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THE AWARE CONSUMER

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OPINION
Jan Aushadhi Stores Gaining Popularity

GOVERNMENT PERSPECTIVE
Who is the better 'Medicine Man' of India's Poor?

Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana

BREATHING LIFE INTO INDIA'S HEALTHCARE

Based on the principal of Not for Profits but with Minimal Profits this programme has been re-launched with the objective of ensuring availability of quality medicines at affordable prices to all.

PLUS REPORT • MY MARKET • THE LAST MILE

MAKE IN INDIA

QCI
Quality Council of India

ZED™
ZERO DEFECT • ZERO EFFECT

Certification Scheme

A roadmap to World-class manufacturing

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"

SHRI NARENDRA MODI
Hon'ble Prime Minister

Free Registration at www.zed.org.in

zed@qcin.org @ZED_QCI

VIEW  POINT

BEJON KUMAR MISRA | bejonmisra@consumerconexion.org

Towards Affordable Healthcare

ACCORDING TO WORLD Health Organisation estimates (2008), 65 per cent of India's population does not have access to modern healthcare. Further, according to National Statistics Office estimates, up to 79 per cent of health care expenses in rural areas are due to the cost of medicines. Thus, access to low-priced generic drugs is critical to ensuring reasonable healthcare.

Brand medicines in India appear cheap when compared with international prices, however the brand medicines in India are expensive in comparison with generic medicines. The brand medicines despite being expensive are preferred over generic medicines by the prescribers due to exhaustive marketing practices by the manufactures. Although generic medicines are available at affordable prices they are not preferred over brand medicines. The price sensitivity for medicine appears to be very low. Medicines that are sold in government-run medical shops are 50-90 per cent cheaper compared to the branded ones and they strictly adhere to the international norms prescribed by the World Health Organization (WHO).

Several people have been realizing the benefits of these medical stores called 'Jan Aushadhi Kendras' run under the government's 'Pradhan Mantri Jan Aushadhi Pariyojana' .

Echoing the thoughts of our Hon'ble Prime Minister who feels the motive behind this scheme is making healthcare affordable and encouraging Ease of Living. This is a great help for the common man, especially for senior citizens who require medicines on a daily basis and results in a lot of savings. There are over 3000 such generic stores operational across the country.

This has led not only to availability of cheaper medicines, but also new employment opportunities for individual entrepreneurs. Affordable medicines are now available at 'Amrit Stores' at Pradhan Mantri Bharatiya Jan Aushadhi Centres and at hospitals.

The sole aim behind this step is ensuring availability of quality and affordable health service to the poorest of the poor, so that a healthy and prosperous India comes into being.

Medicines that are sold in government-run medical shops are 50-90 per cent cheaper compared to the branded ones.

Message from the Editor-in-Chief

POOJA KHAITAN
pooja@jagograhakjago.com

An Effective Market Intervention Strategy

DEMONETARIZATION OF CURRENCY notes of five hundred rupees and thousand rupees denominations is hailed because of surgical strike against black money, terrorist funding and also corruption. On the comparative lines the Government of India has introduced the Jan Aushadhi scheme to give a jolt to the uncontrolled medicine prices across all therapeutic category of medicines in India. The *Jan Aushadhi* campaign is expected to make a great contribution by way of achieving the socio-economic goal of affordable healthcare, by ensuring availability of quality drugs at affordable prices for all.

The scheme is also expected to reduce expenditure on medicines, thereby extending patient coverage under the public health scheme. Popularisation of the use of unbranded generic medicines will reduce out-of-pocket expenses on medicines for the common man, thereby making healthcare affordable and safe. 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' will prove to be an effective market intervention strategy to bring down the prohibitively high prices of medicines, and will create market for drugs manufactured in Central Public Sector Undertakings (CPSUs), other state PSUs and private sector, particularly small and medium enterprises.

However, in order to promote generic drugs, some additional measures are required, such as the use of software to make the names of generic drugs available to all doctors. to facilitate generic medicines prescription and better awareness among prescribers, consumers and sellers; a drug policy which supports local industry; effective regulatory framework; and legislation making prescription of generic drugs (except when options in generic not available) should be mandatory. The journey of providing affordable healthcare should not end here. In a lecture on the subject at Tata Institute of Fundamental Research, Nobel Laureate Amartya Sen said that healthcare should include other social determinants (nutrition, sanitation & social equity) too. He also laid emphasis on a higher allocation of GDP towards healthcare. Lamenting on the exploitation of poor patients by private doctors, he said, "many of the private doctors know extraordinarily little, combining quackery with crookery," and stressed on the need to protect poor patients from being exploited by these private doctors.

We need to carry on this journey forward taking our cue from the past failures and the way suggested by various experts.

INSIDE

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UNLOCKING CONSUMER POTENTIAL
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Bejon Kumar Misra
PUBLISHER
Address: F - 9, Second Floor, Kailash Colony,
New Delhi - 110048
E-mail: bejonmisra@consumerconexion.org

EDITOR-IN-CHIEF
Pooja Khaitan

EDITORIAL CONSULTANTS
Praful D. Sheth
Bina Jain
Suman Misra
Manisha Bhatla
Pyush Misra
Maanav Khaitan
Harshal Gajjar
Shashank D. Sudhi
Shashi Bhushan

MANAGER CIRCULATION
Nirmal Dayal

DESIGNER: Galaxy
DESIGN CONSULTANT: Maanav Khaitan

WEB DESIGNER:
Manish Mohan
Ebrahim Bhanpurawala

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Greater Kailash Enclave - I, New Delhi-110048

For any queries, please contact us at
pooja@jagograhakjago.com
Phone: 011-26271421/22/23

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DR YASMIN ALI HAQUE
UNICEF'S COUNTRY REPRESENTATIVE IN INDIA

There has been a decline of 22% in maternal mortality ratio, from 167 per 100,000 live births in 2013 to 130 in 2016. It is a great achievement for a country like India and it makes us believe that India will meet the target it has set for 2030 (bringing it under 100 per 100,000 live births) under the sustainable development goals.

ROUNDUP

Jan Aushadhi Scheme 2.0

An Overview

A REPORT PUBLISHED in May 2017 by Global Burden of Disease, has revealed that India has recorded a poorer healthcare index as compared to the neighbouring Asian nations of Bangladesh, Bhutan, Sri Lanka and China in the last 25 years.

The Inclusive Growth and Development Report 2015 published by the World Economic Forum suggested that India must take further action to ensure that the growth process is broad-based in order to expand a small middle class and reduce the share of the population living on less than $2 a day (many of them in poverty despite being employed). The report pointed out that on a policy level, social spending continued to be low, which limited accessibility of healthcare and other basic services, resulting in poor health outcomes.

DATA BRIEFING

The Indian healthcare market, which is worth around US$ 100 billion, will likely grow at a CAGR of 23% to US$ 280 billion by 2020.

First Drug Policy formulated in 1978

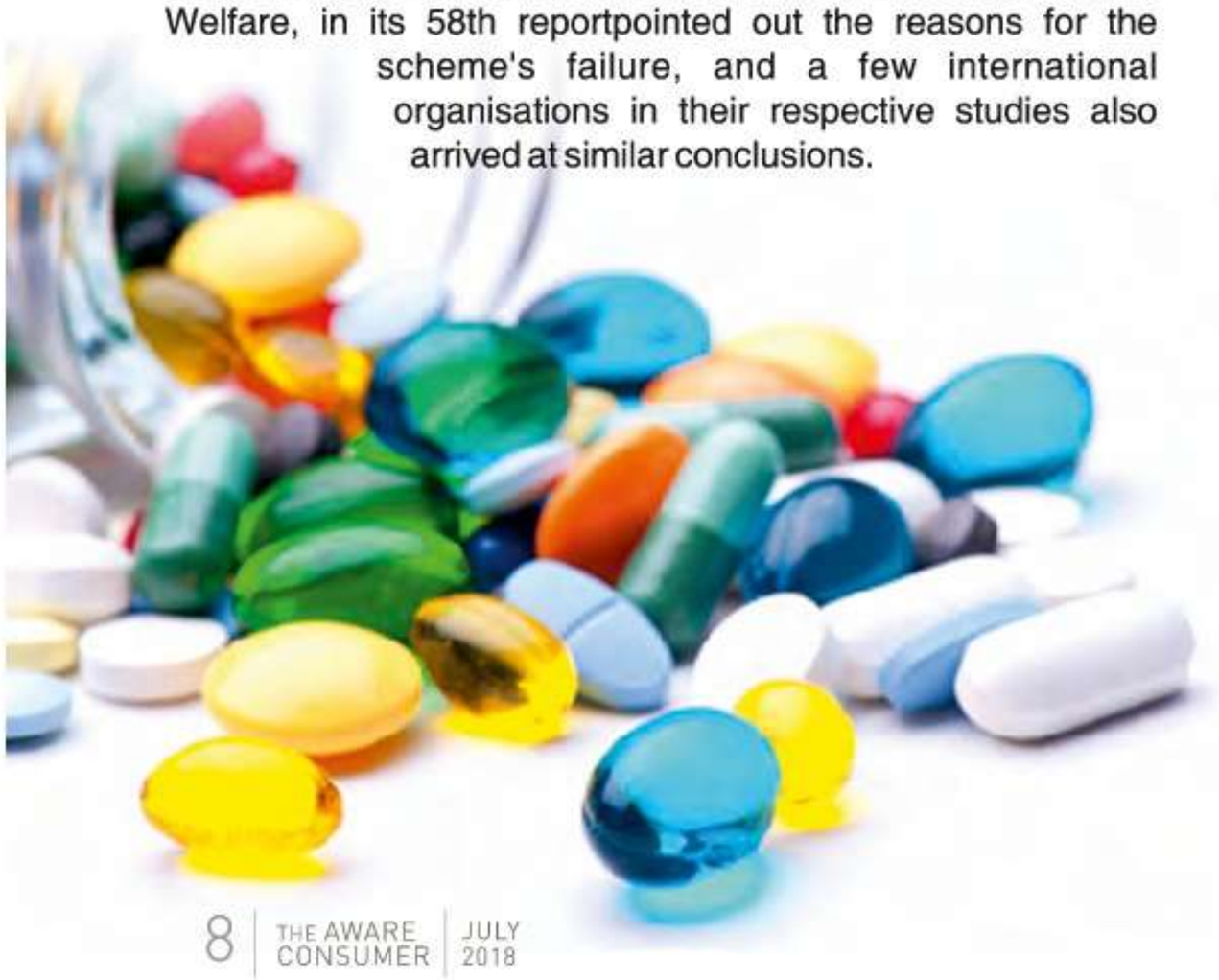
A careful analysis of the past initiatives by the government establishes that lack of policy is certainly not the reason for this poor healthcare index. In 1978, on the basis of the Hathi Committee report, the first Drug Policy was formulated. The report, among other issues, suggested measures for ensuring that all essential drugs were made available to the consumers at reasonable prices. This was followed by the Drug Policies in 1978-79, 1986-87, 1994-95, the Pharmaceutical Policy of 2002, which too mostly dealt with price control. Though the industry evolved over the years with a strong capability in producing quality branded and generic medicines, which compared to other countries was reasonably priced, yet a large population of poor people in the country could not afford the more expensive branded category of medicines.

Jan Aushadhi Scheme (JAS) launched in 2008

Hence, to provide institutional healthcare support to the relatively poor, the *Jan Aushadhi* Scheme (JAS) was launched for the first time in 2008.The campaign aimed at achieving the following goals:

1. To make available quality generic medicines at affordable prices for masses by sale through outlets called *Jan Aushadhi* stores.
2. To encourage doctors in government hospitals to prescribe generic medicines.
3. To reduce the out-of-pocket expenses for patient treatment.
4. To promote awareness about cost-effective drug prescriptions through education.
5. To develop a sustainable business model for the programme.

The campaign failed to achieve its desired results. The Parliamentary Standing Committee on Health and Family Welfare, in its 58th reportpointed out the reasons for the scheme's failure, and a few international organisations in their respective studies also arrived at similar conclusions.



jan aushadhi
Quality Medicines At Affordable Prices for All

Why Did the Scheme Fail to Take Off?

The Public Health Foundation of India (PHFI) was entrusted the task of a third party evaluation of the scheme. In its final report, "Rapid Assessment and Potential Scale up of *Jan Aushadhi* Scheme" submitted on December 18, 2012, PHFI identified potential challenges in scaling up the scheme. The report pointed out that over-dependence on support from state governments, poor supply chain management, non-prescription of generic medicines by the doctors, state governments launching free supply of drugs and lack of awareness among the public were the main reasons for the failure of the scheme.

Additionally, not all JAS prices were lower than branded medicines. For example, the cheapest branded *cefuroximeaxetil* (500 mg) (antibiotic) in the market was almost three times cheaper than its JAS price.

Pricing of Medicines

From the policy perspective, it raised serious questions regarding the pricing of medicines in the JAS and its overarching goal. Since patients were dependent on physicians for medicine prescriptions with little knowledge of the price variations among branded and generic medicines, the JAS did not provide the cheapest alternative for the patients. Hence, there was a need to urgently review the JAS prices to achieve its goal of providing low-cost affordable medicines. Furthermore, strong supply-side regulations such as prescription audits were necessary to prevent the widespread prescription of costly branded medicines. In the absence of such steps, the JAS policy did not meet its objective of providing low-cost affordable medicines and financial risk protection to households from the cost of medicines.

Also, due to lack of awareness and owing to old habits, doctors in government hospitals continued to prescribe branded medicines. The Drugs and Cosmetics Act 1940 and the rules framed there-under do not allow the substitution of branded medicines with generic medicines by the pharmacists at store. News reports indicate that modifications to the Drugs & Cosmetics Act to legally allow pharmacists of *JanAushadhi* stores to offer alternate generic drugs to customers instead of prescribed branded drugs have been suggested by the ministry concerned. This should be expedited and safeguards evolved so that interest of poor patients is secured.

This issue was discussed in the 45th Report of the Parliamentary Standing Commmittee on Health andFamily Welfare in the following words:

"One of the suggestions put forth before the Committee was to make it mandatory for all doctors to write all prescriptions in generic names only. However, the Committee feels that going for a "generic only" prescription policy has its flip side. Even if the doctor prescribes a drug by generic name, the chemist will be free to dispense any equivalent. Thus the power will shift from doctors to the chemists. The pharma companies would unethically start wooing the chemists instead of doctors. This will be worse than current situation. If the patient does not get any relief, doctor will blame the chemist. Moreover, while the

Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana

doctor has some interest in the continued patronage from the patients, chemists could not care less. For them profits will be the only criteria of selling medicines." Taking clue from this, immediate steps are required to provide cheaper medicines to the poor people, as envisaged under the government programme.

Major Bottlenecks in Implementation

1. **Stringent Eligibility Criteria for Operating Entities:** Although the revised plan permitted any NGO/charitable society/institution/self-help group with experience of minimum three years of successful operations in welfare activities, supported by three years audited accounts, eligible and individual pharmacists/registered medical practitioners even outside the hospital premises, in addition to the state government's nominated operating agencies, to open *Jan Aushadhi* Stores in the government hospitals, the scheme did not succeed. Thus it seems that further revised lenient criteria would be required.
2. **Medicines for All Ailments Were Not Available:** Even the reviewed and further expanded list of items for sale at the *Jan Aushadhi* stores failed to cover all therapeutic categories of drugs.
3. **Supply-Chain Management Non-Efficient:** The lack of adequate monitoring of availability of medicines at the Bureau of Pharma Public Sector Units of India (BPPI)'s warehouse, led to stock out situation of medicines. This non-availability of medicines due to lack of supervision frustrated the purpose of the scheme.
    1. **Sourcing of Drugs:** All the drugs were not procured through open tender system, resulting in short supply of drugs due to issues with manufacturers and suppliers.
    2. **Working Capital:** Under the scheme there was a lack of adequate funds for providing working capital advance to the Central PSUs to facilitate the production and supply of medicines in time.
    3. **Arbitrary Policies of the States:** All the states did not have the same policies and some state governments provided free medicines to all patients visiting government hospitals. This restricted the success of the scheme.
4. **Lackadaisical Media Campaign:** Media campaigns play an important role in educating people about government schemes, especially on the use of generic medicines, and more specifically, on the benefits of the *Jan Aushadhi* Campaign. The scheme did not initiate necessary steps so that people could take full advantage of the availability of generic medicines at affordable prices at the Jan Aushadhi stores.
5. **Lack of Monitoring:** Progress in implementation of the scheme was not reviewed regularly, thus negating accountability.

SUPPORT THE CAMPAIGN

LOOK OUT FOR THE RED LINE

BE RESPONSIBLE

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.

Campaign Partners

OPPI · MSAI · IAPG · Consortium of Association of community Pharmacist of India & Kautilya Society for Pharmacoeconomics and Outcome Research · Patient Safety and Access Initiative of India Foundation, a Partnership for Safe Medicines India Initiative

SIGN THE PLEDGE.

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

Jan Aushadhi Scheme 2.0

IN ORDER TO infuse life into the previously failed scheme, a laudable step forward by the present government is the '*Pradhan Mantri Bhartiya Janaushadhi Pariyojana*' a campaign re-launched by the Department of Pharmaceuticals to provide quality medicines at affordable prices to the masses through special *kendra's* known as *Pradhan Mantri Bhartiya Jan Aushadhi Kendra* (PMBJK).

Thus, PMBJKs have been set up to provide generic drugs, which are available at lesser prices but are equivalent in quality and efficacy to expensive branded drugs. In essence, this is a revamped JAS, with better strategies in place.

However, the focus on generic drugs has inherent nomenclature issues in India. The Drugs and Cosmetics Rules do not identify the distinction between generic, branded generic and branded medicines. The basis of categorisation is as follows:

1. **Branded Medicines** contain one or more ingredients marketed under brand-names given to them by their manufacturers in India. These are normally promoted to doctors. [In western countries, brand-name medicines are defined differently: the term refers to new drugs developed by the innovator patent holding companies].
2. **Generic Medicines** are those which are marketed under their chemical/salt names. [In western countries "generic" medicines are defined differently i.e. products that contain the same ingredient(s) as brand-name medicines but are manufactured after the expiry of patents by companies other than innovators. These are marketed under new brand names]
3. **Branded-Generics** is an exclusively Indian terminology and refers to branded products [same as category (a) above] but not promoted to the medical profession and marketed through heavy incentives to retail chemists. Obviously such products are unethically and illegally sold either without prescriptions or by substituting prescribed brands.

The distinction that is drawn in India between branded products and generics has more to do with marketing strategies than nomenclature of the product. The so-called generics in India are pushed directly through retailers rather than through doctor's prescriptions. As a consequence, the generics in India provide high trade margins as opposed to the high promotional costs that are built into the pricing of the branded products.

To make matters worse, even the so-called generics typically have specific brand names and the name of the "Active Pharmaceutical Ingredient", although given the prominence required by law under the Drugs & Cosmetics Act, is not popularised in the manner that it should. This state of affairs tends to obscure the fact that true generics have no role to play at present in the Indian drug scene, as was observed by the Task Force in 2005.

Suggestions on Making the Scheme a Great Success

THE TASK FORCE to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices submitted its report in September 2005. It felt that in order to make the proposed system of price regulation effective, a number of collateral measures need to be implemented. Some recommendations of the task force, worthwhile in the context of promotion of generic drugs, are given below:

All other drugs (other than controlled drugs) should be brought under a comprehensive price monitoring system with appropriate market-based reference prices and with mandatory price negotiations, if necessary.

The regulatory mechanism should be significantly strengthened both at the Centre and in the states. Since quality, quantity and price are to be addressed in an integrated manner, there should be a unified regulatory structure covering all aspects.

A process of active promotion of generic drugs should be put in place, including mandatory de-branding for selected drugs. All public health facilities should be required to prescribe and dispense generic drugs, except in cases where no generic alternative exists. The government should consider providing financial support to dedicated generic manufacturers and small-scale units for achieving Schedule M compliance. For this, the Department of Chemicals & Petrochemicals should formulate a separate planned scheme to be funded through the budget. The government should create and maintain a public website with complete data on prices of all formulations by APIs (Active Pharmaceutical Ingredients) and therapeutic categories which can be used by medical practitioners, and perhaps even consumers, for price comparison purposes.

Consumers, Beware

Brand Name Drugs

- Also called “innovator drugs”
- Initially marketed as new chemical entities
- First version sold by the innovator manufacturer

Generic Drugs

- Copies of brand name drugs
- Produced after the original patent expires

IF YOU'VE HAD a prescription filled recently, there's a good chance you're taking a generic drug. Almost 80% of prescription drugs sold are generics. That option helps save patients and hospitals billions of dollars every year.

It's estimated that you could save at least two-thirds of your drug costs if you use generic drugs.

According to the FDA, generic drugs can be trusted to have the same quality as brand-name drugs -- but at a cheaper price. That's important to know because no one wants to skimp on health, even if it means saving money.

How Are Generics the Same as Brand-Name Drugs?

The FDA requires a generic drug to meet standards that ensure it's the same basic product as the brand-name drug. That means the generic drug is safe and can be taken:

- The same way as a brand-name drug
- For the same reason as a brand-name drug

For the FDA to approve a generic drug, it must be the same as the brand-name product in:

- Active ingredient
- Strength
- Use and effect
- How you take it (for example as a pill, inhaler, or liquid)
- Ability to reach the required level in the bloodstream at the right time and to the same extent
- Testing standards

How Are Generics Different From Brand-Name Drugs?

Some differences between generics and brand-name drugs are allowed. These may change the look of the drug. But they don't affect how it works or its safety.

Generic drugs may differ in:

- Shape
- Color
- Packaging
- Labeling (minor differences)

Generic drugs are allowed to have different inactive ingredients than brand-name drugs. For example, they may have a different:

- Flavoring
- Preservative

The inactive ingredients in a generic, though, must be considered safe by the FDA.

Generic drugs may also have a different expiration date than brand-name drugs. But even so, the generic must keep its effectiveness until its expiration date, just like a brand-name product.

Why Are Generic Drugs Cheaper Than Brand-Name Drugs?

You may be wondering how a generic drug can be sold at a much lower price than a brand-name drug.

The difference in price has to do with the different costs drugmakers have in bringing generics and brand-name drugs to the pharmacy shelf.

Making a new drug is expensive. A manufacturer's costs for the launch of a new drug include money for:

- Research
- Large-scale drug testing
- Advertising, marketing, and promotion

The FDA has tried to balance the rights of the maker of brand-name drugs to recoup its investment with the rights of patients to have access to lower cost generic drugs. To help a drugmaker recover its costs, new brand-name drugs are given patent protection when they are first sold.

The patent gives a drugmaker exclusive rights to produce and sell the drug for a limited time. The average time a brand-name drug is protected by the patent after it hits the market is 12 years.

When the patent ends, other companies are allowed to make and sell a generic version. The generic drugmaker's costs are relatively low because the product has already been developed and tested by the brand-name company.

So makers of generic drugs can pass the savings along in the form of lower prices to pharmacies and ultimately to us. The competition among multiple companies producing a generic version of a drug also helps keep the price low.

Are Any Groups Challenging the Safety of Generic Drugs?

Some groups have raised questions about the FDA requirements for proving a generic drug acts in the same way as the brand-name drug.

To prove a generic drug works the same way as a brand-name drug, the manufacturer needs to show there's no significant difference in the rate and extent to which the drugs are absorbed into the body.

Scientists perform tests to measure this difference and describe the results in the form of a percentage. Most scientists agree that a 20% difference in the way a drug is absorbed is acceptable.

Some groups, though, claim that percentage is too large and could cause problems based on how much of the drug is in a person's system at any one time.

The FDA reports that there have been no recorded problems related to the variation in absorption for drugs that meet this requirement.

The FDA has conducted two large studies to learn the actual variation in absorption between brand-name drugs and their generic versions. The studies show that the average variation is 3.5%. That's a variation that can be expected even between two separate batches of the same brand-name or generic drug.

> "There's a need to engage small scale drug industries to produce quality generics
> **— Universal Health Coverage report**

Should You Be Taking Generic Medication?

Generics are not available for all medications. The best way to find out if a generic is available for a medication you are taking -- and whether or not you should take it -- is to ask your doctor and pharmacist.

Generally, your pharmacist can substitute a generic drug for a brand-name drug. If a generic is available, but for some reason your doctor thinks you should still take the brand-name drug, he'll write "Do Not Substitute" on the prescription.

If your pharmacist for some reason does not substitute a generic for a brand-name drug, you can ask your doctor to indicate on the prescription that substitutions are acceptable. That way, you can get the same drug for a lot less money.

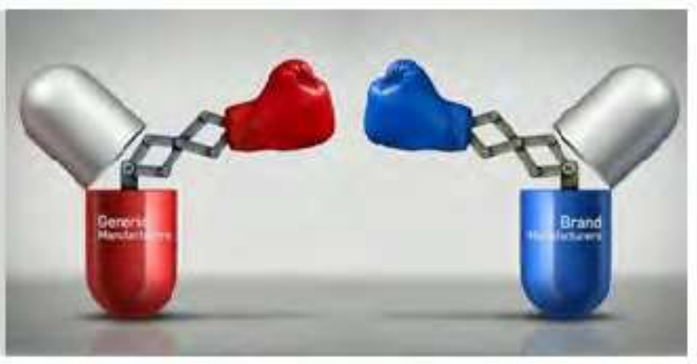
It can get confusing. Don't be afraid to ask your pharmacist if the medication you received is the generic form of the medicine you are used to taking.

Tell your doctor if you notice any change in your condition or have any unusual side effects when changing from a brand-name to a generic drug.

And don't forget that nonprescription drugs may also be sold as generics. You might find them under the store's in-house label. They can also save you money.

Bottom Line

- Generic and brand name drugs are bioequivelant.
- Clinically important differences have not been reported in well-controlled trials.
- Generic drugs create savings that can be redirected elsewhere.



Breathing Life Into India's Healthcare

THE GOVERNMENT OF India breathed life into the Jan Aushadhi Programme, 2008, and plans to run it on a Campaign Mission Mode. The Jan Aushadhi Campaign is a self-sustaining business model re-launched in March by the Department of Pharmaceuticals under the Pradhan Mantri Jan Aushadhi Scheme. Based on the principle of Not for Profits but with Minimal Profits, this programme has been re-launched with the objective of ensuring availability of quality medicines at affordable prices to all. The Pharmaceutical Industry in India has developed a strong capability to produce quality branded and generic medicines in most of the therapeutic categories, and has in the past three decades evolved from a 1500 crore industry in 1980 to a 1,19,000 crore industry in 2012. Unfortunately, though most of these medicines are priced reasonably as compared to other countries, the poor in India are still unable to afford the branded ones. The Government of India had stepped in to help the poor through regulations such as Price control of Scheduled and Non-Scheduled Drugs, Uniform VAT, and Reduction in Excise duty. To further alleviate the condition of the poor and help them attain better quality of life through access to quality medicines, the government has now launched the Jan Aushadhi Campaign.

What are Generic Medicines?

Generic drugs are drugs with the same chemical composition as its equivalent with an advertised brand name.

- It is basically the chemical name of a drug.
- It is comparable to its counterpart with a brand name in dosage, strength, quality and performance.
- Without the brand name, generic medicines are available at a lesser price.
- It goes without saying that when a generic drug is made available in the market, the cost of the same medicines under a brand name also drop substantially.
- Generic drugs can be legally produced in India after the patent time period of 20 years has elapsed.
- The expiration of a patent removes the monopoly of the patent holder on drug sales licensing.

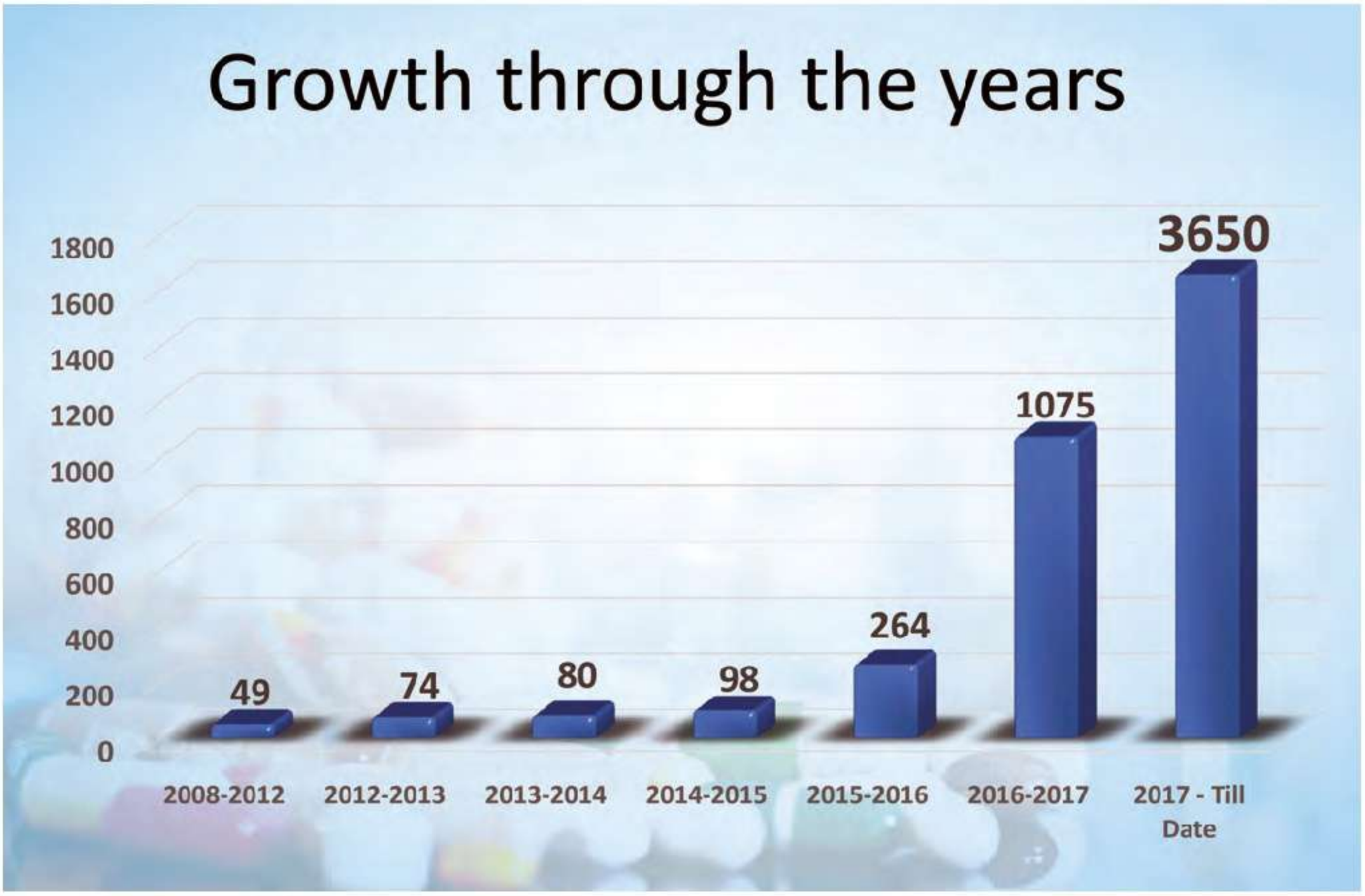
The Features & Objectives of Jan Aushadhi Campaign

A Task Force of senior officers of the Department of Pharmaceuticals, CEOs of Pharma CPSUs, representatives of Pharma industry, NGOs/charitable organizations, State Governments, doctors from reputed national level institutions like AIIMS, Maulana Azad Medical College and RML Hospital, and senior representatives from WHO was constituted to implement the Jan Aushadhi Campaign. This programme has been launched in collaboration with the Central Pharma Public Sector Undertakings (CPSU) as part of their Corporate Social Responsibilities agenda.

With the aim of making generic medicines more accessible and available to the public at large and to the poor in particular, the following steps are being taken under the scheme:

- Make quality the hallmark of medicine availability in the country, by ensuring, access to quality medicines through the CPSU supplies.
- More than 700 medicines will be available under the scheme.
- The medicines will be tested by the National Accreditation Board for Testing and Calibration Laboratories (NABL).
- Extend coverage of quality generic medicines under the budget to redefine the treatment cost per person. The budget outlay for Jan Aushadhi stores is around Rs.35 crore.
- To make generic drugs available to every strata of the society; the poor as well as the rich.
- This campaign will not be restricted to Public Health System. The Private Sector will also be encouraged to participate with zeal and conviction for maximum coverage to the most remote locations in India.
- Create an awareness drive among the people about the generic medicines and their potency in spite of their lower prices.
- Encourage doctors to prescribe unbranded generic medicines.
- Enable substantial savings in health care, particularly in the case of poor patients and those suffering from chronic ailments requiring long periods of drug use.
- To open Jan Aushadhi stores across India to ensure availability of unbranded quality generic medicines at lower prices.
- The stores will be opened in Government hospitals and other suitable places with easy accessibility.
- The aim is to open 5000 Jan Aushadhi Stores. The government has already opened 3650 stores.
- The government is giving incentive to the storeowners with a financial assistance of up to Rs two lakh and a further Rs 50 lakh for purchase of hardware.

More than 500 medicines will be available under the scheme.



- The storeowners will also be able to buy the medicines at 16% discount, which will be a profit for them.
- To help other under-developed and developing nations in the common goal of improved quality of affordable healthcare through the model created.

Expectations from the Programme

The Jan Aushadhi programme is expected to redefine the principles of production, retail trade and drug prescription by doctors. A National List of Essential Medicines, 2003, which can be bought over the counter, has been prepared for the purpose. A list of Unbranded Generic medicines, commonly used by patients for chronic and other diseases, has also been prepared. The National List of Essential Medicines, 2003 (NLEM, 2003) has also been used for this purpose. Each State has been asked to add on to this list names of drugs which are commonly used by the people in that particular area.

It is ironic that even though Indian pharma companies rank among the top performers in the global generics market, offering quality medicines at affordable prices to patients across the world, an initiative to do the same within the home market floundered for seven years. As Dr Ajit Dangi, President and CEO, Danssen Consulting informs, "The old scheme of Jan Aushadhi, which was launched in 2008, is already struggling to survive. The new scheme is a fresh lease to infuse some life into the old". Currently less than 200 shops are functional under the old scheme. Study shows that, largely due to the dependence on public sector unites for supply, availability of medicines was only about 33 per cent.

The key challenge in the scheme will be implementation and execution with due care that the end customer does not land up with fake or spurious drugs. However, there is no doubt about the fact that this scheme should be implemented on a war footing so that the rich and the poor alike are able to avail quality healthcare for a better life.

Who can open Jan Aushadhi stores?

Non-governmental organizations, charitable institutions, private hospitals, reputed professional organizations and self help groupscan open new Jan Aushadhi stores. Individual entrepreneurs are eligible to apply for new Jan Aushadhi stores. The applicants shall have to employ one B Pharma / D Pharma degree holder as Pharmacist in their proposed store.

One-time assistance of Rs.2 lakh for establishment and one time start up cost of Rs. 50,000 is paid to the operating agency of each outlet as government assistance.

Product Basket

Product basket comprises more than 700 medicines and 154 surgical items and consumables

- Medicines cover covering all major 22 therapeutic groups like
  - Anti Diabetics
  - Cardiovascular Drugs
  - Anticancer
  - Analgesics & Antipyretic
  - Anti allergic
  - Gastro Intestinal Agents
  - Vitamins, Minerals & Food supplements
  - Topical Medicines
- Surgical & Consumables include
  - Crepe Bandages
  - Cotton Bandages
  - Syringes
  - Needles
  - Sanitary Napkins
  - Baby Diapers etc

How many medicines are covered under this scheme?

At present 700 medicines and 150 surgicals are covered by this scheme and the government proposes to increase it further. These medicines are packed in special Jan Aushadhi packs with bilingual labels stating clearly the generic name of the drug.

About Jan Aushadhi Store (JAS)

1. JAS have been opened across the country.
2. The normal working hours of JAS are 8 Am to 8 PM.
3. All therapeutic medicines are made available from Jan Aushadhi Stores.
4. In addition to medicines and surgical items supplied by BPPI, Jan Aushadhi stores also sell allied medical products commonly sold in chemist shops so as to improve the viability of running the Jan Aushadhi store.
5. OTC (Over-the-counter) products can be purchased by any individual without a prescription. A prescription from a registered medical practitioner is necessary for purchase of schedule drugs.
6. BPPI (Bureau of Pharma Public Sector Undertakings of India) has been established under the Department of Pharmaceuticals, Govt. of India, with the support of all the CPSUs for co-coordinating procurement, supply and marketing of generic drugs through the Jan Aushadhi Stores.
7. The quality, safety and efficacy of medicines are ensured by getting each batch of medicines procured from CPSUs as well as private suppliers tested from NABL approved laboratories and conforming to the required standards before the same are supplied to Supers tockists /Jan Aushadhi Stores from the Warehouse of BPPI.

Financial support available for Jan Aushadhi Store (JAS) store owner

The following financial support is available:

NGOs/agencies/individuals establishing Jan Aushadhi stores in Government hospital premises where space is provided free of cost by Government to operating agency:

BPPI will provide one time financial assistance up to Rs. 2.50 lakh as per details given below

- Rs. 1 lakh reimbursement of furniture and fixtures.
- Rs. 1 lakh by way of free medicines in the beginning.
- Rs. 0.50 lakh as reimbursement for computer, internet, printer, scanner, etc.

- 20% trade margin shall be included in MRP for retailers and 10% for distributors.
- Jan Aushadhi stores and Distributors will be allowed 2% of total sales or actual loss, whichever is lower, as compensation against expiry of medicines. Expired goods need not be returned to BPPI. Stocks expiring at the C&F level will entirely be the loss of BPPI.
- Credit facility will be given to all Jan Aushadhi stores for 30 days against postdated cheques. Distributors will also get credit of 60 days against post dated cheques. C&F agencies will have to deposit a security amount depending upon the business.

Jan Aushadhi stores established anywhere else by private entrepreneurs / institutions / NGOs / Trusts / Charitable organizations which are linked with BPPI headquarters through internet.

- Financial support of 2.5 lakhs. This will be given @ 15% of monthly sales subject to a ceiling of Rs 10,000/ per month up to total limit of 1.5 lakhs. In NE states, and naxal affected areas, tribal areas, the rate of incentive will be 15% and subject to monthly ceiling of Rs.15,000. up to total limit of 2.5 lakhs.
- The Applicants belonging to weaker sections like SC/ST/Differently-abled may be provided medicines worth Rs. 50,000/ - in advance within the incentive of Rs. 2.5 lakhs which will be provided in the form of 15% of monthly sales subject to a ceiling of Rs. 10,000/ - per month up to a total limit of Rs. 2.5 lakh.
- 20% trade margin shall be included in MRP for retailers and 10% for distributors.

- Jan Aushadhi stores and Distributors will be allowed 2% of total sales or actual loss, whichever is lower, as compensation against expiry of medicines. Expired goods need not be returned to BPPI. Stocks expiring at the C&F level will entirely be the loss of BPPI.
- Credit facility will be given to all Jan Aushadhi stores for 30 days against postdated cheques. Distributors will also get credit of 60 days against post dated cheques. C&F agencies will have to deposit a security amount depending upon the business.

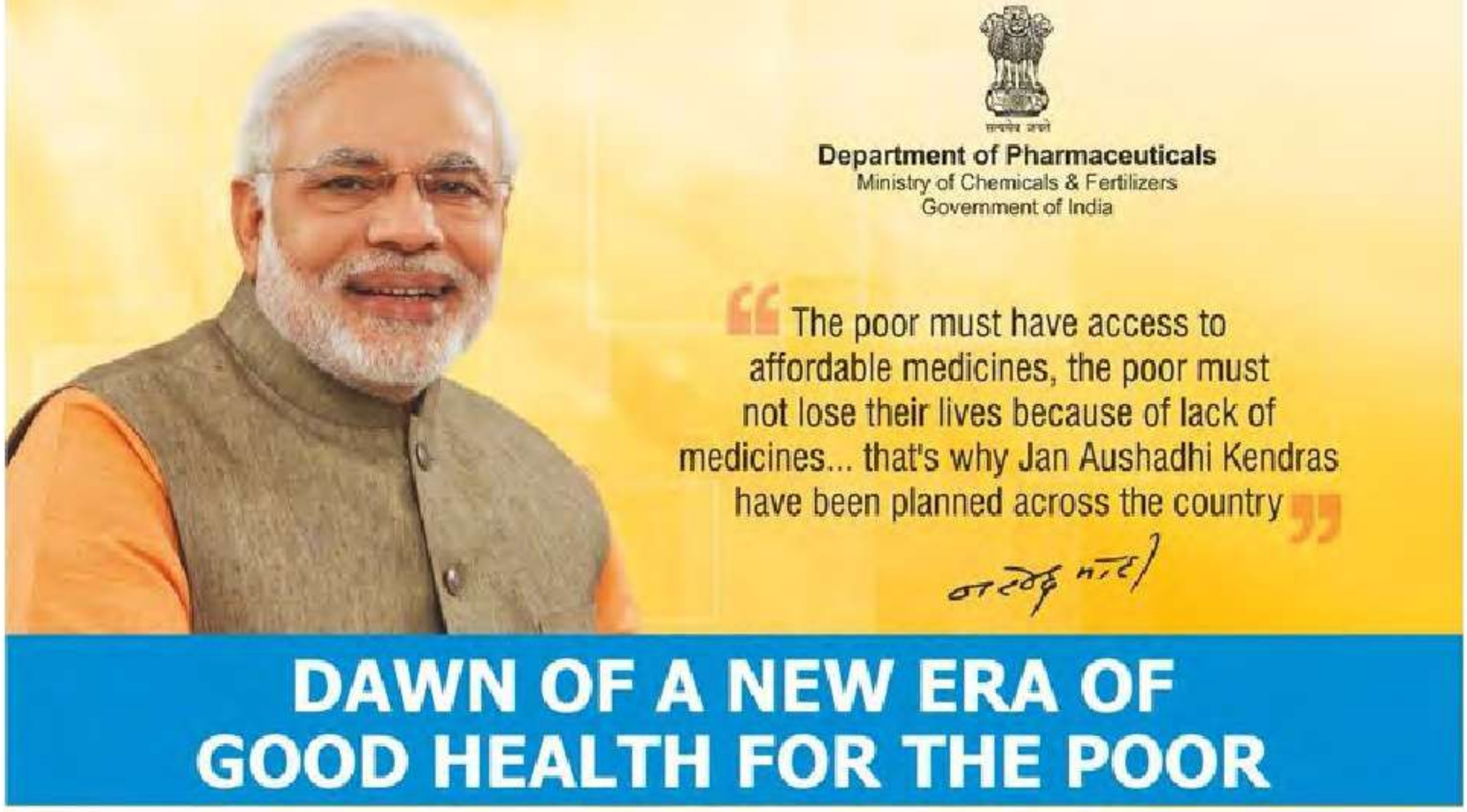
The Counterpoint

The JAS is a direct market intervention by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers but not Health Ministry. The JAS needs to be supported mutually for better success. In India, the production of medicines is under the Ministry of Chemicals and Fertilizers and Ministry of Health deals with healthcare programs and health issues of the nation. In India, the health is a state subject and GOI only controls national health programs. Health is also not a fundamental right as per the Constitution of India. These factors have a huge impact on any scheme and program related to health like JAS. The JAS, which is for improving the health of the citizens and helping the marginalized populations with affordable medicines, needs to be supported by all. The fragmented concern is one of the major reasons why the golden step like JAS is not successful even after 8 years of its introduction.

REPORT

Pradhan Mantari Jan Aushadi Kendra :

Demonetarization of Medicine Prices in India



MEDICINES ARE THE vital components of therapeutics which are manufactured, distributed and sold to the patients under various regulations like Drugs and Cosmetics Act and Drug Price Control. The handling of drugs at various stages are carried out by a team of healthcare provider's viz., Doctors, Pharmacist and Nurses. Healthcare professionals are registered and regulated by respective statutory bodies. The PCI is supposed to monitor, nurture and maintain standards of Pharmacy profession in India. Similarly Medical council of India and Nursing council of India are responsible for establishment and maintaining of respective professional practices. The objective of the council is to establish professional standards. Collaborative healthcare in which the contributions of Doctor, Pharmacist and Nurses in team work is to ensure patient safety and optimize acceptable outcomes is a mirage in healthcare delivery.

In India healthcare practice is greatly influenced by the lobby of Pharmaceutical industry and organizations of Doctors and Pharmacist. These organizations are meant to protect interest of their members of pharmaceutical industry and organization has not shown interest in public healthcare issues like affordability and medicine prices. The Pharmaceutical industries are governed by Drugs and Cosmetics Act, Drugs and Magic remedies Act, Narcotic drugs and poisons Act and Drug price control order, they are supposed to protect the patients and health consumers from the danger and damages caused by irrational prescription medicines. Drug safety is a major issue of healthcare provision, which is masked by the corrupt practice of the healthcare providers. Distribution and sale of medicines are governed by Drugs &Cosmetics Act (Schedule N) and Pharmacy Act. The pharmacists are licensed to establish whole sale outlet and retail outlets as per the provisions of the Drugs and Cosmetics Act. The Pharmacist is a custodian for all prescription medicines and are supposed to dispense the medicines against prescription by a registered medical practitioner. It is an

offence to sell prescription medicines without prescription to patients and health consumers. The pharmacists also establish the organization and offices across the countries that are involving in protecting the interest of their own members rather than public health.

All therapeutic medicines carry a risk on health. Hence they are capable of inflicting serious injury and damage if they are used indiscriminately. Every medicine has dose response relationship. The response of the drug is usually determined by the concentration of drug in the blood. There are two critical concentrations which determine the response of the drug on the human body, the minimum critical concentration and minimum toxic concentration. The gradient between minimum toxic concentration and minimum effective concentration is known as the therapeutic window. It is desirable that the drug concentration should remain below the minimal toxic concentration, if the concentration exceeds minimum toxic concentration the drug is likely to act like poison leading to various adverse drug reactions and organ damage. For example the drugs like gentamycin which is known to cause damage to kidney and the blood levels, should be monitored while using and never be allowed to exceed the minimum toxic concentration. Some important drug related various vital organs toxicity is listed in **(Table 1)**.

The Pharmacovigilance which was not carried out in earlier times has gained much importance in recent times. Patient Safety has become more important than therapeutic efficacy as the medicines are causing much harm than being useful. Indiscriminate use of medicines is bound to cause severe ill effects on human health. Hence the government of India has made it mandatory for all the Pharma industries to establish the Pharmacovigilance program for its own products and submit data for continuing the licenses for marketing the product.

The potential risk of health in therapeutics need to be documented and revived by continuous surveillance of effect of drugs on human health.

The collected data from various companies are analyzed by the Central Drugs Standard Control Organization (CDSCO). After reviewing the data the risk of the medicine over the benefits is analyzed by CDSCO and has been empowered to recommend banning of the unsafe medicines. This data is shared with world Pharmacovigilance center in Uppsala, Sweden for further scrutiny of Global policy recommendations.

The International Pharmacovigilance program is promoted by World health Organization located in Uppsala, Sweden.

The aim of Pharmacovigilance is to collect various adverse drug reactions caused by medicines and view the collected signals across the world to identify the cause and magnitude of adverse drug reaction (ADR). If the risks involved are serious then they further alert the various governments to ban unsafe drugs by respective governments. India is described as den of poor man medicines. Indian pharmaceutical sector produces quality branded and generic medicines in most of therapeutic categories. In 2012, industry had a business of one lakh ninety thousand crores Indian Rupee rates, even though the medicines are priced reasonably cheaper in comparison to global prices. Despite the availability of cheap medicines majority of Indians afford the branded medicine. The brand medicines in India are registered just by name, packaging and other external features rather than the quality and intellectual property. Hence a brand in India is not having any advantage to patient and consumers in terms of safety and efficacy. The patients are made to buy expensive brand, which looks attractive in terms of presentation and does not offer any benefit as medicine. In India there are one lakh brand medicines which are registered, and are made by one thousand Active Pharmaceutical Ingredient.

Table 1: Drugs induced Concentration related Organ toxicity

Name of the drug related toxicity	Category	Therapeutic applications	Concentration
Aceclofenac	Non-steroidal anti-inflammatory (NSAID)	Analgesic and anti-inflammatory	Hepatotoxicity
Cefixime	Cephalosporin antibiotic	To treat bacterial infection	Hepatotoxicity
Cyclosporine	Immunosuppressant's	To prevent organ rejection in organ transplant	Nephrotoxicity
Gentamicin	Amino glycoside antibiotic	To treat bacterial infection	Ototoxicity
Nimesulide	COX-2, NSAID	Analgesic and antipyretic	Hepatitis and acute liver failure
Paracetamol	NSAID	Analgesic and antipyretic	Hepatotoxicity
Ranitidine	Histamine-2 blockers	To treat peptic ulcer	Nephrotoxicity
Vancomycin	Glycopeptide antibiotics	To treat serious bacterial infection	Nephrotoxicity

There are many "Me Too" formulations marketed in the country. Most of these brands pose a burden to various stake holders. Doctors are unable to remember the medicines by active pharmaceutical ingredients and are prescribing the brand with lot of hesitations. Similarly the pharmacists are also facing the problem due to short lived market of brands. It is causing waste of investment on inventory and confusing the health care providers. The other issues like management of drug stores is becoming difficult due to look alike and sounds like names of the brands. To resolve this issue, the government of India enacted Jan Aushadhi Act 2008. The Price control of prescription medicines is one of the major objective of Jan Aushadhi Act Kendra that sells generic medicines. The National pricing control of prescription drugs has begun through the National drug pricing authority under the drug price control order in 1995.

The Drug price control Act 1995 has given the guidelines for fixing the maximum retail price of brand medicines, bulk drugs and their formulations.

The government of India has also instructed doctors working in government hospitals to prescribe generic medicines instead of brand medicines. By doing so government wants to challenge the dominance of brand medicines in private structure by the launch of Jan Aushadhi scheme in 2008 and encouraging the establishment of exclusive generic drug stores. Government of India wants to play a key role. The Government of India by utilizing the local resources for manufacture, distribution and sale of prescription medicines has established the study supply. **(Table 2)** Here is list of the generic drugs that are sold at predetermined affordable price to the public. At present more than 651 formulations of generic medicines are sold through exclusive Jan Aushadhi Kendra's.

The Jan Aushadhi Kendra's are franchises of BPPI. The generic medicines are likely to dislodge the demand for expensive branded medicines which are sold in the market by adopting unethical marketing practice by the private pharmaceutical industries.

The brand medicines in India are marketed by prescription of a medical practitioner and hence doctors are pampered by the Pharma industries to sell the branded medicines despite being expensive.

Doctors are provided with expensive gifts and incentives and sometimes even cash to prescribe the specific brands. This has caused great damage to the professional practice of healthcare. It is observed that few doctors themselves are indulged in the sale of medicines to the patients directly in the hospital premises. The patients who have trust on the doctors are getting duped by these few doctors who have become extremely greedy. This is also linked to the high cost of medical education.

On the other hand the chemist and druggist are also responsible for sale of prescription medicines without prescription. They are selling prescription medicines to the public as the income of Pharmacy is mainly determined by the volume of sale of medicines. The pharmacists have forgotten their role and responsibility of protecting public health of patients and customers. If the good quality of medicines are made available at an affordable price by the Government then public acceptance is possible. In order to achieve this objective the government itself has initiated the Jan Aushadhi Yojana in which generic medicines are sold. The Prime Minister of India realizing the socio-economic value of the project adopted the generic aushadhi Kendra's which is known as Prime minister Jan aushadhi Kendra. In this scheme an individual pharmacist, a NGO and the government agencies are invited to open a PMJAK. PMJAK should also apply for a license which is needed from the state drugs control department of respective state.

PMJAK license holder who is a registered pharmacist earns a 20% commission on sales and is also encouraged with one time subsidy of 2.5 lakh Indian Rupees Rate. The PMJAK are not allowed to sell the branded prescription medicine. However they are allowed to sell other products like cosmetic and general items.

The branded medicines are expensive because the pharmaceutical industry invests lavishly in building a brand image for the product.

For example "a branded" liquid oral is presented in an attractive bottle with an eye catching label packed in an expensive carton. The brand image is built by giving advertisement in various medical journals and mass media. Further they are engrossed by the celebrities who pay huge money. For marketing these brand products the company provides free samples for prescribes. They also give attractive schemes to drug stores, for example buy 10 bottles-get 10 bottles free. The medical shops also behave like trade unions, putting the conditions for marketing the product in their territory. They also demand trade bonus in the form of gifts and compliments. The Pharma Company has to spend money to push the products all along the product supply chain. Above all this, the company has to make the substantial profits which add on the price of brand medicine.

The definition of Generic medicines is different in India to the definition of generic medicines in the regulated markets like North America and Europe. As per the international norms the generic medicine is the one, which is licensed to sell by the drug name instead of brand name after the expiry of the patent period. The market exclusivity of innovator brand ceases to be null and void of the expiry of the patent period. The competitors of the innovator company develop the generic version by formulating the medicine which is exactly similar in terms of bioavailability and bioequivalence. The development of generic medicine involves establishing the formulation which is identical to

Table 2: Comparison of prices of brand and Generic medicine

S. No.	Name of medicine	Therapeutic class	Unit	Jan Aashaadha price (including all taxes)	Brand	Brand price (including all taxes)	Difference in price
1.	Aceclofenac+Paracetamol (100 mg+500 mg) Tablet	Analgesic	10's	14.49	Zerodol-P (Ipca)	38.50	24.01
2.	Acetaminophen+Tramadol Hydrochloride (325 mg+375 mg) film coated tablet	Analgesic/Anti inflammatory	10's	8.16	Ultacet (Johnson & Johnson)	142.00	133.80
3.	Amikacin 100 mg inj	Antibacterial (Antibiotic)	Vial	15.04	Amiject (Alkem)	27.00	11.96
4.	Cefixime (50 mg/5 ml) Dry syrup	Antibacterial (Antibiotic)	30 ml	25.93	Taxim-O (Alkem)	42.21	16.28
5.	Glimepiride 1mg Tab	Anti-diabetic	10's	3.48	Glimestar-1 (Mankind)	22.00	18.52
6.	Insulin Injection IP 40 IU/ml (Insulin Human Recombinant)	Anti-diabetic	10 ml	118.61	Huminsulin (Eli Lilly & Company)	141.24	22.63
7.	Albendazole (200 mg/5 ml) syrup	Anthelmintic	10 ml bottle	14.30	Band (Mankind)	17.10	2.80
8.	Omeprazole 20 mg film coated Tablets	GERD	10's	10.03	Omez (Dr.Reddys)	36.36	26.33
9.	Pantaprazole 40 mg film coated Tablets	GERD	10's	9.97	Pan-40 (Alkem)	120.00	110.00
10.	Atenolol 50 mg Tablet	Anti-hypertensive	14x10	55.57	Aten50 (ZydusCadila)	24.40	31.17
11.	Alprazolam 0.5 mg film coated Tab	Anti-anxiety	10's	3.97	Anxit (Micro Labs) 1x15	34.96	30.99
12.	Dexamethasone Tablet I.P. Strength 0.5 mg	Anti-Inflammatory/ Anti-allergic	10's	3.69	Dexona (ZydusAlidac) 1X20	3.78	0.09
13.	Betamethasone Tablet IP 0.5 mg	Anti-fungal	20's	6.74	Betnesol (gsk)	8.10	1.36
14.	Clotrimazole 100 mg vaginal Tab	Fungicide	10's	11.93	Candid-V6 (Glen mark)	60.32	48.39
15.	Dusting Powder (Povidone 5%)	Antiseptics	10 gm	28.62	IntadineIntas Pharmaceuticals	29.70	1.08

Bioavailability and Bioequivalence generally in terms of pharmacokinetic and Pharmacodynamics parameters these formulations.

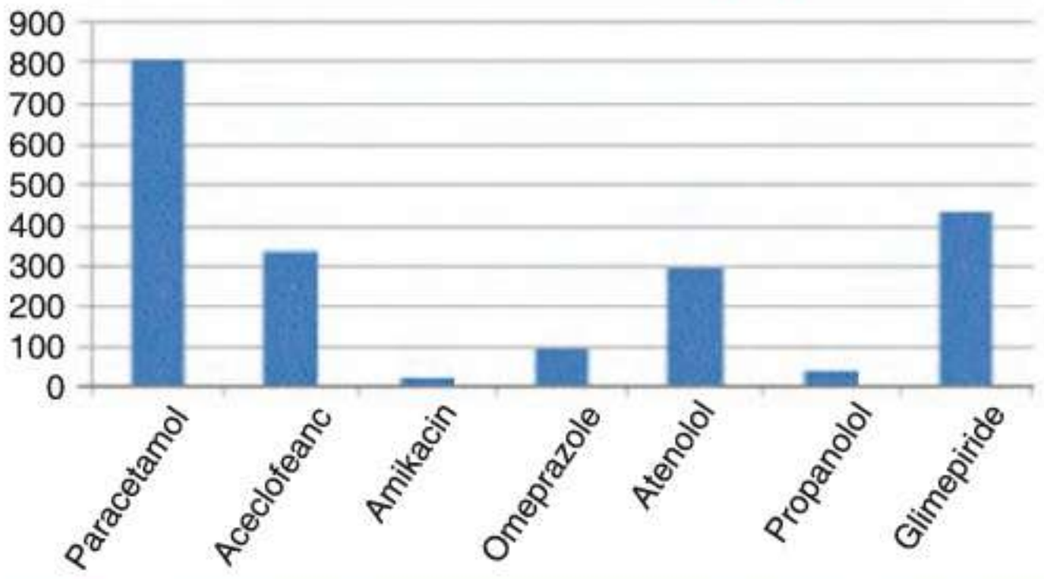
The Clinical data should be submitted to the regulators like US Food and Drug Administration (USFDA) for getting approval to sell in the US/Europe. After verifying the data for its correctness, USFDA gives license to sell the generics. Generics are comparatively cheaper than innovator brand. There will be no difference as per the therapeutic outcome is concerned. The generic medicines are advocated by insurance companies to save the money on prescription medicines **(Figure 1)** [11]

However the generic medicines in India mean an alternative similar formulation which is labeled by the generic name without any brand name. The formulations are packed with necessary requirements and costs on attractive packaging marketing expenses are cut. It may

Table 3: "Me-Too" brands in the Indian market

S. No.	Classification of drugs	Examples
1	Non-Steroidal Anti-inflammatory drugs	Aceclofenac, Paracetamol, Tramadolol, Nimesulide, etc.
2	Antibiotics	Amikacin, Cefixime,Tetracycline, Penicillin, etc.
3	Beta-Blockers	Atenolol, Propanolol, Timolol, Sotalol, Pindalol, etc.
4	Proton Pump inhibitors	Pantaprazole, Omeprazole
5	Sulfonylurea antidiabetic drug	Glimepiride, Glipizide, Tolbutamide
6	Anxiolytic of the Benzodiazepine class	Alprazolam, Clonazepam, Lorazepam, etc.
9	Anthelmintic of the Benzimidazole	Albendazole, Mebendazole, Triclabedazole,etc.
10	Antifungal of the Azole derivatives	Clotrimazole, Econazole
11	Steroidal class of Corticosteroid	Betamethasone, Dexamethasone, etc.

Figure 1: Brand medicines available in the Indian market [11]



not be similar in terms of Pharmacokinetic/ Pharmaco-dynamics requirements Bioavailability and Bioequivalence.

The generic medicines in India means a plane formulation which is not promoted vigorously like brand medicine and are sold at a cheap price. It is now clear that the marketing of generic medicines is disturbing brand medicine market which would bring the expenditure of medicines for Government and Public. In India, expenditure of medicines are paid by out of pocket model. There are issues and bottle necks for the coverage of patient's medicine expenses by health insurance schemes.

Conclusion

Indian pharmaceutical market is flooded with brand formulations exceeding more than one lakh. This scenario has created serious issues in implementing drug regulations, evaluation of the quality of the products and management of inventory in retail drug stores confusing the prescribes and Pharmacists etc. In India the product registration and approval of brand name is done by Drug Control Department of individual states. However the product gets licenses all across the country. As a result of this the local manufacturesby registering the products in one state are marketing all across the country.

There are nearly thousands of Pharma industries involved in manufacture and sales of brand medicines. The brand medicines' Quality control and Quality assurance available in the market cannot be effectively done, as it requires huge infrastructure and drug analysis. Hence Quality assurance and Quality control are the in house responsibility of the industrialist. However they are also cross checked by the Drug control department from time to time. Hence the quality of medicines are certified by the analyst appointed by the company.

The government of India has carried out a nationwide survey by collecting samples of brand medicines from the open market and subjecting it to analysis for content and quality of the medicine. The preliminary report indicates a huge cap in a label claim in content in brand formulation.

The large number of brand formulations in the market poses a challenge for the prescriber and the retail Pharma-cists. The look alike and the sound alike (LASA) is one of the causes of medication error and patient safety. The retail pharmacist has to maintain a huge inventory as the market is flooded with "Me-To" brand medicine... see **(Table 3).**

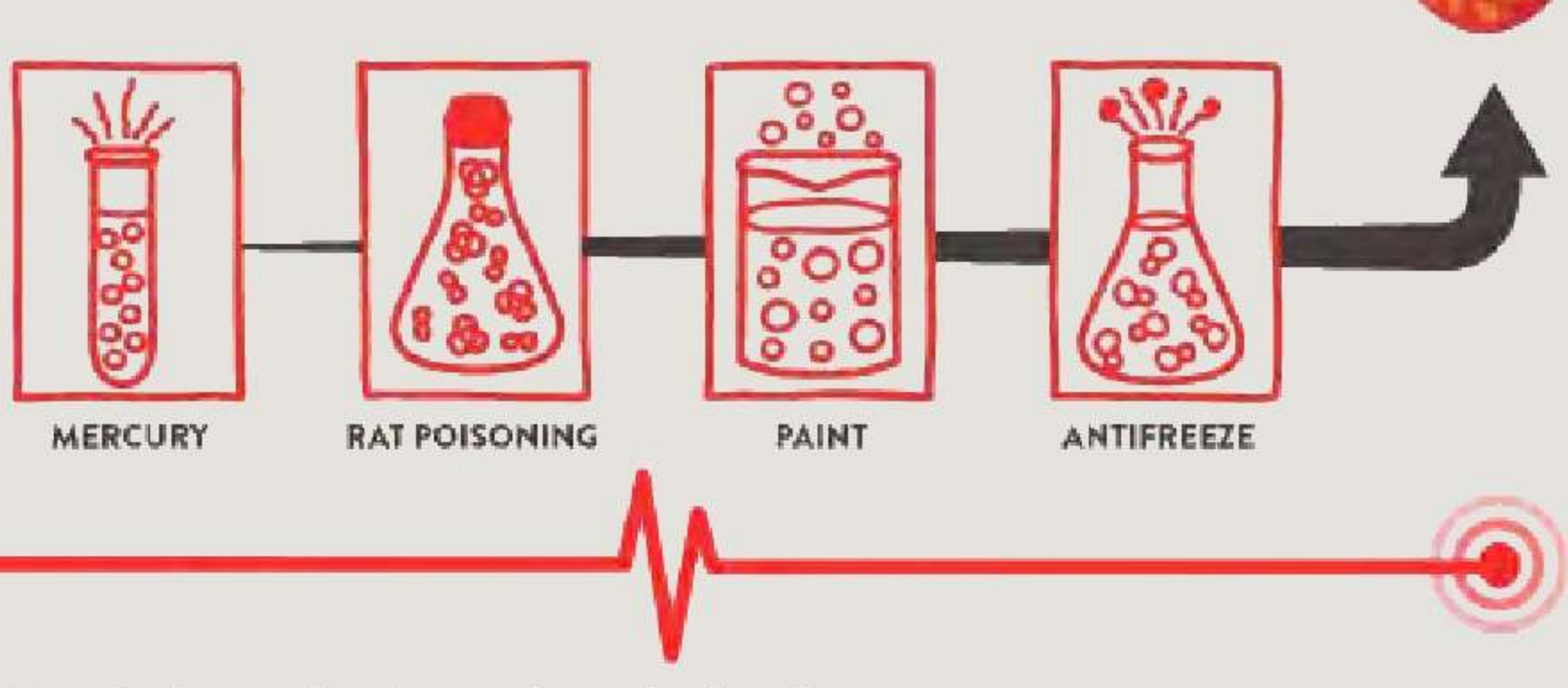
FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

VISIT FIGHTTHEFAKES.ORG

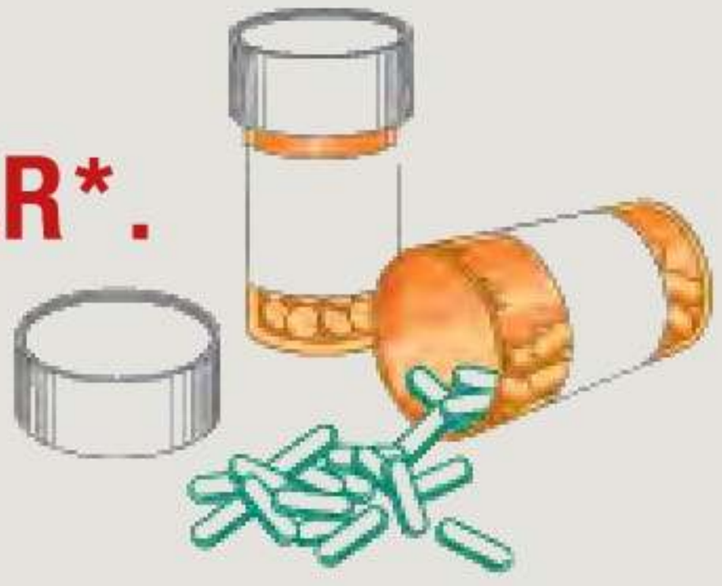
FAKE MEDICINES HARM – NOT HEAL

There are a lot of shady ingredients found in fake medicines that are directly responsible for serious disability and even death. This includes poisons such as mercury, rat poison, paint and antifreeze.



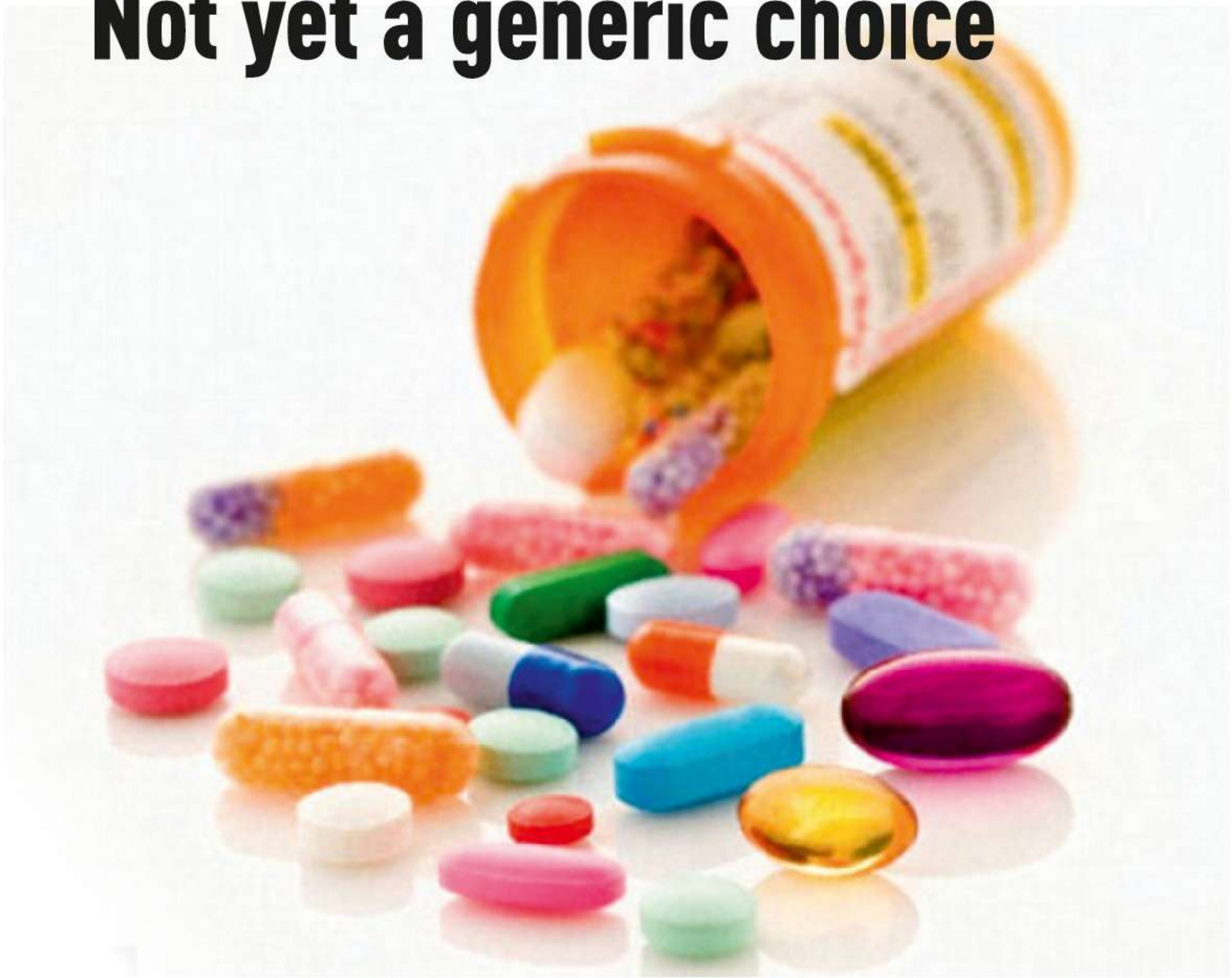
Fake tuberculosis and malaria drugs alone are estimated to

KILL 700,000 PEOPLE A YEAR*.



*International Policy Network

Jan Aushadhi: Not yet a generic choice



Despite Jan Aushadhi's recent achievements, there's more work to be done.

CHEMICALS AND FERTILIZERS

Minister Ananth Kumar vowed to end the "medicine mafia" in the country by opening many more Jan Aushadhi kendras, stores that sell generic medicines at affordable prices. Kumar was echoing the mission outlined by Finance Minister Arun Jaitley in Budget 2016. And the initial mission was to get to 3,000 stores by March 2017. Now it is 5000 by 2018-19.

Two months short of the year coming to an end, Mission Jan Aushadhi was still shy of that target, with 3650 stores operational, according to official data from the Bureau of Pharma PSU of India (BPPI). Operating under the Department of Pharmaceuticals, the BPPI implements the "revamped" 'Pradhan Mantri Jan Aushadhi Yojana' (PMJAY), which was first launched under the UPA Government.

Political detractors wonder aloud whether BJP supporters have been given a not-so-overt diktat to participate in this initiative, the BPPI data shows traction in non-BJP ruled states like Kerala, Karnataka and West Bengal.

This may not yet mean that it's all hunky dory for the initiative as there still remains much ground to be covered. But certainly, some things have worked on the ground.

Greater ownership

So what worked? The Centre has taken greater ownership of this campaign since the new Government was elected in 2014, says a BPPI insider on conditions of anonymity. The project was made more viable, upping incentives to start a store to ₹2.5 lakh (from ₹1.5 lakh), and distributor and trade margins were increased.

The Government's decision to allow people to open Jan Aushadhi stores outside public hospitals may have also worked as a catalyst. The Centre encouraged non-government organisations, doctors, unemployed pharmacists and so on, to open Jan Aushadhi shops, supporting their medicine procurement and reimbursing some of their expenses, says the representative.

The processing of bills is easier and shop owners are reimbursed within a month of their expenses, he claims, countering an often made complaint in the past that Government payments were delayed. The payments are made online and are more transparent now. Now there's maximum sale and maximum incentive.

More shops & stocks

Despite its recent achievements, there's more work to be done.

More transparency is required on how these shops are doing as that will ensure whether it is sustainable or not, says veteran health expert Amit Sengupta with the Jan Swasthya Abhiyan, a health advocacy organisation.

A country like India will require more shops to improve access. More shops also means more stocks. And though the product basket includes 600-plus medicines — including antibiotics, skin products, diabetes, heart related and medicines for other therapeutic areas — patients often complain that the shops are ill-stocked, and high-end or critical drugs like cancer products are not available.

The BPPI claims that medicines for Jan Aushadhi stores are sourced from public sector pharma units and about 125 private suppliers. But big guns of the pharmaceutical industry complain that participation becomes difficult because the of the Government's apparent tendency to source from suppliers who give the lowest price. "This could disregard quality," says an industry expert. The BPPI representative counters that the medicines come from licensed suppliers and with technical quality checks from Government-accredited labs.

Generic prescriptions

In the past, the Jan Aushadhi initiative also suffered because doctors did not prescribe medicines using their generic names. (A generic drug has the same active ingredient of an original branded drug, but is less expensive as it does not include the cost of research and development.)

In fact, now the move to prescribe generic drugs received a nudge from Prime Minister Narendra Modi who called for a law to get doctors to prescribe using the generic names of medicines. The other counter narrative to this programme is that states like Karnataka and Tamil Nadu run efficient healthcare programmes. So for Jan Aushadhi to make a mark, it will need to have a much bigger basket of medicines with low prices, say people familiar with the initiative.

It also needs to be much more visible so it pops up in peoples' minds as a popular option to buy medicines. The challenges are only going to increase as the pharma retail landscape changes. Online pharmacists and retail chemists are getting more tech-enabled, bundling in services and discounts to customers.

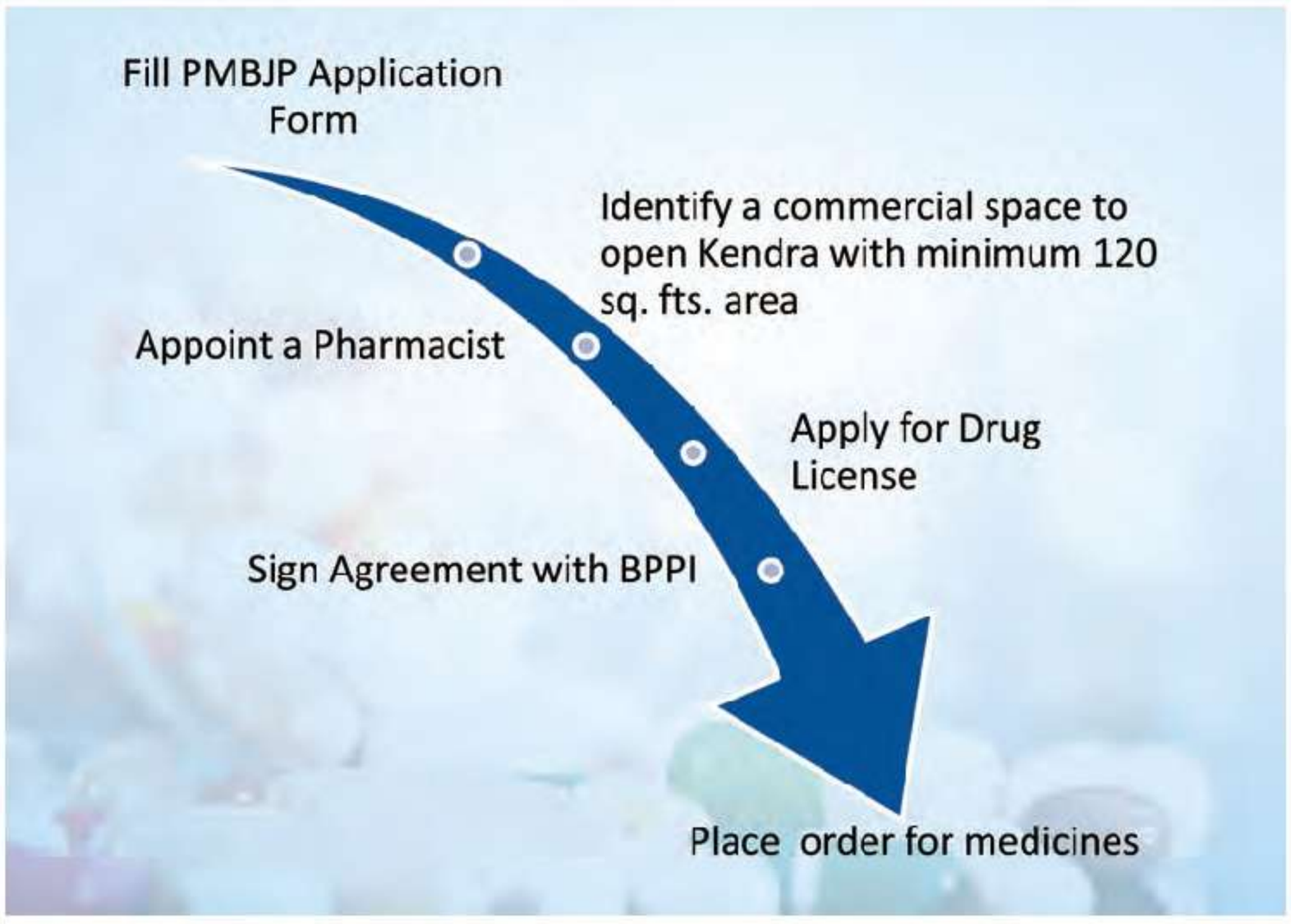
These challenges are a clear indicator that Jan Aushadhi too will need to get more nimble-footed if it wants to break the high-priced "medicine mafia" and become a generic choice for people.

Who Is The Better 'Medicine Man' Of India's Poor?

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) gives self employment and income opportunity with just 120 sq. fts. Space and a Drug License.

Come be a part of this noble mission….

SIMPLIFIED PROCESS TO OPEN PMBJP KENDRA



LAUNCHED BY THE UPA as the Jan Aushadhi Yojana in November 2008, the scheme aims to ensure "availability of quality medicines at affordable prices to all" by selling cheaper generic medicines at more than 3,000 outlets across the country.

Modi has often reiterated his government's commitment to the programme since coming to power.

"The sole aim behind this step is to ensure the availability of quality, affordable health service to the poorest of the poor, so that a healthy and prosperous India comes into being," Modi had said in his first Mann Ki Baat address of 2018.

Questions over quality

Modi claimed that generic drugs sold in Jan Aushadhi stores conform to World Health Organization (WHO) standards.

However, five medicines have been recalled from Jan Aushadhi stores in April due to quality lapses. There were six other recalls between January and March, taking the total to 11 in just the first four months of 2018 while there were 11 recalls in all of 2017.

Such frequent drug recalls are unusual in India, where a single recall can land a company in serious trouble, including legal action, an export ban, and financial losses.

Drugs are typically recalled if the product is defective, contaminated, contains

How PM Narendra Modi put new life in an ailing scheme

ALTHOUGH THE PROBLEMS plaguing the scheme are considered significant, it is still thought to have recovered some of the sheen it had lost under UPA-2.

Prime Minister Narendra Modi has given a new lease of life to a sickly scheme from the second term of the Congress-led United Progressive Alliance (UPA) coalition government.

Few had heard of Jan Aushadhi Scheme before September 2015, when the Modi-led government renamed it first as Pradhan Mantri Jan Aushadhi Yojana. It was renamed again in November 2016 as Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP). The UPA II scheme, which aims to provide quality generic medicines at affordable prices in place of branded medicines, not only got a new name but also a big push.

The scheme has drastically brought down medicine prices. For example, anti-diabetic drug glimepiride is priced at Rs 4.02 under the government scheme while it costs Rs 54 in market.

The Jan Aushadi Scheme saw only 80 stores till March 31, 2014. Under the NDA rule, the number of Jan Aushadhi Kendras have jumped manifold. As per latest data, 3650 Jan Aushadhi Kendras are operational across the country. The target is to open 5000 stores by 2018-19, it is still a big leap compared to the growth during the previous government.

A turnaround

How Modi turned the scheme around

Medicines: From 2014 to 2018, 700 medicines and 150 surgical/consumable items have been brought under the scheme as compared to nearly 100 from 2008 to 2014 under the UPA II government. These drugs are for acute

a foreign object, fails to meet specifications, or is misbranded.

Problems plaguing its implementation

The agency implementing the scheme, the Bureau of Pharma PSUs of India (BPPI), recalled the products after they were declared 'not of standard quality (NSQ)' by state-level drug inspectors. Despite the increasing frequency of complaints, BPPI's quality control department remains without a head.

Also, three CEOs have resigned in three years, the last of whom, Biplab Chatterjee, has been running the show on an interim basis ever since he put in his papers in November 2017. The official line is that BPPI is looking for a new CEO and an "official announcement will be made soon".

Meanwhile, the ministry of chemicals and fertilisers, which heads the initiative, has launched an internal probe into 14 allegations, including charges of financial misappropriation, flouting of procurement rules and excess spending.

The audit report made by the government's auditor, the Office of the Chief Controller of Accounts, has alleged that some medicines are being sold at prices higher than the market price, defeating the purpose of the initiative. ›

as well as chronic diseases such as hypertension, diabetes, cancer and asthma.

Therapeutic basket: The therapeutic category basket of the scheme was incomplete earlier. Now the basket covers all 23 major therapeutic categories such as anti-infective, anti-diabetics, cardiovascular, anti-cancer and gastro-intestinal.

Suppliers: Till 2014, only PSUs had been assigned to make and supply drugs. But now 125 suppliers, certified under the WHO's Good Manufacturing Practice (GMP), are also part of the scheme.

Quality control: Bureau of Pharma PSUs of India (BPPI) tests the medicines procured from the suppliers for its quality. "Each batch of each drug is tested at BPPI's empanelled National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited laboratories in order to ensure quality, safety and efficacy of medicines and conformation with required standards," said the BPPI.

Turnover: The annual turnover of PMBJP has also increased to Rs 73.66 crore in 2017-18 (as on October 30, 2017) from Rs 33.4 crore in 2016-17 and Rs 12.43 crore in 2015-16.

Incentives and margins: The government has increased the incentive to start a store to Rs 2.5 lakh from Rs 1.5 lakh. The government has also increased the margins from 16% to 20% for retailers and from 8% to 10% for distributors.

Accessibility: Indian Railways has been roped in for making cheaper medicines more accessible to people. It plans to open Jan Aushadhi Kendras at 1,000 railways stations. Petroleum Minister Dharmendra Pradhan announced in August this year that government would open Jan Aushadhi stores at PSU-run petrol pumps too.

The Modi government has been making concerted efforts to put essential and critical medicines within the reach of the masses. It put a cap on prices of stent and knee implants after they were lowered by more than 50 per cent. In April this year, Modi promised a legal framework to ensure that doctors prescribed low-cost generic medicines instead of expensive branded medicines. The new law will hit hard at the nexus of doctors and pharma companies.

Who ran the scheme better?

Experts blame the expansion frenzy for the problems being faced by the scheme.

Under the UPA, the government opened 199 stores. A report by a standing committee of Parliament, issued in 2014-15 said only 99 of these were operational, the remaining having faced challenges in scaling up. It said the UPA was going "too slow" on expansion.

However, K. Sujatha Rao, former secretary in the ministry of health and family welfare, said: "The UPA government failed to promote Jan Aushadhi but their drugs never failed quality tests. They probably suffered shortage of stock at times, but it is better to suffer that than sell drugs of poor quality."

The number of Jan Aushadhi outlets has jumped manifold under the NDA government, crossing the target of 3,000 stores. However, critics say, the Modi government has gone too fast in expanding the number of outlets while failing to invest in quality control, back-end operations, supply chain management and human resources.

To regain the confidence of retailers, BPPI's CEO Chatterjee has issued a circular to assure them that the government is taking all possible steps to procure high-quality medicines.

"In a recently concluded quality advisory committee workshop, we have moved towards developing processes that will help achieve the gold standard in quality medicines in Jan Aushadhi," Chatterjee said in the circular,"and this will be possible with the active participation and total compliance of kendra owners. ›

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सत्यमेव जयते

Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

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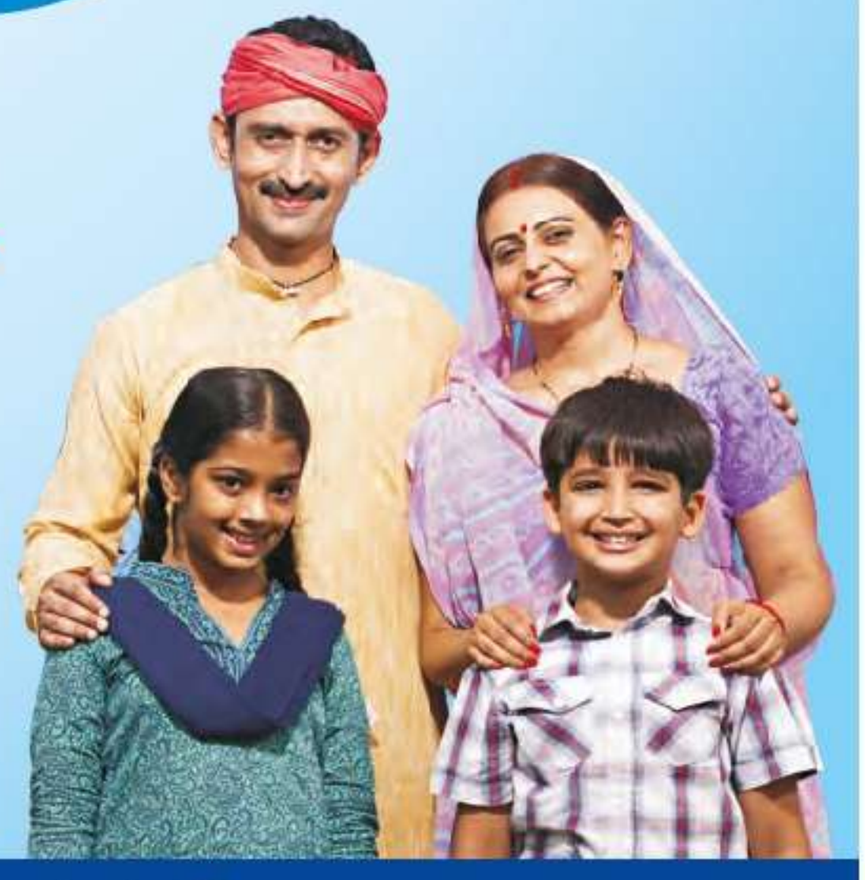

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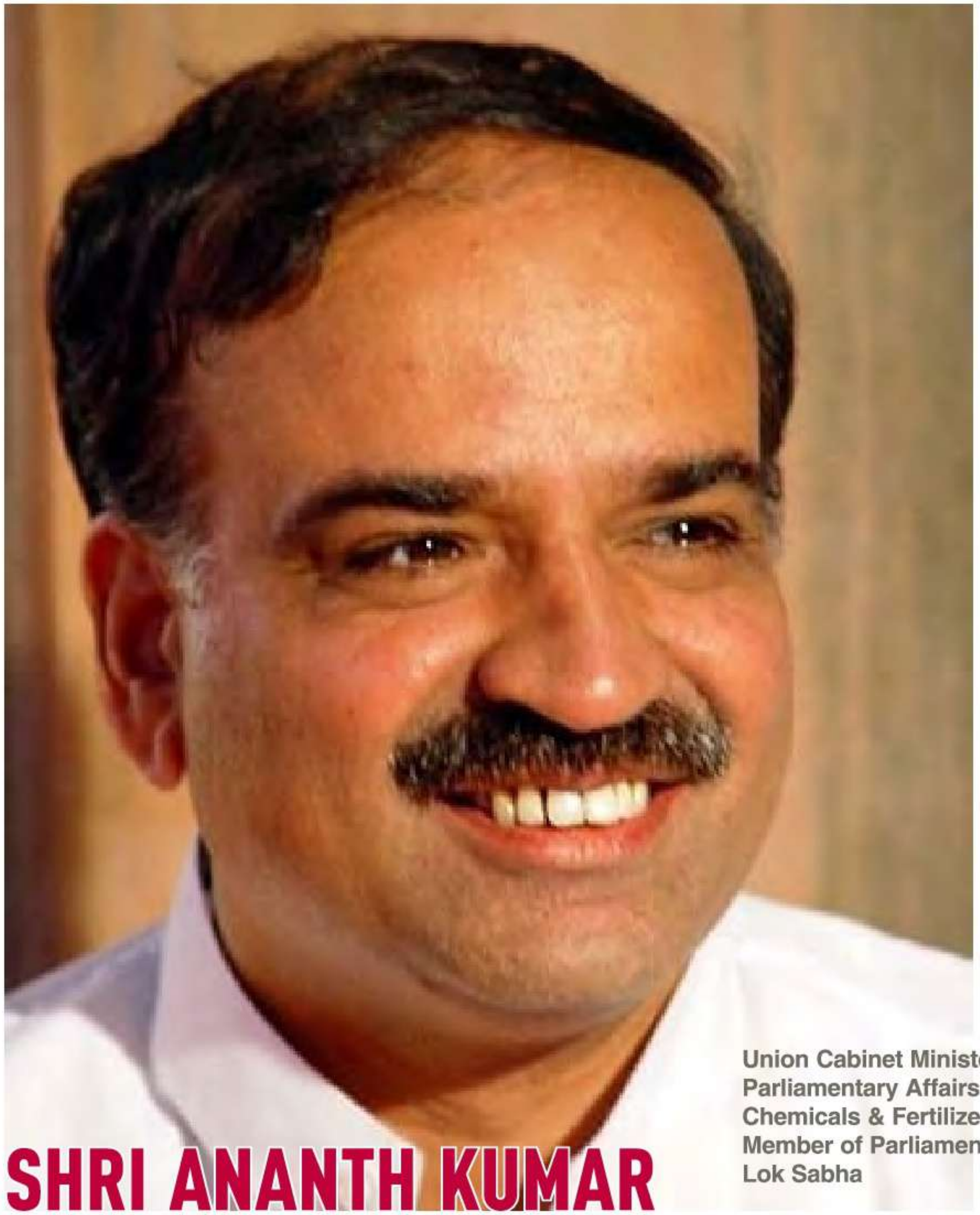
"Medicines Are Being Made Affordable For Poor Under PMBJP"



SHRI ANANTH KUMAR

Union Cabinet Minister for Parliamentary Affairs and Chemicals & Fertilizers Member of Parliament of the Lok Sabha

\\ "MEDICINES ARE BEING MADE AFFORDABLE FOR POOR UNDER PMBJP"

In nearly four years of the Narendra Modi government, the Union Ministry of Chemicals and Fertilisers, led by **Ananth Kumar,** also minister of parliamentary affairs, has contributed significantly to meet the three objectives closest to the PM's heart — improving farm incomes, universal healthcare, and imparting skill development and creating jobs. Of the three, Minister Kumar has worked diligently on the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana and has scaled it to great heights. Excerpts from an interview.

Q How do you feel the govt. is addressing the challenges thrown by the healthcare sector?

When it comes to tackling the challenges thrown up by the country's healthcare sector, the current Narendra Modi government seems to be focusing on 3As to begin with since it came to power - availability, affordability and authenticity, the last being most important.

Q What was the first step taken in this direction?

The first step taken was to make medicines affordable to the poor through Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP). The scheme actually turned out to be the signature programme of our ministry, which has found mention occasionally in the PM's public speeches and has helped realise his 'Health for All' mission to a large extent.

Q Could you please throw some light on your journey since you joined office?

As soon as I joined office, I asked my officers to explain how medicines worth Rs 1 lakh crore are consumed domestically. This is not very encouraging. There are people from below poverty line, economically weaker sections and low income groups. Somewhere, the foundation is weak at the level of facilitating healthcare services for the poor. This needed to be worked upon.

Within three years, we have reached from 99 to 3650 jan aushadhi centres in 550 districts and all are providing medicines at 30 per cent of the market price... these are very authentic and cheap. India is producing medicines worth Rs 2 lakh crore every year, out of which Rs 1 lakh crore is exported and the rest is consumed in India.

Q You mentioned that the Modi Govt. was focusing on the 3As, of which 'Authenticity' being the most important. What steps have been taken in this regard?

We are ensuring that all jan aushadhi centres have WHOGMP (good manufacture practice) certified medicines only.

Q Any concrete steps to make medicines affordable?

Oh yes. The government is also ensuring that

Within three years, we have reached from 99 to 3650 jan aushadhi centres in 550 districts and all are providing medicines at 30 per cent of the market price.

medicines are made affordable for the citizens at large. There would be no hike in prices of medical procedures. From 2014-17, 700 medicines and 150 surgical items were brought under the scheme as compared to nearly 100 from 2008-14. Since May 2014, the government has brought nearly 1,000 drugs under price control and as a result, the benefit in terms of money value passed on to patients is worth Rs 2,810 crore. Before May 2014, only 404 medicines were under price control.

Q We hear that an effective price regulation has taken place in the medical devices area. Could you please elaborate?

Regulated prices of medical devices can make stents and knee implants more accessible to the lower and middle income groups now.

Prices of stents have been brought down by nearly 85% benefitting about six crore cardiac patients. More than five lakh angioplasties are estimated in 2017-18 and the total savings to patients will be to the tune of about Rs 5,000 crore or more every year. The National Pharmaceutical Pricing Authority (NPPA) capped the price for stents to avoid irrational use of the life-saving healthcare device, which is used to save the lives of patients diagnosed with coronary artery diseases.

Stents, which used to cost Rs 1 lakh, now cost Rs 30,000. Our government has regulated the prices of vital life saving medical devices to stop irrational profits made by pharma industries. This is a major relief for people who are in real need. Now, bare metal stents cost just `7,500, while drug-eluted stents cost Rs 30,000, which earlier used to come in lakhs.

Soon after this move, the government also cut down prices of orthopaedic implants ranging from Rs 80,000 to Rs 1 lakh. Knee implants, which used to cost more than `1.60 lakh are now easily available at just Rs 50,000.

Q You have worked assiduously to expand the PMBJP. What motivated you?

It involves a painful memory from my life. (Minister is moved to tears as he reminisces about it). My father was a second-division clerk in Indian Railways, and I grew up in the railway workers' colony in Hubli, Karnataka. My father was the sole breadwinner, and while I was still young, my mother was diagnosed with cancer. The doctor prescribed her two tablets daily of Nolvadex.

Each tablet was priced at Rs 20 then. My father earned Rs 1,200 a month. A month's dose of the medicine also cost nearly that. The choice with my father was whether to give my mother two tablets a day, which would leave little money for the family to buy food, or one tablet.

My father did what he thought was best for the family, which meant only one tablet a day for his wife. The memory of how my mother suffered because the medicine was expensive motivated me to expand the PMBJP network.

Q Any target for the coming months?

The government has signed MoUs for 6,000 Janaushadhi Kendras and it also has 20,000 applications for individuals interested in opening such stores.

We are in the discussions with the Health Ministry, drug controllers at the central as well as state levels for quick approvals to open Janaushadhi Kendras. Our sole target is to make authentic medicines available and affordable to every citizen of our country.

Janaushadhi scheme will provide life saving medicines at lowest prices

"Branded medicines are expensive because of the expenditure of the drug companies on promotion, marketing and doctors' commission. The medicines available on 'Janaushadhi' centers are brought from WHO-certified pharmaceutical companies. These medicines are also examined in NBL lab. Subsequently, these generic medicines are dispatched to 'Janaushadhi' centers. To maintain the quality of these medicines, even godowns are built under the guidelines of WHO," said **Mansukh Mandaviya,** MoS for Road Transport & Highways, Shipping and Chemicals & Fertilisers, in conversation with Ravi Mishra. Excerpts:

Q What initiatives have been taken by Prime Minister Narendra Modi in health sector?

Keeping health education in mind, Prime Minister Narendra Modi has worked in four ways in this sector. These are: Preventive Healthcare, Affordable Healthcare, Supply Side Interventions, and Mission Mode Interventions.

We want that no poor in this country die without medicines or without any medical treatment. The important steps taken include: we have decreased the price of more than one thousand life-saving medicines and regulated the prices of stent and knee implants. For providing useful and low-priced generic medicines to the poor, more than 3500 generic medicine centers have been opened under 'Pradhanmantri Janaushadhi Pariyojana,' where more than 700 important medicines are available on 50-90 per cent lower prices than that in the market. Scheme like 'Indradhanush' has been initiated for vaccination. To provide medical treatment to the fellow Indians, the government has recently launched 'Ayushman Bharat'–world's largest health insurance, which will directly benefit 50 crore people in the country. No doubt, I can see the growth of health sector, at the present rate, will double in coming days.

Q What is 'Janaushadhi' scheme?

Janaushadhi scheme has been initiated by Chemical and Fertilizer Ministry. The main rational behind this scheme is to provide various life-saving medicines at a very low price. Under this scheme, generic centers are being opened up at block levels of every district.

Q How will you link up 'Ayushman Bharat' scheme with 'Janaushadhi' scheme?

'Ayushman Bharat' scheme ensures 5 lakh rupees per year for health insurance to one family. Under this scheme, 10 crore families will get benefit. 1.5 lakh wellness centers will be opened up under this scheme. In this situation, 'Janaushadhi' centers will be means for low-priced necessary medicines. Prime Minister has taken the onus on himself to tackle the health problems of the poor people.

Q What is the present condition of 'Janaushadhi' scheme? In how many districts have 'Janaushadi' centers been opened up?

Under 'Janaushadhi' scheme, 3500 generic medicine centers have already been established in 600 districts of 33 states and union territories.

Q What is the procedure to start a 'Janaushadhi' center?

A pharmacist, a businessman, an NGO, a trust, a society, an institution or anyone who has 120 square feet of shop or a skilled pharmacist is eligible to open a 'Janaushadhi' center. To open a 'Janaushadhi' center, people can apply online on www.janaushadhi.gov.in. After applying for a 'Janaushadhi' centre, BPPI head office issues an in-principal approval letter. On its basis, to take drug license, one has to apply for drug licensing authority in the name of 'Pradhan Mantri 'Janaushadhi' center. After getting the drug licence, medicines are supplied from BPPI.

JANAUSHADHI SCHEME WILL PROVIDE LIFE SAVING MEDICINES AT LOWEST PRICES //

Mansukh Mandaviya at the inauguration of a Janaushadhi store

Q How does the government help in opening a 'Janaushadhi' center?

2.5 lakh rupees of help is given by the government to run a 'Janaushadhi' center successfully, which depends on monthly sell. This amount can only be to the tune of Rs 10 thousand per month. It is continued by the government unless one gets Rs 2.5 lakh. Software and marketing resources are also provided for sell of medicines.

Q Will generic medicines be on fixed prices?

Prices of all the medicines available on 'Janaushadhi' centers are already fixed. It is printed on every medicine. It will be same at every centers of the country.

Q Why are these medicines so low-priced and what would you say about their quality?

Branded medicines are expensive because of the expenditure of the drug company on promotion, marketing and doctors' commission and the medicines available at a 'Janaushadhi' center are brought from WHO-certified pharmaceutical companies. These medicines are also examined in NBL lab. Subsequently, these generic medicines are dispatched to 'Janaushadhi' centers. To maintain the quality of these medicines, even godowns are built under the guidelines of WHO.

Q Doctors often advise branded medicines to patients. What would you say about it?

'Janaushadhi' scheme will be successful only if doctors support it. I think we are getting a good response from doctors.

Q How will you connect 'Janaushadhi' scheme with start-up initiative?

I have already told you that any unemployed person, who has 120 square feet of shop, is eligible to start a 'Janaushadhi' center. If money requires the in initial period, then loan can be taken under 'Mudra' scheme.

Q How much money has been saved by patients under this scheme so far?

In financial year 2017-18, medicines to the tune of Rs140.84 crore were sold (sale at MRP) and if you compare it with branded medicines, it will be approximately 634 crores of rupees. Therefore, in the year 2017-18, we saved 493 crore rupees. This year's saving will be more than Rs 1000 of crore.

Q Which categories of medicines are being sold on 'Janaushadhi' centers?

Under this scheme, we have included 23 categories of necessary medicines, for instance, diabetes, blood pressure, gastro, cancer, allergy etc. We are fully commited to providing all categories of medicines available in the market.

Q The government has decreased the price of stent and 'knee implant'. How are people getting benefits of this?

The government has fixed the maximum price of a bare metal stent at Rs 7260 and that of a drug-eluting stent at Rs 29,600. Due to this, a total of Rs 4450 crore have been saved. The government has reduced 70 per cent price of knee implant, which has saved Rs 1500 crore of people.

Pyush Misra
Director,
Consumer Online Foundation

How India Can Make Cheap And Quality Medicines Available To All

IN THE MID-1990S, India identified availability, accessibility and affordability of medicines as the major weaknesses in its drive for quality and affordable healthcare for all. More than a decade passed before the UPA government started the Jan Aushadhi Scheme (JAS) in 2008 to counter high prices of branded drugs with affordable generic medicines sold at dedicated JAS outlets.

However, until 2012 only 157 JAS stores were opened. The Modi government tried to galvanise JAS — renamed Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) — by increasing the number of stores and the basket of medicines. Doctors in government hospitals increasingly prescribe generic medicines and encourage patients to buy from PMBJP stores. But the scheme is far from popular because PMBJP stores are few and medicines are often unavailable.

Although the number of PMBJP stores has now increased, it is just 0.4% of the roughly 5 lakh pharmacies in India. Tangled procedures have denied approval to about 8,000 other applicants. Most PMBJP stores have only about 200 medicines at a time out of a planned list of over 600 when non-PMBJP stores stock 2,400 medicines, on average.

Medicines for chronic ailments are especially scarce at these stores, with some delivered at six month intervals. Extensive stock-outs across stores discourage patients, who already have

doubts about the quality of generics, from coming back. A few PMBJP stores across Mumbai and NCR claimed their sales are at about a fifth of non-PMBJP pharmacies in their neighbourhood, and their operating costs are significantly higher than their margins. Noble as the PMBJP scheme is, it needs to be salvaged with PM Modi's pragmatic 'minimum government, maximum governance' formula.

Instead of shackling it to BPPI, the scheme's commercial operation can be auctioned region-wise to 4-5 private players. Privatisation will include responsibility for all aspects of the business, from procurement to distribution, under the price guidelines and quality controls set forth by National Authority (NPPA) and DCGI (Drug Controller General of India).

They could procure medicines from any manufacturer complying with WHO current good manufacturing practices (cGMP) but would incur heavy penalties for repeated stock-outs. Private players should be allowed to open as many PMBJP stores as they can cater to, either themselves or via franchisees, with guidelines on the minimum number of stores to be opened in rural areas.

To enlarge the distribution network, all 5 lakh pharmacies in the country, online pharmacies and ecommerce players like Amazon and Flipkart can also be licensed to sell PMBJP medicines on the condition that they will educate consumers about value buying through prominent advertisements. With its expanded distribution network and logistical muscle, PMBJP could be a game changer.

The programme can be fast-tracked by genericising the National List of Essential Medicines (NLEM) and linking it with PMBJP. Currently, over 75% of branded NLEM products are contractmanufactured but have high prices because pharma companies aggressively market them to doctors and chemists with monetary and non-monetary benefits.

For genericisation of NLEM products to work, the government will have to provide quality assurance. NPPA has the competence to set prices of generic drugs while DCGI has the expertise to certify manufacturers abiding by the compliance monitoring programme (CMP). Even then the regulatory ecosystem will need to be considerably strengthened over the next three years. The real challenge will be to get buy-in of PM Modi's vision from the powerful lobbies of pharma companies, medical practitioners and chemists.

Disrupting Domestic Pharma Market

– By R N Bhaskar

This is like many other schemes that the previous government merely talked about, introduced, and then forgot. The Jan Aushadhi (literally translated as medicine for the people) is one for which the current government should be lauded. It has the potential to disrupt the $15 billion market for pharmaceutical products in the country. It was started in 2008 to provide quality generic drugs to people at affordable prices. As the adjoining table shows, the drugs are being offered at prices that make those of branded medicines two times to 14 times more expensive.

Redefining Healthcare through Affordable Generics

Price Comparison Chart

Names of Medicines	Pack Size	Avg. Price of leading brands	Jan Aushadh MRP	Price Difference
Cardiovascular agents				
Amlodipine 5 mg and Alenolol 50 mg film coated Tablets	10's	36.86	3.54	10 times
Ramipril 5 mg Tablets	10's	72.80	9.68	8 times
Losartan 50 mg and Hydroclorrthiaze 12.5 mg Tablets	10's	68.23	9.05	8 times
Rosuvastatin Tablets IP 20 mg	10's	211.00	27.34	8 times
Alorvastatin 10 trig Tablets	10's	50.90	5.11	10 times
Anti-diabetic agents				
Glimepiride 2 mg Tablets	10's	50.00	5.05	10 times
Glimepiride 2 mg + Metformin Hydrochloride 500 mg SR Tablets	10's	70.00	17.78	4 times
Metformin HCL SOO mg tablets	10's	14.00	5.15	3 times
Anti-cancer				
Bicalutamide Tablets IP 50 mg	10's	636.00	137.50	5 times
Paclitaxel Inj. 100 mg	Vial	3,458.00	540.00	6 times
Imatinib Mesylate Tablets IP 400 mg	10's	2,133.00	477.00	4 times
Gastro-intestinal-tract agents				
Rabeprazole 20 mg Tablets	10's	54.00	7.16	8 times
Pantaprazole 40 mg Tablets	10's	63.00	7.20	9 times
Domperidone 30 mg + Pantoprazole 40 mg Tablets	10's	86.00	18.48	5 times
Antibiotics				
Amoxycillin 500 mg + Clavulanic acid 125 mg Tablets	6's	96.84	52.24	2 times
Cefixime 100 mg Tablets	10's	82.60	25.65	3 times
Ofloxacin 200 mg Tablets	10's	52.60	14.80	4 times
Azitthromycin 500 mg Tablets	10's	178.30	86.60	2 times
Analgesic/anti-inflamatory/Anti-pyretic drugs				
Tamado 50 mg labels (should it be Tramadol Tablet?)	10's	60.00	4.38	14 times
Nimesulide 100 mg Tablets	10's	39.00	2.52	15 times
Diclofenac Sodium+Serratiopeptidace (50 mg+10 mg) Tablets	10's	103.20	7.02	15 times
Notes: MRP = Maximum retail price; Avg. = Average				
				Source: Government of India, CLSA

Wonder scheme

According to a comprehensive report by CLSA (http://www.asiaconverge.com/wp-content/uploads /2017/10/2017-10-05_CLSA-Healthcare.pdf) brought out in August 2017, the achievements totted up by the government under this scheme are truly amazing. This is something the government should be crowing about more aggressively. It is intriguing that very few people, including doctors, know anything about it.

CLSA's recent visit to one such Jan Aushadhi store in Mumbai suggests increasing acceptance for this scheme (300 prescriptions daily). If the model scales up and there is a shift from brands towards generics, then it could be a cause of concern for many major India-focussed pharma players.

India is unlike developed countries, where much of the pharma market is funded by insurance companies. Here, the public health care system has collapsed. Medical insurance penetration is scant. Expenses relating to diagnostic, dental and geriatric care often excluded from most insurance schemes.

That is the reason why any move to make critical medicines available to the common man at cheaper prices is an immensely welcome step. It could also help clean up the oft-reported practice of doctors getting

'kickbacks' from pharma companies once they prescribe their high-priced drugs.

At the same time, it could presage similar moves towards regulating prices of other critical health related equipment and services. The markets have already witnessed one such move being made where cardiac stents are concerned. Combine the twin moves of regulating stent prices and introducing generics at affordable prices, and you have the beginnings of a healthcare movement that could spread like wildfire.

Modus operandi

All generic medicines are sought to be sold through franchised retail outlets known as Pradhan Mantri Bhartiya Jan Aushadhi Kendras (PMBJKs or the Prime Minister's medical outlets for people).

Public sector companies have been mandated to procure drugs only from WHO (World Health Organisation) and GMP (good manufacturing practices) compliant companies. This – as the CLSA survey points out — is done at the central level after performing adequate quality checks. These drugs are then sent to distributors in the various states. The distributors then supply the drugs to franchised PMBJK stores which are guaranteed a fixed 20% margin on sales. Today, Jan Aushadhi has a list of over 600 medicines (chronic and acute) and 150 consumables.

The plan is to have around 3,000 PMBJK stores by the end of 2017. Currently there are 2,091 such stores covering 400 (of the country's 630) districts. The idea is to cover each of the tehsils (administrative blocks) that dot the country.

CLSA explains that the plan suffered supply side constraints initially. But, these appear to have been overcome. It is also hoped that the recently introduced GST regime will lead to seamless transport of medicines across states thus partially addressing the supply-side constraints.

The big question that gives pharma companies the jitters is whether the Jan Aushadi model can be a threat to existing, established pharma practices. Well, say medicare experts, that would depend on three factors:

(a) the number of products that the PMBJK centres would offer. That would let pharma companies decide on the products they would like to focus on, leaving the Jan Aushadhi products out of their range of activities. If the number of products is extremely large, it could squeeze many pharma players out of this sector altogether.

(b) the ability of the government to create more suppliers for this scheme. But that will also depend on the guarantees the government gives for both timely payment and specified minimum offtake. Nobody likes a government that reneges on contracts. If the terms and the guarantees are attractive, there should be no dearth of suppliers.

(c) easy accessibility to such outlets. There is no sense having a retail outlet in Borivali (which is the case in Mumbai) when the patient lives in or around Parel.

Global possibility

There is a silver lining too. It could help India create a few giant pharma producers in a market that is fragmented by high-priced producers. There is also a huge market for clandestine sale of pharma products from low cost countries like India. A good example is anti-cancer drugs, which cost ten times more in China than they do in India. Even at current prices, there is a steady flow of anti-cancer drugs to neighbouring countries where they can be sold at higher prices. When Jan Aushadhi offers these very drugs at one-fourth the current prices, expect the profit margins for such clandestine sales to become bigger.

But that could actually be good for India. If Indian pharma producers can sell larger quantities at one-fourth the current prices, and still make money from such production and distribution, they should not worry about margins others make. If Jan Aushadhi can guarantee quality, consistency and assured supply, it can even make India the global hub for – and the largest exporter of — pharma products.

- Scheme can have negative impact on Pharma companies which resort established unholy nexus of doctors and drug industry.
- Large pharma companies would not be keen to participate in this as it would disturb their existing cost structure and also directly cannibalise their products in the retail market.
- Scheme will be beneficial for small scale industries and improve their quality.
- The scheme can foster rise of pharma industry in the nation which can compete globally with their assured quality and competitive cost.
- The ability of the government to create more suppliers for scheme will depend on the guarantees the government gives for both timely payment and specified minimum offtake.
- Pharma companies would decide on the products they would like to focus on, leaving out products covered under scheme.
- If the number of products is extremely large, it could squeeze many pharma players out of this sector altogether.

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The Serialization Sprint: Where is Pharma at in Implementation?

COMPLIANCE IS A serious issue for India's pharmaceutical manufacturers, distributors, and retailers; due to the complicated nature of the pharmaceutical supply chain. Serialization requires pharmaceutical manufacturers to invest in new technology, adapt their current processes and systems and ensure the entire working line understands the new regulatory environment in which they are working.

Not only do companies need to accelerate their learning but find a solution provider who has a full-service implementation plan and support across all channels.

The right partner will have a set of user requirements that are well defined for the industry and a collaborative kick-off meeting to make the implementation process seamless. This approach ensures customers are well-aware of the implementation roadmap, what to expect and how the partner will support them in every step of the road.

Most recently, India has come to the fore as a major player in the global pharmaceutical market. According to the India Brand Equity Foundation (IBEF), the Indian pharmaceutical market is the third largest in the world by volume and 14th largest by value (approximately 1.95 trillion INR, or 30 billion USD)[1]. At present, pharmaceuticals manufactured in India account for approximately 10 percent of the world's pharmaceutical volume and are exported to more than 200 countries)[2], with further growth expected.

India has made strides in taking its first step to ensure the security of the global pharmaceutical supply chain - largely through its leadership in recognizing the importance of pharmaceutical serialization and traceability processes. However, recent international regulatory changes are now having a significant impact on the data, connectivity and technology infrastructure companies must have in place.

[1] India Department of Pharmaceuticals, Indian Pharmaceutical Industry—A Global Industry, available at: http://pharmaceuticals.gov.in/pharma-industry-promotion.

[2] Indian Brand Equity Foundation, India Pharmaceutical Industry.

With the race against time for pharmaceutical companies to not only comply with the EU Falsified Medicines Directive (EU FMD) and US Drug Supply Chain Security Act (US DSCSA) regulations, but also to understand the unwritten rules of supply chain best practice, if Indian pharmaceutical firms are to continue to manufacture and export internationally, then they must start taking a hard look at the evolving international serialization requirements.

Decoding Serialization Regulations

Serialization is the process by which products are marked with a standards-based unique identifier- typically a unique number or alphanumeric code-and is the enabling technology for systems and processes to enhance supply chain security.

The regulatory push to secure the pharmaceutical supply chain comes as a result of rising drug-related criminal activities and supply chain inefficiencies. Efforts are aimed at addressing drug counterfeits, unauthorized parallel supply chains, improving supply chain visibility, difficulty in tracking returns/recalls and scarcity of data-driven tools for predicting patient behaviour.

However, serialization of pharmaceuticals (i.e., applying the unique identifier to medication packaging) itself provides virtually no benefit to the supply chain. Rather, it is the use of that serialized data in a manner to efficiently realize the goals of the end-to-end system that enhances supply chain security. This complementary use of the serialized data is commonly referred to as "traceability" or "track-and-trace".

India has made great strides toward improved supply chain security through serialization requirements and the creation of a traceability system, with most manufacturers beginning their serialization programmes to satisfy the Directorate General of Foreign Trade (DGFT) requirements for export markets, laid out in early 2011.

In 2015, a further draft proposal for domestic drugs was published, but no timelines have been established for the adoption of that set of serialization, labeling, and reporting regulations.

Latterly, further regulations across the globe have started to take shape.

Passed in 2013, the US DSCSA roadmap for end-to-end traceability is stretched across a period of 10 years, with deliverables outlined for all entities of the supply chain. In the US, lot-level traceability began in January 2015 under the act with package-level serialization to be completed by November 2018, following an extension granted by the FDA in June 2017. The entire supply chain is expected to be electronically integrated and all nodes of traceability to be established by November 2023.

The European Union (EU) has followed suit with a compliance requirement by enacting Falsified Medicines Directive (FMD). Unit-level serialization and dispenser authentication has been mandated by February 2019.

India being a major exporter to the US, Europe and other regulated markets, these regulations have a significant impact on Indian pharmaceutical manufacturers, and the trend is now clearly visible. The end objective of all the regulations is traceability, where serialization is acting as the key enabler. Taking a cue from these global proceedings, Indian manufacturers are being urged to review at their serialization programmes with traceability as a core component of their strategy.

Serialization in Practice

Serialization and traceability require three key components: an understanding of all products distributed through the supply chain; an understanding of all parties that participate in supply chain; and a mechanism for identifying and ensuring the good standing of all parties that participate in the supply chain.

To achieve this understanding, and then be able to act it, is a significant undertaking. It requires the implementation of processes and software to generate, affix, and capture data related to the unique identifier. It may also require the potential reconfiguring of packaging lines, which in itself takes time to install and validate.

In addition, systems and processes between downstream trading partners, such as wholesalers and

Serialization and traceability are significant undertakings, but compliance to international regulations and understanding of supply chain best practice are vital to the continued growth and success of the Indian pharmaceutical market.

pharmacies, must be in place to receive, ship and dispense products. And, particularly in relation to the US market, full traceability requires serialized packages to be aggregated to cases, bundles, pallets, and other logistical units. As its most basic, if the data isn't in the system, then the product can't get through the supply chain.

Finally, the systems must be in place for the serialized data to be submitted to the relevant regulators and databases, from DAVA, to the FMD EMVO hub and the FDA in the US. Finding a serialization partner who is GS1 compliant and registered with the EMVO hub is critical.

Implementing Serialization and Traceability

"Pharmaceutical manufacturers face obstacles to meet global compliance due to the complexity of regulations, system integration and cost. The rfxcel solution, rfxcel Traceability System (rTS), offers a complete track and trace solution with a full service implementation plan, and hyper-care support across all channels of the integration process. Based on our experience, pharmaceutical supply chain companies can adopt these best-practices to maximize their ROI on a full-service implementation plan." says Vikash Pushpraj (SVP), an Executive of rfxcel.

Appreciating the complexity of the regulatory requirements, those organizations embarking on their serialization and traceability journey should adopt a comprehensive approach to ensure success.

1: Get executive buy-in

Serialization is a board level issue, with ramifications that could directly affect business performance. It is a business continuity risk that touches every aspect of an organization. So the first step is to appoint an executive sponsor, ideally with board level oversight, to lead a holistic strategy.

2: Assemble a multi-disciplinary team

Multi-disciplinary engagement is essential. Many organizations don't understand all their business processes in sufficient detail to overlay serialization. It's therefore vital that a multi-disciplinary team (MDT) is convened at the earliest opportunity to map the process flow of the business and establish a roadmap of how serialization can be applied across multiple organisational boundaries. An MDT should actively engage representatives from manufacturing, supply chain, IT, legal/regulatory and partner/contract management.

3: Understand the data implications of FMD

The barcodes required must include 4 lines of data; the unique identifier or Global Trade Item Number (GTIN), serial number, batch number and expiry date. These datasets often live in disparate systems within organizations. The master data - including GTINs - is fixed information that's commonly stored in an enterprise resource planning (ERP) system.

Having said that, many Indian pharmaceutical companies, whilst serializing, currently may not be applying numbers that are internationally compliant. Today's serialization and traceability requirements demand that organizations are registered with the global standards authority GS1. As part of the GS1 registration process, organizations are effectively buying the licence to use the intellectual property known as the GS1 identifiers (GTINs) to globally identify your company and products and converse with other companies. around the globe.

Even with the relevant licences and identifiers in place, the master data still requires attention to ensure it's clean and accurate when uploaded to the repositories. In terms of variable data, the processes required to generate serial numbers, transfer them to production and ensure they're used appropriately are complex. Managing that immensity of numbers throughout the supply chain lifecycle is hugely important; mistakes can lead to expensive delays, medicines shortages and loss of revenue. Serialization software is therefore an essential requirement to help you maintain control of all aspects of fixed and variable data.

4: Choose the right software

There are numerous factors to consider when selecting software:

Quality

Serialization should not be divorced from the founding principle of Good Manufacturing Practice (GMP) - quality. GMP guidelines, as well as data integrity advice from regulators such as the UK MHRA, state that users of computer systems must always be in control. However, multi-tenant serialization solutions (where multiple independent entities share the same instance of a software solution) can sometimes impose software updates without prior dialogue, leaving users out of control. The potential impact on quality is significant. Passive acceptance of change is not an option. Multi-tenant solutions require license-holding companies to ensure that risk assessment processes are in place to monitor and adapt to change. By contrast, the most effective solutions allow users to maintain control of their specific software instance and to dictate the timing, relevance and nature of upgrades.

Data Validation

An effective solution will focus on both connectivity and data integrity. Some systems concentrate on enabling a connection and flow of data across and between organizations but are blind to data quality. Companies should never assume that the data entering, or generated within, their systems is clean, tidy and accurate. Internal data checks are essential. The best solutions routinely monitor data to detect human error, inaccuracy and duplication. Smart solution providers validate data flowing through a system - in some cases up to 70 data validation checks on incoming records to ensure its integrity - essentially preventing bad data entering the EU or DAVA hubs.

Network connectivity

It's not enough to ensure your own business is ready: your partners must be ready too. With outsourcing now common across the industry, it's important that the software you use connects all parties to a single version of the truth. The most effective solution providers understand the varied nature of the connections you are going to have to make and will commit to connecting your entire partner network as standard. This means more than just having a potential connection - it means working with you and your partners to make sure that data really flows end-to-end across the supply chain.

5: Choose the right partner

Finally, it's important to find a vendor that can partner with you to design responsive solutions that go beyond technology. As stated above, certification of your vendor by the European Medicines Verification Organization (EMVO) is a pre-requisite if you want to be compliant.

In addition, a partner should be a recognized provider with experience, credibility and evidence that shows it can implement effectively within tight timeframes, including a "follow the sun" implementation model, operating across a number of time zones to ensure that time zone issues don't become your stumbling block.

A good partner will be committed to your success, keeping you abreast of fluctuating global regulations, and collaborating with you to customise solutions that adapt to changes in your business and the wider marketplace.

Conclusion

Serialization and traceability are significant undertakings, but compliance to international regulations and understanding of supply chain best practice are vital to the continued growth and success of the Indian pharmaceutical market. To succeed, pharmaceuticals companies must extend the boundaries of their enterprise. Meeting the EU FMD or US DSCSA requirements requires unprecedented agility, and collaborative capabilities. It is important to find flexible compliance solutions that can bring together data from multiple systems and verify the accuracy of the data to satisfy the regulations. The success of these initiatives depends on a traceability system that is driven by a team who embrace data quality and collaboration.

Investing in a trusted partner, who understands all the nuances of the international landscape and has the relevant registrations, resources, technology and processes in place, can help you successfully navigate hitherto uncharted territory.

By choosing rfxcel [https://www.rfxcel.com/], we set you up for success in meeting the EU FMD and US DSCS regulations. Reach out to our India lead, Vikash Pushpraj at india@rfxcel.com to find out how you can leverage our programs to ensure your supply chain meets international standards.

Serialization *from unit to pallet*

Consumer Organisation Promotes Sale Of Jan Aushadhi Store In Varanasi

Over the years India, has developed a strong capability in producing quality branded and generic medicines in most of the therapeutic categories, evolving from an mere Rs 1,500 crores industry in 1980 to a more than Rs 1,19,000 crores industry in 2012 and now almost touching Rs. 2,00,000 Crores.

FOR THE FIRST time a Consumer Organisation/Patient Group got engaged in managing a "Jan Aushadhi Store" to improve accessibility to quality generic medicines in India at the most affordable price in collaboration with Mata Anandamayee Hospital, Shivala, Varanasi. In order to build a pan India campaign to improve accessibility to quality generic medicines Government of India launched the 'Pradhan Mantri Bharatiya Jan Aushadhi Pariyojana'. The store was inaugurated on 1st January 2016 by Dr. V. K. Subburaj, IAS, Secretary to the Government of India, Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers. The project was jointly promoted by Consumer Online Foundation and Patient Safety and Access Initiative of India Foundation. This was part of a pilot project launched in Varanasi on 9th August 2015 to make India move towards Universal Health Coverage (UHC).

Dr. V.K. Subburaj, IAS, Secretary to the Government of India, Department of Pharmaceuticals, inaugurating the Jan Aushadhi Kendra at Mata Anandamayee Hospital on 1st January, 2016.

Over the years India, has developed a strong capability in producing quality branded and generic medicines in most of the therapeutic categories, evolving from an mere Rs 1,500 crores industry in 1980 to a more than Rs 1,19,000 crores industry in 2012 and now almost touching Rs. 2,00,000 Crores. The challenge is how to build the trust amongst the medical practitioners and the consumers that the quality of Jan Aushadhi Medicine is comparable to the leading brands. The only way forward is to create credible evidence on quality by regularly testing the medicines in accredited laboratories and making the report public so that the medical practitioners and the consumers start trusting the quality of generic medicines and encourages use of generic medicines to provide choice to the consumers. We all know through studies conducted in India that 80% of the healthcare cost for the patients in India is on medicines, medical devices and diagnostic procedures. Voluntary Consumer Organisations (VCOs) should partner with Government to take the campaign forward and reach the target of more than 3000 Jan Aushadhi stores becoming functional in the interest of patients.

On 3rd December 2016, The Jan Aushadhi Store Managed by VCOs within the premises of Mata Anandamayee Hospital was declared as one of the most successful Jan Aushadhi Store in India. We are keen that based on the Banaras Model many more VCOs should join the movement to improve accessibility to quality medicines at the most affordable price.

Jan Aushadhi Stores To Sell Sanitary Pads At A Third Of Market Price

RAILWAY MINISTER PIYUSH Goyal is exploring the possibility of facilitating manufacturing units for cheap and bio-degradable sanitary pads at 8,000 railway stations of the country.

In a move to improve menstrual hygiene practices in India, and ensuring that every woman in India has access to sanitary pads, the government will offer sanitary pads at all of its Pradhan Mantri Bhartiya Janaushadhi Pariyojana stores from May-end. Not only are these pads, branded 'Suvidha', expected to be a third the price of napkins currently available in the market, they will also be environmentally friendly because they are biodegradable, according to Minister of Chemicals and Fertilizers Ananth Kumar.

The Bureau of Pharma Public Sector Undertakings of India is expected to decide the manufacturer through a tender process and the pads will be available at all Janaushadhi stores from May 28, according to the minister.

The government aims to cater to all women in the Below Poverty Line category, he said.

"In the first phase, all 3,200 PJBJP outlets will sell...Later, we will again brainstorm and decide how to expand the program," the minister said.

There are currently over 3,200 PMBJP stores dispensing generic medicines at less than half the prices in the open market, stated a release by the ministry of chemicals and fertilizers.

The average market price of a pack of four sanitary pads is Rs 32, whereas the price of a similar pack of biodegradable pads will be Rs10 at PMBJP stores, according to the release.

Poor menstrual hygiene can cause final infections, reproductive tract infection, urinary tract infection, cervical cancer and infertility, according to the ministry.

"Disposable sanitary pads are the cheapest and most readily available, so its use is being promoted," it stated. At the same time, most disposable pads available in the country contain chemicals, gels and plastic sheets that pose health hazards and create "a lot" of waste that is poorly managed, it added.

India generates estimated 13 tonnes of menstrual waste annually in the form of 12.3 billion disposed sanitary pads, the ministry said cutting a report by PATH, Water aid and Water Supply and Sanitation Collaborative Council.

More than two-thirds of women in urban centres use hygienic methods of protection during periods, but this number is not even half in rural areas, according to the National Family Health Survey 2015-2016.

Narendra Modi Lauds Karnataka Man In 'Mann Ki Baat' Over Affordable Medicines' Scheme

PRIME MINISTER NARENDRA Modi lauded Mysurean Shriman Darshan in his 'Mann Ki Baat' address, for sharing information on buying medicines at affordable prices from Pradhan Mantri Jan Aushadhi Kendra counters.

He said that Darshan, who was spending Rs 6,000 a month on medicines alone for his father's treatment, has reduced his expenses by about 75 per cent by buying medicines from Pradhan Mantri Jan Aushadhi Kendra counters.

"It is a matter of joy learning about happenings like these. It gives you inner satisfaction. I felt good to see Shriman Darshan ji think about sharing with others what he gained from it," he said.

This has led to not only availability of cheaper medicines, but also new employment opportunities for individual entrepreneurs, Modi said.

Medicines available at the Jan Aushadhi Centres are 50 per cent and 90 per cent cheaper than branded drugs available in the market, he said.

"This is a great help for the common man, especially for senior citizens who require medicines on a daily basis and results in a lot of savings," Modi said.

Generic medicines sold under this scheme strictly conform to prescribed standards set by World Health Organisation, and hence good quality medicines are made available at affordable prices, Modi said.

Today, over 3,000 Jan Aushadhi Kendras have been set up across the country, he said.

Affordable medicines are now available at Amrit Stores' at Pradhan Mantri Bharatiya Jan Aushadhi Centres and at hospitals, Modi said.

Jan Aushadhi Stores Gaining Popularity

T.N. DILLIBABU, WHO has diabetes, has significantly brought down his monthly medication costs. He now buys generic medicines from a Jan Aushadhi store in the city. "I used to spend about ₹900 a month, but now it is within ₹300," he said.

Mr. Dillibabu is one of several customers who now goes to one of the city's 12 Jan Aushadhi pharmacies for their medication. Store owners say the scheme is helping many get drugs at a fraction of the cost they used to incur, but supply problems are affecting some stores, and awareness among the public remains low.

Santhosheema Ravi, State-in-charge, Tamil Nadu of the Bureau of Pharma PSUs of India, which implements the project, said sales were increasing month on month. There are 245 stores across the State and the project has 600 drugs available, of around a total of 3,600.

"Most patients come in for medicines for hypertension, diabetes and cholesterol. We have 300 drugs available, but there are supply issues, and we have to tell customers to inform us in advance," said one store owner.

"Instead of focusing on many drugs, if the project could just cater to drugs for chronic conditions and medicines such as immunosupressants for transplant patients, it would help with stocks and benefit patients too," he said. "Awareness of the stores also cannot be increased until there is adequate supply," he said.

Another store owner said sales were somewhat slow because of the supply issue.

On supplies, Ms. Ravi said that they were working to resolve the issue and ensure a streamlined supply of drugs.

Generic names

Store owners also said that if doctors prescribed generic names, this would make it much easier for them to dispense medication. Even though the Medical Council of India has directed doctors to prescribe medicines by generic names, concerns have been raised about this.

"Prescribing combination drugs with generic names is difficult. In addition, there could be a difference in quality between a generic drug and a branded one. As it is, quality control of drug manufacturing is very poor in the country. Mandating generics only may turn out to be risky for patients," said K. Senthil, State president, Tamil Nadu Government Doctors Association.

Also, Dr. Senthil said, there could be brand substitutions made by pharmacists if only generic names are given, which will not serve the purpose. "Instead, a law for manufacturers to use generic names could be brought in, and doctors could write out both brand names and generics on their prescriptions," he added.

However, Ms. Ravi said the quality of Jan Aushadhi generic drugs was excellent and that there were no issues there.

1st Generic-drugs Store A Hit With Consumers In Mumbai

THE CITY'S FIRST medicine shop that sells only generic drugs, at Ghatkopar, is proving a hit with consumers.

According to Shweta Mehta, co-owner of the Jan Aushadhi store in Ghatkopar, which began operations on February 16, generic medicines cost anywhere from one-fifth to one-tenth of the price of their branded counterparts."These stores give people the option of buying unbranded, quality medicines at affordable prices. They will especially benefit patients who suffer from chronic ailments and need to take medicines over a prolonged period," said Mehta.

Sandesh Paul,40, a resident of Navi Mumbai, learnt about the chain of stores from this year's budget announcements. "I have has been buying medicines for my mother's diabetes and hypertension treatment for over a decade and the expenses are very heavy on the pocket," said Paul, who recently started buying generic drugs from the Jan Aushadhi store.

Although doctors are not supposed to mention brand names in their prescriptions, according to guidelines set by the Medical Council of India, some doctors said that naming brands ensures that patients take good-quality drugs. "There is no doubt that generic drugs give people an affordable option, but we must wait and see the quality and efficacy of these drugs before prescribing them to all patients," said Dr Atul Shah an orthopedic surgeon at Aadhar OrthopedicClinic, Ghatkopar.

A comparison

Atorvastatin

It belongs to a class of drugs used primarily as lipid-lowering agents. They also help prevent conditions associated with cardiovascular diseases.

10 atorvastatin tablets, 10mg each
Average market price: Rs 70
Jan Aushadhi price: Rs 12.64

Ramipril

This drug is used to treat high blood pressure (hypertension) andcongestive heart failure.

10 tablets of Ramipril, 5mg each
Average market price: Rs 80
Jan Aushadhi price: Rs 8.53

Piperacillin

It is a common injectable antibioticused in the treatment of a number of bacterial infections.

Average market price: Rs 350 to Rs 1,200
Jan Aushadhi price: Rs 40

Details of all medicines sold at Jan Aushadhi stores is available at www.janaushadhi.gov.in

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JAN AUSHADHI: In Need Of A Right Prescription

Generic prescription patterns, supply-chain management must for low-cost drug availability

AN EARNEST-SOUNDING VOICE answers the Jan Aushadhi hotline number and assures the person calling that more stores are being planned by the Government in districts across the country. That response was to the caller's query if there was a Jan Aushadhi (JA) store in Mumbai. As it happens, there is one in Maharashtra, but in Pune!

It's been over six years since the Government set up its first JA store in Amritsar with the aim of supplying less expensive generic drugs to consumers. But, the project has been struggling, despite several revival plans announced by the top brass at the Department of Pharmaceuticals.

About 100-odd JA stores presently operate largely in North India. Another 50 have been closed and the. And latest reports speak of 1,000 more stores by mid-June.

So will the plan take wing this time? Experts who have dissected the struggling JA project, identify key problem areas — prescription patterns (whether the medicine is suggested by brand name or the generic-chemical name) and supply-chain management (involving sourcing, warehousing, etc). This impacts the availability and quality of medicine reaching the consumer, they point out.

Prescription problems

The JA idea was to supply quality generic drugs at rock bottom prices by removing the several intermediaries between the drugmaker and consumer. But there was an over-dependence on pharmaceutical Public Sector Units (PSU), observes a senior health economist with the Public Health Foundation of India.

Though relying on Government-owned drugmakers is desirable, problems arose because they did not supply the entire basket of essential medicines. And this resulted in shortages and stockouts at the JA stores.

In damage control mode, the Government roped in non-government organisations, tinkered with the revenue model, etc, but prescription patterns continued to trip-up the plan.

Unless medicines are prescribed by generic names, it will not drive patients to buy these chemically similar versions of branded products. In fact, the revenues these shops make in a month are comparable to what a regular chemist makes in a day, the economist observes.

Amit Mookim, Country Principal (South Asia) at IMS Consulting Group, echoes similar thoughts. Supply-chain management and prescription patterns are essential for the plan to supply generic drugs at a fraction of the market price to succeed.

Question of choice

The over-dependence on Central PSUs led to reduced selection of drugs at the JA store. So consumers moved to a better stocked chemist if their medicine was not available at JA. The Government needs to assess the commercial viability of these stores, the real-estate cost, operational costs in storing and selling such medicines, etc, he points out. Consumer awareness on generics, its benefits and the existence of JA stores is also low, observes Mookim. There is some headway here, with a mobile application now helping consumers get the generic name of a particular drug, he adds.

Other issues, such as competition from organised chemists, etc, are secondary. The primary need of JA stores is to be well-equipped with quality and cost-effective drugs, he says. Medicines need to be sourced from multiple vendors and this robust supply chain needs to be supported with a change in prescription patterns, he suggests.

Business wise

Meanwhile, JA is scouting for a Chief Executive. And though healthworkers are not optimistic that it will help revive JA, pharma industry representatives point out that it might, if Government pays good money to attract resourceful people for the top job.

JA needs to be run like a business, possibly by someone who understands the consumer goods sector and intricacies of supply chain management, observes Mookim.

Taking it a step further, he suggests, that the Government should look at innovative partnerships like the Passport office–TCS alliance. In JA's case, he says, it could include private medical practitioners into the net to prescribe generics, since they are the first port of call when someone is unwell.

Conceptually, the JA idea is appealing, says the PHFI economist. But, if the Government cannot do it in India — lauded as pharmacy to the world — then no one else can, he points out.

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POINTSTONOTE

1. What is Pradhan Mantri Bhartiya Janaushadhi Pariyojana ?

'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' is a campaign launched by the Department of Pharmaceuticals, Govt. Of India, to provide quality medicines at affordable prices to the masses through special kendra's known as Pradhan Mantri Bhartiya Jan Aushadhi Kendra. Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK) have been set up to provide generic drugs, which are available at lesser prices but are equivalent in quality and efficacy as expensive branded drugs.

2. What is a Generic Medicine?

Generic medicines are unbranded medicines which are equally safe and having the same efficacy as that of branded medicines in terms of their therapeutic value. The prices of generic medicines are much cheaper than their branded equivalent.

3. What is BPPI?

BPPI (Bureau of Pharma Public Sector Undertakings of India) has been established under the Department of Pharmaceuticals, Govt. of India, with the support of all the CPSUs for co-coordinating procurement, supply and marketing of generic drugs through Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK).

4. How the quality, safety and efficacy of medicines are ensured?

The quality, safety and efficacy of medicines are ensured by getting each batch of medicines procured from CPSUs as well as private suppliers tested from NABL approved laboratories and conforming to the required standards before the same are supplied to Super stockists /PMBJK's from the Warehouse of BPPI.

5. Are generic drugs as effective as branded ones?

The generic drugs are having the same efficacy and therapeutic value as that of branded medicines

6. How do generic medicines benefit the patients?

The cost of generic medicines having the same quality as that of branded medicines is much cheaper than their branded equivalent.

7. What are the medicines available from Pradhan Mantri Bhartiya Jan Aushadhi Kednra and what are their prices ?

The endeavour of BPPI is to make available all therapeutic medicines from PMBJK's. A list of medicines with their MRP which are presently available are given under the heading “Price List of PMBJP medicines” on website: janaushadhi.gov.in. More medicines are being added to this list.

8. How many Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK) have been opened and what are their locations ?

More than 850 Pradhan Mantri Bhartiya Jan Aushadhi Kednra's are presently functional spread over 28 States/UTs. List of State-wise / District-wise JAS along with their locations are available under the heading “PMBJK” of the website of Jan Aushadhi.

9. What is timing (opening and closing) of the Pradhan Mantri Bhartiya Jan Aushadhi Kendra ?

The normal working hours of JAS are 8 Am to 8 PM.

10. Who can purchase medicines from Pradhan Mantri Bhartiya Jan Aushadhi Kendra?

OTC products can be purchased by any individual without a prescription. A prescription from a registered medical practitioner is necessary for purchase of schedule drugs.

11. How the medicines are procured and supplied to Pradhan Mantri Bhartiya Jan Aushadhi Kendra?

Earlier, only medicines manufactured by CPSUs were being supplied to Pradhan Mantri Bhartiya Jan Aushadhi Kendra. Since CPSUs are not able to make supply of all the medicines proposed to be supplied to PMBJK, procurement of medicines which the CPSUs are not able to supply are being made from the private manufacturers. These medicines after getting tested from empanelled NABL Laboratories and sent to PMBJK through Super stockists/CEF agent/Distributors appointed by BPPI.

12. Who can open a Pradhan Mantri Bhartiya Jan Aushadhi Kendra ?

The main objective of the Bureau of Pharma PSUs of India (BPPI) is to open maximum number of Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK) in the country. Under the Jan Aushadhi Scheme, the State Governments are required to provide space in Government Hospital premises or any other suitable locations for the running of the Jan Aushadhi Kendra. PMBJK may also be opened by any Government agencies in any Government building owned by Government bodies like Railways/ State Transport Department/ Urban Local Bodies/Panchayati Raj Institutions/ Post Offices/ Defense/ PSUs etc. Any NGOs/ Charitable Society/Institution /Self help Group/Individual Entrepreneurs/Pharmacist/Doctor can also open the Jan Aushadhi Kendra at outside of the hospital premises or any other suitable place. BPPI have simplified the application format so that a common man can easily fill up the same. Besides above, the application fee of Rs. 2000/- which was charged earlier have been waived of to make the scheme popular. Financial support to Pradhan Mantri Bhartiya Janaushadhi Kendras: An amount of Rs.2.5 lakhs shall be extended to NGOs/agencies/individuals establishing JAK in government hospital premises where space is provided free of cost by Govt. to operating agency: Rs. 1 lakh reimbursement of furniture and fixtures Rs. 1 lakh by way of free medicines in the

beginning Rs. 0.50 lakh as reimbursement for computer, internet, printer, scanner, etc JAK run by private entrepreneurs / pharmacists / NGOs / Charitable organizations that are linked with BPPI headquarters through internet shall be extended an incentive up to Rs. 2.5 lakhs. This will be given @ 15% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a limit of Rs. 2.5 lakhs. In NE states, i.e. naxal affected areas and tribal areas, the rate of incentive will be 15% and subject to monthly ceiling of Rs. 15,000 and total limit of Rs. 2.5 lakhs. For SC/ST and differently abled persons applied in individual category shall be benefited with free medicines worth of Rs. 50,000/- to set up their Pradhan Mantri Bhartiya Janaushadhi Kendra in the beginning. Remaining amount i.e. Rs. 2.00 lakhs will be given in the form of incentive, as per above norms. Trade margin to retailers and distributors: Trade margins have been revised from 16% to 20% for Retailers and from 8% to 10% for Distributors.

13. What are the requirements for opening a Pradhan Mantri Bhartiya Jan Aushadhi Kendra by organization/individual other than government nominated ?

(a) Own space or hired space duly supported by proper lease agreement; (b) Minimum required space conforming to standards as approved by the BPPI i.e. 120 sq. ft. (c) Sale license from competent authority (Retail drug license in the name of the applicant and/or Tin No.); (d) Proof of securing a pharmacist with computer knowledge (name of the pharmacist , Registration with the State Council etc. needs to be furnished) ;

14. What is the procedure for opening a Pradhan Mantri Bhartiya Jan Aushadhi Kendra?

BPPI writes to all the State Governments with a request to open Pradhan Mantri Bhartiya Jan Aushadhi Kendra in their states. The State Government, Department of Health would make recommendations in favour of the operating agency who would run the Kendra and also instruct the District Hospital Authority to provide the minimum space conforming to standards as approved by BPPI in the Hospital premises. The location of the Kendra should be at such a place which is easily accessible to the OPD patients, preferably at the entry of the hospital & given to the agency free of cost. The State Government needs to issue suitable instructions to the Hospitals/ Doctors for prescribing generic medicines. Other entities may approach BPPI either on the basis of advertisement issued by BPPI or suomoto with a complete application along with the supporting documents mentioned at sl. no 13 above. An agreement is to be entered into between BPPI and the operating agency before the JAS starts functioning and BPPI makes arrangements for dispatch of medicines. For detailed procedure, please visit our website: janaushadhi.gov.in.

15. Do we need to pay any charge for opening Jan Aushadhi Kendra?

No, you don't need to pay any charge for opening Jan Aushadhi Kendra, Software Installation, Media inputs or for any other service. If anybody asks for money for any services of BPPI please bring it in notice of BPPI management. For any complaint/ suggestion please fill up the feedback form which is available in our website

16. What incentives are available to a Pradhan Mantri Bhartiya Jan Aushadhi Kendra owner ?

An amount of Rs.2.5 lakhs shall be extended to NGOs/agencies/individuals establishing JAK in government hospital premises where space is provided free of cost by Govt. to operating agency: Rs. 1 lakh reimbursement of furniture and fixtures Rs. 1 lakh by way of free medicines in the beginning Rs. 0.50 lakh as reimbursement for computer, internet, printer, scanner, etc JAK run by private entrepreneurs / pharmacists / NGOs / Charitable organizations that are linked with BPPI headquarters through internet shall be extended an incentive up to Rs. 2.5 lakhs. This will be given @ 15% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a limit of Rs. 2.5 lakhs. In NE states, i.e. naxal affected areas and tribal areas, the rate of incentive will be 15% and subject to monthly ceiling of Rs. 15,000 and total limit of Rs. 2.5 lakhs. For SC/ST and differently abled persons applied in individual category shall be benefited with free medicines worth of Rs. 50,000/- to set up their Pradhan Mantri Bhartiya Janaushadhi Kendra in the beginning. Remaining amount i.e. Rs. 2.00 lakhs will be given in the form of incentive, as per above norms.

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Inadequate Supply Of Medicines, Lack Of Awareness Hurt Central Drug Scheme

In a quaint corner in Navi Mumbai's Nerul area, NGO Anandi Seva Kendra sells generic medicines at up to 70 per cent less than the prices of similar branded medicines. Its drug store, Jan Aushadhi Kendra, was started about eight months back after Finance Minister Arun Jaitley announced the opening of 3,000 such centres in the Budget last year.

Rajendra Shelar, the centre's president, was certain that the highly affordable medicines will sell like hot cakes. But his hopes have dashed, as he struggles with losses due to poor medicine supply chain combined with a lack of awareness about the scheme.

With daily sales of less than ₹1,000 per day, Shelar is not able to meet even operating expenses like electricity and the pharmacist's salary.

Miles away, in Telangana's Ranga Reddy district, Jan Aushadhi Store owner S Raju too is saddled with losses, which have been compounded by the presence of a Patanjali medicine store next door. "Nearly 99 per cent people don't know about the scheme in the absence of any promotion about it," says Raju, who has tried distributing pamphlets to create awareness but to no use. He is now planning to move into a new and bigger store — his last attempt to make things work.

While the government has opened 645 Jan Aushadhi stores so far, according to the list on its website, it has not yet got the supply chain right. Currently, the Bureau of Pharma Public Sector Undertakings of India (BPPI) cocoordinates procurement, supply and marketing of generic drugs. Each State has one distributor who supplies them to the stores. The store owner gets a commission varying from 15 to 20 per cent for various medicines.

Raju says the supply of medicines for diabetes and blood pressure, which are the most in demand, is extremely poor. "A customer filed a complaint against us for not stocking the medicine she required even though the fault lies with the supply chain," he says, adding that minimum daily sales of ₹10,000 are necessary for the store to make any profit.

But in the Mumbai suburb of Borivali, Vijay Bhailal Gosar is happy to have opened the Jan Aushadhi store last year. He has plugged some of the loopholes by creating awareness through social media and putting up banners at key places like police stations and blood donation camps. "We get medicine (from the supplier) twice a week. We call up every two hours to ensure that he dispatches the medicine within two days after placing the order," he says laughing.

With a Twitter handle, Facebook page and a senior citizens WhatsApp group of over 5,000 locals, Gosar has ensured that his store does not go unnoticed.

Mahendra Bhavsar, a real estate agent who is a regular at Gosar's store, says the medicine for diabetes, which costs around ₹70 for a strip of 10 tablets, is available at ₹14-15 at Jan Aushadhi centres. "It is a huge saving, especially for health conditions like BP and diabetes, which require lifelong medicines," he says.

Amrendra Kumar in Bihar's Muzaffarpur is also selling medicines worth about ₹3,000 per day.

Kumar too does not face any supply issues, possibly because there are just four Jan Aushadhi stores in Bihar at present. Once the numbers in the state become large, he may also have to wait for 15 days to get medicines.

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