aims: expanding the National List of Essential Medicines (NLEM), authorizing the National Pharmaceutical Pricing Authority (NPPA) to regulate prices of India's NLEM, and authorizing the NPPA to regulate price increases of non-essential medicines.

For price capping, the DPCO uses a market-based pricing mechanism. The ceiling price is decided on the basis of the simple average price of all brands having at least 1% market share of the total market turnover of that drug. But, the market based pricing (MBP) mechanism is highly debatable and has come under severe criticism from various experts.

The DPCO 2013 too has received much flak for failing to increase the affordability of medicines. According to a media report, the data from the Department of Pharmaceuticals show that in majority of the cases, there has been 20% or less reduction on the medicine prices.

Changes: Good or Bad?

In 1997, the Government of India had constituted the National Pharmaceutical Pricing Authority (NPPA) as an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers. NPPA was to function as an independent regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices. However, in January 2019, the central government formed a committee housed in its think tank NITI Aayog to recommend medicines for price control. This effectively diluted the central role of the NPPA in setting drug prices.

Drug pricing is a sensitive issue

IMAGE: PIXABAY

With this order, the existing mechanism in which drugs declared essential would automatically come under price control also came to an end. As per the order, going forward the NITI Aayog committee will decide which drugs should be under price control.

Formed by an order of the Ministry of Chemicals and Fertilizers, the standing committee on affordable medicines and health products (SCAMHP) is to be led by member (health), NITI Aayog. It would include the chief economic adviser in the ministry of finance; secretary of the department of health research; NLEM vice chairman; joint secretary of the department of industrial policy and promotion (DIPP); director general of health services and a subject expert on biomedical devices/pharmaceuticals.

The order also makes it clear that the committee would be housed in the NITI Ayog and serviced by it. It also makes SCAMHP the recommending body to NPPA regarding prices of drugs and health products.

Earlier, the health ministry was preparing the list of drugs eligible for price regulation. The department of pharmaceuticals (DoP) then incorporated NLEM into Schedule 1 of the DPCO. Following this, NPPA fixed the prices of drugs in this schedule.

Medicines and devices listed under NLEM were to be sold at the price fixed by NPPA, while those on the non-scheduled list were allowed a maximum annual price hike of 10%. More than 750 formulations are currently on India's list of essential medicines. However, under the order, SCAMHP has been empowered to take up any matter in pricing. Experts argue that the order curtails the powers of the NPPA as an enforcement body.

While the government feels that the SCAMHP with members drawn from various field will bring a holistic view to the drugs pricing, experts disagree.

For instance, the NPPA exercises Para 19 powers in public interest, delegated to it in 2013 by the government. It uses these powers for setting the price cap of scheduled and non-scheduled drugs and had exercised it in 2017 to cap prices of cardiac drugs, stents and knee implants.

Now the new committee by encompassing these powers of the DPCO will weaken the NPPA as an enforcement authority.

Source: Secondary research and media reports

NEED FOR STRINGENT REGULATIONS

While the government is keen to straighten up the mess in the medical devices sector, industry and experts demand a separate law to regulate it.

PHOTO: PIXABAY

THE MEDICAL DEVICES industry in India is at the cusp of high growth. According to estimates by Nishith Desai Associates, legal and tax consultants, the medical device industry is presently valued at USD 5.2 billion and is growing at 15.8% CAGR.India is among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea. The sector ispoised to grow to USD 50 billion by 2025 as per industry estimates.

The medical devices market is largely import dominated with domestic manufacturers mostly engaged in producing low end products for local as well as international consumption. According to estimates, imported products comprise around 80% of total sales. Around 80% of the imports include high-end products used in critical care. Several international players have entered the market either starting a new business or acquiring existing domestics firms.

Despite the potential, the industry is not without its share of challenges.

Government Measures

The Government of India is keen on promoting the sector through various supportive measures. For instance, in 2017, it overhauled the regulatory framework for medical devices order to bring it at par with international. By introducing the concept of 'risk-based' regulation; made the regulatory licenses issue norms for import, manufacture or sale of medical devices perpetual in nature effectively cutting down the unnecessary and time-consuming paperwork and improved the ease of doing business in India; and to promote investment in the sector it allowed foreign direct investment in medical device manufacturing sector without any prior approval from the government. This now enables business to scale-up existing operations by infusing capital or engaging in time-sensitive strategic acquisitions.

Other steps taken by the government include strengthening the already robust intellectual property rights regime by tweaking of rules for grant of patent and trademark in the last two years. Various fiscal measures to promote research, development, manufacturing and import of medical devices have also been introduced. For example, to incentivize scientific research and development, it provides weighted deduction for the expense incurred on that front. Further, on certain medical devices, there is minimal or no import duty.

The challenges faced by the industry may soon be addressed in the five-year plan that the Health Ministry is charting out. It may be noted here that Prime Minister Narendra Modi had tasked all ministers to draw up such a plan for their respective ministries after taking oath of office for the second term. Media reported that the health ministry is planning stakeholder consultation on the implementation of expert advisory body's recommendations to ensure that the medical devices manufacturers are made accountable for the safety and quality of products. Notably, more than 90 per cent of the India's estimated billion medical devices industry is unregulated, according to AiMeD. This includes over 6,000 devices like pacemakers, MRI machines and even tubes that collect blood samples. According to reports, the ministry plans an inter-ministerial consultation to ensure implementation of the “detailed roadmap” for devices that was outlined by the Drugs Technical Advisory Board (DTAB), country's top drug advisory body, earlier this year.

It is felt that notifying all medical devices in a phased manner as recommended by DTAB would be a first significant step towards holistic regulation of the sector. DTAB's recommendation in April this year to notify all medical devices under India's Drugs and Cosmetics Act in a phased manner came after a media report highlighted lapses in regulation of India's medical devices industry and the impact it has had on patients. A glaring example of this is the case of Johnson & Johnson. The global company had used loopholes in US laws to obtain approval for and market hip implants in India. The faulty implants had to be later recalled globally in 2010.

IMAGE: PIXABAY

Prices of medical devices are monitored by the government.

Experts and industry bodies on their part have been demanding a separate law for medical devices sector as most feel that medical devices have different issues from medications and cannot be regulated under drugs laws. They feel that the old laws are inadequate to ensure safety and quality of medical devices. There are also demands to address patient safety under a separate medical devices law and to revamp CDSCO, which is the country's top drug regulatory body, to make provisions for inclusion of a separate division for medical devices.

Price control

In July 2018, the Ministry of Health and Family Welfare had issued the list of medical devices under public monitoring. The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, regulates the safety, efficacy and quality of 23 devices under the provisions of Drugs and Cosmetics Act, 1940 and Rules there under, out of which 15 medical devices are notified under Section 3(b)(iv) of the Drugs and Cosmetic Act.

Medical Devices Rules, 2017 was implemented with effect from January 2018. It detailed provisions for regulation of manufacture, import, sale and distribution of medical devices covered under the Act to ensure their quality. The DTAB also included all implantable medical devices, CT scan equipment, MRI equipment, Defibrillators, Dialysis Machine, PET equipment and X-Ray Machine under the purview of section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 with the objective of ensuring their quality.

Notably, the government has little control over prices

of medical devices. Of the 23 medical devices, listed as drugs, only four items — cardiac stents, drug eluting stents, condoms and intra uterine devices — are in the National List of Essential Medicines and fall under government's purview. Apart from these, only knee implants have been recently brought under price control.

The MRPs of remaining medical devices, being under non-scheduled category, are monitored to ensure that no manufacturer increases the maximum retail price by more than ten percent of the price during the preceding 12-month period.

However, this has not proved an effective measure. Now, as a step towards controlling high prices of commonly used medical devices, the government may soon identify a list of “essential medical devices”, according to reports. This could be the precursor to anti-profiteering measures such as capping trade margins in the range of 30-50%. This list may become the basis for policy action to prevent distributors, wholesalers, retailers and even hospitals from seeking exorbitant trade margins on products like stents, catheters and various implants.

Keeping in view the demands of the pharmaceutical sector, the government is not looking at capping MRP. Rather, it may bring in measures to check trade margins. According to media reports, a number of consultations have taken place involving Department of Pharmaceuticals (DoP), National Pharmaceutical Pricing Authority (NPPA), Niti Aayog and Prime Minister's Office (PMO). Commerce minister Piyush Goyal is also reported to have sought representations from the industry after concerns over price cap on medical devices were raised, particularly by American companies.

Experts opine that capping trade margins is not a solution to the problem of high costs. They suggest price fixation instead as they fear that the capping could legitimize the real possibility of high landed costs and therefore, higher selling price to the patient. They feel ceiling price fixation is the only recourse from the consumer's point of view.

Conclusion

The government seems to be working towards regulations with the interests of consumers at heart. According to reports, a nine-member medical devices sub-committee headed by former director general of health services (DGHS), Dr B. D. Athani, is putting the final touches to a compensation formula which would be legally binding o the manufacturers and importers of such devices. As per reports, new provisions added to the Drugs and Cosmetics Act would add a compensation plan for faulty medical devices having adverse impacts on patients. Under current law, compensation is to be paid by companies only when something goes wrong during a clinical trial. The new regulations would take into account extent of disability, age and risk factor to determine the compensation.

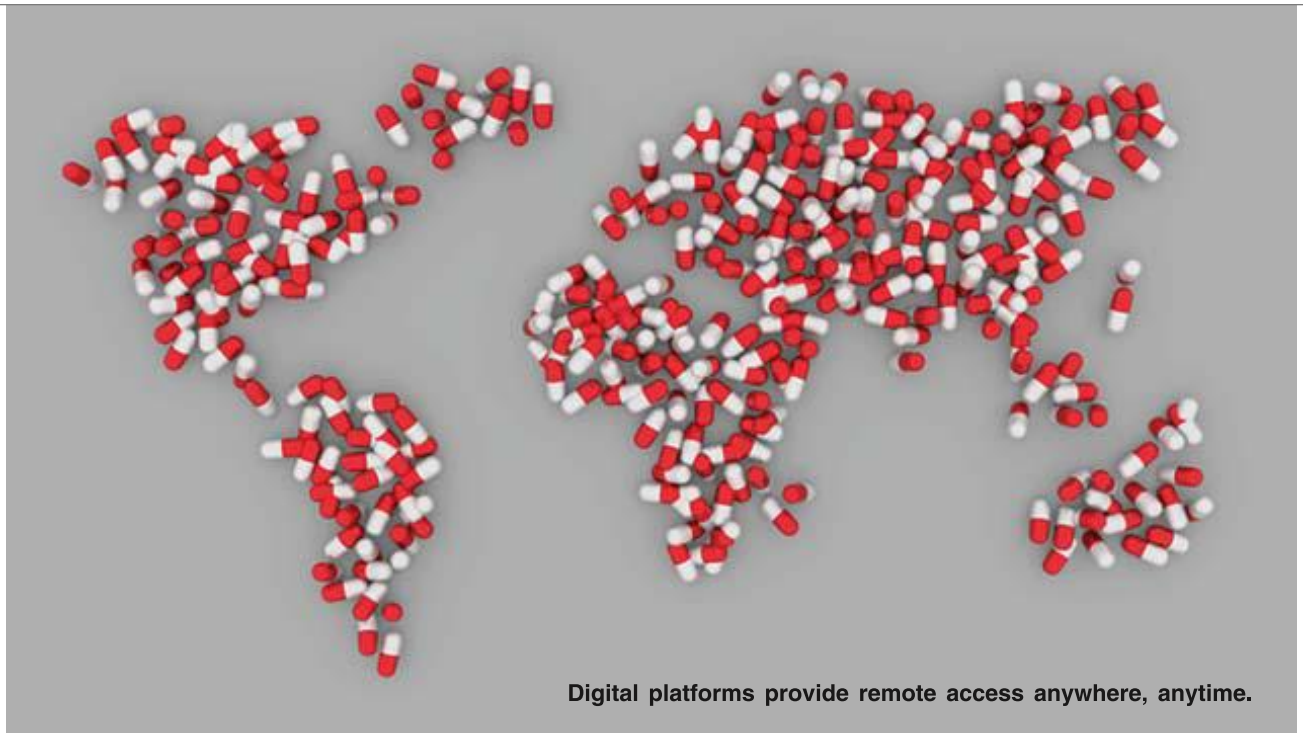
In a latest decision, the Union health ministry constituted a committee – Medical Devices Technical Advisory Group (MDTAG) – to advise the Central Drugs Standard Control Organisation (CDSCO) on strengthening of medical devices regulations in the country and also to examine issues relating to their implementation. The aim is to strengthen the regulations to make medical device companies accountable for quality and safety of their products.

Source: Secondary research and media reports

Given the advantages that e-pharmacy model has and the benefits it brings to the consumer, it is not surprising that it is giving a tough competition to retail pharmacy sector.

e-Pharmacy

THE TIME IS NOW



Digital platforms provide remote access anywhere, anytime.

PHOTO: PIXABAY

WITH YOUR TOILET roll to morning tea online, could your daily medicines be far off? In the last couple of years, online pharmacies are disrupting drug retail in the same manner that a decade or so back online retail platforms did to general retail. No wonder last September, the government's draft proposal to formalize online sales of drugs erupted in protest by the All India Organization of Chemists and Druggists (AIOCD). Such was the threat perception that around 8.5 lakh chemists across the country joined the call for a pan India band threatened by online retailers that account for just 2-3% of the total drug sales in India.

But can there be a Digital India without e-pharmacies? The answer is a resounding NO.

Why e-pharmacies?

Digital pharmacies are an answer to the needs of a wired generation. As many millennials live on their own away from family, sometimes even in the same city, when sick, delivery of medicines at the doorstep is a blessing. Used to ordering almost everything online and given the obvious advantages – discounts on e-wallets, drugs at almost 10-20% lower prices than in offline retail stores – e-pharmacies are a natural choice.

For the elderly with mobility issues and for those living in remote location there are obvious advantages too. Another big plus is the availability of a wide range of drugs, which your neighborhood chemist may not have in stock when you need it. Stocking some expensive drugs that may not have many users does not make business sense for a small chemist store but online drug retailers for whom the entire country is the customer base do not face such restrictions.

Online players are supplying to more than 22,000 pincodes and locations including far out Andaman and Nicobar Islands. The advantages of this model are then obvious.

Additionally, the 10-12% price saving on drugs for chronic or critical diseases like cancer, arthritis, diabetes, etc., translates to big saving for the consumer and is an added incentive to buy drugs online.

Innovation being the key to the survival and success of a digital business and the competitive environment they operate in, many also offer additional services through apps like reminders to take doses, to fill out prescription, stock availability information, etc., which cannot come from an offline retailer.

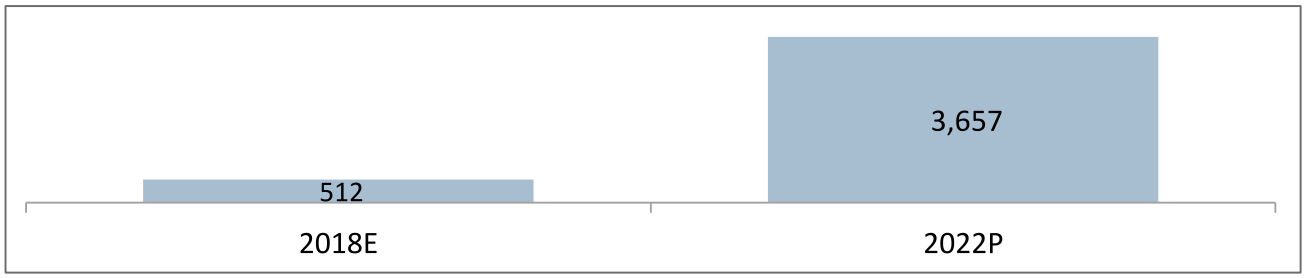
Another big advantage is the digital trails, e-billing and tracking facilities that provide confidence to customers and have attracted health insurers to partner with them.

Digital trails also ensure greater regulatory adherence and there is less opportunity for manipulation and fraud.

e-Pharmacy market in India

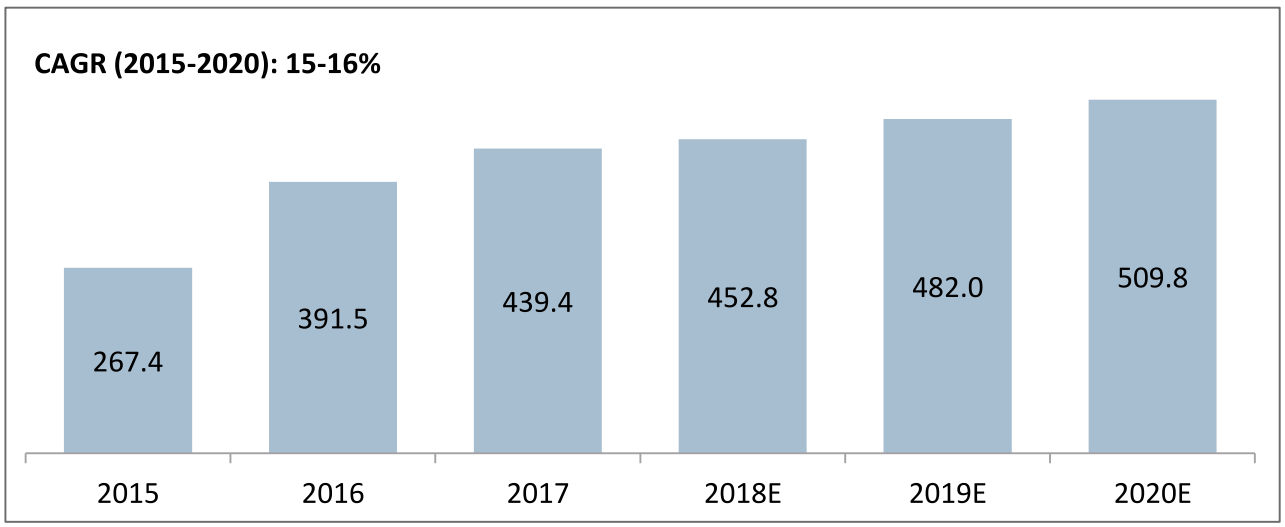
"IN THE SPOTLIGHT: e-Pharmacy in India – An Exponential Growth Opportunity", a Frost & Sullivan report of January 2019 says, e-pharmacy has taken the centre stage in addressing the need gap in India. The report estimates the e-pharmacy market in India at around US $512 million (~INR 3,500 crore) in 2018 and forecasts it will grow at a CAGR of 63% to reach US $3,657 million (~INR 25,000 crore) by 2022. Though the global e-pharmacy market is led by North America and Europe, the report sees a shift as the major opportunity lies in addressing the vast unmet needs of the developing Asia Pacific market.

e-pharmacy market in India (US $ million)



Source: Frost & Sullivan, Economic Times (dated 7 December 2018)

Internet Users in India (Million)



Source: TRAI

The e-pharmacy market in India is undoubtedly in the nascent stage but it is expected that the it could account for 15%-20% of the total pharma sales in the country over the next decade, largely by enhancing adherence and access to medicines for a majority of the underserved population. There are several e-pharmacy players in the Indian market, including Medlife, Netmeds, 1MG, Pharmeasy, Myra, CareOnGo and Pharmasafe.

Drivers of growth

India's booming internet population and smartphone penetration has given rise to a culture of online transactions. e-Pharmacy brings another ease of purchase in the lives of Indians.

The incumbent government's focus on digital has also provided a conducive atmosphere for e-retailers' growth in the country. In a bid to improve accessibility to quality healthcare and strengthen the healthcare system, the government has launched a number of e-health initiatives. These include national health portal, online registration system, e-Hospital@NIC and Central Drugs Standard Control Organization. All these services including the National Health Stack are bringing more and more patients online.

Another reason for the growth of e-pharmacy is the rising penetration of health insurance. According Frost & Sullivan, health insurance penetration stood at 437 Million in 2016-17, registering a CAGR of 20.5% between 2012-13 and 2016-17. Since insurance vertical is also aggressively pursuing online penetration through own and web aggregators' platforms, they are partnering with e-pharmacies that allow patients' audit trail and e-prescription.

The government's Ayushman Bharat Yojana, or National Health Protection Scheme aimed at covering urban poor and rural citizens, will push e-pharmacy as more consumers will gravitate to purchasing medicines for its benefits.

The changing disease pattern in the country as it shifts from communicable to non-communicable diseases like diabetes and hypertension will also push sales of medication online.

Regulations for e-Pharmacy

DRUGS WHICH CANNOT BE SOLD ON THE E-PHARMACY PORTAL

The e-Pharmacy registration holder must not deal in drugs that are covered under the narcotic and psychotropic categories as referred to in the Narcotic Drugs and Psychotropic Substances Act, 1985.

CONFIDENTIALITY OF INFORMATION GENERATED THROUGH THE PORTAL

The e-Pharmacy will be required to keep all its customer information confidential but will be duty bound to disclose any information to the State or the Central Government, whenever required, for public health purposes.

HELPLINE AND GRIEVANCE REDRESSAL

The e-Pharmacy will be required to keep all its customer information confidential but will be duty bound to disclose any information to the State or the Central Government, whenever required, for public health purposes.

DATA COLLECTION

It is mandatory to establish an e-Pharmacy portal in India and all the data generated is to be kept in the country. The data generated or mirrored through the e-Pharmacy portal cannot be sent or stored, by any means, outside the country.

MAINTENANCE OF THE E-PORTAL

Data to be available on the e-Pharmacy portal Registration issued in Form 21AA, constitution of the firm (details of directors and partners with ownership patterns), official logo of the e-Pharmacy portal, details of the logistic service provider, return policy of the dispensed drugs, etc

ADVERTISEMENT AND PUBLICITY

e-Pharmacies are forbidden to advertise on any media platform like print, television, or the digital medium.

Supportive regulatory environment like 100% FDI under the automatic route in the medical devices manufacturing subject to certain conditions, single window to provide consents, approvals, and other information to improve ease of doing business, will provide the necessary environment for the growth of the pharmaceuticals sector, benefitting e-pharmacy sector as well.

The changing demographics of the country with a rising population of silver citizens who are sound of purse, rising lifestyle diseases and consumer spending, rapid urbanization, and rising healthcare insurance will lead to increased spending on medicines in India. According Frost & Sullivan, spending on medicines in India is expected to increase at a 9-12% CAGR between 2018 and 2022 to US $ 26-30 billion.

With developments in the financing sector, there has been an increase in healthcare financing products like different types of health insurance policies, cashless hospitalization claims, health financing services, etc., which have led to increased spending on healthcare which has benefitted e-pharmacy sector as well.

India is forecast to become one of the top three economic powers of the world over the next 10-15 years. According Frost & Sullivan, India's GDP at current prices (in US $ terms) grew at a CAGR of 5.4% from 2010 to 2017, making it the 2nd fastest growing major economy in the world after China. A booming economy has brought more purchasing power in the hands of its citizens and there is an increase in domestic demand. This means rising demand for medical treatments and pharmaceutical products. All these will give a push to the e-pharmacy sector.

Regulations for e-pharmacy sector

In India, digital platforms are regulated by the Information Technology Act 2000. On the other hand, the Drugs and Cosmetic Act 1940, Drugs and Cosmetics Rules 1945 and Pharmacy Act 1948, are the regulations for pharmacy retailers. While online pharmacies are currently being regulated under the Drugs and Cosmetics Act too, the Union Health Ministry had released draft rules on the sale of drugs by e-pharmacies in August 2018.

However, the government appears to be dragging its heels on formulating a regulatory structure for the pharmacy sector. As a result, the Indian pharmacy players are facing an uncertain future. It must be noted here that after the draft e-pharmacy rules were first notified in September 2018, the next month in October, the Madras High Court had announced a ban on the online sale of medicines.

On July 4, in a statement to the division bench of Chief Justice DN Patel and Justice C Hari Shankar, the government's standing counsel Kirtiman Singh said that steps have been taken to formulate the rules and the process of consideration is on.

With their future still uncertain, what e-pharmacies can look forward to is the rising interest of investors in the sector. In the past few months, e-pharmacy startups have raised nearly $80 million in funding from existing and new investors.

Frost & Sullivan report provides the key highlights of the e-pharmacy Draft Guidelines:

Regulatory Authority

- e-Pharmacies are currently governed by state drug regulators. The draft proposes that the DCGI should be the sole agency granting approvals to e-Pharmacies.
- The DCGI will be regulated under the Drugs and Cosmetics Rules 1945 as well as the Information Technology Act 2000 under which eCommerce companies are regulated.
- Companies operating e-pharmacies are required to take one license in any state, which will enable pharmacies to sell drugs all over the country.
- The portal would also have to abide by the provisions of the Drug and Cosmetic Act, 1940. Failing to follow the guidelines could lead to suspension and cancellation of the e-portal.

Verification

The registered pharmacist must verify the details of the patient, registered medical practitioner, and arrange for the dispensing of drugs as per the instructions of the registered medical practitioner. The details of the drugs dispensed along with the patient details are to be maintained on the e-pharmacy portal.

Conclusion

The retail pharmacy model poses certain issues that make its long-term sustainability challenging. Compared to e-pharmacy, single retail pharmacy has low profit margins as the drugs are purchased in small volumes at high cost. On the contrary, e-pharmacies buy drugs in bulk at discounted prices.

One of the major advantages of e-pharmacies is that they can contain the sale of spurious and substandard drugs as they have built in tracking systems. This is not possible in retail pharmacy sector.

The retail pharmacy model needs a good dose of investment to modernize its operations, billing, tracking, etc. They lack the resources to invest in upgrades and digitalization. e-Pharmacies do not face these constraints.

There are also challenges of high rentals, rising overhead costs and the rising threat from online pharmacies. For e-pharmacies, the only real challenge is weaning away customers loyal to their friendly neighborhood pharmacist.

However, ease of access, cost savings and convenience could be the right mix for e-pharmacies to make the killing.

Source: Secondary research & media reports

Good Intentions Need Strong Will

Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP) has the right intent, all it needs is stronger regulatory structure and proper awareness to make it a success.

WITH THE CENTRAL tenet and the vision "To bring down the healthcare budget of every citizen of India through providing 'Quality generic medicines at affordable prices for all'", the Government of India launched its laudable Pradhan Mantri Jan Aushadhi Yojana (PMJAY) initiative in November 2016. The program was not a new one. Rather, it was the revamped version of the 'Jan Aushadhi Scheme', which was launched earlier in September 2015. The program was later renamed as Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) to give it further impetus.

PMBJP is more a campaign than a mere scheme for the healthcare of masses. Launched by the Department of Pharmaceuticals to provide quality medicines at affordable prices to the masses, the government focussed on setting up PMBJP stores across the country to ensure wider reach. The drugs sold at the stores, called Jan Aushadhi Kendra, would be equivalent in quality and efficacy as expensive branded drugs – this assurance was part of the program's central aim. The mission of the program is as follows:

- Create awareness among public regarding generic medicines.
- Create demand for generic medicines through medical practitioners.
- Create awareness through education and awareness programs that high price need not be synonymous with high quality.
- Provide all the commonly used generic medicines covering all the therapeutic groups.
- Provide all the related healthcare products under the scheme.

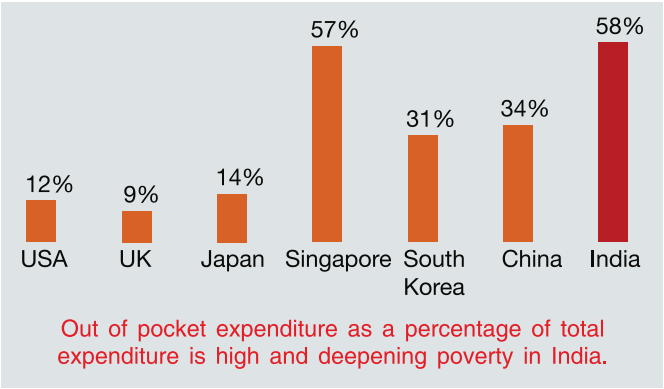
Need of the nation

The intent is good and the scheme a crying need. According to Frost & Sullivan, India has an increasing aging population base with a higher predisposition to chronic diseases. In 2010, 12% of the total Indian population was estimated to be above the age of 54. This number is expected to increase to 14% by 2020. Needless to say, that this would stress the already inadequate healthcare resources and pose a serious challenge to the idea of healthcare access for all. This brings to fore the need for development of healthcare infrastructure for all levels of care delivery – primary, secondary, and tertiary.

Add to this the changing disease pattern in the country. Frost & Sullivan states that there has been a major epidemiological transition in India in the last 25 years, and the focus has shifted from communicable to non-communicable diseases (NCDs). With the morbid population base with diabetes and hypertension expected to rise to 263 million by 2020, and the fact that many do not seek medical help due to a lack of awareness and the high cost of treatments, the picture is grim. Further, as per estimates, in 2014, an estimated 77.2 million people in India were pre-diabetics.

Deepening poverty

While the need for healthcare is rising at an alarming pace, India's healthcare expenditure remains among the lowest in the world. India's Total Health Expenditure (THE) stood at $91.7 billion in 2015. Current Healthcare Expenditure (CHE) for India stood at $82.9 billion for 2015, whereas the capital healthcare expenditure was at $8.75 billion, as per a report released on National Health Accounts by WHO in October 2017 (Source: Frost & Sullivan).



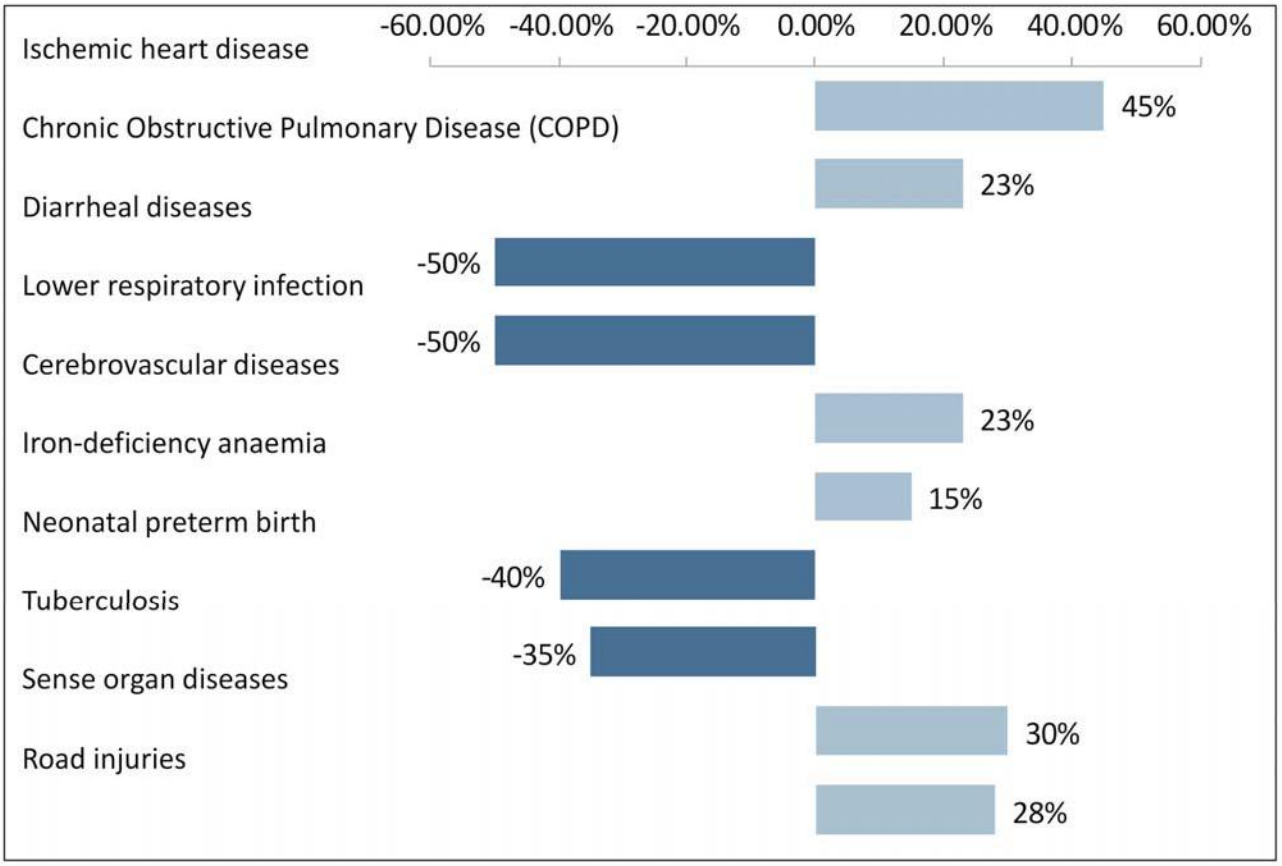
Out of pocket expenditure as a percentage of total expenditure is high and deepening poverty in India.

Source: PwC

According to reports, the average per capita spending on healthcare in a year is just Rs 1,112 in India. According to a report by Public Health Foundation of India (PHFI), an advocacy, which was released on June 6, 2018, out-of-pocket (OOP) health expenses drove 55 million Indians – more than the population of South Korea, Spain or Kenya – into poverty in 2017, and of these, 38 million (69%) were impoverished by expenditure on medicines alone. Over 80% of Indians incur OOP – direct payments individuals make to healthcare providers – on healthcare, according to 2011-12 figures cited in the study. It was 60% in 1993-1994. Medicines contributed to more than 67% of OOP healthcare expenditure in 2011-12. In real terms, monthly OOP payments increased by more than 100% – from Rs 26 in 1993-1994 to Rs 54 in 2011-2012.In real terms, monthly OOP payments increased by more than 100%–from Rs 26 in 1993-1994 to Rs 54 in 2011-2012.

In May 2017, IndiaSpend reported that India spends the least on public health among BRICS nations and ranked 147 among 184 countries, even below Pakistan. As per a June 2018 report by IndiaSpend, an analysis of 1,290 prescriptions from 100 public health facilities across 15 districts in Chattisgarh showed that only 58% prescribed medicines were available at government pharmacies. Left with no alternative, consumers have to buy medicines from private pharmacies. This explains the heavy expenditure on medication incurred by consumers in the country. Due to the inadequate public healthcare

Top ten diseases causing the highest mortality and morbidity in India, 2016



Source: Global burden of diseases, Healthdata

Changing disease profile in India, calls for newer ways in healthcare.

facilities in India, it has become the sixth biggest private spender on health among low-middle income nations.

According to a World Health Organization report, around 68% of Indian population has limited or no access to essential medicines. Add to it the the declining availability of free medicines in public health facilities in the last two decades – from 31.2% to 8.9% for inpatient care and from 17.8% to 5.9% for outpatient care, according to a 2011 PHFI study.

Medicine for the people

Janaushadhi literally means medicine for the people. The aim of the program to make available unbranded quality medicines to the masses at a reasonable and affordable price through retail outlets set up with the help of the government, would have ideally answered the pressing need of affordable quality drugs.

As of March 2019, there were more than 5,000 Jan Aushadhi stores, with 2,500 more in the pipeline by 2020. As per reports, these stores are serving 10-15 lakh people per day. Under the PMBJP, the government provides more than 800 medicines and 154 surgicals through Jan Aushadhi Kendras, said reports.

To provide an impetus to the movement, the government also decided to celebrate March 7 as 'Janaushadhi Diwas'. The government expects the program to:

- Promote greater awareness about cost effective drugs and their prescription.
- Make available unbranded quality generic medicines at affordable prices through public-private partnership.
- Encourage doctors, more specifically in government hospital to prescribe generic medicines.
- Enable substantial savings in health care more particularly in the case of poor patients and those suffering from chronic ailments requiring long periods of drug use.

To ensure high quality, medicines are procured from WHO Good manufacturing practice (GMP), Current Good Manufacturing Practice and CPSUs manufacturers for supplying to Pradhan Mantri Bhartiya Janaushadhi Kendras. Each batch of drugs procured is tested randomly at BPPI's empaneled National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited

Components Of Out-of-Pocket Expenditure, 1993-2012			
Financial Burden Indicators	**1993-1994**	**2004-2005**	**2011-2012**
Percentage households reporting OOP payments			
Any OOP payments (%)	59.2	64.4	80.5
Medicines OOP payments (%)	57.5	63.6	79
Monthly per capita expenditure (INR at constant 1999-2000 prices*)			
Household consumption expenditure	517	619	794
OOP expenditure on health	25.59	36.3	54.3
Medicine OOP expenditure	20.86	26	36.1
Share of health to total household expenditure (%)			
Share of total OOP expenditure to total household expenditure (%)	4.84	5.78	6.77
Share of medicine OOP expenditure to total household expenditure (%)	3.93	4.1	4.49
Share of health to non-food household expenditure (%)			
Share of total OOP payments to non-food expenditure (%)	12.37	10.82	11.46
Share of medicines OOP payments to non-food expenditure (%)	10	7.68	7.6

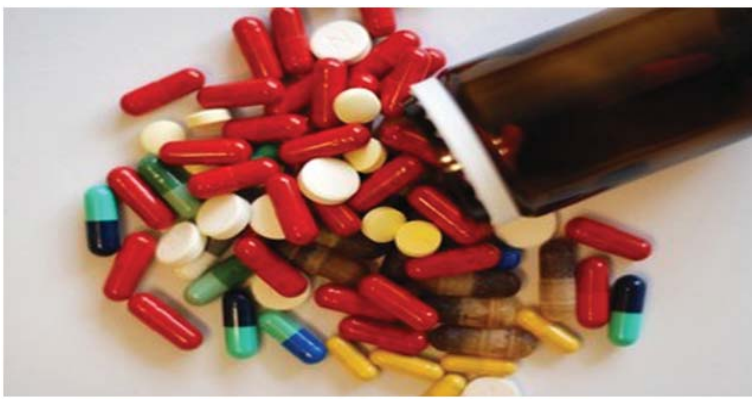
Source: Public Health Foundation of India Study 2018

laboratories thereby ensuring quality, safety and efficacy of medicines and conformance with required standards. Only after being certified by these laboratories, medicines are dispatched to C&F agents, Distributors and JAKs.

Quality issues

The quality of generic medicines came under the scanner post the 2013 Ranbaxy issue. Earlier too, doubts were voiced in various quarters but had failed to garner much attention. However, despite the quality assurance from the government, generics have failed to generate confidence among the people. While generic medicines cost between 30–80% less than their originator equivalents, there is a question mark on their efficacy as compared to brand or innovator drugs. Skeptics believe illness may be prolonged or the line of treatment may even fail with generic drugs. Scientifically, the critical issues with generics are purity, potency, stability, and drug release, and these should be controlled within an appropriate limit, range, or distribution to ensure the desired drug quality.

Not just patients, even doctors lack of confidence in generic drugs. One reason is the absence of stringent regulatory requirements for the quantity of the drug in its generic version and the permissible impurities in it.



Janaushdhi or medicine for the people: A dream?

Incidents involving generics drugs' poor manufacturing practices or Jan Aushadhi Kendras involvement in scam also defeat the purpose of promoting manufacture and sale of generics. For instance, in June this year, media reported that drug sale licenses of 44 Jan Aushadhi stores in Kerala were to be cancelled following widespread complaints about their functioning. The stores were found to be selling expensive branded medicines, while claiming a shortage of cheaper generic drugs. Following the case, the Bureau of Pharma PSUs of India (BPPI), the implementing agency of

IMAGE: FREEIMAGES.COM

India spends the least on public health among BRICS nations and ranked 147 among 184 countries, even below Pakistan. Only 58% prescribed medicines were available at government pharmacies.

India need modern tech-enabled inventory management system.

the Pradhan Mantri Janaushadhi Pariyojana, was reportedly planning to tighten the norms for setting up Jan Aushadhi Kendras.

It is to be noted that there is a condition in the sale agreement of these stores that binds them to sell only generic medication and that too distributed by the BPPI alone. Also, some of these stores were not using the software mandated by the BPPI to monitor their functioning.

Three main impediments in the path of Jan Aushadhi stores' success are:

1. **Inventory Management:** More often than not, consumers do not find the generic prescribed in the store. This defeats the purpose of prescribing generics as the patient ends up buying either more expensive branded generics or brand name drugs. The government needs to haul up the current procurement and distribution system for supplies to the stores to ensure complete inventory. Only then can the Jan Aushadhi stores service the patients properly.
2. **Maintenance of Quality Standards:** In a recent case, the BPPI, responsible for procurement and supplies of medicines to the Jan Aushadhi Kendras, took stringent action against 18 companies for supplying medicines 'not of standard quality'. The action no doubt is indicative of the government's commitment to the program. But, to ensure that such cases do not crop up again, the BPPI must develop a reliable bank of suppliers and the process of procurement must embed a resupply quality check before accepting any batch for distribution.
3. **Low footfall:** It has been found that the footfalls at the Jan Aushadhi Kendras situated far from hospitals are abysmally low. The government must undertake steps to increase the footfall at these stores, else they will become a liability.

Conclusion

As of now, generics rarely find shelf space in chemist stores and pharmacies, though you may find branded generics being sold. The sale of unbranded generics is limited to pharmacies in government-run hospitals and clinics. Also, when a generic drug is prescribed, the pharmacist generally dispenses his favored branded generic.

There is an urgent need to develop the medical fraternity's confidence in generics and inculcate the habit of generic prescribing in them. This can be achieved by providing relevant information and education to the medical fraternity in areas of generics, regulations regarding it, and by dispelling doubts and myths about generic medicines. Guidelines alone will not suffice in enhancing the quality of generic drugs or the habit of prescribing them.

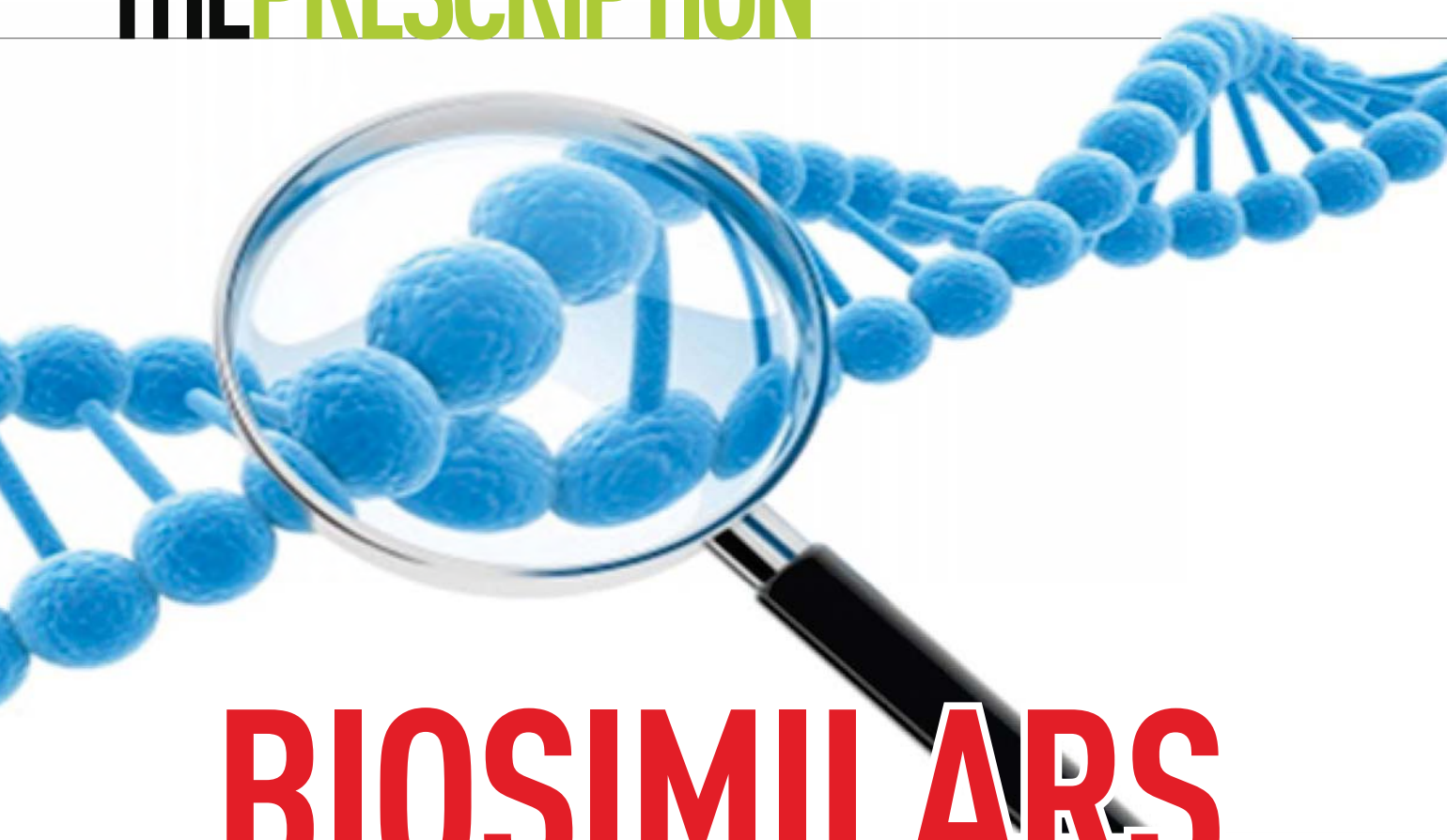
Ensuring quality with strict regulatory mandate and providing updated information regarding the generic drugs (as given by United States Food and Drug Administration in its Orange Book) will eventually enhance prescription of generic drugs.

The government must bring in legislation to ensure that the quality of generic drugs is equivalent to its branded version and that this equivalence is diligently maintained. This could go a long way in ensuring compliance in generic drug manufacturing and testing and may work towards promoting their sale.

It is vital for the success of the Jan Aushadhi program that the government streamlines the entire procurement and supply chain rather than scaling up the number of stores. This would help build confidence in the patients and the medical fraternity.

The vision of PMBJP 'to bring down the healthcare budget of every citizen of India through providing quality generic medicines at affordable prices' is a much needed one and requires more concerted effort to make it a success.

Source: Secondary research & media reports



BIOSIMILARS

The Next Frontier For India

India has already marked its presence in the biosimilars market and impetus can become the global leader in the space.

MANY KEY BIOLOGICS are slated to lose their patent by 2025. This comes as a huge opportunity for other biopharmaceutical companies to develop the similar biologics – biosimilars. According to a report by Morgan Stanley, either nine biologics to go off patent by 2025 or have already done so. The total revenue of these drugs was $62 billion in 2018. The revenue of their biosimilars is estimated to grow by 24 per cent annually for seven years to $13.3 billion in 2025 in the US and Europe.

The buzz around biosimilars is understandable then.

Biosimilars are to biologics what generics are to chemical drugs, however unlike generics, biosimilars are not an exact copy of biologics. The first biosimilar was approved in early 2000 and since then it has gained popularity around the world, as an affordable alternative.

Biologics have complex characteristics, which makes it impossible to develop an exact replica of them. Due to this complexity, a manufacturer of a biosimilar drug will be required to invest in additional trials and tests to prove that the efficacy of the drug is comparable to the original version.

Since biosimilars are similar to biologics but not identical to them, they require separate marketing approval and involve a lot of documentation. Therefore, various countries around the world are establishing strict regulatory and administrative regimes to ensure a balance between the cost benefit and risk management of the product.

Biosimilars have a huge potential to reduce the overall cost of treatment as evidenced from a study in the US where it was estimated that over 10 years biosimilars can save USD 54 billion in the United States.

In India biosimilars are called “similar biologics” by regulatory agencies. While Europe was the first in the world to formulate a policy framework for approval of biological products, followed by the US, India developed a new guideline in 2012 for the pre- and post-marketing approval of similar biologics. These guidelines were revised in 2016.

It was the Central Drugs Standard Control Organization (CDSCO) that in collaboration with the Department of Biotechnology (DBT) developed the “Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorization in India”. CDSCO is responsible for establishing the standards for the drugs and ensuring that the requirements regarding the manufacturing process and quality are met, for providing approvals for clinical trials, granting marketing rights, granting import or export licenses and ensuring pre-market, and post-market regulatory requirements for biologics.

India is one of the leading manufacturers of similar biologics. According to 'Biosimilars in India; current status and future perspectives', a paper by Meher, et al., there is a thriving biosimilar ecosystem in India and Indian pharmaceutical companies have risen as global market leaders in biosimilars. Notably, the first biosimilar in India was approved much ahead of the United States and Europe in 2000 for hepatitis B. However, at that time, no guideline was available for the development and marketing of biosimilars in the country.

At the last count there were more than 100 companies in India engaged in the manufacturing and marketing of biosimilars. According to media reports, India is leading the global biosimilar pipeline and has launched the largest number of products. The biosimilar leader is from India –Reliance Life Sciences – followed by Intas and biotin. Though Indian companies are marketing their products only in emerging economies, recently, an Indian biopharmaceutical company got the USFDA's nod for marketing its novel biologic. According to reports, Herceptin (active drug is trastuzumab) was the first biologic to be approved by FDA, which is used in certain breast and stomach cancer. This was also the first similar biologics manufactured by an Indian company, which received approval to market in the United States.

Experts believe biosimilars will have a positive impact on drug pricing. They expect the use of biosimilars to reduce the cost of biologics and eventually lead to better access to lifesaving drugs for patients. It is estimated that biosimilars can reduce the overall cost of treatment to a great extent.

IMAGE: PIXABAY

Biosimilars are similar to biologics but not identical to them.

While many Indian companies are taking steps to get into the manufacturing and marketing of biosimilars, there are several challenges that they face in research and development (R&R). Biosimilars are expensive to create and Indian pharmaceutical companies that have been into generics will need to reorient their R&D and manufacturing processes to be able to start developing biosimilars.

Additionally, the process of biosimilar production needs to be stringently controlled and must adhere to stringent clinical timelines under clearly defined regulatory procedures and require comprehensive clinical programs to prove they are as effective as biologics in treating the indicated disease.

As of now most biosimilars approved and used in India are of the vaccines, monoclonal antibodies, insulin,

A biosimilar is a biological product

FDA-approved biosimilars have been compared to an FDA-approved biologic, known as the reference product. Reference and biosimilar products are:

Large and generally complex molecules

Produced from living organisms

Carefully monitored to ensure consistent quality

A biosimilar is highly similar to a reference product

For approval, the structure and function of an approved biosimilar were compared to a reference product, looking at key characteristics such as:

Purity

Molecular structure

Bioactivity

The data from these comparisons must show that the biosimilar is highly similar to the reference product.

A biosimilar has no clinically meaningful differences from a reference product

Studies were performed to show that biosimilars have no clinically meaningful differences in safety, purity, or potency (safety and effectiveness) compared to the reference product:

Pharmacokinetic and, if needed, pharmacodynamic studies

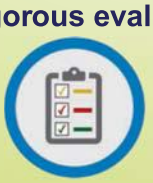
Immunogenicity assessment

Additional clinical studies as needed

Studies may be done independently or combined.

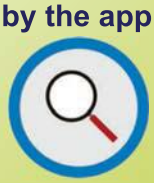
A biosimilar is approved by FDA after rigorous evaluation and testing by the applicant

Prescribers and patients should have no concerns about using these medications instead of reference products because biosimilars:



Meet FDA's rigorous standards for approval

Are manufactured in FDA-licensed facilities



Are tracked as part of post-market surveillance to ensure continued safety

and recombinant proteins. India is currently the second largest supplier of vaccines in the world. Various biosimilars have been approved by India for use in different diseases.

But there lies a huge opportunity ahead of India in the biosimilars market. While it is difficult for new companies to enter the market given the complexity and the novelty of the product, Biocon, Glenmark Pharmaceuticals, and Zydus Wellness that are actively focusing on the biosimilars market are already established names. Dr Reddy's Laboratories, Cipla, Lupin and Aurobindo, four of the largest pharma companies in India have an established reputation in biosimilars.

According to a report by Associated Chambers of Commerce of India (Assocham), the global market for biosimilars is forecast to be $240 billion and the Indian market will be over $35 billion by 2030. However, a lot will depend on how India's pharmaceutical companies access critical technology, regulatory guidelines and the price difference between biosimilars and the underlying biologics. For, a wide price difference will mean faster adoption of biosimilars. It is to be hoped that with more pharmaceutical companies in India developing the capability to produce biosimilar products and a stable regulatory and legislative regime, the barrier to entry to the market will gradually be lowered. It wouldn't be a surprise to see India go from being pharmacy of the world to becoming biosimilars supplier of the world.

Source: Secondary research & media reports

All State Governments Are Supposed To Draw Drug Samples And Test Them Regularly

– *Bejon Misra*

The survey helped us to exactly pinpointed in which district or in which part of the country the maximum not-of-quality standard medicines were found.

BEJON MISRA, Founder Director of Patient Safety & Access Initiative of India Foundation, New Delhi speaks on the need for scientific investigation and the Nation Drug Survey undertaken to establish India's drug quality.

Nation Drug Survey 2014-16: Key issues you looked at

There is a lot of data floating around in the public domain which talks about India being the hub of spurious medicine or not of quality standard medicines. It was a very urgent requirement that how do we create an authentic data in terms of India because India is doing extremely well in terms of producing quality medicines at the most affordable price and globally it is being acknowledged that India is the pharmacy of the world.

We in the healthcare delivery system on behalf of the patients wanted to know what it is exactly. So we convinced the government that we should do a scientific study in terms of the level of spurious or not of quality standard medicine today floating around in the supply chain in our country. So that was the whole motive that how do we come out with credible data.

Nation Drug Survey 2014-16: Outcomes

The most important thing was that whenever you create any data it has to be done in a very scientific manner. That's why we created an extremely robust sampling process and we engaged with the Indian Statistical Institute to recommend the sample size and how to create that sample.

The next point is also making a very transparent process to ensure that there is no biasedness in the collection of the sample. So we made sure the citizen representative and representatives from the Pharmacy Council of India accompanied the inspectors who went to draw the samples from the market place.

Hence, we made the process very transparent. We also made sure that the labs are accredited labs or government labs that are competent to do these tests. The labs were given the samples in a masked manner so they won't know whose samples they were testing.

So it was all coded and done by the use of technology i.e., we created software which made sure that there is no biasedness or any kind of interference in terms of the whole sampling test process. So we ensured to do that very scientifically.

In the key outcomes which came out, we found that there were only 0.04% of the samples found to be spurious and on a pan India basis, it was about 3% which was not of quality standards.

The most alarming thing was that the government sourced medicine had as high as 10%, not of quality standards because it gave evidence that the procurement of the government medicines is not being done in a manner in which it should be done. Another very important aspect which came out of these surveys was, we exactly pinpointed in which district or in which part of the country the maximum not-of-quality standard medicines were found.

This was a revealing factor that there are certain pockets in the country that are the culprits. We are trying to figure out that even if there is 1%, not of the quality standard then how do we ensure that we reduce it. So we should work towards how do we reduce it.

Recommendation

Finally, the recommendation came out with a process where we created software. So as per law, all state governments are supposed to draw samples and test them regularly.

We suggested that it should always be done in a scientific manner in terms of collection of the samples. It should not be left with the whims and fancy of the drug inspector to walk into a place and draw the sample.

Hence, it should be done in such a statistic and significant manner that it is unbiased and nobody can interfere with the process. This was one recommendation that came out.

The second recommendation was that we should follow the same process and software that the government already invested in, why can't we use this in future for all the states and make it a common platform and help government to come out with these kinds of results in a regular manner and make them public so that at least there is a good robust recall system.

The collected samples of not of good quality should be destroyed in a manner which is again very robust and credible and people should start building trust in terms of the system. This is where we have given a recommendation to the government that there should be a portal, technology should be used and it should become pan India and every state should become a party to this.

This interview was published in ET Healthworld.com

Need For A New TRANSPORTATION STRATEGY

Pharmaceutical supply chain must become more technologically advanced in order to fulfill the rising requirements of the industry.

PHOTO: FREEIMAGES.COM

THE PHARMACEUTICAL INDUSTRY in India is undergoing rapid transformation to cope with the demands of the rapidly evolving industry. From supply chain to distribution channels, all must upgrade rapidly to support the industry's evolving requirements. This is the era of breakthroughs in every field of science. From biologics, gene therapies and personalized medicine, pharmaceutical products have undergone a sea change. However, such evolutionary products with short lifespans require special handling. From temperature-controlled conditions and just-in-time timelines, they have special needs to fulfill in which the supply chain management for pharmaceutical industry must play a proactive role. The requirement today is a transportation strategy that promises quality, safety and efficacy.

To keep pace with the needs of the industry, the supply chain must undergo a radical overhaul. According 'Pharma 2020: Supplying the future – Which path will you take?', a report by PwC, there are three directions that the pharmaceutical supply chain can take to cope up with the demands;

- It will fragment, with different models for different product types and patient segments
- It will become a means of market differentiation and source of economic value
- It will become a two-way street, with information flowing upstream to drive the downstream flow of products and services.

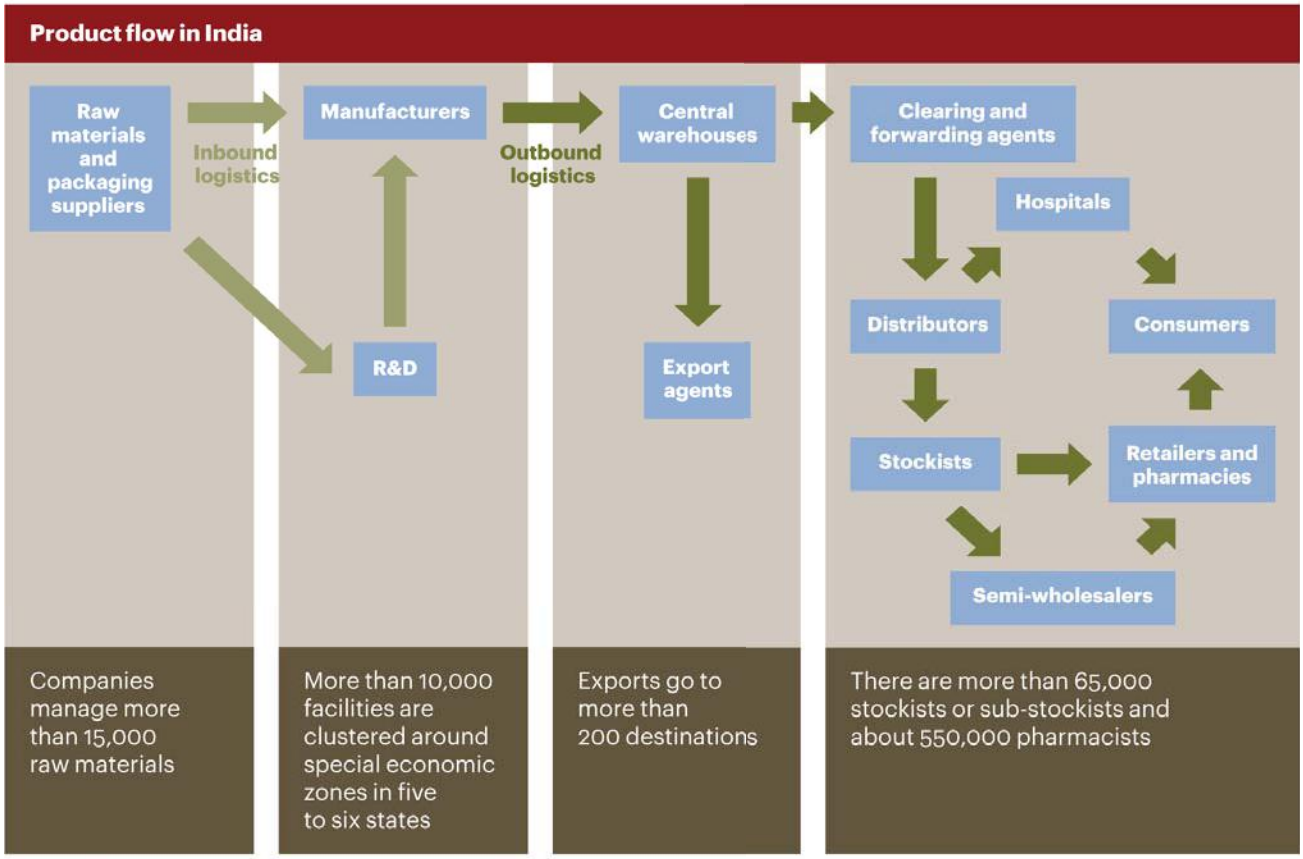
According to a Cognizant report, supply chains are stressed by SKU proliferation, demand variability and lower margins. There is rising competition from generics as the patents are expiring and governments are stressing on generics to save out-of-pocket expenditures incurred by consumers, curbing the top-line potential of branded pharmaceutical business units. There is also increasing competition from online pharmacies with their direct-to-customer delivery processes that pharmaceutical distribution channels must address.

The tightening regulatory scenario as governments become more aware is adding to the pressure on pharmaceutical companies. They must rethink their supply chains and IT strategies and develop more collaborative models that enable them to be more agile, flexible and compliant, says the Cognizant report.

IMAGE: PIXABAY

Old system will not work. A new tech-enabled transportation system must evolve to cater to the rising needs of the pharmaceutical industry.

The pharmaceutical supply chain is complex



Source: A.T. Kearney analysis

Why change is needed?

For one, to fulfill the needs of the booming India industry. According to a report by A. T. Kearny, 'India's Pharma Supply Chain: Does the Industry Have What It Takes to Win?', from 2005 to 2015, the revenue of the top 10 pharmaceutical companies grew at about 19 percent while the industry grew at about 18 percent. Media reports state India's pharmaceutical exports rose 11 per cent to $19.2 billion in 2018-19, mainly driven by higher demand in regions such as North America and Europe. The market grew by 22 percent in the past decade and continues to grow. By 2020, India is expected to capture 6 percent to 7 percent of a $760 billion global generics market.

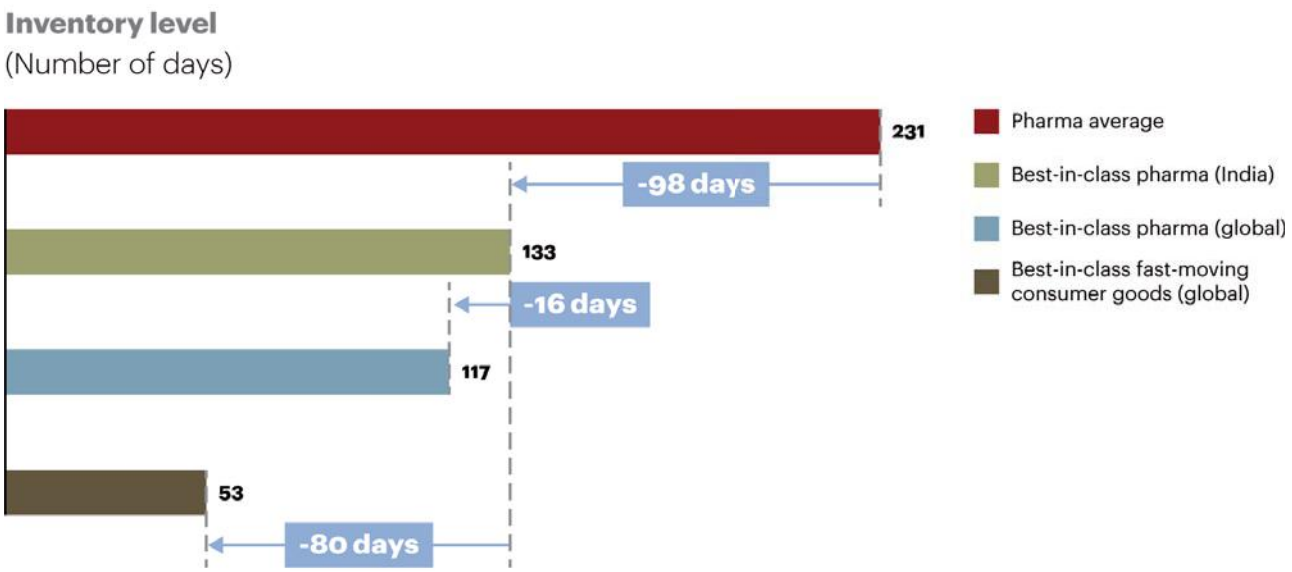
According to IBEF, the country's pharmaceutical industry is expected to expand at a CAGR of 22.4 per cent over 2015–20 to reach US$ 55 billion. The pharmaceutical sector was valued at US$ 33 billion in 2017. A. T. Kearny notes India has the highest number of sites approved by the US Food and Drug Administration (FDA) after the United States itself—a clear indicator of the pivotal role Indian companies play in both local and global markets and the growing appetite to invest in the country.

Apparently, it is critical for the growth of this market to have an assured integrity of the supply chain till it reaches the patient. Currently, supply chains of most pharmaceutical players are neither flexible nor cost-effective. There is an urgent need for supply chains to become more advanced adopting the latest technologies in order to survive the changing scenario.

Among the numerous forces demanding a different kind of supply chain, PwC has identified seven. They are:

1. **New product types:** As mentioned earlier, pharmaceutical portfolio is changing and becoming more diverse with the advances in various disciplines of medicine. These new products more complex manufacturing and distribution processes. For instance, biologics can be contaminated easily during production process and damaged during transportation.
2. **Live licensing:** PwC sees live licensing replacing the conventional system. It forecasts a system whereby new therapies are granted 'live licenses' contingent on further testing to confirm their safety and efficacy in different patient populations. This would put an end to the hugely publicized launches of new drugs and in this phased scenario the demand for product would

Pharmaceutical inventory moves slowly in India



Source: A.T. Kearney joint study with the Organisation of Pharmaceutical Producers of India and the Indian Pharmaceutical Association

rise as the license is extended. This would change the supply chain requirements as companies would look at a distribution channel that could adjust to the phased extended demand rather than just peak demand of the current system.

3. **Increasing emphasis on outcomes:** As the focus increases on demonstrated effectiveness of medicines, with governments stretched financially, the onus of manufacturing and distribution of drugs as also ensuring supportive services that supplement therapies will be on pharmaceutical companies. The supply chain will play a key part in providing that value for money by commissioning and supervising aspects of the services patients need to manage their health.
4. **New modes of healthcare delivery:** The global trend is to reduce reliance on hospitals and specialists. Patients are becoming empowered and being encouraged to play a more active role in their own care. There is a rising trend of self-medication. Many diseases will eventually be treated at home. As healthcare becomes more diffused with nurses and caregivers working from multiple locations, pharmaceutical products will have to be delivered to these many care points, including patients' homes. Pharma industry will require to harness the most efficient last mile distribution networks in order to deliver medicines to the doorstep as economically and efficiently as possible. Further, as healthcare delivery digitalizes, electronic health records, e-prescribing and remote monitoring will become the norm. E-prescriptions would then act as point of sale and this data will enable pharmaceutical companies to build demand-driven supply chains.
5. **The growing importance of emerging markets:** The needs and the means of patients in emerging markets like India are different from their developed counterparts. To cater to this market, pharmaceutical companies need to tailor their products to specific needs as also their supply chain, which would need to be both more geographically dispersed and more secure.
6. **Greater public scrutiny:** Pharma companies will need to develop the ability to manage risk and compliance throughout the supply chain. With increasing globalization the risks are also increasing. There is also greater public awareness and more diligent enforcement that are raising the bar. Medicine recalls are common and counterfeits are rising. This means more robust and secure supply chains will be required.
7. **Environmental pressures:** The green agenda would force pharmaceutical companies to reduce their environmental footprint further. Extreme weather conditions would also affect manufacturing and transportation. Supply chains would have to evolve to be able to manage under these changing environmental conditions.

The challenges

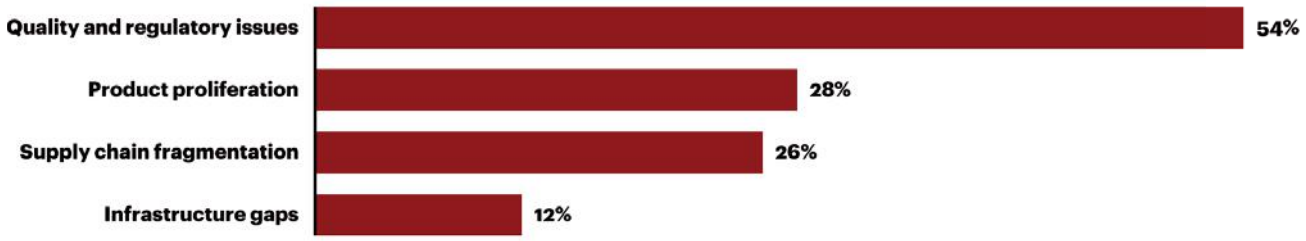
According to A.T. Kearny, there are several challenges that supply chain operators struggle against. The four major as identified in the report are:

1. **Quality and regulatory issues:** India has 600 to 700 FDA-approved sites in India and quality continues to be hot topic with increased scrutiny from global regulatory agencies. As a result, quality issues have

India's pharma companies face four supply chain challenges

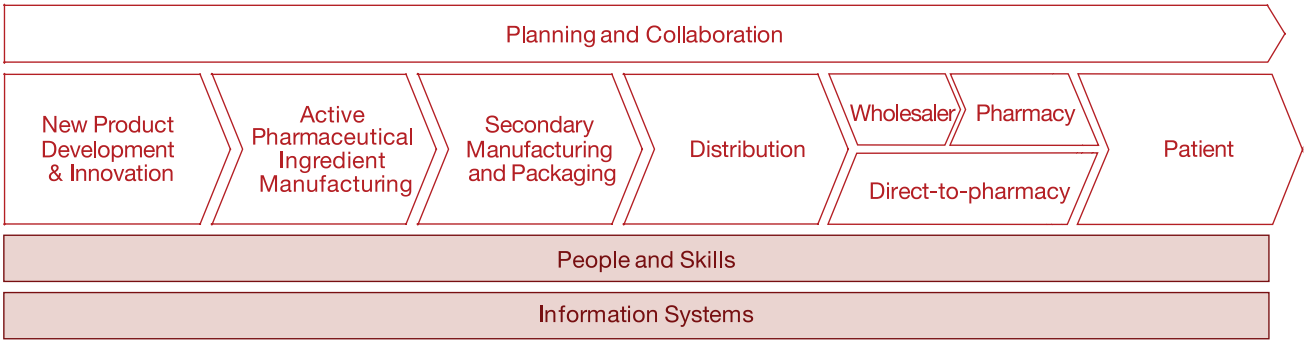
Major supply chain challenges

(% of executives who cite the challenge as "extremely relevant")



Source: A.T. Kearney joint study with the Organisation of Pharmaceutical Producers of India and the Indian Pharmaceutical Association

The supply chain is the backbone of a pharma company



Source: PwC

deepened and widened across the value chain. Procurement, manufacturing, logistics, R&D, pricing regulation – all are bearing the impact the deepening quality consciousness and resultant tightening of the regulatory mechanism.

2. **Product proliferation:** The product portfolio is expanding as there are new product developments, new dosage forms, enhanced formulations, and changes in packaging and labeling to cater to new markets. Leading Indian pharmaceutical companies launch between 15 to 30 products/SKUs annually. This has several implications for the supply chain, including higher manufacturing and distribution costs, more inventory, and a larger supplier base.
3. **Supply chain fragmentation:** India has a complex pharmaceutical value chain with a number of players at each stage. There is lack of integration and this impacts the traceability and visibility of products as they move down the chain. This poses concerns about the quality and safety of products.
4. **Infrastructure gaps:** There are many gaps in supply infrastructure, including in transportation, storage, and power supply – inadequate road, rail and air network. There is a lack of a robust cold chain network to support the supply chain. This is a major gap in the pharmaceutical industry infrastructure. As a result, companies do not have visibility and control over the product's movement beyond a certain point. In addition, warehouses, distributors, and far-flung retailers lack adequate infrastructure to store the products.

Conclusion

There is an urgent need to reduce supply chain complexity, create agility and visibility in the supply chain, build a robust quality and compliance system, and upgrade supply chain incorporating latest technologies to build a robust and secure system that could support the pharmaceutical industry's growing needs. There is a need for complete supply chain transformation. A tech-enabled supply chain would allow pharmaceutical companies end-to-end and "outside-in" visibility into the supply chain. Adopting emerging technologies like Artificial Intelligence and machine learning can revolutionize the supply chain and transform the pharmaceutical's industry.

Source: Secondary research & media reports

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Government Steps Up Quality Control

The Government of India has taken several steps to ensure pharmaceutical companies maintain quality of drugs.

THE GOVERNMENT OF India has taken numerous steps to to ensure the quality of drugs including generic drugs manufactured/marketed in the country. In 2018, there were 10 amendments to the Drugs & Cosmetics Rules, 1945 (the 'Rules'), in this regard. In March this year, the government came up with a proposal to color code generic drugs to enable consumers to differentiate between them and brand drugs and then take an informed decision. Apart from color coding the government is also planning to use symbols for the same purpose. Earlier, the government had made it mandatory for pharmacists to have a separate shelf for displaying generics. Doctors were also asked to prescribe generics in legible handwriting.

Some of the important measures include:

1. Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offenses have also been made cognizable and non-bailable.

2. The states/UTs were requested to set up Special Courts for trial of offenses under the Drugs and Cosmetics Act for speedy disposal. Till December 2018, 22 states had set up designated special courts.
3. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.
4. The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) was increased from 111 in 2008 to 510 in 2018.
5. The testing capacities of Central Drugs Testing Laboratories under CDSCO are being constantly strengthened.
6. On 03.04.2017, in order to ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 was amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.
7. On 10.04.2018, the Drugs and Cosmetics Rules, 1945 were amended making it mandatory to submit evidence of stability, safety of excipients, etc., of all drugs to the State Licensing Authority before grant of product manufacturing license by the Authority.
8. Draft Rules were published to amend the Schedule M of the Drugs and Cosmetics Rules, 1945 to make it more comprehensive and at par with the WHO-GMP guidelines
9. On 27.10.2017, the Drugs and Cosmetics Rules, 1945 was amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.
10. The licensed manufacturing premises shall be inspected jointly by the Drugs Inspectors of Central Government and State Government for not less than once in three years or as needed as per risk-based approach.
11. The Government has decided to strengthen both the Central and States drug regulatory system enabling them to keep more effective watch on unscrupulous elements indulging in unlawful activities relating to quality of drugs. The Cabinet Committee on Economic Affairs (CCEA) has approved the proposal for strengthening the drug regulatory system in the country, both under the Central and State Governments at a total expenditure of Rs. 1750 crores. Out of this, Rs 850 crore is the Central Government's share. The share of the Centre and the States in case of state component will be in the ratio of 60:40 for all States except Jammu and Kashmir, Himachal Pradesh, Uttarakand, Sikkim and North-Eastern States, for which the ratio will be 90:10.

PHOTO: PIXABAY

The Government of India is strengthening laws to help protect consumer interest.

Some important amendments with direct impact on consumers include:

1. Printing of Drug's Generic Names in Bigger Font than Brand Name

On March 13, 2018, Rule 96 of the Rules was amended to make it mandatory to print the name of the drugs (generic) in a conspicuous manner, in the same font but at least two font size larger than the brand name or the trade name, if any. The labelling requirement was to be on a voluntary basis for the period from 13.09.2018 to 31.03.2019 and thereafter it became mandatory.

2. Steroidal drugs included under Schedule H of Drugs and Cosmetics Act, 1940

On March 23, 2018 the Drugs and Cosmetics (Second Amendment) Rules, 2018 were notified which updated Schedule H provided under the Rules, with an addition of 14 Steroidal drugs – Alclometasone, Beclomethasone, Betamethasone, Desonide, Desoximetasone, Dexamethasone, Diflorasone diacetate, Fluocinonide, Fluocinolone acetonide, Halobetasol propionate, Halometasone, Methylprednisone, Prednicarbate, and Triamcinolone acetonide – making them prescription drugs for patient use.

3. Extended validity of Drug import license for personal use

On June 01, 2018, the Drugs and Cosmetics (Sixth Amendment) Rules, 2018 updated Form 12B, which now allows permit holder to import the medication for personal use till such time as the patient requires the drug as per the prescription of a registered medical practitioner, and the permit holder shall submit details of drugs imported and utilized to the licensing authority on yearly basis, which was for only six month period earlier.

4. Oxytocin reclassified as Schedule H1

On August 21, 2018, the Drugs and Cosmetics (Seventh Amendment) Rules, 2018 reclassified oxytocin from the

list of Schedule H drugs to Schedule H1 drug, which requires retail chemists to document the customer and physician details for each sale for at least 3 years to check the indiscriminate use of drug. Strict regulatory control over manufacture, sale and distribution of oxytocin to curb its misuse under section 26A of the Act was also announced.

PHOTO: PIXABAY

Consumers must know the laws to safeguard their rights.

5. Mandatory unique ID number system to keep a check on misleading advertisement for ASU drugs

On December 21, 2018 the drug and cosmetics (Eleventh amendment) Rules 2018 inserted new Rule 170 in Rules, introduced unique ID number system for Ayurvedic, Siddha and Unani (ASU) medications sold in the country, which provide a stringent regulatory check for misleading and inappropriate advertisements.

Conclusion

As can be seen the government is keen to ensure that consumers can access low cost quality drugs. However, it requires political will to defeat the forces working against this plan. From pharma lobbies, to doctors protesting the compulsory prescription of generics, to the culture of 'brand popularity', to pharmacists pushing drugs with bigger margins there are various forces at work to scuttle the plan to benefit consumers. A lot needs to be done to ensure the consumer gets the best deal.

Source: Secondary research & media reports

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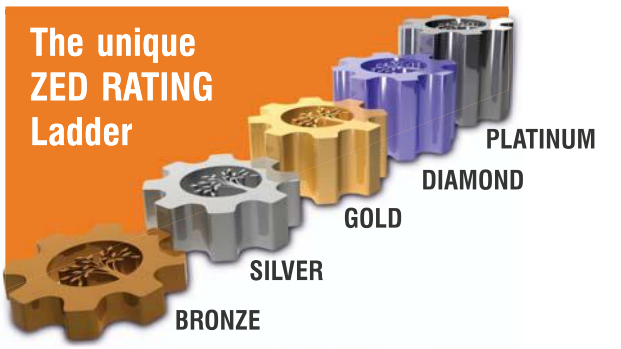

HIGHLIGHTS

- A scheme by Ministry of MSME, Govt. of India
- Certification on the systems and processes of MSMEs
- Handholding MSMEs towards world class manufacturing
- Special emphasis on MSMEs supplying to Defence Sector
- Direct subsidy to participating MSMEs
- Creating a credible database of MSMEs for OEMS/CPSUs/Foreign Investors under "Make in India initiative"
- Quality Council of India (QCI) to function as the NMIU (National Monitoring and Implementing Unit) of the scheme

"Let's think about making our product which has 'Zero Defect'; so that it does not come back (get rejected) from the world market and 'Zero Effect' so that the manufacturing does not have an adverse effect on our environment"

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