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THE AWARE CONSUMER

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Evolving

Consumer-Centric Pharmacy Practices

MY MARKET
Promoting Fair Pricing and Marketing of Medical Products

GOVERNMENT PERSPECTIVE
Legal Cornerstone of Pharmacies and Medical Products

NATIONAL CONSUMER DAY
24th December, 2023

INTERVIEW

RAJ VAIDYA
(M. Pharm, Fellow of IPA)

IN FOCUS
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VIEW  POINT

MESSAGE FROM PUBLISHER & EDITOR

Pharmacist – A Pillar of Support for Healthcare!

MEDICINES AND MEDICAL devices play a critical role in delivering healthcare to the consumers. The power of healing, well-being and vitality is packed into every dose, thus unleashing the promise of a healthier existence!

In India, there literally is a medical store at every nook and corner dispensing a range of drugs and medical devices. Walking into a pharmacy - with/without a prescription in hand - and getting the necessary tablets, capsules or syrups as a remedy for our ailments is a matter of course. That's not all, we often approach the local pharmacist with our everyday health issues and seek their 'medical advice' on suitable medications.

The role of the pharmacist is not limited to merely dispensing drugs and other medical products to the walk-in customers. It goes much beyond and encompasses advising the patients on the proper administration of the medications, potential interactions with food or other drugs, possibility of adverse events, etc.

Experts around the world have acknowledged that simply getting the right medicine or medical device is not always enough to ensure the desired health outcome for the patient! In fact, it can end up causing unnecessary harm when not used 'correctly'. Therefore, pharmacists can be termed as the custodians of pharmaceutical products charged with ensuring their safe and efficacious use!

The question is - will our pharmacists make the well-being of patients the main philosophy underlying the practice of their profession, a profession which is actually a service to society?

As India celebrates National Consumer Day on 24th of this month, The Aware Consumer turns the spotlight on the need for good pharmacy practices to ensure access to safe and quality medical products. This day commemorates the same date circa 1986 when the Consumer Protection Act received the assent of the President and came into force for the very first time. It was a historic milestone for the consumer movement in India and is observed every year to spread awareness about consumer rights and responsibilities.

Prof. Bejon Kumar Misra
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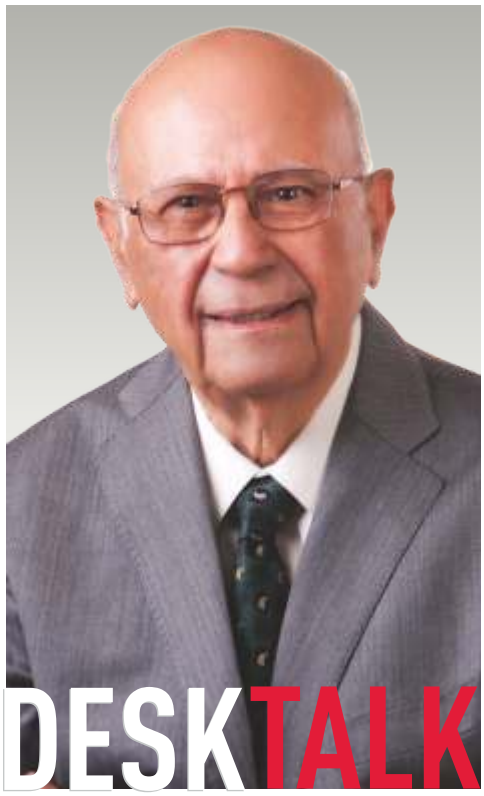

PRESSING NEED TO REWRITE THE PROFESSION OF PHARMACY

DESKTALK

INDIA HAS ESTABLISHED itself as the leading global provider of generic drugs and earned the moniker of 'Pharmacy of the World'. But the irony is that the pharmacies back home continue to play it by ear and go about their 'business' of selling medicines without sparing a thought for how they will actually be used!

Indeed, lack of access to healthcare facilities and the elevated cost of healthcare are not the only barriers to good health in our country, but poor access to quality medicines and medical devices is another bane which mars the healthcare landscape across India.

This happens primarily because in most of our pharmacies, the custodians of pharmacy fail to acknowledge their professional, moral and ethical responsibilities towards the society. Even though the pharmacy profession celebrates 25th September as World Pharmacist Day to highlight and honour pharmacists for their contributions to enhancing world health, in India they lack professionalism.

WORLD PHARMACISTS DAY
SEPTEMBER 25

Under the World Health Organization, a revised Drug Strategy was adopted by the World Health Assembly in 1986. WHO organised two meetings on the role of pharmacist - in New Delhi, India as far back as in 1988 and in Tokyo, Japan in 1993. This was followed by the adoption, in May 1994, of the WHA 47.12 resolution on the role of pharmacist in support of the Revised Drug Strategy. In 1992, FIP (International Pharmaceutical Federation) developed standards for pharmacy services under the heading 'Good Pharmacy Practice in community and hospital pharmacy settings'. Alas, despite several efforts by the Indian Pharmaceutical Association (IPA), our country still lacks a comprehensive statute of Good Pharmacy Practice while such guidelines have been established in the global arena.

In 2007, the Bangkok Declaration on good pharmacy practice in the community pharmacy setting in the Southeast Asia region was adopted by the FIP Southeast Asia Pharmaceutical Forum (SEARPharm Forum) and set out the commitment of its member associations towards standards of pharmacy services and professional practice. But in India, the profession has not been able to adopt this commitment towards professional standards of pharmacy services.

The health of the public is fundamental to the happiness and welfare of all people. Barriers to good health include poor access to quality medical products, lack of access to trained pharmacists and unaffordable cost of healthcare. Medicines are an essential and critical part of healthcare services for the society for disease prevention and health promotion. The adoption of good pharmacy practices is a pressing need. Will our pharmacists rise above considering this as a mere 'trade'?

INSIDE

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UNLOCKING CONSUMER POTENTIAL
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MS. BINA JAIN
PAST PRESIDENT, PATRON AND TRUSTEE OF ALL INDIA WOMEN'S CONFERENCE (AIWC)

Ms. Bina Jain sowed the seed for the theme of this edition of The Aware Consumer when she shared with the editorial board her experiences and concerns about the malpractices in the pharmacy sector. She is also Chairperson of Healthy You Foundation, Board Member of Partnership for Safe Medicines India Initiative and an active member of our Editorial Board.

ROUNDUP

GOVERNMENT DRAFTS PHARMACY COMMISSION BILL

ON 15TH NOVEMBER, the Union Ministry of Health and Family Welfare released the draft National Pharmacy Commission Bill, 2023 to supersede the antiquated Pharmacy Act, 1948 and replace the existing Pharmacy Council of India (PCI) with the National Pharmacy Commission. This is aligned with the enactment of the National Medical Commission Act, 2019.

The groundbreaking legislation aims to enhance pharmacy education by improving access to affordable, high-quality education, and availability of pharmacy professionals. It seeks to promote equitable healthcare by making pharmacy services accessible to all citizens.

The bill proposes regular, transparent assessments of pharmacy institutions, maintenance of a national pharmacy register and also establishing an effective grievance redressal mechanism for relevant matters.

The National Pharmacy Commission will be tasked with setting education standards, facilities, assessments, training, research and tuition fees. It will establish standards for the pharmacy faculty and clinical facilities, implement a uniform admission mechanism, and regulate pharmacy education and training policies.

The commission will also make regulations to ensure the competency of pharmacy professionals. It will evaluate professionals "to ensure adequate competence of the pharmacy professionals for enrolment in the National Register or State Register, as the case may be, and for granting licence to practice as a pharmacy professional".

Additionally, the government will constitute three boards - Pharmacy Education Board, Pharmacy Assessment and Rating Board and Pharmacy Ethics and Registration Board to function under the commission.

The Pharmacy Assessment and Rating Board will evaluate and rate pharmacy institutions and publish assessment documents

DATA BRIEFING

Pharmacy education was started in India at Banaras Hindu University in 1932 by late ML Schroff, better known as 'Father of Pharmacy in India'

on its website. New pharmacy institutions/ courses cannot be established without prior permission from the Board. The Pharmacy Ethics and Registration Board will maintain a National Pharmacy Register (NPR) containing details of pharmacy professionals.

The bill adds that every State Government shall, within one year from the commencement of this Act, constitute a state pharmacy chapter (where no such state chapter exists in that State by a State Law) for exercising such powers and discharging such duties as may be laid down under the Act.

In short, the new bill aims to reinvigorate pharmacy education which has remained stagnant for the last many years. While it is being touted as the government's commitment to reforming healthcare regulatory bodies and advancing healthcare education/services, reservations are coming in from various quarters. As Dr. Suresh R. Saravdekar, former Assistant Director, Ministry of Medical Education & Research observes, “Looking at the draft for framing career opportunities for budding pharmacists, there is a clear dominance of and only for epidemics. Teachers have framed it without considering the professional needs of the industry, hospitals and community pharmacies”.

Dr. Suresh R. Saravdekar

Kerala Plans India's First Private Drug Quality Assessment Drive

THE NATIONAL MEDICAL Commission's order for medical practitioners to prescribe only generic medicines has been put on hold for now. However, the intense debate on the topic triggered a group of doctors and scientists in Kerala to assess the quality of generics in India.

Launched by the 'Mission for Ethics and Science in Healthcare' group — a network of biomedical experts, mathematicians, clinical researchers and lawyers apart from doctors and scientists — it will test ten categories of generics and branded generics. These include commonly used medicines such as those for treating fever, diabetes, high cholesterol and hypertension.

Dr Cyriac Abby Philips, a hepatologist-clinical researcher from Kerala (known on social media for his critical views on traditional medicine) is at the forefront of the initiative. He said he got the idea when he randomly tested four medicines - generics and branded generic versions of Metformin and Atorvastatin, used to treat diabetes and high cholesterol respectively - in a private laboratory at Cochin.

He explained, “One of the house helps in our building had been taking generic medicines given to her by a state-run hospital for these conditions for the last three to four months and was not showing any improvement. After the patient was transitioned to the branded versions of the medicines, her symptoms improved, so I decided to get these four medicines tested in a drugtesting laboratory using money from my own pocket.”

The generic form of Atorvastatin failed the assay test — which tests whether the amount of molecule present in a drug as specified on the label meets Indian Pharmacopoeia standards — and was declared 'Not of Standard Quality (NSQ)' by the laboratory. All the other medicines cleared the test.

This first-of-its-kind project aims to ring the alarm bells so that drug regulators take the issue of quality control more seriously!

> When one out of four medicines tested has failed this crucial test, it is evident that the problem is very widespread and that's why we want to expand the project!
>
> ***– Dr Cyriac Abby Philips***

Colleges Persuade Students to Pursue Pharmacy to Build a Flourishing and Recession-Proof Career

PHARMACY COLLEGES ACROSS the country are positioning the pharmacy course as a recession-proof career. Qualified pharmacists employed across academia, industry, research institutions and healthcare centres are touted as having stable jobs compared to some other industries during economic downturns. This was evident during the COVID-19 pandemic when the pharmaceutical industry was actively involved in the bulk production of vaccines and other life-saving medications, which were then dispensed by the pharmacies. Therefore, it can safely be said that pharmacists will never face a slowdown in their careers, as the healthcare industry will continue to thrive irrespective of the state of the economy.

> Opting for pharmacy as a promising career catapults one to tapping global exposure and growth. The avenues are plenty for a qualified and registered pharmacist. There is a perpetual demand for pharmacy professionals across trade outlets, primary care, hospitals, government and industry, besides research and other medical avenues like dentistry, mental health, to name a few.
>
> ***– Prof. R. Raveendra,***
> *Head, Department of Pharmaceutical Chemistry,*
> *Cauvery College, Mysuru*

West Bengal to Go Tough on Sale of Antibiotics Without Prescription

FOLLOWING SEVERAL REPORTS and findings of increasing growth of multiple drug-resistant bacteria in human bodies, the West Bengal health department has decided to act tough on the rampant sale of antibiotic drugs in retail medicine shops in the state without proper prescription from any registered medical practitioner.

Asenior health department official said "Rampant use of antibiotics has become a vicious circle. Once certain drug-resistant bacteria for a certain level of antibiotics are developed in the human body, people are resorting to stronger dosage to antibiotics.This circle is resulting in the growth of multiple drug-resistant bacteria in human bodies: This is happening because a section of the retail chemists and druggists are selling antibiotic drugs without any sort of prescription. We have now decided to act tough in the matter".

The state health department will also start awareness campaigns - in coordination with the doctors' associations -to make the people aware of the proper use of antibiotics as per doctors' advice only and also complete the dosage of antibiotics as prescribed by doctors. The official added, "Besides purchasing antibiotic drugs without proper prescription, often people are not completing the required dosage of antibiotics for perfect remedies. Such things add to the complications further and hence what is necessary is creating public awareness on this count. No effort on our side will work unless the people are aware of the ill-effects of rampant and unscientific use of antibiotics".

Simultaneously, the state health department will work closely with the state animal husbandry department to monitor the rampant use of antibiotic substances in agricultural farms, poultries, hatcheries and pisciculture farms.

Suspending and Cancelling Drug Licenses of Chemists

TO CURB THE illicit sale of habit-forming drugs, including painkillers, the state Directorate of Drug Control in Chennai, Tamil Nadu revoked the licenses of six chemists in November 2023. In addition to this, at least 117 licences were suspended temporarily for violations under the Drugs and Cosmetics Act, 1940.

Health Secretary, Mr. Gagandeep Singh Bedi disclosed that this decision came in response to alarming reports received from the police of unauthorised sales of these drugs without prescriptions from doctors over the last six months.Concerned by the widespread availability of habit-forming drugs, he stated, "We have formed teams to crack down on such sales. Drug inspectors will inspect pharmacies in their region at least three times a week to check on sales records. They will be accompanied by police."

Prior to this, in May, the Food and Drug Administration (FDA) officials cancelled the licences of 107 chemists and suspended the licences of 402 chemists in Pune, Maharashtra. These pharmacies were found violating the Drugs and Cosmetics Act, 1940 while carrying out inspections from April 2022 to March 2023.

According to the officials the violations included, operating without a pharmacist or qualified staff, poor recordkeeping, dispensing medicines without a valid prescription, improper storage of temperature-sensitive drugs, and non-maintenance of records of scheduled drugs amongst others.

A senior FDA official explained that licences are cancelled only in case of serious violations. For instance, a pharmacist unavailable for a couple of days or during the inspection is less serious and the license can be suspended. But if a pharmacist is unavailable for several months, the consequences are grave and can lead to cancellation of the license.

In June this year, licenses of 9 chemists in Hyderabad, Telangana were cancelled for similar reasons.

While action is ongoing against errant pharmacies, it remains sporadic and ineffective in curbing the widespread violations in the country.

PM Modi makes a strong case for focus on 'consumer care'!

PM Modi Pitches for International Consumer Care Day!

Our Honourable Prime Minister proposed a novel idea to global businesses - consider designating an annual 'International Consumer Care Day'! This will help strengthen trust between businesses and consumers.

WE TALK ABOUT consumer rights, but what about consumer care? Prime Minister Narendra Modi stressed on this dimension at the Business 20 (B20) Summit India 2023 organised by the Confederation of Indian Industries (CII) as part of India's G20 Presidency.

Speaking at the path-breaking Summit, the Prime Minister hailed that the future of global growth is dependent on the future of business. He stated, “We all know business can transform potential into prosperity, obstacles into opportunities, and aspirations into achievements. Whether they are small or big, global or local, business can ensure progress for everyone.”

Noting the large number of global business leaders attending the valedictory session of B20, he urged them to look beyond consumer rights and focus on consumer care. His words echoed around the conference, “Consumer Rights Day is celebrated across the world.

The B20 Summit India 2023 - held from 25th to 27th August in New Delhi - saw one of the largest gathering of leaders from the national and global stages, who converged to share their perspectives covering a huge spectrum, spanning almost all facets of growth and development. CII functions as the B20 Secretariat – it is a non-government, not-for-profit, industry-led and industry-managed organisation, with around 9000 members from the private and public sectors.

> **Every year, can global businesses come together to pledge themselves for the good of the consumers and their markets?**
>
> **– PM Modi**

Can we take the initiative for consumer care? Once we start celebrating Consumer Care Day, the environment will change with a positive signal. If we talk about consumer care, then the issues related to rights will automatically be solved. Therefore, International Consumer Care Day - I want you all to think on this. This will further strengthen trust between the consumer and the business!"

The Prime Minister further emphasised that a profitable market can be sustained when there's a balance in the interests of producers and consumers, and this also applies to nations. He underlined, "Consumers can be both individuals and countries. Treating countries just as a market will not work. It will even harm the producing countries sooner or later. Making everyone equal partners in progress is the way forward." The point of contention is that retail consumers are not confined to a particular geography, but extend to nations that are consumers of global trade, global goods and services.

Mr. Modi made a sound case for focusing on improving the purchasing power of more and more people. This entails reconsidering the traditional approach to business by going beyond brands and sales. Highlighting that 13.5 crore Indians have come out of poverty in just 5 years, he stated that these people are the new consumers - the neo middle class that is giving momentum to India's growth.

The Prime Minister went a step ahead and made a bold call for making businesses more consumer-centric while stressing that the yearly campaign of Consumer Care Day can take care of the interests of consumers. He cautioned that a self-centric approach will not do any good to the businesses or the world at large. Referring to the challenge of uneven availability and universal need of rare earth metals, he sounded the warning that if those who have them do not look at them as a global responsibility, it could result in a 'new colonial model'!

Above all, he asserted the need for a more integrated approach and suggested creating a global framework where issues of all stakeholders can be addressed.

In conclusion, the PM lauded that businesses have successfully gone beyond borders and boundaries; now it is time to take businesses beyond the bottom line. He also stated that the B20 Summit has paved the way for a collective transformation!

> I truly feel very redeemed when I see the enthusiasm that the B20 has been able to generate across continents, the high quality of dialogue and discussion, and the serious interest in the India story that we see around the world. It's a moment of pride for all of us.
>
> ***– Mr. Piyush Goyal, Minister of Consumer Affairs, Food & Public Distribution, Government of India***

Consumers, Beware

Pharmacists

– The Gatekeepers of Medication Management!

Pharmacists play a crucial role in the healthcare system that goes much beyond merely providing drugs and medical devices to the patients. In the bigger picture, they are charged with pharmaceutical care - guiding people about the medications while ensuring their safe and appropriate usage.

The role of the pharmacist in patient safety is evolving by the day!

THE PHARMACY PROFESSION traditionally involves preparing and dispensing medications and other health supplies. However, with most pharmaceutical companies manufacturing drugs in standardised doses and prepackaged forms, pharmacists no longer have to compound the drugs in the pharmacy.

Does this mean that just about anyone can simply stand behind the counter and fill the prescriptions from the shelves loaded with boxes of ready-to-use medications and medical devices?

Not by a long shot, especially as it is increasingly being recognised that providing consumers with medicines alone is not sufficient to achieve the treatment goals. In fact, taking the wrong drug, the wrong dose or even at the wrong time, can lead to serious consequences, including death.

And it is the pharmacist – also known as chemist – who is rightfully placed to close the gap between the potential benefit of medicines and the actual value realised from them. Indeed, the role of the pharmacist encompasses many more dimensions of medical products-related needs in the interests of patient safety.

Safe Use of Medical Products

A pharmacist is a healthcare professional who is specifically educated and trained to store, handle, prepare and dispense various medications. However, he/she cannot get by with mindlessly dispensing the drugs or medical devices requested by the consumers. It is their prime duty to use their medication expertise to review the prescriptions to ensure that the patients get the right medical products for their health conditions with minimal or no adverse consequences. This includes:

- Read the prescription and provide the correct drug as prescribed. In case it is not available, a substitute or generic version can be suggested.
- Check whether the prescription is legitimate and the medication is appropriate for the specific condition of the patient.
- Verify the dose regimen and dosage form of the medications prescribed by the healthcare professional.
- Provide correct usage instructions to the patients - like when and how to take the medication, so that they don't take the wrong dose or in the wrong manner.
- Advise patients about potential side effects of medications, drug-drug interactions, medicine-food interactions, known and predictable adverse medicine reactions due to allergies and other contraindications, how to store the drug, how to dispose unused doses, etc.
- Warn against actions that can be dangerous while using the medicine, such as consuming alcohol or operating heavy machinery. Also, inform about foods or other medicines to be avoided when taking a dose and what to expect after taking the medicine.
- Answer any questions people may have about the drugs or medical devices.
- Encourage adherence to the prescribed treatment by stressing on the importance of taking medicines properly, following correct timing of doses, etc.
- Listen carefully to consumers to interpret their needs, issues or symptoms and advice suitable over-the-counter medicines. In other

In India, the Pharmacy Act, 1948 and the Drugs & Cosmetics Act, 1940 mandate that every pharmacy should employ a registered pharmacist. This includes retail pharmacies as well as pharmacies in healthcare settings like clinics, hospitals and other healthcare centres.

"Pharmacist is the bridge between doctors and patients who counsels and advices the patient to maximise the desired effect of the drugs and minimise the untoward/adverse effects of the drug." - Hemant Kumar Sinha, ex-State Drugs Controller, Patna, Bihar

words, they can become the first point-of-contact for inquiries about regular ailments while those that require additional diagnostic skills or treatment should be referred to an appropriate doctor or hospital.

- Provide information on the management of complex diseases like diabetes, hypertension, arthritis, etc. to assist patients.
- Offer general advice on a healthy diet, exercise, stress management and recommend non-prescription drugs like vitamins and other supplements.

Although it can be argued that ensuring efficacy of medications and preventing errors is primarily the responsibility of the physician, pharmacists can serve as a last-mile check as they are a learned intermediary between the prescriber and the patient. What's more, they can even go a step ahead and reach out to the doctors to discuss alternative medicines or changes in dosage, when needed.

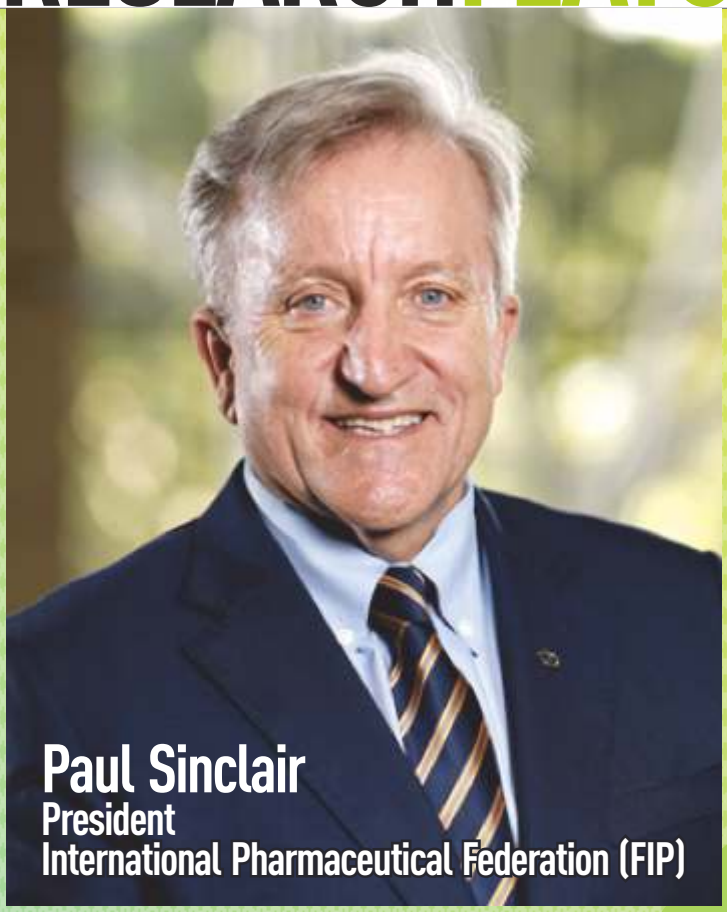
The Honourable Courts have also emphasised the importance of pharmacists for improving the use of medicines by repeatedly upholding that "Services of pharmacists are not only necessary to ensure supply of medicines in proper and just manner, but it will also work as a check against unauthorised sale of medicines for the purpose other than treatment."

There is a significant shift in the practice of pharmacy - from drug product-oriented to a patient-oriented approach to achieve definite outcomes that will improve the quality of life of the patients. Termed as pharmaceutical care, it requires pharmacists to assume the role of caregiver, communicator, decision-maker, teacher, researcher, life-long learner, leader and manager, to provide individualised care.

In addition to the above, a pharmacist is also required to ensure the quality and safety of medical drugs by:

- Ensuring that the drugs are bought from licensed distributors only
- Supervising the supply chain to assure complete integrity at all levels
- Checking that the drugs are stored properly in accordance with the specified conditions
- Preserving the pharmacy premises and systems as required
- Maintaining detailed records of the purchase, sale and even disposal of drugs
- Detecting spurious/falsified/ counterfeit/expired medicines
- Complying with healthcare policies and regulations
- Reporting adverse drug reactions and other unexpected medicine events to the requisite authorities

To sum up, the pharmacists are charged with a patient-oriented role that assures effectiveness of the medicines as well as prevents undue harm from them. In other words, they should become the trusted ally of the consumers by evolving into critical partners of healthcare delivery, thus improving patient care outcomes!



Paul Sinclair
President
International Pharmaceutical Federation (FIP)

fip International Pharmaceutical Federation

Where To Go When You Need Quality Medicines And Reliable Health Advice

GOOD HEALTH IS key to a fulfilling life and affects every aspect of our existence, including our physical, mental and emotional well-being, our social interactions and our financial stability. And often times, an illness or a need to care for a loved one who is ill puts us at our most vulnerable. This is why pharmacies, with a certified or officially registered pharmacist present, are essential places within our communities, supporting people with their health. Pharmacists are there to give advice, based on scientific evidence, so that people get the best possible treatment outcomes and avoid ill-health. Pharmacists are recognised by the World Health Organization as healthcare professionals who are most accessible to the public and as a cornerstone of primary health care.[1]

You might go to a pharmacy for something relatively simple like a painkiller for a headache or to pick up prescribed medicines for a long-term condition such as diabetes. Either way, we must keep in mind that medicines are a special type of product, in that although they can treat or alleviate symptoms of an illness, they also have the potential to do harm if used incorrectly. This special category of product, therefore, requires advice from pharmacists — medication experts — to always be available.

In India, a minimum 2-year diploma in pharmacy or any higher education in pharmacy is required in order to be registered as a pharmacist. This education gives pharmacists in-depth knowledge of medicines, their proper usage, whether any lifestyle modifications are needed to maximise their effectiveness, interactions with other medicines and side effects. Indeed, pharmacists are recognised as medicine experts. In addition, one of the essential roles of pharmacies is to ensure the quality and safety of the medicines they supply. Pharmacies store medicines under controlled conditions, ensuring that they maintain their potency and integrity until they reach the hands of patients. They are also part of a protected pharmacy supply chain that prevents fake or substandard medicines from getting to consumers.

Not Just Medicines

Yet, pharmacies are not just places to pick up medicines. They also serve as centres of care, valuable advice and community. Among the services being provided by community pharmacies around the world, beyond the supply of medicines, are testing for HIV and cholesterol, management of chronic conditions such as high blood pressure, diabetes and asthma, help to stop smoking, and health promotion. Many of these services are carried out in consulting rooms in pharmacies.

In India, some pharmacies are also contributing to reducing the burden of tuberculosis by offering convenient access to treatment along with a service to ensure that patients complete their treatment, which also helps to prevent the spread of this disease. In addition, in at least 48 countries pharmacists are now protecting communities by administering vaccinations against other infectious diseases.[2] Through services such as these and the millions of other interactions taking place in pharmacies every day around the world, pharmacists are playing a vital role in early detection and prevention of various health issues. This multifaceted approach to health care helps people take proactive steps to improve and maintain their health.

[1] World Health Organization Regional Office for Europe. The legal and regulatory framework for community pharmacies in the WHO European Region. 2019. Available at https://bit.ly/3LcsKjZ

[2] FIP data.

The Public Trusts Pharmacists

For many years, pharmacists have consistently been named among the top five most trusted professionals in national surveys.[3-7] As healthcare professionals, pharmacists uphold a duty of care to the public, with well-beingas their primary concern. As members of a registered profession, pharmacists often belong to professional associations, such as the Indian Pharmaceutical Association, which work to support them in good practice through continued education (since the pharmaceutical field is constantly evolving with new medicines and technologies), and to promote the highest professional and ethical standards in the profession.

From across the globe, 156 such national professional organisations are members of the International Pharmaceutical Federation (FIP). FIP is therefore the global body representing over 4 million pharmacists, pharmaceutical scientists and pharmacy educators, in 154 countries and territories, including India. Established in 1912, FIP is also a non-governmental organisation in official relations with the World Health Organization and UNESCO. Our vision is a world where everyone benefits from access to safe, effective, quality and affordable medicines and health technologies, as well as from pharmaceutical care services provided by pharmacists, in collaboration with other healthcare professionals. Part of our work towards this vision is to promote good practice, through reference guides such as “Good pharmacy practice in community and hospital settings”[8], joint guidelines with the World Health Organization on standards for quality of pharmacy services[9], and FIP's Oath of a Pharmacist[10].

Future of Pharmacy

FIP also gathers evidence of the actions of pharmacy. During the COVID-19 pandemic, which presented unprecedented challenges to us all, community pharmacists around the world showed themselves as frontline healthcare professionals. When many doctors closed their doors, the doors of community pharmacies remained open to provide continued health care, reliable information, and to ensure that patients got their medicines. Pharmacists took on expanded roles, performing testing and vaccinations. Never had so many governments acknowledged the valuable contribution of pharmacy to health.

The pharmacy profession has clearly demonstrated that it is indispensable to communities and that it is integral to well-functioning health systems. Over the past three years, we have seen the pharmacy profession advance at an unprecedented rate. However, further advancements in all countries is needed, especially in light of the vulnerabilities in our health systems exposed by the pandemic and the challenges we now face to ensure the recovery of healthcare and to make sure that our health systems are sustainable so that we can meet the United Nations goal of 'Health for All' in 2030.

FIP looks forward to seeing further recognition of the expertise, capabilities and contributions of pharmacists and is working to support this.

Around the world, pharmacists are preparing for this future, keeping up-to-date with the latest knowledge and training to provide new services, which include prescribing, adding to the valuable services they already provide.

My hope it that pharmacists in India will be among those allowed by authorities to practise to the full scope of their expertise, for the benefit of the population.

Where there are medicines, there should be pharmacists!

All pharmacies must have a presence of a registered pharmacist for all the opening hours of the pharmacy. We are aware that in some pharmacies in India, medicines are being sold in the absence of a pharmacist and the pharmacist is not on duty all the time. This is a serious concern. My wish is for every member of the public to understand that a pharmacy should have a pharmacist on duty. Consumers must be able to expect and demand services from pharmacists and the pharmacy community must be prepared to develop and provide services tailored to this evolving mindset.

The Last Word

Prioritising health is an investment in your present and future, helping to ensure a longer, more prosperous and purposeful existence. Health is a gift that, when nurtured, enables us to enjoy our relationships, pursue our dreams, and make a positive impact on the world. Whether you live in a bustling city or a remote village, there is usually a community pharmacy nearby. Taking care of your health and that of your loved ones means accessing the best possible advice and care available to you. When you need quality medicines and reliable health advice, be sure to go a pharmacist!

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5 Nuremberg Institute for Market Decisions. Trust in professions 2016. www.nim.org/sites/default/files/medien/7500/dokumente/trust_in_professions_2016_-_englisch.pdf(accessed 24 February 2021).

6 Gallup. Nurses Continue to Rate Highest in Honesty, Ethics. 6 January 2020. https://news.gallup.com/poll/274673/nurses-continue-rate-highest-honesty-ethics.aspx (accessed 24 February 2021).

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FIGHT THE FAKES

The Unabated Menace of Spurious and Substandard Medical Products

There is a parallel world where substandard and fake medical products are being produced and sold! Meanwhile, we purchase medicines from our neighbourhood medical store without a second thought about their purity, efficacy or safety. What if the medical product we buy ends up worsening our health or causing adverse side effects?

The problem of counterfeiting is as old as drugs themselves! However, the incidence is increasing at an alarming rate, putting our health and lives at risk!

THE PHARMACEUTICAL MARKET abounds with substandard, adulterated, unlicensed, spurious, falsely-labelled, falsified and counterfeit medicines and medical devices.

According to the World Health Organization (WHO), counterfeit drugs account for around 10% of the global medicine market, with an estimated value between $200 and $450 billion. It further estimates that over one million deaths occur per annum due to counterfeit and substandard drugs, causing a global financial impact of $21 billion.

The Pharmaceutical Security Institute, a trade group, reported that theft and counterfeiting of pharmaceutical products has increased significantly over the past two decades.

The problem is not just limited to drug companies manufacturing sub-standard, adulterated or fake products. Even medical store owners try to make a quick buck by selling counterfeit medicines. Then there are pharmacies that sell fake drugs by illegally using the name of an established pharmaceutical company that remains completely unaware of the incident. Spurious and substandard medicines and medical devices are also sold online through illegitimate pharmacies and in unregulated online marketplaces.

India is in the crosshairs of the counterfeit market – several studies have named India as one of the top countries in the world that are producing and distributing fake medicines.

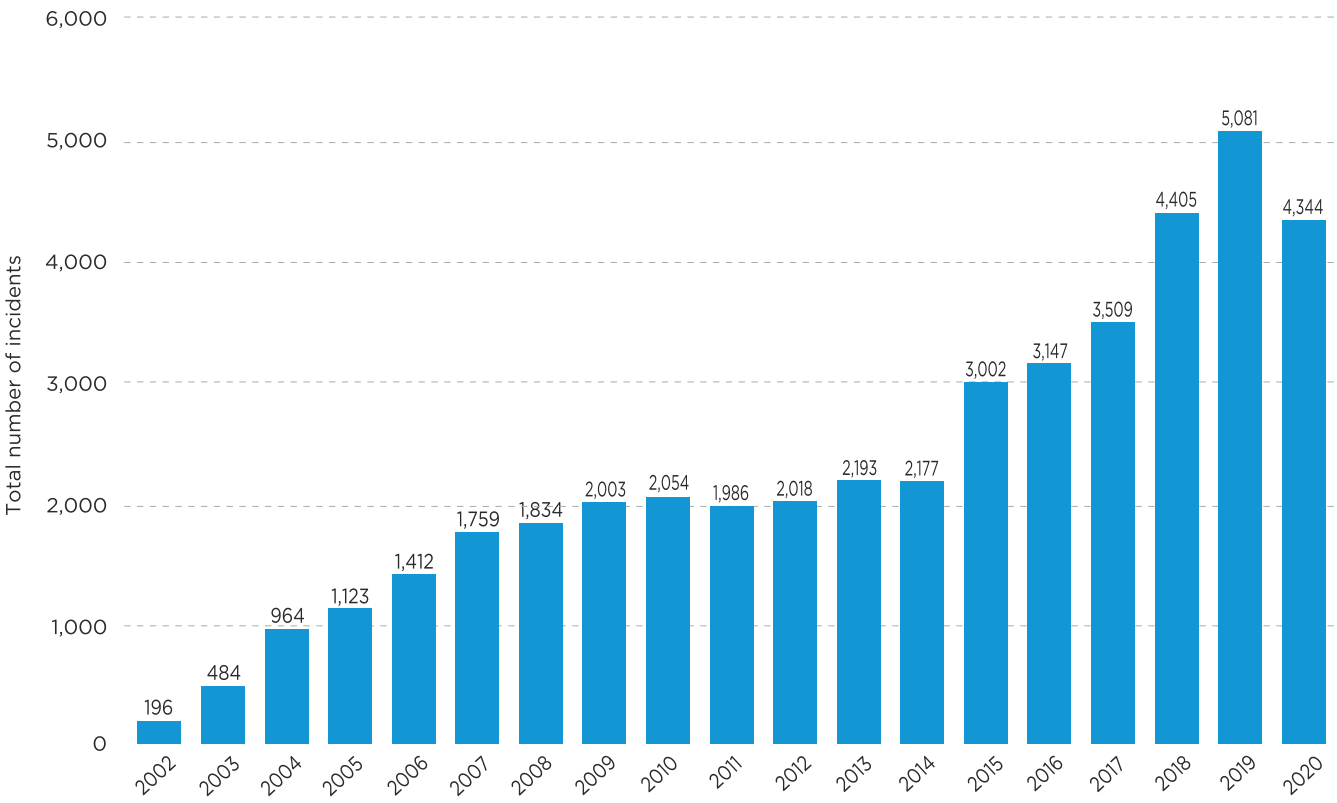
ASPA Report

The Authentication Solutions Providers' Association (ASPA) – a non-profit organisation promoting awareness of counterfeiting - released a report on 'Substandard and Falsified Medical Products, Learning from COVID-19 Pandemic and Technological Tools to Ensure Medicines & Patient Safety' in March 2022. The report highlights the trends in pharma crime and incidents of substandard and falsified medical products during COVID-19, with recommendations to combat it.

Pharmaceutical companies should only be held responsible for producing poor-quality drugs. It is fraudulent drug sellers at the retail level that should be held responsible for fakes, because they procure these from dubious suppliers. Fighting this menace is beyond the purview of individual pharmaceutical companies, and calls for intervention from authorities like the drug controller and even law enforcement agencies.

– Gajendra Singh, public health expert

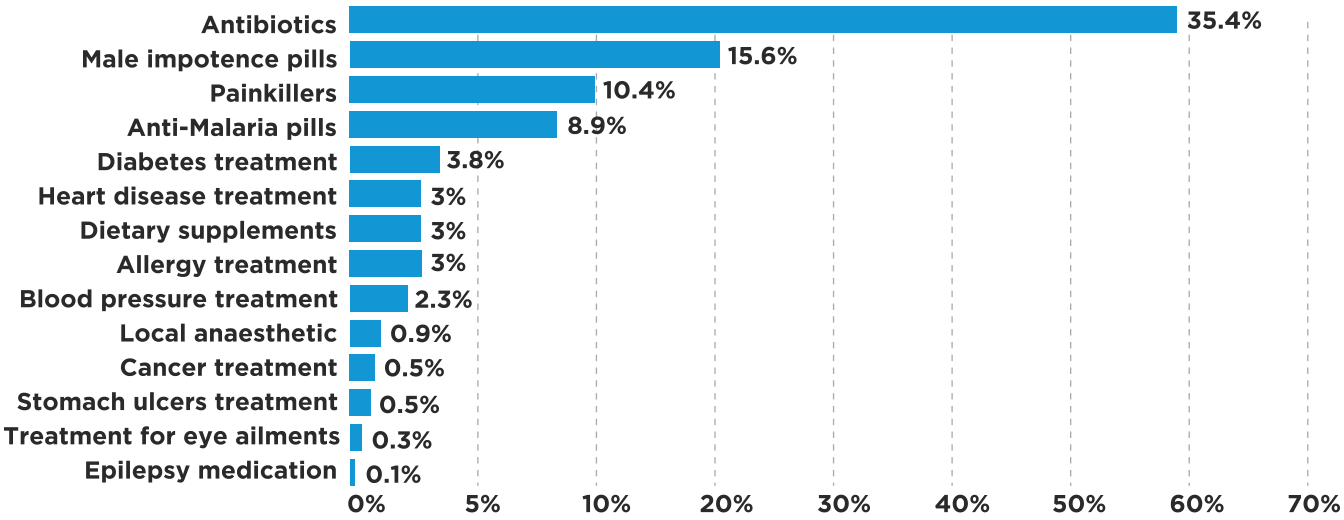
Total number of counterfeit incidents concerning pharmaceuticals worldwide from 2002 to 2020



Source: https://www.psi-inc.org/incident-trends

The most counterfeited pharmaceuticals

Share of the global value of seizures of fake pharmaceuticals



Source: https://www.oecd.org/industry/covid-19-crisis-underscores-need-to-address-trade-in-fake-pharmaceuticals-say-oecd-and-euipo.htm

According to the study, the incidents of substandard and falsified medical products increased by 47% between 2020 (91) and 2021 (134) in India. Counterfeiters took advantage of demand scarcity and there were numerous instances of counterfeiting in sanitisers, face masks, antibiotics, painkillers and even vaccines. During these two years, instances of counterfeiting of COVID-19 products were observed in 23 out of 29 states and in 7 union territories.

The report welcomed the Government of India's decision to make QR Codes mandatory on the labels of all Active Pharmaceutical Ingredients (APIs) manufactured or imported in India, at each level of packaging, to enable tracking and tracing of the ingredients. It also recommended clearly defined mandatory regulations regarding secure packaging, authentication solutions implementation and robust track and trace mechanism to ensure that consumers are not duped by counterfeit products. The government has to focus on taking a comprehensive approach to build an authentication ecosystem in the country.

According to ASPA's white paper, while substandard and falsified medical products are not a new problem, the foremost factor contributing to the increase in counterfeiting is the lack of awareness about the severity and impact of this menace.

The report further stresses that pharmacists, nursing staff and medical professionals form the most crucial part of the defence against substandard and spurious drugs. Their expertise makes them an excellent judge of the authenticity of the product which they are handling. If they are aware of the process and if the right mechanism is available, they can identify a falsified product and report it!

A FEW OF THE INSTANCES:

- Gujarat FDA busted racket selling fake anti-viral drugs – Favimax-400 and Favimax-200
- As soon as black fungus cases started being reported in hospitals, criminals started taking benefit. More than 3500+ vials of black fungus injections were found in a raid in New Delhi.
- Kanpur crime branch arrested a gang and seized fake medicine worth Rs 4 crore. The criminals accepted that they were producing medicines as per the demand and using UP Transportation Buses as modus operandi for distribution. The code word Parle-G and Cadbury were used for order bookings.

The tremendous adverse impact of the huge increase in circulation of spurious medicines and medical essentials during the fight against the COVID-19 pandemic has almost gone unnoticed. It is unfortunate as criminals produce ineffective or harmful products in packaging that appear identical to genuine products to make them difficult to detect. The circulation and use of these substandard and falsified medical products violate the Right to Health and slows down the pace of providing quality health services that people deserve. It is high time for firm action to curb this menace. If preventive steps are taken now, we will be better positioned to deliver effective healthcare to patients.

– Nakul Pasricha, President, ASPA

Illicit Goods and Global Health Programme (IGGH)

Interpol's IGGH programme shares a strong commitment with member countries and industry alike to continue to improve global cooperation and enforcement capabilities in the area of pharmaceutical crime.

Operation Pangea is a well-established international effort by Interpol to disrupt the global online trafficking of counterfeit and illicit pharmaceutical products. Since its launch in 2008, the annual dragnet of coordinated raids across countries has removed more than 105 million units (pills, ampoules, sachets, bottles, etc.) from circulation and made more than 3000 arrests. It also aims to raise public awareness of the risks associated with buying medicines from unregulated websites.

Conclusion

There is a need for a system of assuring the integrity of the supply chain to ensure the value of medical products used for the prevention of disease and the treatment of patients.

The 94 country Operation Pangea XV conducted in 2022 seized illicit medicines worth $11 million covering everything from fake COVID-19 tests to hazardous erectile dysfunction tablets.

Under Operation Pangea XVI, Interpol arrested 72 people and seized $7 million worth of drugs, closed more than 1300 websites and initiated 325 new investigations between 3-10 October, 2023 across 89 countries.

The union Ministry of Health & Family Welfare (MoHFW) conducted a national survey on 'Extent of Problems of Spurious and Not of Standard Quality (NSQ) Drugs in the Country" in association with the National Institute of Biologicals (NIB) from 2014 to 2016.

47,012 drug samples (224 drug molecules from 15 different therapeutic categories of NLEM 2011) were tested, of which 13 samples were found to be spurious and 1,850 samples were NSQ. Therefore, the percentage of NSQ drugs in India stood at 3.16% and that of spurious drugs at 0.0245%.

These percentages may seem quite small, but even such small amounts of poor-quality medicines are unacceptable as it leads to drug related morbidity and mortality. It was suggested that countering the problem of circulation of spurious and NSQ drugs calls for support and cooperation of all the stakeholders - policy makers; drug regulatory and law enforcement agencies; drug testing laboratories; manufacturers and distributors including retailers; healthcare professionals and members of civil society.

The survey remains relevant today as there is no letting down in the proportion of NSQ and spurious drugs prevailing in the market.

Legal Cornerstone of Pharmacies and Medical Products

A pharmacy serves as the final link in the healthcare delivery chain, charged with the big picture of pharmaceutical care. There is a clear regulatory framework for the practice of pharmacy in India. It ordains that only qualified individuals are involved in the sale of drugs and medical devices. Similarly, availability and pricing of essential medical products are also regulated in the interests of the patients.

Strengthening the healthcare tapestry with pharmacy regulations!

THE GOVERNMENT OF India promulgated the Pharmacy Act in 1948 to regulate the profession and practice of pharmacy. The objectives were two-fold –

- Provide uniform pharmacy education and training throughout India
- Maintain control over the persons entering the pharmacy profession

The purpose of the Act was clearly stated as, "It is desirable that, as in most other countries, only persons who have attained a minimum standard of professional education should be permitted to practise the Profession of Pharmacy. It is accordingly proposed to establish a Central Council of Pharmacy, which will prescribe the minimum standards of education and approve courses of study and examinations for Pharmacists, and Provincial Pharmacy Councils, which will be responsible for the maintenance of provincial registers of qualified pharmacists. It is further proposed to empower Provincial Governments to prohibit the dispensing of medicines on the prescription of a medical practitioner otherwise than by, or under the direct and personal supervision of, a Registered Pharmacist."

Accordingly, the Pharmacy Council of India (PCI) was constituted as a statutory body in the year 1949. It functions as the national pharmacy education regulator and is responsible for setting the minimum standards of education for qualifying as a pharmacist. It also maintains a central registrar of pharmacists apart from regulating the activities of pharmacists.

Every state is required to constitute a State Pharmacy Council (two or more states can enter into an agreement to form a Joint State Pharmacy Council). The councils register the pharmacists and maintain a register of pharmacists in the specific state. They also appoint pharmacy inspectors in all districts who are authorised to inspect the pharmacies, ensure that medicines are dispensed by qualified pharmacists, check registrations of pharmacists, investigate complaints and institute prosecution.

Registration

It is mandatory to get registered under the Pharmacy Act, 1948 to practice pharmacy in India. A Registered Pharmacist is defined as a person whose name is entered in the register of the state in which he/she is residing or carrying on his profession/business of pharmacy.

Moreover, every pharmacy should have a registered pharmacist on board. Section 42 of the Pharmacy Act, 1948 expressly mandates that "no person other than a registered pharmacist shall compound, prepare, mix or dispense any medicine on the prescription of a medical practitioner".

Pharmacy Practice Regulations

PCI published the new Pharmacy Practice Regulations in 2015. The primary provisions of the guidelines are:

- Drugs can be dispensed only by qualified registered pharmacists.
- Registered pharmacists cannot give their registration certificate at more than one pharmacy.
- Registered pharmacists should comply with the dress code of a clean white coat and apron with a black badge displaying their name and registration number.
- Every registered pharmacist should dispense only those medicines as prescribed by a registered medical practitioner.

One of the main purposes of the Pharmacy Practice Regulations was to curb the malpractices prevailing in medical stores and thereby enhance the status and practice of pharmacy profession in the country. It also laid down a uniform code of pharmacy ethics, responsibilities of pharmacists towards patients and the role of a community pharmacist.

Even though the Pharmacy Act was enacted in 1948, the state governments were empowered to bring Section 42 into effect on a date of their choosing. The leeway was provided to give them time to set up pharmacy colleges to train professional pharmacists.

However, when most states failed to notify the provision into law even after three decades, the Pharmacy Act was amended in 1976 to bring Section 42 into effect in all states in a five-year period. Finally, since 1984, all pharmacies across India are required to sell medications in the presence of a registered pharmacist during working hours.

- Pharmacists should provide professional services like patient counselling, primary care for simple illnesses and Adverse Drug Reactions reporting. A separate cell should be arranged within the pharmacy for this purpose.
- Pharmacists should promote the rational use of drugs and follow other guidelines of ethical conduct.

Licensing

The Drugs and Cosmetics Act, 1940 complemented by the Drugs and Cosmetics Rules, 1945 restrict and regulate the sale and distribution of drugs in India. Obtaining a license from the state licensing authority is mandatory to sell, stock, exhibit/offer for sale or distribute drugs. The establishment can apply for a wholesale, retail or restricted drugs license to conduct business accordingly.

Furthermore, the law also prohibits the sale of specific classes of drugs – like misbranded drugs, spurious drugs, adulterated drugs and drugs not of standard quality, expired drugs, physician's samples, etc.

Then there are specific requirements for the pharmacy pertaining to space in the premises, storage facilities, recordkeeping, etc. One of the conditions for obtaining a pharmacy licence is that all dispensing and compounding of drugs - against the prescription of a registered medical practitioner - should be done either by a registered pharmacist or under his direct or personal supervision (Rule 65 of the Drugs & Cosmetics Rules, 1945).

Access to Quality Essential Medicines

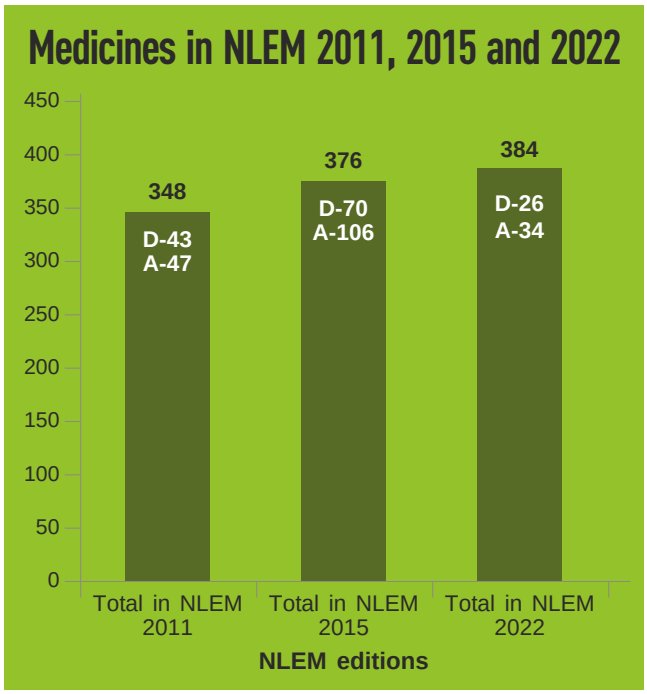
The World Health Organization (WHO) defines essential medicines as those that satisfy the priority health care needs of the population. Accordingly, it drew up the first Model List of Essential Medicines in 1977 (consisting of 279 medicines) based on the disease prevalence, efficacy, safety and comparative cost-effectiveness of the medicines. The consideration is that these medicines should be available in adequate amounts, in appropriate dosage forms and strengths with assured quality, thus resulting in better quality of medical care, better management of medicines and cost-effective use of healthcare resources.

As the priority healthcare needs as well as the disease burden differs from one country to another, WHO urges the member states to develop a list of essential medicines at the national/regional/hospital level based on the concepts followed by WHO. Accordingly, the Ministry of Health and Family Welfare, Government of India prepared and released the first National List of Essential Medicines (NLEM) in 1996 (consisting of 279 medicines). It also specifies the level of healthcare (primary, secondary, tertiary) at which each drug is considered essential.

The primary purpose of NLEM is to promote rational use of medicines considering the three important aspects - cost, safety and efficacy. It is intended to have a positive impact on the availability of medicines, ensuring accessibility of affordable quality medicines at all levels of healthcare and optimising the available health resources of the country. Above all, it serves to guide safe and effective treatment of priority disease conditions of the consumers.

> **This limited list of carefully selected medicines will improve quality of healthcare, provide cost-effective healthcare and better management of medicines.**
>
> *– Dr. Mansukh Mandaviya*
> *Union Minister for Health and Family Welfare*

The NLEM is a dynamic document that is updated regularly considering the changing public health priorities as well as advancement in pharmaceutical knowledge. It has been revised in 2003, 2011 and 2015. The latest revision was released in September 2022 (NLEM 2022) with the addition of 34 drugs (anti-cancer formulations, antibiotics, vaccines, etc.), while 26 from the previous list were dropped. There are now 384 drugs on the new list categorised into 27 therapeutic categories. It covers everything from analgesics, antiallergics, diuretics, antiseptics and anaesthetics to hormonal medicines, cardiovascular medicines and gastrointestinal medicines to even vitamins and minerals. The list contains drugs used to treat fever, infection, hypertension, anaemia, etc. and includes commonly used medicines like paracetamol, azithromycin etc.



Affordability of Medicines

The National Pharmaceutical Pricing Authority (NPPA) is the government regulatory agency that controls the prices of pharmaceutical drugs in India. It fixes the ceiling price of all scheduled formulations appearing in the NLEM. All manufacturers of these drugs are required to price their products equal to or lower than the ceiling price. Apart from regularly fixing/revising the prices of various controlled bulk drugs and formulations and even certain medical devices, it also recovers any amounts overcharged to the consumers by the manufacturers.

The NPPA also maintains a strict vigil on the prices of non-controlled drugs to keep them at reasonable levels and prevent fleecing of patients. A manufacturer cannot increase the price by more than 10% of what was prevalent during the preceding twelve months. It operates the Pharma Sahi Dam and Pharma Jan Samadhan platforms for information on medicine prices and registering public grievances.

> **The ceiling prices of 915 scheduled formulations and retail prices of around 2450 new drugs have been notified as on 17th July, 2023.**
>
> *– Dr Bharati Pravin Pawar*
> *Union Minister of State for Health and Family Welfare*

The Takeaway

The government stands committed to quality healthcare and is taking several measures to ensure that medicines are easily accessible, affordable and safe to use. The watchful eye of pharmacy regulations ensures that we can trust the medicines we take and become the guardian of our health and well-being!

Major Transformation on the Cards?

THE PHARMACY ACT has not been amended in the last 75 years, save for a few changes and rules brought in by the PCI. In March this year, the Union Ministry of Health and Family Welfare constituted a 16-member Expert Committee under the chairmanship of **Dr. Y K Gupta (President, All India Institute of Medical Sciences (AIIMS), Jammu and Bhopal)**. The committee is tasked to:

- Review the Pharmacy Act, 1948
- Review pharmacy education
- Make recommendations for restructuring the Pharmacy Council of India

This is a welcome move as drastic changes in the law, education and regulatory authority are essential for India to meet the global standards of pharmacies. Moreover, this will create more employment opportunities for pharmacists.

Following this, the Central Government Health Services (CGHS) pharmacists submitted some comprehensive suggestions to the expert panel for their perusal and consideration:

- The minimum qualification for registration as a pharmacist should be raised from the current Diploma in Pharmacy (D Pharm) to Bachelor's Degree in Pharmacy (B Pharm) on the lines of the developed countries.
- Pharmacist registration should not be permitted by any state pharmacy council or a tribunal on the basis of experience in dispensing medicines in pharmacies. Registration should be allowed only on achieving a graduation in pharmacy (B Pharm) from a recognised university and on the submission of the degree certificate.
- To strengthen efficiency, the PCI (central council) should have representatives from the Central Drugs Standard Control Organisation (CDSCO), National Pharmaceutical Pricing Authority (NPPA) and Indian Pharmacopoeia Commission (IPC).
- The six elected members should include practicing pharmacists, clinical pharmacists, industrial pharmacists and regulatory pharmacists with an emphasis on selecting the experts in each field.

Even better than revamping the existing law, it should be scrapped and replaced by a new Act (on the lines of the National Medical Commission Act, 2019).

INTERVIEW

Mr. RAJ VAIDYA

(M. Pharm, Fellow of IPA)

is a practicing Community Pharmacist since 34 years at his family-owned Hindu Pharmacy in Panaji, Goa. He is an Ex-co member of International Pharmaceutical Federation (FIP), Community Pharmacy Section.

In addition to this, he has held the post of Vice-President and Chairperson, Community Pharmacy Division of Indian Pharmaceutical Association (IPA). He was also the Project Leader for a pilot project on 'Accreditation of Pharmacies in India' and another project on Good Pharmacy Practice (both by IPA in collaboration with Drugs Controller General of India & WHO India Country Office). Mr. Vaidya was a major contributor towards the writing of GPP Training Manual for Community/Retail Pharmacists and a resource person for training workshops for pharmacists.

Q Can you explain the concept of Good Pharmacy Practice (GPP) and its importance in the pharmacy profession. How is the ground reality of pharmacies in India impacting the safety of patients?

The FIP (International Pharmacy Federation) has defined Good Pharmacy Practice (GPP) as the practice of pharmacy that responds to the needs of the people who use the pharmacists' services by providing optimal, evidence-based care. In GPP, the pharmacist's first concern has to be the welfare of patients. It requires that all activities at the pharmacy should be done appropriately and take into consideration the patient´s and public health. And that the medicines and other healthcare products supplied are of assured quality, and appropriate information and advice is provided to the patient, and the effects of their use is monitored.
It also requires that the pharmacists contribute to the promotion of rational, cost-effective, economic prescribing and of appropriate use of medicines, and that they collaborate with other health care practitioners for successful medicine therapy management. Such practices are over and above the legal requirements for pharmacies and pharmacists mentioned in the drug laws and the Pharmacy Act.

Implementing GPP can not only provide a big boost of confidence and recognition to pharmacists, it can also benefit public health at large. Unfortunately, in India, GPP still has not got the due recognition, nor has it been well accepted or put in practice by the pharmacy community. In our country, where implementing laws is a deficiency, GPP unfortunately takes a back step. The pharmacies that implement GPP will definitely benefit from it!

Q Why does the role of the pharmacist continue to be sub-optimised despite having regulatory legislations in the country?

There are multiple reasons for this. The biggest one is the implementation of the law. As in multiple other areas, as we commonly know, we have many wonderful laws/regulations in place. However, we lack in implementing them. This is also the case with pharmacy. One of the prime reasons for the sub-optimised role of the pharmacist in our country is that a pharmacist is not always present in many of the pharmacies across the country. The second reason is that in our country, quite often, prescription medicines are available without having to produce a prescription.

I see these as the two major setbacks for the profession. The reasons for non-implementation of the laws are multifactorial, and it will need a strong political and regulatory will to implement these. It is no easy task considering that the ills are deep-rooted. However, at some point of time, and somewhere, the system has to plan and step up the implementation. Of course, one step at a time. Implementing the laws will not only benefit the pharmacy profession, but in turn, the public will tremendously benefit from the good services that pharmacists can provide if the circumstances are made more conducive for them. Ultimately, it is a step towards patient benefit and safety.

Unfortunately, people also fail to realise the importance of the drug laws, and have become used to buying prescription medicines without a proper prescription, and often do not like it when the pharmacy insists on a prescription…..

Q India is the Pharmacy of the World. What do you think is lacking on the domestic front?

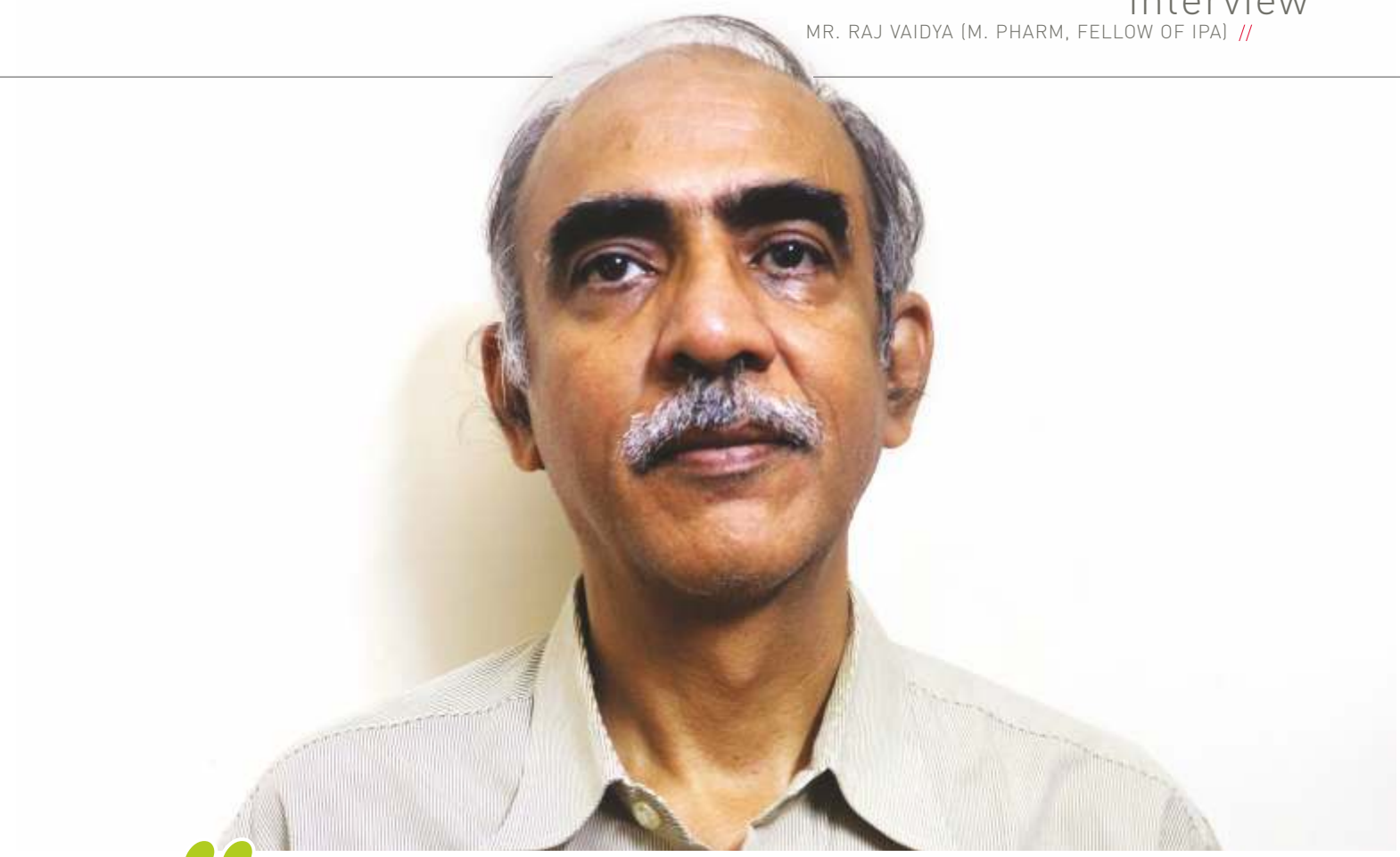
Over the past seven decades, the strength and expertise of India's pharmaceutical manufacturing industry has grown from strength to strength. India has been able to export large quantities of quality medicines to a large number of countries in the world, including the developed countries. India's acumen in exporting vaccines, especially the COVID vaccine during the pandemic, further strengthened this image as the pharmacy of the world.

The regulatory controls and requirements of the regulatory agencies of developed countries are very stringent, and the pharmaceutical companies are bound to have stricter control over their manufacturing and quality. The same, unfortunately, cannot be said for implementations of the regulations in India. India has a large number of pharmaceutical companies, and the regulatory manpower is proportionately low. Self-regulation in the industry may not necessarily exist all across the board, and therefore some blacksheep tend to give the overall industry a bad image.

Q How can AYUSH medicines bridge the gap of access to quality and affordable medical products in India?

Yes, AYUSH medicines can definitely bridge the gap of access to quality and affordable medical products in India. But the rider here is that these products have to be rational, cost effective and of good quality.

Presently, one may have noticed the trend that, in the name of AYUSH products, a lot many things are being promoted/pushed, with massive advertisements, testimonials, etc. with tall claims Too many irrational medicines have mushroomed over the years, and often, with no price control. There needs to be rationalisation in AYUSH medicines too. Only then can it bridge the gap of access to quality and affordable medical products in India. The faith of the Indian traditional systems of medicines is



"A generic medicine is a medication which not only has the same dosage form, safety, strength, route of administration, and quality, but most importantly has the same performance characteristics as an already marketed brand-name product."

deep-rooted in the country, and a large populace would still prefer to use it, provided they are guided properly and have access to the right medicines, and the medicines are of low cost.

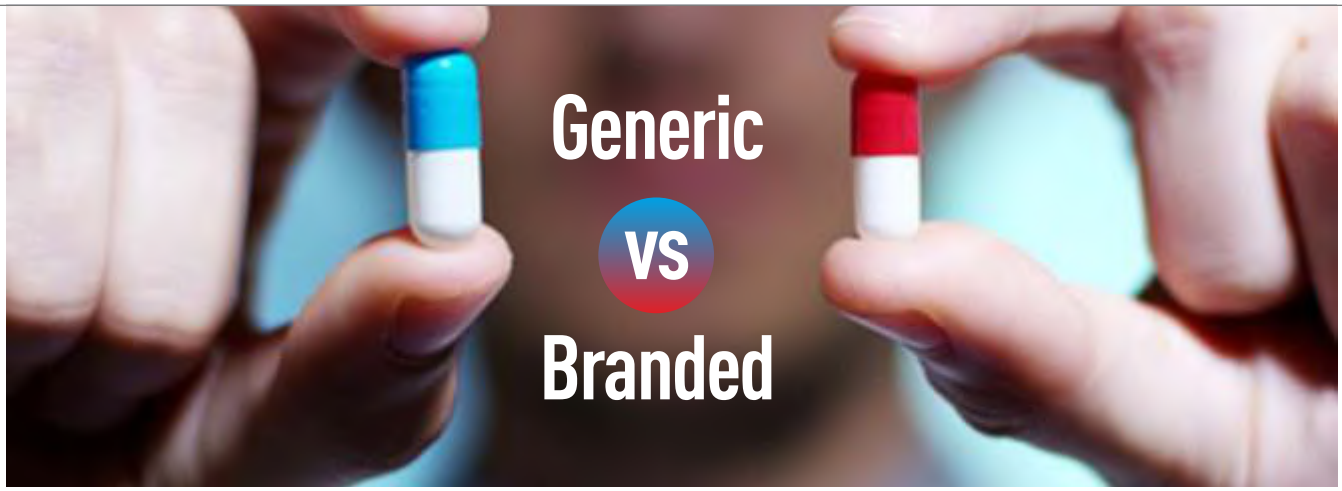
Q Do you think the Pharmacy Act, 1948 needs to be revamped? What changes are required?

There certainly needs to be a revamp, since one should understand the drastic changes that have taken place in the last seven decades, in terms of computerisation, digitalisation, newer drugs and advances, skilling requirements, and redundancy of various tasks and aspects. The Act has to be made more holistic, and bring in changes in light of advancements. The Act must bring in changes to ensure not only a system of enforcement of the Act, but strong systems to enforce self-discipline and also checks and balances with transparency so that there are lesser risks of wrongdoings.

There is a strong need to bring about changes in pharmacy education – including upgradation of the curriculum with changing times, changes in the examination/testing methods for student performance. A more hands-on, skill- and knowledge-oriented curriculum will take the pharmacy student ahead in the fast-changing world.

Q Why are pharmacies not accredited in India? What benefits will pharmacy accreditation bring to healthcare?

Besides the drug rules which are a mandatory provision for pharmacies, it is important to have Good Pharmacy Practice in place. This will enhance the working and image of the pharmacies, as well as benefit public health. Unfortunately, as yet, the accreditation system for private retail pharmacies has not generated enough interest in the accreditation bodies in our country. One of the reasons could be because, unfortunately, retail pharmacies are seen



more as traders rather than professional outlets. The other, as I mentioned above, is that implementation of the law is not in place to varying extents in pharmacies. Accreditation is one step above GPP, which is one step over drug laws. So, if the drug laws are not being followed, GPP falters to a great extent, and if GPP is not in place, then an accreditation activity will be futile. Of course, if the step is taken to have a multi-pronged approach to regulate the pharmacies, introduce and implement GPP, achieving accreditation will be easier.

Q The generic vs. branded medication debate is raging in the country ever since the National Medical Commission tried mandating doctors to prescribe generic drugs. What is your take on this?

The term 'Generic Medicines' is not properly understood by many of the authorities, politicians and the public too. The massive drives to promote 'Generics' are not taking into consideration the true meaning of 'Generic Medicines'.

A generic medicine is a medication which not only has the same dosage form, safety, strength, route of administration, and quality, but most importantly has the same performance characteristics as an already marketed brand-name product. The crux of the matter in the present cases in India, is whether all the 'so-called' generic medicines (or those bearing various trade/brand names) being marketed and promoted have the same 'performance characteristics' as the original brand, i.e., do they have an equivalent pattern of levels in the blood when consumed (the technical term for this is whether the two products are 'bioequivalent')? Unless such equivalency is proven/granted by the drug regulating agencies, it is difficult to say so with a 100% guarantee.

This is the same dilemma that the medical profession has largely put forward and so has strongly opposed the mandate of the NMC to prescribe by generic name. India's drug control department had announced, I think a couple of years back, that bioequivalence studies should be mandatory, for certain medicines which belong to Class II and Class IV (Class II –drugs which have low solubility, high permeability, Class IV –drugs which have low solubility, low permeability). However, from what I understand, most state FDAs have not implemented the same. So, today, we cannot say with full confidence that all the medicines being marketed are 'generic equivalents'.

Considering the importance of the situation, and in line with what is being followed in most countries in the world, it is imperative that India too implements this. This is likely to entail some costs, but for the greater benefit of patients, this is a must. We need to start by defining in our official documents, the definition of a 'generic medicine'.

Q What do you think should be done to regulate marketing practices of pharmaceutical companies?

Besides self-regulation by the companies themselves, there has to be a legal check. And a check with teeth. Besides this, awareness has to be there amongst the public. Consumer forums and consumer organisations have an active role to play in creating awareness, as well as bringing up cases/issues where there are inappropriate marketing practices. Public should be encouraged to lodge their queries and complaints against inappropriate marketing practices.

There is also a need to increase the levels of health literacy in our country. People must be made aware of responsible use of medicines, the right questions to ask about their health, illnesses, as well as the medicines prescribed to them. Pharmaceutical companies and health professionals should provide unbiased, easy to access and easy to understand information to patients about their medicines, and they should be made accountable to provide such information – so that patients can make informed choices. Presently, the dialogue is missing largely, and the patient many times is ignorant of his/her condition and the correct course of action to take.

Irrational medicines and fixed dose combinations (FDCs) are one offshoot/way out by companies to manufacture inappropriate medicines. There has to be strict control over licensing of new FDCs, and also, existing irrational FDCs have to be weeded out. The use of unnecessary medicines is not only a cost burden to patients, but it is also a cause of side effects, drug-drug interactions, and increased morbidity. Rational marketing and rational use of medicines has to be promoted as a 'mantra' in the country – and this includes for medicines of the AYUSH systems too.

AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

Pharmacies Brazenly Operating Without Registered Pharmacist!

"The focus of pharmacy practice has to shift from product-centric to patient-centric. This will happen only when medical stores make it a point to employ registered pharmacists who can expertly counsel the patients and educate them on how to use medicines and medical devices safely and effectively."

– Pyush Misra

DRUGS SAVE LIVES! However, it cannot be denied that medications are technical products that, when not stored, dispensed or used properly, can cause severe harm or even death. Therefore, dispensing of drugs requires judicious caution as even petty mistakes can impact the health and life of people.

It is well-known that a large number of medicines are misused for purposes of intoxication. A report published in USA stated that prescription drug abuse is a major cause of deaths, surpassing deaths due to car accidents!

Accordingly, every pharmacy in India (like many other countries) is required to have a registered pharmacist on the premises of the pharmacy during business hours. They are charged with everything from reviewing and approving prescriptions, providing professional advice to patients to managing drug inventory, maintaining oversight of other pharmacy staff and developing good pharmacy policies and procedures.

The Honourable Supreme Court gave a landmark judgement stating that a pharmacy functioning in the absence of a registered pharmacist is a contempt of law!

Ground Reality

The legal mandate for every pharmacy to have a D. Pharm or B. Pharm pharmacist onsite remains merely on paper. A significant number of pharmacies audaciously flout the law and continue to operate without employing a registered pharmacist.

It has been documented as well as observed by the courts that in several states the number of pharmacies far exceeds the number of registered pharmacists in the state!

The proprietors are least concerned about the safety of the patients when they fail to store the drugs properly or dispense the wrong drugs; they just want to avoid paying high salaries to the professionals. Some of them hire a pharmacist on a token basis (who is never present on the premises) or even go to the extent of renting pharmacy diplomas or degrees from the qualified professionals. As a result, 'one person' is using his/her registration certificate in several medical shops!

There is no fear of criminal penalties either. The Pharmacy Act, 1948 ordains imprisonment for a term which may extend to six months, or fine not exceeding Rs.1000 for contravention. Under the Drugs & Cosmetics Act, 1940, the punishment for violation is a maximum of two years imprisonment and a fine of Rs 20,000.

Despite the employment of pharmacists mandated and punishable under two different legislations, drug inspectors themselves admit that hundreds of pharmacies are being run by non-pharmacists. The anomalies in regulating the sales of medicines are compounded by the leniency adopted by the courts in the rare case of prosecution.

In the case of State vs Indulal Bogilal Shaha, the pharmacy owner pled guilty to operating without a registered pharmacist. The court merely sentenced him to 'simple imprisonment till the rising of the court' and a fine of Rs 20,000. He was thus allowed to leave once the judge rose from the bench.

In a recent directive, Dr. Rajeev Singh Raghuvanshi, the Drugs Controller General of India (DCGI) directed the drug controllers of all states and union territories and the Pharmacy Council of India (PCI) to strictly implement Section 42(a) of the Pharmacy Act and Rule 65 of the Drugs and Cosmetics Act in retail pharmacies. Time and again, the drug control departments of various states also direct medical shops to mandatorily have a pharmacist manning the outlets and selling medicines after reviewing prescriptions, but to no avail.

Reports state that a pharmacy certificate can be obtained in Bihar, Uttar Pradesh, Chhattisgarh, Jharkhand, Punjab, Rajasthan, Haryana and Telangana for an annual fee ranging from Rs.15,000 to Rs. 70,000!

It is highly unethical for a registered pharmacist to lend his or her registration to any other person!

Imagine this!

Dr. Montu Kumar Patel
PCI President

In June this year, Jharkhand Chief Minister Hemant Soren granted permission for opening pharmacies in rural areas without registered pharmacists. He publicly announced that those who are educated enough to read and write the name and composition of the medicine written on the boxes can start a medical store in the state.

This move shocked the pharmacists and their associations alike. The Pharmacy Council of India (PCI) wrote a letter to the state government demanding it reverse the decision and also withdraw the permissions already given by some district administrations. PCI President, Dr. Montu Kumar Patel unequivocally stated, "Drugs and medical devices are essential and special commodities. Their handling by an unqualified person will ignite the possibility of misuse, irrational use and wrong dispensing and will be detrimental to public health".

What is confounding is when the authority acknowledges the critical importance of having a registered pharmacist and how dispensing of medicines by unqualified people can lead to serious health hazards, why doesn't it implement the legislation in letter and spirit?

Final Nail in the Coffin?

The Jan Vishwas (Amendment of Provisions) Bill - to amend certain enactments for decriminalising and rationalising offences to further enhance trust-based governance for ease of living and doing business was recently passed in both houses of the Parliament.

It proposes amending Section 42(2) of the Pharmacy Act to delete the imprisonment clause and replace it with a fine of Rs 1 lakh and making Section 27(d) of the Drugs & Cosmetics Act compoundable on payment of Rs 5 lakh (creating room for out-of-court compromise).

Having only monetary penalties and settlements for claiming to be a registered pharmacist or dispensing medicines without a registered pharmacist can make it easier to enforce the laws and achieve compliance.

However, there is also the possibility that this will increase the risk appetite of pharmacies to the detriment of public health!

Final Thoughts

Pharmacy owners cannot treat their pharmacy like a regular business of selling goods. You are also responsible for the outcome of the medication treatment. Can you allow your lack of technical education or even misconceptions about medicines to lead to drug accidents or even cost lives? The argument that you don't have time to do anything but selling does not hold water. Don't be a mere salesman of medicines – own up the greater responsibility and get a registered pharmacist on board! Are you ready to do the right thing?

REPORT FOR NATION

Madhya Pradesh: ED gets into fake Remdesivir probe

Substandard and falsified medical products, learnings from COVID-19 pandemic & technological tools to ensure medicines & patient safety

Fake Covid Vaccination Camps Reported In UP, Maharashtra, Bengal: Centre

Arrested for running fake Remdesivir injection factory in Uttarakhand, already sold 2,000 injections

Mumbai fake vaccination scam: Police lodges 11th FIR; first case filed in Navi Mumbai

Payal Agarwal
Editorial Consultant

Promoting Fair Pricing and Marketing of Medical Products

"The prices of drugs and medical devices should be in tune with meeting their needs in society. High and rising MRPs can compromise the affordability of healthcare. This is further compounded by unfair and unethical promotion practices. Government intervention is often necessary to ensure price and marketing discipline in the market."

– Payal Agarwal

Managing the costs of medical products is essential for achieving universal health coverage!

MEDICINES AND MEDICAL devices are not ordinary goods – they are essential for maintaining good health of the people. Accordingly, India has declared drugs as 'Essential' by placing them under the Essential Commodities Act, 1955. Here, it is not just about the quality and availability of medical products, even their prices have a significant bearing on accessibility of healthcare.

It follows that high prices of drugs and medical devices add to the consumers' stress of managing household expenses. The rapid increase in prices is attracting public concern across the world.

Pharmaceuticals are the single largest contributor to out-of-pocket expenditure on health in India - they account for an estimated of 62.7% the total health spending in the country!

In a 2019 global survey of 1500 patient groups in 78 countries, only 9% respondents believed that pharmaceutical companies were 'excellent or good' at having 'fair pricing policies'.

The Pharmaceutical Supply Chain

Drugs and medical devices pass from the manufacturer/importer to the distributor, wholesaler and retailer before reaching the end consumer. Expenses are incurred for research and development, regulatory approval, procurement, freight, insurance, registration, manufacturing, transport, storage, marketing, taxes, labour and other normal business overheads. There are a number of entities in the supply chain and mark-ups and profit margins come into play at every level.

Manufacturers and sellers usually have the freedom to set the prices as they want. This is leading to exorbitant differences between the actual cost of a medicine and its final selling price. There are inflated margins at every link of the supply chain. In fact, many chemists and wholesalers charge margins as high as 1000% for some medicines. This not only causes undue financial hardship but also fleeces the patients who have no choice but to cough up the money or forego the treatment!

The Association of Indian Medical Device Industry (AiMeD) pointed out that consumers suffer from artificial inflation. Retailers and hospitals prefer to use imported medical devices for the derived higher profitability - in many cases imported unit packs do not carry MRP; it is labelled only on their shelf box. This enables them to charge any price as they wish. On the other hand, domestic manufacturers comply with the requirement to print MRP on unit packs.

Even with imported devices that carry MRP, there are huge disparities between brands of various suppliers for same/similar products - higher MRP (and higher trade margin) strategy is used to induce retailers and hospitals to push the brand. The market is not operating based on open competition to drive down prices. Domestic manufacturers also increase their MRP to catch up and offer similar profitability.

In June 2017, the government made it mandatory for all medical devices to print MRP on unit packs as well as the country of origin. However, measures to ensure compliance are still lacking.....

Ever wondered how much money do manufacturers, suppliers and pharmacies make?

A recent presentation by India's National Pharmaceutical Pricing Authority (NPPA) revealed that:

- **For tablets that are priced up to Rs 2 (per tablet), the margin is usually up to 50%**
- **For tablets that are priced between Rs 15-25, the margin is under 40%**
- **For tablets that are priced between Rs 50-100, 2.97% of the medicines have margins between 50% and 100%, 1.25% have margins between 100% and 200% and 2.41% have margins between 200% and 500%**
- **For tablets that are priced above Rs 100, 8% of the medicines have margins around 200% to 500%, 2.7% have margins around 500-1000% and 1.48% have more than 1000% margins.**

International Arena

Price controls serve as a crucial tool for governments to make medical products affordable. The World Health Organization formulated the 'Guidelines on Country Pharmaceutical Pricing Policies' (WHO Guidelines 2020). These are a set of recommendations on how countries can approach price control. Many countries have implemented various pharmaceutical pricing policies and procedures in order to determine and regulate the prices of pharmaceutical products.

Government Interventions in India

The primary objective of the Drug Policy of India is ensuring abundant availability of good quality essential, lifesaving and prophylactic medicines at reasonable prices.

The union Ministry of Chemicals and Fertilisers introduced the Drug Price Control Order (DPCO) to regulate the prices of drugs in order to protect public health. First introduced in 1970, the latest order was issued in 2013. Additionally, the health ministry also draws up the National List of Essential Medicines (NLEM) which automatically come under price control under the DPCO.

The National Pharmaceutical Pricing Authority (NPPA) is charged with enforcing the provisions of the DPCO and monitoring of drugs and medical devices. This national watchdog has an independent panel of experts that fixes/revises the ceiling prices of the scheduled drugs (NLEM). They are applicable to imported drugs as well. The maximum prices are revised on or before the 1st of April every year based on the annual Wholesale Price Index (WPI) of the previous year.

The price capping of essential and lifesaving drugs and medical devices is done to ensure fair and equitable pricing, boost transparency and help maintain a level playing field. It also supports the pharmaceutical industry and focuses on promoting fair competition. The overall aim is to achieve a balance between the interests of the consumers (affordability) and the pharma companies (profitability).

Apart from scheduled drugs, the NPPA also keeps track of the annual price increase of unscheduled medicines and medical devices. While medical products that are not under price control have the liberty to fix their launch price, thereafter, the manufacturers can increase the MRP only by 10% per annum. Therefore, essential medicines are subject to price controls in the form of ceiling prices and non-essential medicines are subject to managed price increases.

Non-compliance with the regulations by the manufacturers, distributors or retailers can lead to legal penalties, market exclusion, loss of reputation, increased regulatory scrutiny and market competition challenges.

Additionally, para 19 of DPCO 2013 gives the NPPA the special authority to bring any item of medical necessity under price controls in the public interest. This provision was invoked to cap the prices of 106 anti-diabetic and cardiovascular drugs, cardiac stents and knee implants followed by 42 anti-cancer drugs using the trade margin rationalisation (TMR) approach.

During the COVID-19 pandemic, the government set the maximum retail price for medical devices related to COVID-19 management – first the oxygen concentrators and then pulse oximeters, blood pressure monitoring machines, nebulisers, digital thermometers and glucometers (trade margin capped at 70% at the first point of sale).

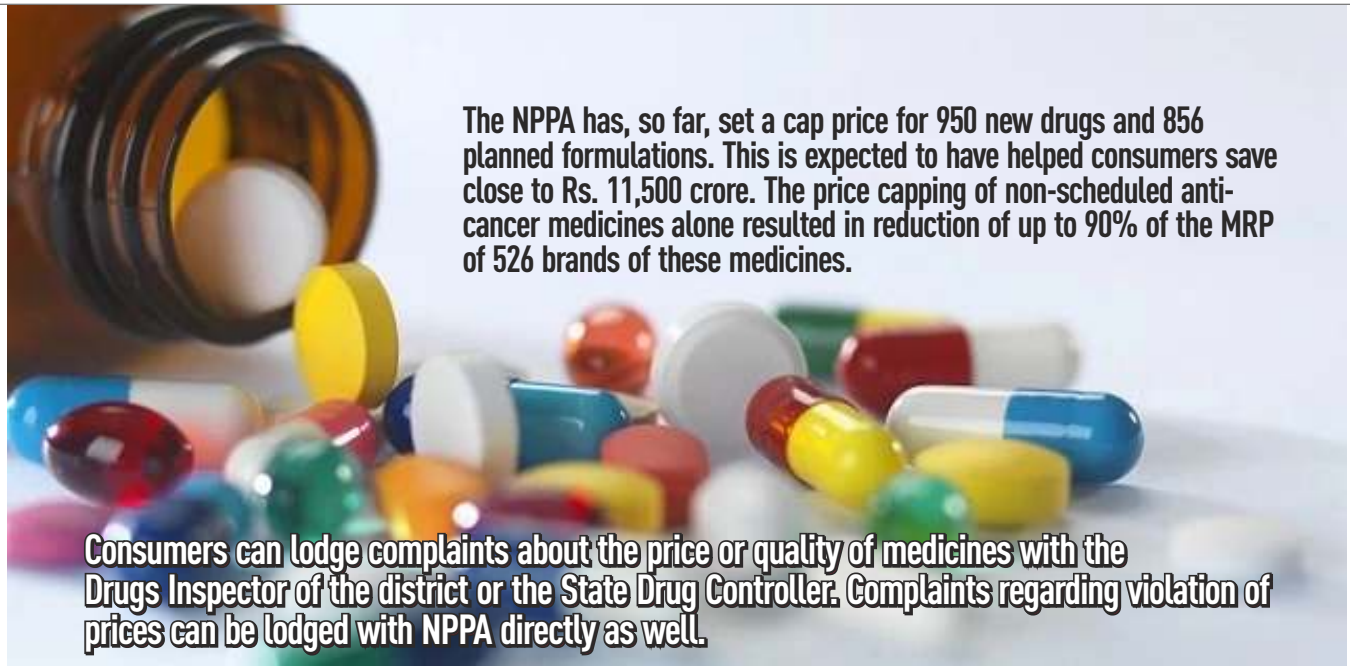
It was stated that existing margins across the last five categories were as high as 709% from price to distributor to MRP level. According to the Economic Survey, 2022, the capping lowered prices of most of the brands by up to 89%! It reduced black-marketing as well as made them affordable during the unprecedented health crisis.

The Debate over Trade Margin Rationalisation

Since last year, the regulator has been working on cutting down the traders' margins on non-scheduled (but widely used and expensive) drugs that are not covered by the price control mechanism. This move will bring down prices of specific therapeutic categories and classes of medicines such as anti-infectives, and those used to treat cancer and chronic kidney diseases.

"We discussed the implementation approach and calculation methodology with the industry. Pharma companies agreed that TMR is a good move and a balanced approach will reduce the prices of drugs substantially," so said a government official who was part of the NPPA meeting with representatives of big pharma companies last year.

Trade margin is the difference between the price at which a manufacturer sells a drug or device to a distributor and the final price charged to the end patients (MRP)



This conversation of using trade margin data to rationalise the costs of drugs and medical devices started in 2017. At that time, government think tank, NITI Aayog released a consultation paper titled 'Rationalisation of Trade Margins in Medical Devices' based on the discussions between the central government and the healthcare sector.

One of the key points of the discussion was deciding what is the point of first sale where the capping of trade margins starts. Currently it is considered as the price paid to importers/manufacturers by the distributors of the medical devices. Thereafter, caps are placed on the difference in the prices to stockists and to patients.

However, arguments have emerged that the point of first sale should be when the drugs/devices first enter the supply chain - selling cost of goods from the factory (ex-factory price). For importers, it should be the point where the drug or device enters India (landed price). Otherwise, there is a grey area which remains overlooked till now.

Then again, it is the distributors that rake in most of the profits; not the manufacturers. This kills the incentive for innovation, maintaining quality standards and so on.

Trade margin rationalisation is a mode of price regulation that involves capping the trade margins in the supply chain. The capped trade margin is used to calculate the maximum retail price of a medical product.

However, the most important consideration is that rationalisation should not impinge on quality in any manner!

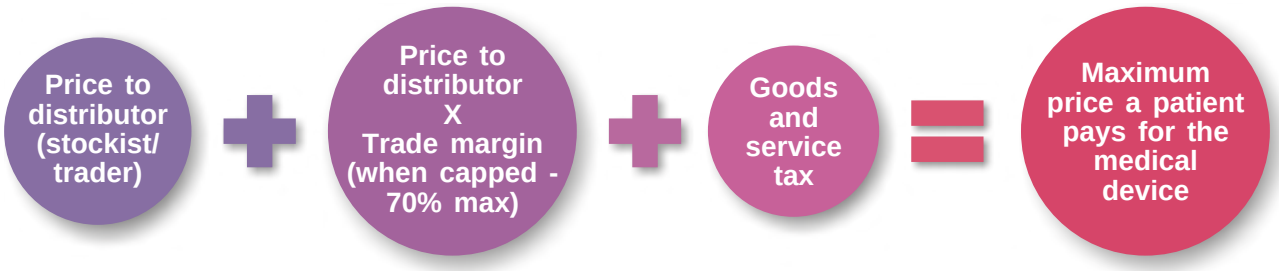
Marketing Malpractices

Pharma companies are notorious for their rampant, vigorous, excessive and unethical marketing practices to push sales. They spend exorbitantly on promotions to lure physicians, as they are the primary decision-makers of medical treatment.

Medical representatives constantly make the rounds of clinics and hospitals to woo healthcare professionals with 'bribes' of free samples, gifts and even cash incentives. The freebies range from branded souvenirs like pen stands, calendars, diaries and sanitisers to free dinners, tickets to events, holiday trips, etc. – all aimed at

AiMeD has suggested capping of MRP to maximum 4 times the first point of sale. It further called for price capping of medical devices with identical specification but a huge price differential. The association also suggested other measures to discourage high MRP and usage of high trade margins as a marketing ploy!

Calculation of MRP Using Trade Margin Rationalisation



incentivising them to prescribe their drugs. We are bound to see a couple of them loitering in the waiting area whenever we visit a doctor! Similar promotional activities are targeted at pharmacies as well.

While manufacturers argue that they are simply promoting 'top-of-the-mind recall' of their brands, numerous studies have shown that the aggressive promotion tactics do influence the prescribing behaviour of physicians. This is not only against the spirit of competition in the market, but can also lead to overprescription (higher doses or for longer periods) and prescription of irrational combination of drugs. Moreover, it can increase the financial burden for patients as doctors may prescribe an expensive drug (rather than a cheaper/better option) to cash in on the incentives! This has also eroded consumer trust in the entire healthcare system.

The Central Board for Direct Taxes (CBDT) stated that the makers of Dolo650 (pain and fever tablets) spent a whopping Rs 1,000 crore to distribute freebies to doctors for prescribing the medicine, making it the go-to drug during the second wave of the pandemic. As per market estimates, the company enjoyed record sales of 350 crore tablets, thus earning Rs 400 crore revenue during the said period.

The government instituted a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) in 2015 to prevent unethical promotion and marketing of drugs and medical devices by pharmaceutical companies. It duly covers various aspects of marketing practices like medical representatives, textual and audio-visual promotional materials, samples, gifts, travel facilities, hospitality, cash or monetary grants to physicians, etc.

However, as the code is not legally binding, it lacks teeth to dissuade or punish the defaulters. Even though most pharma associations have accepted it, the door remains open for unethical practices.

Additionally, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 detail professional misconduct by medical practitioners (which includes accepting gifts from drug companies). The Supreme Court also ruled that gifts to medical practitioners by pharmaceutical companies is not allowable expenditure under the Income Tax Act, 1961. All to no avail!

The Uniform Code for Pharmaceutical Marketing Practices is voluntary. We have been demanding that it be made statutory. In 2018, we had everybody in agreement - from the government to the doctors. But the pandemic slowed down things.

– Ramesh Sundar R., *President, Federation of Medical and Sales Representatives' Associations of India (FMRAI)*

There is a thin line between informing and updating doctors about medical products with legitimate promotional activities and illegitimate incentivisation.

In September 2022, the Centre formed a high-level committee - chaired by Dr V.K. Paul, NITI Aayog member (health) - to review marketing practices of pharmaceutical companies in the country. The five member panel is tasked to recommend to the union Health Minister, Mr. Mansukh Mandaviya on harmonising all the codes, rules and regulations pertaining to pharma malpractices. It is also charged with hammering out legally enforceable measures against firms that give inducements for promoting their medical products, in tune with global best practices.

The committee was supposed to submit its report in 3 months; it even held a meeting with the representatives of pharma lobby groups. But nothing has materialised till date.

Recently, the National Medical Commission (NMC) - regulatory body guiding medical professionals - issued an order prohibiting doctors from participating in third-party medical seminars, conferences and other educational activities that have 'direct or indirect sponsorships from pharmaceutical companies or the allied health sector'. However, it was put on hold after the Indian Medical Association (IMA) prevailed on the health minister that these events are only a discussion forum that provide productive opportunities for the exchange of knowledge about advancements in medicine!

Medical education is undergoing advancement with each passing day. If we don't match up with these developments and attend these conferences, then we can't offer new medical treatments to our patients. Had these conferences been shut down 20 years ago, we wouldn't have had expertise in offering cardiac and cancer treatment.

– Mr. Sharad Agarwal, *President, IMA*

Conclusion

Will the regulatory landscape for pricing and marketing of medical products ever become clear and fair? Will we ever witness the dawn of value-based healthcare?

Bina Jain
- Former President, All India Women's Conference (AIWC)
- Chairman, Healthy You Foundation, New Delhi

Unravelling the Confusion Over Generic *vs.* Branded Medicines

"With the raging debate over generic and branded medical products, we delve into the myths and truths of this major healthcare issue. We also take a look at the role of physicians and pharmacists in promoting/inhibiting the use of generic medicines along with a ringside view of the problems ailing Indian generics."

– Ms. Bina Jain

Prescription Drug Cost Comparison

Generic Medicine	⟷	Branded Medicine
₹ 25.00		₹ 85.00

Generic drugs can reduce the overall healthcare expenditure. But how do we know the quality is the same as branded medications? And why are they not easily available in our regular pharmacies?

IT TAKES YEARS of scientific research to develop a drug or medical device to treat a disease or disorder. This is followed by exhaustive animal and human testing before the pharmaceutical company can even dream of getting regulatory approval. Needless to say, a lot of money is invested in the discovery, development, clinical trials, labour, marketing and more.

The drugs that are launched with a new active ingredient get a patent – an exclusive right to manufacture and market it for a specific period of time, usually 20 years in most countries. This allows the manufacturer to recover the substantial investment and reap the profits from the same (in a reasonable manner) without any competition. Other companies are prohibited from making and selling similar medicines based on the said active ingredient.

Exclusive patents allow a monopoly on the drug, and, generally, an expensive price tag!

It is only after the expiry of the patent and other exclusivity rights that other companies can develop medications containing the same active ingredient. These are known as 'generic' medicines.

Affordable Versions to the Rescue

A generic drug is one that is created with the identical chemical composition and intended use of an existing and approved branded drug. It features the same active ingredient, dosage form, safety, strength, route of administration, quality and performance characteristics. Generic medicines are considered bioequivalent and deliver the same therapeutic effect as their non-generic counterparts.

The only differences will be in the shape, size, colour, packaging and inactive ingredients – each of which in no way contribute to the efficacy of the medicine.

Generic medicines should ideally not have a name on them. They should be marketed either by a salt or generic name. In reality, when a generic is made by several companies, they often give their medicine a brand (trade) name.

Above all, as generics are cheaper versions of costly branded drugs, the price will be dramatically lower – can be 40% to 50% less than the original product! In fact, the driving force is that generic medicines and medical devices cost less and are available at affordable prices, thus allowing consumers to save significantly on their medication bills. Little wonder that the use of generic drugs is increasing around the world across applications like pain relief, diabetes, cardiovascular treatments and even cancer.

According to a study, the global generic drugs market was worth $390.57 billion in 2020 and is projected to reach approximately $574.63 billion by 2030, with a CAGR of 5.59% between 2021 and 2030

Generic drugs also have to go through quality check processes and obtain the requisite licenses/permissions from the concerned authorities before entering the market. However, the testing requirements are lower, easier and quicker. Since they save substantial time and money on the research, clinical trials, marketing, etc., it manifests as a significant drop in prices.

The Indian Scenario

India has one of the highest per capita out-of-pocket expenditure on healthcare. And as medicines constitute around 40% of healthcare expenses, generics can lead to substantial savings.

In 2016, the Drugs Technical Advisory Board amended the Drugs and Cosmetics Act to allow pharmacies to sell generic name medicines and/or equivalent brands to patients even if the prescriptions specify a branded version.

Fact of the matter is that the Indian retail pharmaceutical market is largely dominated by generics. Most of them are branded generics where pharma companies sell off-patented drugs under their own brand names. There are also mirror brands - different brand names given to the same generic drug by the same company. Therefore, with several different generic drugs actually having the same active ingredient, the market is flooded with the same medicines under a plethora of brand names. For instance, the generic analgesic drug Paracetamol is sold under the names of Crocin, Calpol, Metacin, Pacimol, etc. A mere 10% are actually sold as unbranded/generic which are mostly procured by public healthcare services.

A study by Competition Commission of India revealed that during 2011-2012, 47,478 brands with 2,871 formulations were marketed in India, making an average of 17 brands for every formulation!

There is a broad price difference between different generics manufactured by different companies. What's more, the pure generics available in the public sector are way cheaper.

Red Flags in India vis-à-vis Global Practices

In USA, the Hatch-Waxman Act established a system of generic drug regulation which is considered the gold standard across the world. Generic drugs have to be approved by the Food and Drug Administration (FDA); the US FDA Generic Drugs Program conducts a rigorous

pre-approval review to make sure generic medicines meet the stipulated requirements. In addition, FDA conducts regular inspections of manufacturing plants, ensuring compliance with the agency's regulations on good manufacturing practices.

The FDA confirms, "Generic drugs go through a rigorous review process to receive FDA approval. The FDA ensures a generic medication provides the same clinical benefit and is as safe and effective as the brand-name medicine that it duplicates."

Moreover, it maintains an Orange Book which is an online list of Generic Equivalents available in the USA. It has a specific coding system under which all generic medicines available are displayed with the exact composition and names of all generic manufacturers. The data is updated every month and helps practitioners identify a product's equivalence for substitution with the original product.

Healthcare professionals in Australia are mandated to write the name of the active ingredient of a medicine on the prescriptions. If they wish, they can add a brand name after the active ingredient.

In India, the Central Drugs Standard Control Organisation (CDSCO) is in charge of evaluating the safety and efficacy of generics before granting approval. However, the testing standards are not stringent and the procedure is very lax.

In 2018, the CDSCO found that nearly 4.5% of all generic drugs circulated in the domestic market are substandard.

A major drawback is that it is not mandatory for generics to undergo bioequivalence studies. A 2017 amendment mandated bioequivalence for certain classes of generic drugs.

GENERIC DRUGS PRICE ADVANTAGE

Drugs	Jan Aushadhi	Unbranded	Branded
Paracetamol	₹ 7	₹ 8.66-19	₹ 28-72
Pain Relief Gel	₹ 50-55	₹ 109.30	₹ 168
Ranitidine (Antacid)	₹ 6-13	₹ 15.70	₹ 40.70

> In India, bioequivalence studies are not conducted before granting a generic license. We don't know if a generic is delivering 100% or only 70% efficacy of the patented drug. This makes it difficult to adjust the dosage.

– Dr Shuchin Bajaj,
Founder Director, Ujala Cygnus Hospital

The Union Health Ministry was considering colour coding generic medicines or marking them with symbols to differentiate them from their more costly branded counterparts. The intention is to both encourage consumers to make an informed decision when buying drugs and promote sales of generic medicines. However, nothing materialised on the proposals.

Under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), the government has set up a nationwide chain of pharmacies that sell only unbranded generic medicines to provide accessible, affordable and quality medicines to the consumers. These Jan Aushadhi Kendras are operated by the Department of Pharmaceuticals in association with central pharma public sector undertakings.

The Jan Aushadhi product basket comprises of 1800 drugs and 285 surgical items. The prices are cheaper by at least 50% and in some cases, by 80% to 90% of the market price of their branded counterparts.

JAN AUSHADHI SCHEME

9,512 Outlets	↑38% FY23 Sales
54% 5-Yr Sales CAGR	4.2% Mkt Vol Share

During its launch in 2008, PMBJP aimed to set up one Jan Aushadhi outlet in each of the 630 districts of the country, to be extended to sub-divisional levels as well as major towns and village centres. More than 9500 dedicated outlets are in operation as of 30th June, 2023.

Furthermore, there is no central database of all brand names or even monitoring of the award of brand names. Therefore, entirely different drugs formulations can have similar or even same brand names – for instance, the name Lona is ascribed to a low sodium salt as well as an anticonvulsant! This is not only creating a lot of confusion and errors, but also resulting in record levels of pharmaceutical trademark litigation across India.

The Scary Truth

India has established itself as the world's generic capital – we are the largest manufacturer and exporter, by volume, of generic drugs. Our companies provide 20% of the supply to the worldwide generic drug market. The generic pharmaceutical exports surpassed $25 billion during 2022-23. Amidst the COVID-19 pandemic, we supplied vital drugs and vaccines to over 150 countries.

However, there is a pressing need to tackle the persistent challenges faced by our generic pharmaceuticals. India is being repeatedly pulled up in the international arena for its lack of regulatory oversight in the form of notices, warnings and even bans on imports due to issues of specific facilities and drugs. Indian-made generic cough syrups have killed dozens of children, eye drops have caused blindness and chemotherapy drugs have been found to be contaminated. The Gambia and Uzbekistan fiasco should be a wake-up call for the authorities and manufacturers.

What is even worse is that many Indian pharma companies produce high quality and effective generic medicines for export to European and American markets (where regulation is tighter) while blithely selling inferior and ineffective drugs in India. This damning revelation has been documented by journalist Katherine Eban in her influential book, 'Bottle of Lies: The Inside Story of the Generic Drug Boom'.

Dinesh Thakur, the famous Ranbaxy whistle-blower and campaigner of reforms in drug regulation has categorically stated that testing drugs in India is just a waste of time as no regulators ever look at the data. Once in a while, the CDSCO and state drug controllers do carry out random quality checks on drugs in the market, but why are people and even doctors not made privy to the results?

Indeed, many people have stated that generic medicines do not work at times. It does happen that no matter how many tablets they take, it does not treat the infection or disease. Some detractors even claim that some generics can prolong illnesses or even end in therapeutic failure. Given the situation, we cannot deny that generic drugs need to be tested properly for their purity, potency, stability and drug release!

Generic Prescription Mandate

The government is trying its best to promote prescription by generic names in India, especially for the National List of Essential Medicines. The Medical Council of India has repeatedly directed physicians to prescribe drugs by their generic names only - by amending the code of ethics in 2002 and recommending in 2016 that every physician should prescribe drugs with generic names legible and should ensure that there is a rational prescription which promotes the use of generic drugs. Again, in 2021, it released a circular stating that doctors who do not abide by the country's generics-related ethics regulations could be subject to disciplinary action that could include license suspension or termination.

However, these remain mere words on paper as doctors continue to prescribe branded medicines to the patients without a second thought. As of now, only government hospitals, CGHS wellness centres, etc. are bound to prescribe generic medicines!

According to WHO, if doctors start prescribing generic medicines, health expenditure can be reduced by 70%. The current generic drugs consumption is only 10% to 12% of the total drug market.

A few months ago, the National Medical Commission had notified guidelines requiring doctors to prescribe drugs using generic names and avoid referring to specific brands. Any failure to comply with the rule could lead to a doctor's licence being suspended for up to a month.

This sparked a heated controversy with several medical associations expressing serious concerns about the order. The Indian Medical Association (national voluntary organisation of physicians) declared that this is akin to 'running trains without tracks' and will pose challenges for physicians in ensuring patient safety and treatment efficacy. Stating that less than 0.1% of the drugs manufactured in India are tested for quality, the

> We (doctors) cannot prescribe medicine in the name of 'cheap medicine' if the medicine is not effective..... I urge government to do research on quality of generic drugs available in government hospitals and share the data with the public and IMA..... Government says that quality control is 50% but what about the remaining 50%?
>
> – ***Dr Sharad Agarwal,*** *President, IMA*

IMA asked the government to defer the order until it can certify and assure the quality of every generic drug manufactured and retailed in India. The order was put on hold thereafter.

The IMA has further suggested that the centre can bring down the cost of branded medicines or even have a 'one drug, one quality, one price' system - all brands should either be sold at the same price or banned with only generic medicines being allowed.

The Way Forward

Everyone from the drug manufacturer companies to the physicians and pharmacies have vested interests in restricting the use of generic medical products. Compulsory prescribing of unbranded generics will cause a sizeable erosion in sales of branded generics. Doctors will miss out on the huge commissions they receive for prescribing original branded or generic brand drugs. Even pharmacy owners are more interested in the kickbacks they get to push these drugs.

However, the stance of physicians that they need safety and efficacy data on generics to prescribe them confidently also holds water. As **Gautam Khanna, CEO,** P.D. Hinduja Hospital & Medical Research Centre, Mumbai, states, “When the doctor prescribes a medicine, he has looked at the clinical efficacy of all the brands and is comfortable with it. Finally, he is the one responsible for the patient's treatment.”

Another roadblock is that most pharmacies (other than in government-run hospitals, clinics and Jan Aushadhi centres) do not stock unbranded generic drugs. So, when a physician prescribes a generic, the pharmacist is likely to dispense the most 'profitable' branded option without caring for the cost impact on the patient. Some many even pretend not to have the generic medicine (as there is low margin on the sale) and offer an expensive alternative.

Furthermore, as **Snehdeep Bohra,** India Director, Fitch Ratings points out, “The mandate may shift the decision-making process about the choice of drug manufacturer from physicians to pharmacists who may not be adequately qualified or lack alignment with the interests of patient safety and drug efficacy”.

> “I strongly urge the concerned authorities to first set their house in order and create a local framework free of corrupt practices to provide quality in generic drug testing and also create stringent process of issuing licenses. Once this is available, the generics would obviously be as good as the so called branded. That would be a win-a-win situation for everyone.”
>
> 
>
> ***– Dr Ashok Panagariya,***
> *Professor Emeritus and former Vice Chancellor of Rajasthan Medical University and a Padma awardee*

It is no secret that most pharmacies are manned by unqualified folks rather than professional pharmacists. As they are ignorant of the technical ingredients of the drug formulations, they may wrongly dispense medications which can lead to serious health implications.

Apart from the regulatory aspects, there is a need to increase consumer awareness about the benefits and affordability of generics while dispelling the common myths, fears and doubts. People should feel empowered to seek generic drug treatment - request doctors for generic drugs where possible and demand generic medicines at medical stores.

The Last Word

It cannot be argued that the quality and efficacy of generics remains variable among different manufacturers. Does this mean that our trust in generic medicines is misplaced? Doesn't the quality of drugs matter more than the prices? Strict regulation of generics is essential to ensure that we can safely take a generic medicine as an equal substitute for its branded counterpart. Only then will consumers have access to good quality and cost-effective healthcare!

Dr. Suresh R. Saravdekar
Former Assistant Director, Ministry of Medical Education & Research Honorary Consultant - Institute of Medical Sciences, Banaras Hindu University, Varanasi

INDIAN HOSPITAL PHARMACY SERVICES URGENT NEED FOR REFORMS

BEFORE INDEPENDENCE, MULTINATIONAL pharmaceutical corporations (MNCs) dominated the manufacturing of pharmaceuticals in India. Like other developing countries, India was dependent on MNCs for supplying all essential medicines. The Indian government took a conscious decision to become self-reliant in production and availability of all essential medicines by promoting domestic pharmaceutical manufacturing. This led to focus on pharmacy education to generate industrial pharmacists on priority. This is the greatest contribution of pharmacy profession in the progress of India and becoming 'Pharmacy of the World'. However, during the same period, the hospital pharmacy remained deprived of its overall development.

For decades, the four facets of pharmacy professions in India, namely, education, industrial, hospital and community services are working in silos, resulting in their sub-optimised conditions.

- **Education Regulator –** The PCI followed the syllabus of pharmacy colleges of developed countries, neglecting the 'ground realities' of community and hospital pharmacy services. The only interest was to start more colleges.

- **Industrial Regulation –** The National Health Policy (NHS) was formulated by Ministry of Health & Family Welfare whereas National Pharmaceutical Policy (NPS) was formulated by Ministry of Chemical & Pharmaceuticals. Consequently, there was a disconnect which was favourably used by the industry for creating more market-based needs than health needs, affecting essentiality, affordability and accessibility of medicines in the healthcare services.

- **Hospital Pharmacy –** Neither pharmacy education regulator nor drugs inspectors ever felt any need or legal responsibility to study and suggest improvement in Indian hospital pharmacy services. As a result, the assessors of hospital pharmacy services under NABH are not pharmacists, but nurses or doctors.

- **Community Pharmacy –** Lack of proper regulation has resulted in many potent medicines and their combinations being marketed and sold without prescriptions, resulting in rampant self-medication, and irrational and improper use of medicines.

Challenges Faced in Healthcare Services

- In public healthcare services, like doctors and nurses, no standards have been developed for pharmacy services. For example, there is no fixed ratio of number of pharmacists posted to number of patients. The job profiles have remained the same for decades - as existed during 'mortar and pestle times' - without any reforms of up-skilling and promotion in services. The lack of proper recognition of the hospital pharmacy profession by the states is resulting in the health workers like ASHA now being trained to dispense medicines to replace pharmacists!
- In private hospitals, only minimum mandatory numbers of qualified pharmacists are appointed to meet regulatory compliance. The consequence is a total disconnect between what is needed and available. What is needed is to identify the domestic health needs and raise the bar of standards of patient care and health services to the desired level.
- With vast number of patients, the physician is not in a position to handle the complex task of medication management effectively, as he is already overworked with his therapeutic responsibilities. This is where the hospital pharmacist should take up the challenge and deliver pharmaceutical care services.
- Due to the disconnect between NHS and NPS, the Indian pharmacy regulations are focused only on manufacturing and pushing sales and less committed to safe use of medicines. As a result, till 2005, there was no mandatory need to maintain data on pharmaco-vigilance, medication errors and post marketing surveillance (PMS)in India.For example, even though 294 FDCs were declared unsafe by national health authorities, they are still in use as industry got court stay orders on the grounds that there is no data on record to prove that these FDCs are unsafe. The real paradox is the case is still pending in Supreme Court and these unsafe FDCs continue to be available in the market!
- There is rampant offline as well as online use of Over The Counter (OTC) and Prescription Only Medicines (POM). There was neither regulation nor definition of OTC before 2019. It was simply assumed that drugs which are not in FDA schedules are OTC drugs. It was in August 2019 that the CDSCO decided to classify OTCs into two categories? OTC-1 and OTC-2? based on the extent of evidence, safety, therapeutic index, need for accessibility to patients, etc. And this is still without having any proper mechanisms in place to ensure safe use. A survey of 20,000 people during 2015 in 10 cities across India revealed that nearly 52% of the population purchase OTC medicines and indulge in self-medication. (https://www.thequint.com/lifestyle/over-50-indians-resort-to-self-medication-study)

Mushrooming of Education Institutes – Dreams Sold Without Career Prospects!

During the last decade, to bring pharmacy curriculum on par with the best in the world, a new course of Pharm D was started by PCI. Unfortunately, it did not generate as much new employment potential in the hospital pharmacy sector as expected. Currently, situation of pharmacy colleges in Indiais as follows: (PCI 2019)

- **3077 Diploma Colleges (Total Seats 1,80,000)**
- **1961 Degree Colleges (Total Seats 1,25,524)**
- **875 Post Graduation Colleges (M. Pharm.)**
- **267 Pharm D colleges started since 2008 (Total Seats 8010)**
- **3,14,304 - Total number of Pharmacists per year**

Thus, yearly, approximately 3 lakh new pharmacists are coming out of these institutes with uncertainty of employment prospects. By proper management of education and training, hospital pharmacies can become a major sector to provide sufficient employment to these pharmacists.

Pharmacy Regulations

Two types of regulations have been initiated in India to regulate hospitals - voluntary regulation (accreditation) and mandatory licensure regulation enacted by the government (Clinical Establishment Act, 2010).

• **Accreditation** – Limited only to Private Hospitals - Due to availability of low-cost medical treatments, the Medical Tourism Association ranked India 10th in Medical Tourism Index (MTI) for 2020-2021, out of 46 destinations of the world. According to data by the Ministry of Tourism, India witnessed 186,644 Foreign Tourist Arrivals (FTAs) for medical purposes in 2020, accounting for 7% of the total FTAs. The industry is expected to reach Rs 2,670.37 billion by 2027, expanding at a CAGR of 34.92% during 2023–2027.

This is not only a boon for the medical industry; it also forced the hospital industry to upgrade their services to the international and national validations and accreditations. This led to the setting up of National Accreditation Board of Hospitals (NABH) to develop standards for hospital services in India. PCI grabbed this opportunity and started a special course called Doctorate in Pharmacy (Pharm D) - a five-year doctorate program specially attached to hospitals that trains the pharmacists in clinical pharmacy, clinical trials, pharmaco-vigilance, pharmaco-economics, inventory and stores management, patient counselling, and helping the physicians in identifying correct drug,dose and various range of drugs interactions.

• **Mandatory Compulsory Licensing –** Both Private and Public Hospitals - The Indian government enacted the Clinical Establishment Act and Rules in 2010to provide for registration and regulation of all hospital services. This Act - prescribing the minimum standards of facilities and services that should be provided in all public and private hospitals and clinics - is already in force and applicable to all Indian states. However, except a few, most states have still not formulated and implemented the provisions under the Act. Private hospitals are reluctant and feel such regulations will infringe on their freedom and restrict them to observe certain minimum standards.

Suggested Reforms

Enforcement of both voluntary and compulsory licensing should be used not only to upgrade standards, but to generate employment in hospital pharmacy services. We need to take full advantage of this situation by introducing reforms at following three levels:

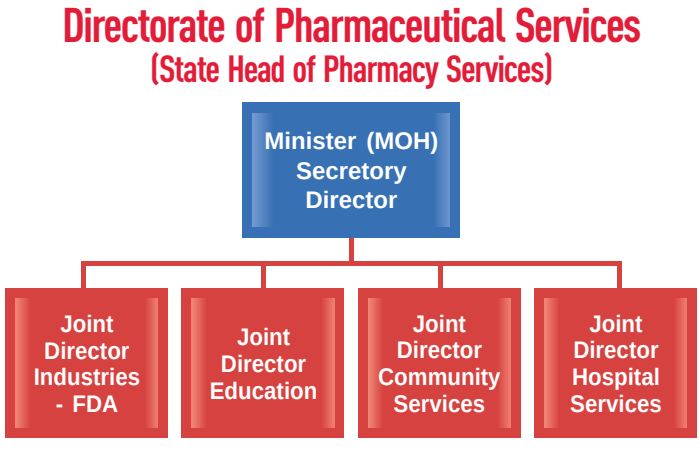
1) **Private Sector –** PCI should take an active part in development of standards in accreditation processes under NABH. We need to nominate senior hospital pharmacists (having knowledge and experience) as an assessor in these accreditation processes.

2) **Public Sector –** Public hospital pharmacy services need a total revamp. PCI's hospital pharmacy members (not teachers) should study and submit a detailed development plan mentioning pharmacist-to-patient ratio, clearly defining duties and responsibilities of pharmacists, with creation of new posts and promotional channel. The following two pharmacy services should be immediately started with active participation of students from pharmacy colleges.

   • **Establish Patient Counselling Centre in Out-Patient Departments (OPDs) of all Hospitals –** Pharmacists should counsel patients to comply with the therapy and proper use of medicines This can be achieved by pharmacy colleges by adopting nearby public or private hospitals and starting a Patient Counselling Centre in the OPDs. The pharmacists can be trained in counselling and posted in these centres for practical training, and later, can be absorbed in hospital services.

   • **Establish Pharmacovigilance Centre in In-Patient Departments (IPDs) of all Hospitals –** Every hospital needs to establish an ADR Monitoring Centre for monitoring on ADR, medication errors and PMS. The pharmacy colleges should adopt nearby public or private hospitalsfor the practical training of Pharm D students at these centres, and later, they can be absorbed in hospital services.

3) **National and State Level –** It is high time that all pharmacy services are integrated under a single umbrella at each state level. This can be achieved by establishing a separate 'Directorate of Pharmaceutical Services' in all states across India.

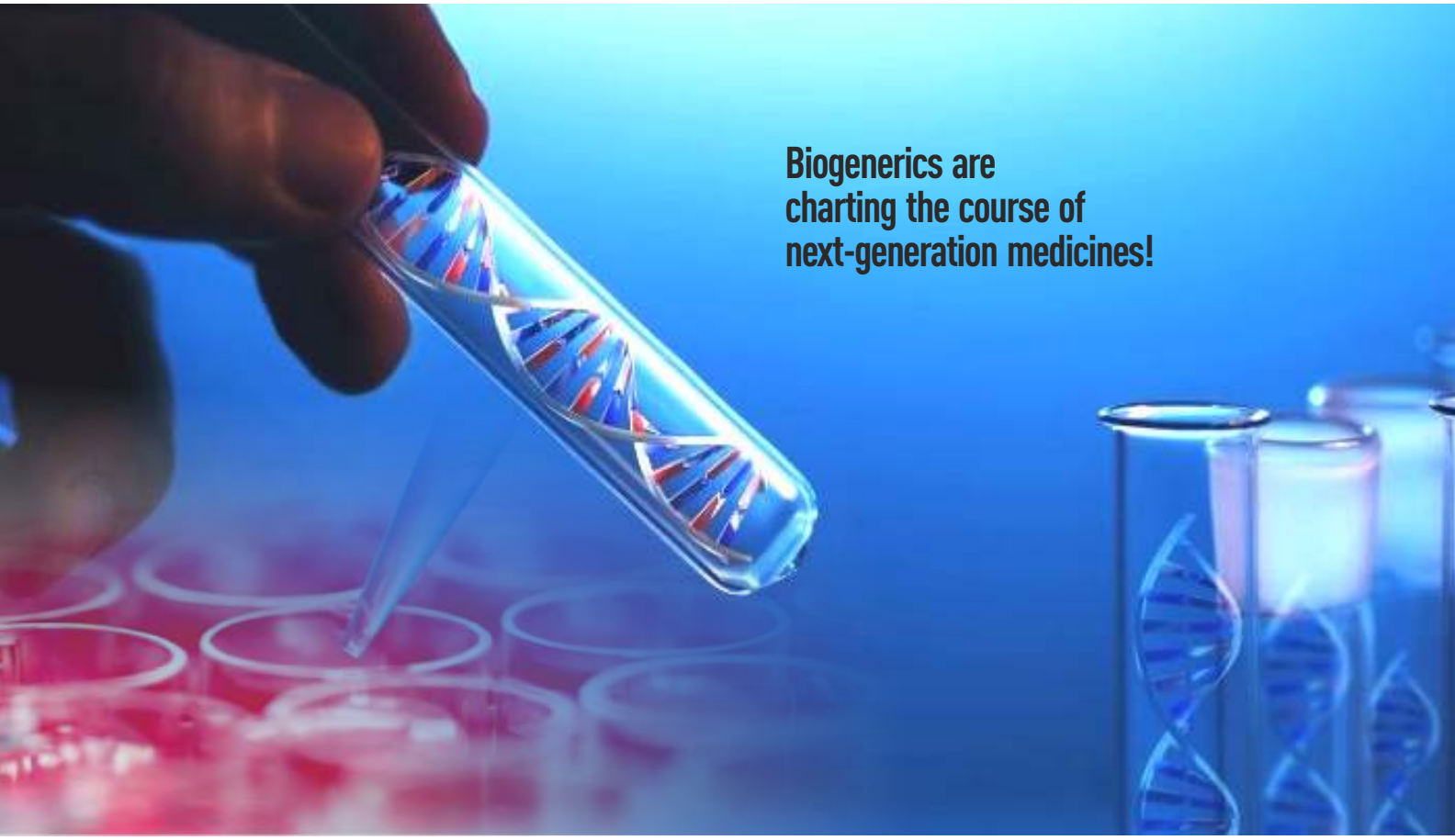


Proposed organisation chart of State Directorate of Pharmaceutical Services for governance of pharmacy profession

This will not only create good employment potential in hospital pharmacy services, but also generate recognition of pharmacy services by the government and public at large!

The Future is Biogenerics!

Biologics are revolutionary but high priced pharmaceuticals. With biologics accounting for a substantial and growing portion of healthcare costs, the biosimilar substitutes are emerging as a cost-effective and accessible solution. And while the effects of the biogenerics are highly similar to the original drugs, it's important for the pharmacist to clarify this to the patients!



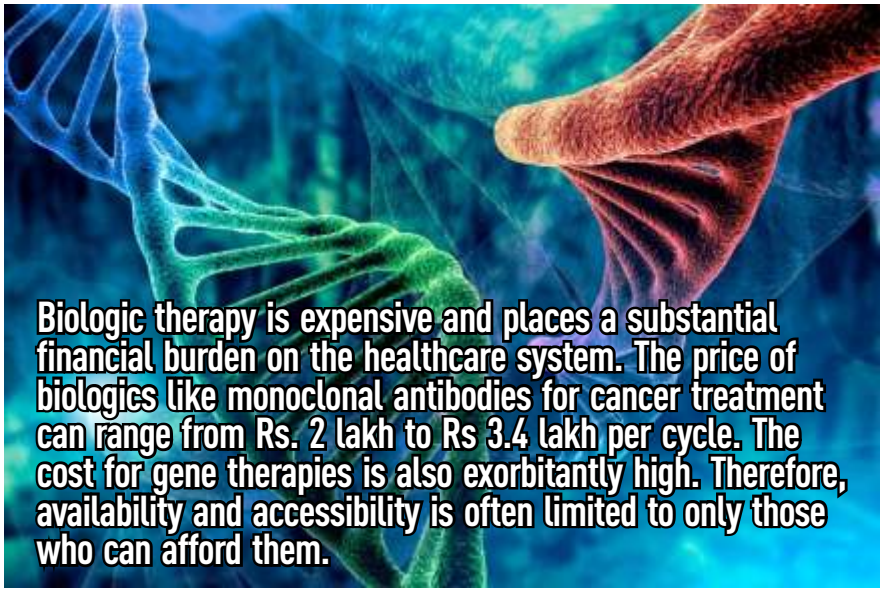
Biogenerics are charting the course of next-generation medicines!

AS NEW DISEASES or old diseases in newer forms are emerging periodically, pharmaceutical research is focused on developing newer and better drugs to fight them. The last few decades have witnessed the advent of biological or biologic drugs that have revolutionised healthcare, providing innovative and effective treatments for various illnesses. For instance, biologic cytokines, hormones, clotting factors, antibodies and vaccines have led to breakthrough results.

Human insulin (for treating diabetes) was the first biotechnologically produced medicine; other common examples are growth hormones and Hepatitis B vaccine. Monoclonal antibodies now play a central role in cancer therapy.

Biotechnology will continue to dominate drug development with the potential that new biological therapies can offer solutions for diseases that have been difficult to treat till date.

Biologics have been found to be successful in the treatment of many severe, life-threatening and chronic conditions - like neuropsychiatric, autoimmune and infectious disorders, anaemia, asthma, psoriasis and cancer - thus becoming the fastest-growing class of medications.

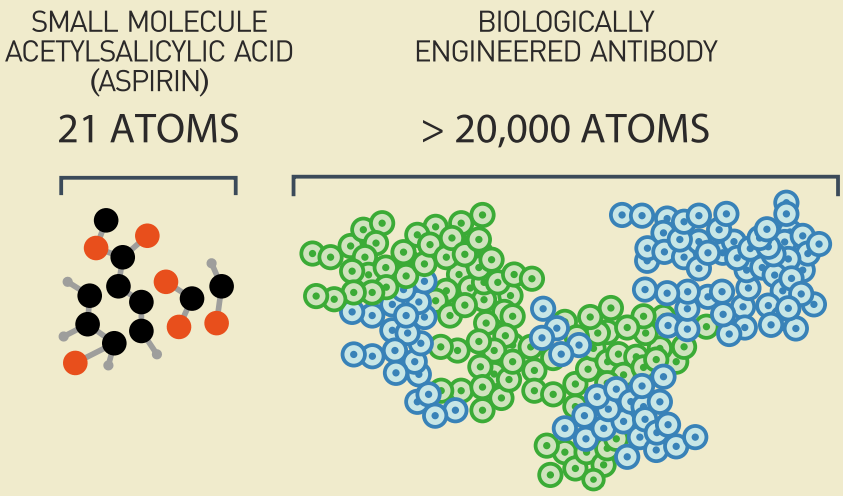


The Making of Biologics

Biopharmaceutical formulations are produced from biological sources or by using recombinant proteins (DNA engineering) while the regular pharmaceutical drugs are largely synthetic. Therefore, biologics involve the use of living organisms - like yeast, bacteria, or plant/animal cells as opposed to chemicals in traditional pharmaceuticals.

While traditional medicines have small molecules, biologics contain very large and complex compounds – the molecular structure can be hundred to thousand times larger than synthetic drugs. The latter also involve intricate production and development processes. Moreover, extensive research and testing is essential to ensure safety and efficacy. Their precision and efficiency is profound; side effects are also lower; but they are also quite costly and not always affordable for many patients.

BIOLOGICS: BIGGER AND MORE COMPLEX MOLECULES



Adapted from: Amgen Inc. Biologics and Biosimilarls: An Overview, March 2014

Enter Biogenerics

With the expiry of patent protection of the leading biologic agents, a number of biogenerics - also termed as biosimilars, follow-on biologics, similar biologics, follow-on protein products and subsequent entry biologics in different countries – are entering the market.

Biogenerics are defined as officially approved versions of innovator biotherapeutic products whose substance patent has expired. They are approved through a simplified and abbreviated registration process before being sold under the generic substance name.

Indeed, these 'near substitutes' do not have to undergo intense clinical trials for their approval. As the drug

manufacturers have to spend less on testing, they become lower-cost versions that are at least 15% to 20% cheaper than the original branded biologics. This way they can provide greater access to vital therapies and promising treatment options for a broader population.

Because there are potential cost savings to the drug industry as a whole, I think we'll see a slow-moving shift toward using biosimilars more and more in the future.

– Jamie Joy, PharmD, Director of Clinical Pharmacy Programs for Cancer Treatment Centers of America

However, while generic versions of traditional chemical drugs are considered identical to their original branded counterparts, biosimilars cannot be an exact replica of the originator - as these pharmaceutical preparations involve a biologically active substance and complex protein molecules that cannot be duplicated accurately. They are mostly similar, hence the popular term, biosimilar!

Experts maintain that the term 'biogeneric' is misleading, as no two biopharmaceutical products can be exactly identical, because of their nature and the complexity of their manufacturing process!

Regulation

Regulatory authorities consider biologicals as a distinct category from synthesised drugs. This is all the more crucial for biosimilars as they are sensitive to both the inherent variability of the protein production system and to changes in manufacturing processes. While no biosimilar can be scientifically or technically identical to the original product, it is vital that these should be 'highly similar' substitutes without any clinically meaningful differences from the reference product.

It follows that robust manufacturing and quality control procedures for production of biosimilars are essential along with a proper framework of pharmacovigilance and education.

The European Medicines Agency (EMA) was the first regulatory authority to set guidelines for biosimilars in 2005. The World Health Organization (WHO) established a regulatory framework for biosimilars in 2009. Many other countries including the USA and India followed suit very soon. Today, most regulatory bodies across the world have established robust mechanisms for the approval of biosimilars, based on comprehensive and rigorous analytical and non-clinical comparisons with the originator. The mandate is that biosimilars should demonstrate high similarity to their licensed reference biologics in terms of their biochemical, immunological, biological, efficacy and safety properties.

However, while USA and EU are considered as regulated markets for biogenerics, countries like India and China fall in the semi-regulated category.

Role of Pharmacist

Given the challenges surrounding equivalence/interchangeability of biogenerics with the original biologics, pharmacists play a pivotal role in raising awareness among doctors and patients, and minimising scepticism about biosimilar quality and safety.

Interchangeability will impact the pharmacy operations too. While pharmacists can substitute interchangeable biosimilars (depending on the national regulations) to allow easier/cost-effective access for the patients, they should also provide unbiased information to the patients and update them about the substitution.

Summary

The biogenetic forms of biologic drugs have signalled a new era in healthcare. The stage is set for a dramatic rise in patient accessibility to biotherapeutic medications. However, the advantages of biosimilars can be fully realised only if the regulatory requirements are sufficiently rigorous!

Probably the biggest issue is that you're going to have patients who've been on their biologic for some time and if they switch the biosimilar, it's going to look different. The syringe may look different from what they're used to, and they're going to be nervous about it. Maybe they'll get a headache and think, "Oh, I didn't get a headache with my other drug." They'll think the headache is a side effect of their biosimilar, but the biosimilar should be working in the same way as their innovator drug. You should be prepared for some handholding.

– Dr Steve Feldman, Professor of Dermatology, Wake Forest University School of Medicine, USA

The Indian Biosimilar Guidelines (2016) mandate animal studies and comparative safety and efficacy studies for the marketing approval of biosimilars. Recently, representatives of various civil societies, community and health organisations, and patient groups wrote to the Union Ministry of Health and Department of Biotechnology asking it to ease the guidelines to facilitate access to quality biosimilars quickly and at an affordable price. Arguing that several regulatory bodies across the globe (including the USA and UK) have reduced these barriers over the last two years to bring down the prices of biosimilars, they requested the centre to "form a committee free from the influence of innovator biologic manufacturers who have a clear conflict of interest promoting the originator products which are exorbitantly priced and clearly out of reach of most Indian people.'

However, a section of scientists and doctors urged both the authorities to not dilute norms for biosimilars, as any such loosening of norms, in a bid to make such treatments affordable, risks compromising patient safety. Amitav Banerjee, Professor, Community Medicine and a Clinical Epidemiologist categorically stated that, "Even when regulations are in place, about 3% of drugs are found to be of non-standard quality and the figure is higher (10%) for drugs supplied to the public sector."

Dr. (Prof)
Amitav Banerjee
Epidemiologist

PHARMACY COUNCIL OF INDIA
(A Statutory body under Ministry of Health and Family Welfare, Government of India)

WORLD PHARMACISTS DAY

25 September

Pharmacists strengthening health systems

Dr. Anamika Wadhera
Director
Consumer Online Foundation

The New Normal of Ordering Medical Products Online – How Safe is It?

"There are growing concerns related to the online sale of drugs and medical devices that can not only render the treatment unsafe and ineffective, but also compromise public health at large. While we cannot paint all e-pharmacies with the same tainted brush, the sector is in dire need of strict regulations and proper implementation."

– Dr. Anamika Wadhera

With a comprehensive regulatory framework, e-pharmacies can help improve access to safe, effective and affordable healthcare!

THE INTERNET HAS completely transformed the way we live and work. We are turning to online platforms not just for communication, entertainment and shopping. The advancements of information technology have enabled us to consult a healthcare professional and get a diagnosis, book a bed in a hospital, check detailed healthcare information and order medications – all at the click of a mouse!

While telemedicine and e-pharmacies were in the nascent stage till 2020, they gained exceptional traction during the unexpected lockdowns and quarantine protocols of the COVID-19 pandemic. Online medical consultations and purchase of medications through web-based vendors bring convenience, safety and swiftness into the picture, as patients can access healthcare from the comfort of their home and get medical products delivered at their doorstep.

Not having to step out of the house for healthcare needs is especially beneficial for the ailing, disabled and elderly populace as well as those living in rural, remote and underserved areas.

The Dark Side

Anyone who has been on the internet even just a couple of times will have come across websites like Medlife, 1mg, Netmeds, Pharmeasy, etc. that offer a range of pharmaceuticals, often at deep discounts.

Mordor Global Industry Reports estimate that the global e-pharmacy market was valued at $0.8 billion in 2020

However, the availability, accessibility and affordability benefits of e-pharmacies harbour other alarming facets of pharmaceutical products being sold through online platforms.

The biggest issue is of counterfeit medical products. While the reduced operating costs of e-pharmacies allow them to offer medicines at lower prices, could the 'unbelievable' discounts be attributed to spurious, substandard, expired or even unapproved drugs which will impinge on your health. They are not only ineffective and unsafe, but can even turn fatal. A shady or disreputable online platform could be providing you a massive 50% discount, but what if it is sending you nothing but sugar pills? Or what if the drug is too strong, too weak, contaminated or adulterated? And what if it hasn't been stored/transported properly? A recipe for adverse reactions for sure!

In 2021, under Operation Pangea XIV - an international operation to crack down on the illegal online sale of medicines - the authorities shut down 113,020 fraudulent websites and social media links for illegal online pharmacies and seized around $23,414,483 worth of illicit medical products that were being sold worldwide.

To add to this, many of the online/app-based pharmacies are illegitimate – they don't have a valid registration and brazenly sell medicines without a license.

Data security and patient privacy issues are also coming to the fore since customers have to provide their personal information like contact number, address, disease profile and credit card information.

More than 40,000 e-pharmacies operate globally with many more popping up by the day. The US National Association of Boards of Pharmacy states that 96% of these online pharmacies are illegal.

In February, 2023, the Ministry of Health, Government of India issued show cause notices to over 20 companies for alleged violation of norms while selling drugs online.

The ease of access is another double-edged sword. This is compounded by the lack of a registered pharmacist, no counselling services and dispensing medicines without a prescription in most online pharmacies. As anyone can order just about any medication online (including children), it is leading to self-medication and substance use disorders. Then there is the issue of easy access to antibiotics, sedatives, narcotic drugs, pregnancy termination kits, etc.

The International Pharmaceutical Federation (FIP) states, "While online pharmacies provide increased access to medicines and services, consumers may inappropriately self-diagnose or self-medicate, engage in medically unnecessary behaviour or substance abuse, or potentially encounter drug-to-drug interactions, contraindications or adverse effects."

fip International Pharmaceutical Federation

Even those that ask for prescriptions find it difficult to trace the authenticity of the prescriptions uploaded on their website. Again, there is a possibility that a person can use the same prescription multiple times, for drug abuse or misuse.

All the above drawbacks boil down to a single factor – the unregulated online marketplace for pharmacies which manifests as lack of authentication, poor quality control and much more.

Keep in mind that brick-and-mortar retail pharmacies also suffer from similar drawbacks; they are just more pronounced in the online realm. Moreover, there are scores of rogue websites with shady, fly-by-night operators that disappear without a trace, at the slightest hint of regulatory action.

Regulation Still a Far-Fetched Dream

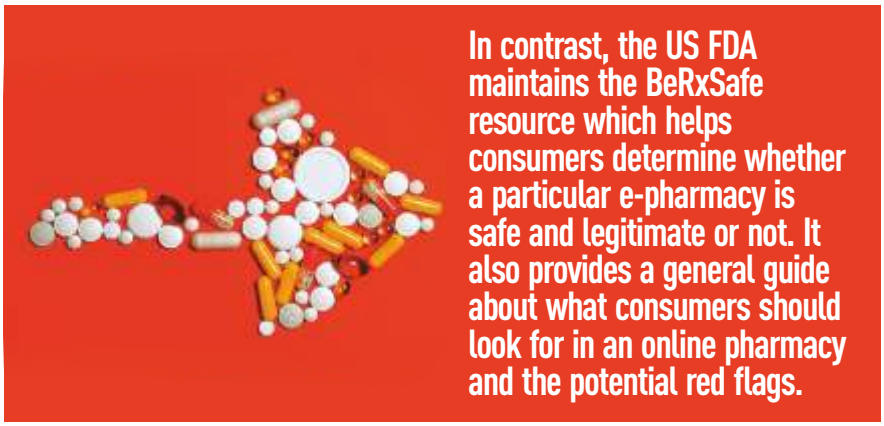
The Government of India had issued Telemedicine Practice guidelines at the onset of the pandemic which provide a robust framework for practice of telemedicine. However, e-pharmacies still suffer from lack of proper regulations.

The union Ministry of Health and Family Welfare issued the Draft Rules for e-pharmacies in 2018. Aiming to regulate online sale of medicines and ensure access to genuine drugs, they necessitated online pharmacies to be registered and comply with guidelines related to verifying prescriptions, maintaining confidentiality of patient details, keeping records of medicines sold, operating a helpline, providing complaint redressal services, etc. It also prohibits e-pharmacy portals from selling tranquilisers, psychotropic drugs, narcotics and habit-forming medicines apart from Schedule H and Schedule X drugs. However, even after five years, they still remain pending approval.

Meanwhile, online pharmacies are subject to the same offline pharmacy legislations under the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945, Pharmacy Act, 1948 and Indian Medical Act, 1956; the e-commerce segment is regulated under the Information Technology Act, 2000.

A chemists' organisation urged the government to ban online pharmacies for violating norms and putting people's lives at risk!

The proposed Drugs, Medical Devices and Cosmetics Bill, 2023 seeks to regulate online pharmacies with stringent norms. The draft states, "The central government may regulate, restrict or prohibit the sale or distribution of any drug by online mode, by notification." However, it has not been tabled in the Parliament as yet following vociferous calls for a recall. Meanwhile, the online retailers easily get away by claiming that they are simply operating as intermediaries facilitating the sale of pharmaceutical products to customers!



In contrast, the US FDA maintains the BeRxSafe resource which helps consumers determine whether a particular e-pharmacy is safe and legitimate or not. It also provides a general guide about what consumers should look for in an online pharmacy and the potential red flags.

On their part, the genuine online pharmacies are themselves seeking engagement and dialogue with the health ministry to remove the regulatory uncertainty. They state that a simple and clear regulatory pathway will open the doors to new entities and innovation in the e-pharmacy sector. In March this year, even a parliamentary committee urged the health ministry to notify the draft e-pharmacy rules.

Role of the Consumer

In the face of the unregulated onslaught of e-pharmacies, the onus is on us to be cautious and aware of safe practices when purchasing medical products online. A rule of thumb is that the e-pharmacy should have well-defined safety and quality benchmarks with uncomplicated privacy and security policies.

Other warning signs of illicit online pharmacies:

- Does not require a doctor's prescription
- Does not have a licensed pharmacist on roll who can answer your questions
- Does not have a verifiable physical address or contact number
- Does not have a pharmacy registration
- The medicines look different, are broken, damaged or do not have an expiry date
- The packaging or labelling is dubious or tampered

In addition to this, never ever buy medications through any social media platform. And, if the price is too good to be true, it is likely to be fake!

The Takeaway

With growing urbanisation, internet penetration and smartphone usage, more and more people will turn to e-platforms for their medical needs. Safety and regulatory measures to ensure sale of genuine drugs and data safety are imperative. But they have to go beyond simple policies and guidelines and incorporate effective enforcement strategies as well!

Ten Recommendations to Improve Pharmacy Practice in Low and Middle-Income Countries (LMICs)

Professor Zaheer-Ud-Din Babar
is the Editor-in-Chief of Journal of Pharmaceutical Policy and Practice. He has taught pharmacy practice and pharmaceutical policy at Universities in UK (University of Huddersfield), New Zealand (University of Auckland) and Malaysia. He understands the health systems and pharmacy globally and is known for his work in pharmaceutical policy and practice, including access to medicines, medicine prices and issues related to pharmacy practice research.

MEDICINES ARE IMPORTANT health interventions and their appropriate use could improve health outcomes. Throughout the globe, pharmacists play a key role to improve the use of medicines. Though high-income countries debate on futuristic approaches; independent prescribing of pharmacists, clinical skills, and to expand pharmacy services, a large majority of low and middle-income countries (LMICs) still lag behind in strengthening pharmacy practice and improving the 'use of medicines'.

It is important to note that LMICs are not a homogenous group, and there are large variations between them. Also, considerable progress in pharmacy has been made by some middle-income countries.However, despite these variations, there are inherent commonalities and the following set of key recommendations could improve pharmacy practice in these countries.

1. Mandatory Presence of Graduate-Level Pharmacists at Community Pharmacies

In LMICs, a large number of pharmacies are non-pharmacist-run pharmacies. Having diploma pharmacists, who are not university graduates but have very similar powers and privileges to open pharmacies and medical stores. This confuses the patients and other healthcare professionals and erodes professionalism.

If only graduate pharmacists are allowed to man pharmacies, this would help strengthen the pharmacy profession. The compulsory presence of pharmacists at pharmacies in LMICs should be a priority, as it also paves the way for 'extended pharmacy services'.

2. Clear Demarcation of the Roles and Responsibilities of Different Categories of Pharmacists (Graduate Pharmacist And Diploma Pharmacist)

There is a need to have a clear demarcation of the roles and responsibilities of different classes of pharmacists. The graduate-level pharmacists should be in charge of running a pharmacy and dispensing medicines. If there are other categories of pharmacists in the country, this should be clearly defined.

One argument given by authorities is not having the required numbers of graduate pharmacists in the country. This needs to be done by increasing the number of graduate pharmacists as well as a phased reduction of diploma pharmacists. However, there are powerful lobbies with financial interests making it challenging to overcome this issue.

3. Effective Categorisation and Implementation of Medicines

It is important to categorise medicines into three different categories - prescription medicines to be sold by prescription from doctors, pharmacists only medicines (which the pharmacist can dispense without a prescription for minor ailments, and over the counter (OTC)medicines.This is the norm in highly-developed western countries and LMICs can follow suit.

Though in many LMICs there are laws and regulations in place for selling these medicines; however, there islax implementation. A large number of medicines are available without a prescription. This is not limited to certain classes of medicines, but include a wide range of medicines including antibiotics.

4. Enforcement of Laws And Regulations for the Sale of Medicines

If the laws and regulations are properly enforced in regards to the sale of medicines, this can greatly improve pharmacy practice. This could be done with political commitment as well as with effective regulation. In most countries, these laws are enforced through a drug regulatory authority or a drug control organisation.

The factors which could impact law enforcement include transparency, corruption, and myriad interests of healthcare professionals, pharmacy traders, and businesses.

5. Prohibiting Doctors from Dispensing Medicines (Dispensing Separation Between Pharmacists And Doctors)

The dispensing separation between doctors and pharmacists is vital to improve the use of medicines. Ideally, the doctors should prescribe medicines, while the pharmacist's role is to dispense. In a large majority of LMICs, doctors are still dispensing medicines. This is because of the economic benefits and the profits they earned through the sale of medicines.

This is a conflict of interest as, if the doctors have to make a profit by the sale of the medicines, then it may compromise their ability to prescribe medicines. Due to financial interests, they may dispense more medicines. Also, if a large majority of medicines are dispensed by doctors, pharmacists get very few medicines to dispense, limiting their ability to sustain businesses and pharmacies.

6. Involving Pharmacies and Pharmacists in Universal Health Coverage Schemes to Improve the Affordability of Medicines

In many LMICs, the public sector provides free medicines to the patients; however, they have to pay for medicines at dispensing doctors' clinics and at private pharmacists. Research estimates that up to 70–90% of expenditures in LMICs are out of pocket.

The pharmacist's role in improving the affordability of medicines is understudied. In many LMICs, the government has started schemes to provide free services or some form of health insurance; however, there is a need to involve primary care doctors and pharmacies in these schemes.

7. Strengthening National Medicines Regulatory Authorities to Improve the Quality, Safety and Effectiveness of Medicines

Drug regulatory authorities' role is key to improve medicines quality, safety and effectiveness of medicines. WHO has done a huge amount of work in this context, improving and strengthening medicines regulatory systems in LMICs.

There is also some debate regarding improving consumers' awareness with regards to medicines safety and counterfeit medicines. Though promoting awareness in society regarding counterfeit medicines is vital; however, this rarely works when a weak regulatory system is in place in a country.

8. Training of Pharmacists in Clinical Skills, Vaccination and Minor Ailment Schemes

There are challenges with regards to pharmacists' education and training across LMICs in clinical skills and in providing patient-oriented pharmacy services. Although there are global professional standards for the provision of clinical pharmacy services, they are not always enforced in LMICs. It is thought that pharmacists can play an increasingly important role in providing care in minor ailment schemes, chronic disease management as well as in providing vaccination.

9. Promoting Independent Medicines Information for Consumers and Healthcare Professionals by Developing National Medicines Information Strategy

Providing independent medicines information to consumers and healthcare professionals is a global challenge. In LMICs, the scale of the problem is much larger. This is coupled with lower levels of health literacy in consumers, as well as the training of pharmacists and physicians in the area of 'independent objective medicines promotion'. LMICs have enormous challenges related to irrational prescribing, fake news as well as wrong and misleading medicines information.

10. Mandatory Continuing Professional Development (CPD) Programs for the Pharmacists

LMICs face challenges both in terms of numbers of pharmacists as well as education and training. Though the need for advanced pharmacy education is recognised globally; however, in many LMICs, there is limited capacity and experience to develop continuing professional development (CPD). In this context, LMICs must develop a mandatory CPD model for pharmacists that can update and advance and update their training and skills. Also, the pharmacy system strengthening and its role in improving clinical pharmacy practice should be a necessary component of CPD.

The complete article is available at https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00288-2

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INDIA'S AILING PHARMACY SECTOR NEEDS A PARADIGM SHIFT TO ACCREDITATION

Pharmacies have to evolve their practices to provide patients with enhanced and safe services. This also requires pharmacists to evolve into healthcare professionals and work in a collaborative manner which will improve the efficacy and efficiency of healthcare delivery. What we need is pharmacy accreditation, or even better, certification!

Why are pharmacies still fighting the change that is staring them in the face? Why not embrace the rapid transition by shifting the focus on ensuring that patients receive medical products appropriate to their needs?

PHARMACY PRACTICE IS a mission that extends much beyond just handing over medical products prescribed by physicians. Pharmacists are not merely salesmen – they can actually help patients with health problems to make the best use of their medicines, and thus, contribute to health improvement. This role came to the fore during the COVID-19 pandemic when pharmacy owners braved the risks and rendered a yeoman service to the society. They have to continue to provide quality and continuum of care for patients in terms of drugs and medical devices outside the clinic/hospital.

At the international level, the role of the pharmacy is becoming increasingly complex and diverse – it is no longer just about managing the distribution of medical products to consumers, but also engaging in appropriate efforts to assure their safe and efficacious use so as to meet healthcare needs. Medical stores around the world are owning up the responsibility of outcomes of drug therapy by working in sync with patients, doctors, etc.

The International Pharmaceutical Federation (FIP) developed standards for pharmacy services – 'Good Pharmacy Practice in Community and Hospital Pharmacy Settings'. Both WHO and FIP provide guidance to national pharmacy organisations for developing their national GPP guidelines.

Good Pharmacy Practice (GPP) is the practice of pharmacy aimed at providing and promoting the best use of drugs and other healthcare products by members of the public. It requires that patient welfare should be the primary concern at all times.

The USA has pharmacy accreditation and certification programs that establish that a pharmacy has demonstrated the ability to meet predetermined criteria in operations, service quality, safety controls, regulatory compliance, etc. The accreditation process also serves as an independent validation that the pharmacy staff have the level of training, expertise and competency necessary to perform patient care services and clinical case management. Additionally, there are stringent quality control procedures and periodic quality check mechanisms to verify adherence to the established standards.

Then there is the voluntary Verified Internet Pharmacy Practice Sites (VIPPS) program for online pharmacies which proves that they have successfully completed a rigorous criteria of review and inspection and can be considered legitimate.

Similarly, Germany recently instituted private accreditation for pharmacies that require compliance with Good Pharmacy Practices, thus assuring consumers that "they are in good hands, receiving the right medicine and the correct dose".

Accreditation is a symbol of the pharmacy's dedication to optimising patient safety. Pharmacies can use their accreditation status to set themselves apart from the competition. It further denotes that the medical store is prepared and capable of handling both the medical products and patient information in a diligent, safe and effective manner.

Gaps in Pharmacy Fabric in India

The pharmacy scenario in India tells a different story. There is widespread corruption – people can easily get a pharmacy license through bureaucratic connections; many even get away with operating without a license. Pharmacies are run like grocery shops with the proprietors least concerned about the quality of medical products they 'peddle'. Lack of resources and political will to enforce the regulations leaves the pharmacy sector broken and a systemic failure on many counts.

Instances abound when the tablet in a strip is broken or the ingredients are coming out. The chemists blatantly claim that this is normal and the medicine will not cause any harm. Who will keep a check on such cases?

fip International Pharmaceutical Federation

FIP observes 25th September as World Pharmacist Day every year to promote and support initiatives that raise awareness of and advocate the vital contributions that pharmacists make to global health improvement. In fact, the theme this year was 'Pharmacy Strengthening Health Systems'. It highlighted how pharmacies can contribute to maintaining and strengthening the healthcare system for the benefit of people and communities.

To be fair, the Indian Pharmaceutical Association did publish the Good Pharmacy Practice Guidelines in 2002 in the form of standards for pharmacy services to be provided to the society. They detail optimum procedures for the facilities, personnel, systems and processes with the ultimate goal of inculcating a patient-oriented approach to pharmaceutical care.

However, the primary question is that how many pharmacies actually work towards achieving these standards of practice.

The Indian Pharmaceutical Association (IPA) is the national body representing over a million pharmacists and pharmaceutical scientists (from industry, academia, regulatory, hospital and community pharmacy) working to meet India's healthcare needs. This non-governmental organisation has official relations with the FIP and WHO. It is also a member of the Drug Technical Advisory Board (DTAB) under the union health ministry.

Accreditation remains conspicuously absent in the Indian pharmacy sector. The National Accreditation Board For Hospitals & Healthcare Providers (NABH) standards have a Management of Medication (MOM) chapter that is limited to a safe and organised process of administration of drugs and devices in pharmacies in hospitals that are seeking accreditation.

India needs to establish definite standards, processes and protocols (based on updated clinical evidence and industry best practices) that will define baseline expectations and aspirational goals for the pharmacy sector. The accreditation standards should cover everything from drug management and pharmacy operations to customer service, communications and disclosure. This will inculcate an atmosphere of quality, safety and efficiency that is both predictable and measurable.

The IPA - in collaboration with WHO India Country Office and the Drugs Controller General of India - undertook a project for preparing an Accreditation Manual of Pharmacies in 2007. They worked for a period of twelve months to prepare guidelines for the desirable upgradation of existing systems in the pharmacies based on Good Pharmacy Practice.

Following a pilot assessment of 45 pharmacies in Mumbai and Goa, IPA prepared a document suggesting the initiation of an accreditation system for pharmacies and methodology for the same.

Implementing this accreditation system will encourage the maintenance of standards of excellence and stimulate the process of continual improvement in community pharmacy practice in the country.

Isn't it ironic that pharmacy education programs are accredited to ensure that pharmacists have the skills and knowledge they need for safe, effective practice, but the same is lacking for pharmacies!

In conclusion, lack of proper regulation and standardisation is eroding both patient confidence and safety. Contrast this with accredited pharmacies that can become the backbone that support, strengthen and sustain the entire healthcare ecosystem. Can we expect pharmacies to stand up and take a front-line role in protecting patient safety?

"In India, the government appoints the Technical Regulator, who unfortunately, by itself becomes the standard setter and the inspector seeking compliance and incorrectly also becomes the informal consultant. This regulatory framework needs to be unbundled for protecting consumers and patients.

Ideally, healthcare service providers (including pharmacies and medical products) need to be certified for regulatory or best trade practices compliance by third party certification bodies (which are accredited to NABCB under QCI). Simultaneously, these certification bodies need to be supervised by a Technical National Regulatory Body.

This kind of conformity assessment route will provide greater credibility and a neutral layer of domain-specific expert auditors ensuring compliance and no conflict of interest - which can possibly set in if an accreditation body that sets standards also seeks direct compliance. In other words, the standards-setting body and the conformity assessment body need to be separate entities for avoiding conflict of interest or bias."

*– **Mr. Rajiv Nath,** Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)*

UPDATE ...

Moving a Step Ahead

Update on the October edition on Right to Repair

Centre Nudges 112 Top Firms to Sign Up for 'Right To Repair'

IT GIVES US great pride to witness our October Issue on 'Right to Repair' generating momentum at the national levelto tackle the corporate malpractice of making products artificially obsolete.

In the middle of last month, the government asked 112 companies (across electronics, farm equipment, automobiles and white goods sectors) to ensure that consumers enjoy the right to repair their products. The list of companies includes Volkswagen Group Sales India Pvt. Ltd, Maruti Suzuki India Ltd, MG Motor India Pvt. Ltd, TVS Motor Co. Ltd, Havells India Ltd, Philips India Ltd, Voltas Ltd, Whirlpool of India Ltd, John Deere, Sonalika Tractors, Escorts Ltd, New Holland Agriculture, (Royal Enfield) Eicher Motors Ltd, Blue Star Ltd, BPL Ltd, Godrej & Boyce Manufacturing Co. Ltd and Crompton Greaves Consumer Electricals Ltd.

The Union Department of Consumer Affairs sent a letter to these companies asking them to support a government campaign aimed at stopping the practice of inadvertently reducing the usable life of goods. Prior to this, 41 leading businesses had already signed for the 'Right to Repair' programme.

Union Consumer Affairs Secretary Rohit Kumar Singh elaborated, "The Prime Minister, in the recent B20 Summit, said that a profitable market can be sustained when there is a balance in the interests of producers and consumers. Hence, making all the stakeholders equal partners in the Right to Repair campaign is the best way forward,"

Indeed, this move can increase company participation on the Right to Repair portal – this will not only help consumers learn more about their goods' repairability and cut down on e-waste, but will also fortify the strategic alliance with all parties involved. The government plans to reach out to more businesses in a variety of industries to include them in the project!

The move seeks to prevent the practice of some companies stopping supply of spare parts and servicing to force consumers to buy new products. An electronic product that cannot be repaired, or falls under planned obsolescence, not only becomes e-waste, but also forces consumers to spend unnecessarily, a top official said on the condition of anonymity. He further stated, "You (manufacturers) are making money because of consumers. So, take care of their interests. We are starting with electronics, farming equipment, automobiles and white goods. These are the sectors in which consumers face trouble the most."

"Getting products repaired in a timely way is a consumer right that is broadly covered under the existing legal framework. However, enforcing it is a challenge. What adds to the complexity is the unequal bargaining power individual consumers have against the original equipment manufacturer in getting their rights honoured. Given that consumers are widely dispersed, giving power back to the consumers by consolidating their voice requires the involvement of grassroots level consumer organizations."

– Amol Kulkarni, Director of Research, CUTS International (a non-profit, non-governmental organisation working on public interest issues)

WEBINAR ON

'Right to Repair – A Challenge for Consumers in Bharat!'

THE OCTOBER MAGAZINE edition was a starting point for creating awareness about the Right to Repair. The Aware Consumer team followed up on this by organising a national webinar - in association with RJS Positive Media on 22nd October, Sunday at 11am - to create a national discussion and demand for Right to Repair.

RJS Positive Media organises regular webinars every Sunday morning on topical themes. Under the leadership of National Convener and torchbearer, Mr. Uday Kumar Manna, they have conducted around 175 webinars till date!

Our editor and publisher, Prof. Bejon Misra moderated the event. Mr. Prafull D Sheth, Chairman, Consumer Online Foundation (COF), gave the welcome address.

Dr. M.S. Kamath, Honorary Secretary, Consumer Guidance Society of India (CGSI) was the keynote speaker on the panel. He is a pillar of CGSI – one of the first and oldest established and recognised consumer organisations in India.

Dr. Kamath opened his talk by saying that CGSI is focused on getting consumers the best possible value for money and best services in every domain. With an interesting PowerPoint presentation, he shared his knowledgeable views and insights on the importance and significance of right to repair for the consumers across various domains. The principal notion that came across was that manufacturers should feel bound by good faith to give proper service!

He informed the attendees that CGSI presented a comprehensive bill to the union Ministry of Consumer Affairs. This is a skeleton framework that the policymakers can use as a drawing board for drafting a full-blown legislation. The bill is an attempt to fast-track the process so that the authorities don't have to work from scratch. Dr. Kamath was willing to share the proposed bill and said that they are not looking for a patent, trademark or even any credit for their inputs. He further appealed to the consumer organisations and the consumers to push this worthy cause!

Dr. Kamath fielded questions from the attendees who were quite interested in this novel and pertinent concept. During the interactive session, he clarified that the right to repair can be added in the form of rules to the new Consumer Protection Act, 2019. However, in his view, it is already quite overloaded, and this being a separate subject warrants a clear legislation with in-built mechanisms to implement it across the board. He stated that he was well aware that getting the right to repair can take years; however, CGSI will persevere till consumers get their right!

During the discussion, the idea of declaring 22nd Oct as Medical Devices Day in India was floated.

Deepchand Mathur, former Director, MCD and RJS observer gave a rousing vote of thanks before closing the webinar.

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YOUR OPINION MATTERS

letters to the editor

We are truly humbled by the praise and acknowledgment that is flowing in from varied sources. Please feel free to send in your comments, views or feedback on The Aware Consumer magazine at bejonmisra@theawareconsumer.in – we will publish your opinions and implement your feedback while ensuring that your voice is heard on the right platforms.

(October issue: Right to Repair – A Challenge for Consumers in 'Bharat'!)

Right to Repair is a very good initiative. I may suggest that all consumer durables must come with a 'best before use' date, like we have in long shelf food products. We don't need an expiry date, but there must be a minimum life which the supplier must indicate. It may be brought in like other quality related standard like CE marking. Supporting repair industry means employment for thousands of youth through skill development. In our new education policy too, there has been a provision for entrepreneurship and skill development from class 6th onwards. Such training could be provided to them right from there.

In developed nations like Germany, carpentry, electrician and plumber course are part of the curriculum. Repair of mobile phones and laptop is on the rise, but still, it is very difficult to make out the skill level of repairer. Government recognised degrees/diplomas/certificates may act as a game changer. On the lines of ONDC, government must create an open platform like Urban Clap so as to bring these repairers online. Only certified repairers could be part of such an app. Their charges will be fixed based on their skill and decided by ranking by the consumers.

This would give more life to the working appliances as there is a general tendency of the consumer to exchange it. Government must put a ban on exchange scheme for such appliances if those are in working condition as it adds to e-waste and plastic waste at large.

This campaign must be taken to the masses for the good of society as well as to curb the compulsive consumption behaviour in today's time, when our propensity to savings is at all-time low. Thanks for spearheading such campaigns and raising society-oriented issues to make India stick to its value-based fabric of delayed gratification.

*– **Kuldeep Sharma,** Noida*
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The subject of Disposal of Unused and Expired Medicines was covered in the TAC October 23 issue. Some data has been given in the write up which was generated by Delhi Pharmaceutical Trust, (DPT)and it has not been acknowledged.

DPT has been working on finding potential solutions to such disposal, but in vain. It planned a pilot study to be done in one locality to ask the citizens to deposit their unused medicines stocks at a set of nearby chemists outlets. In such outlets, specified boxes with lock and key would be kept for such deposits. The Trust was planning to get approved bio-waste collectors to pick these periodically for proper incineration.

In absence of several approvals from regulatory bodies or their active participation, such study is impossible. There is almost nil investment in this area to study how to degrade or treat such stocks and also interactions of medicines on sewage, soil, environment and to identify minimal damage and comeout with list of 'medicines that can be recommended for flushing or put them in soils' which is call of the day.

Misuse of such stocks is a greater risk. Can such small studies be topics for post graduate students of biotechnology/environmental science/microbiology/pharmaceutical sciences? Given the bright youngsters at PG levels, they can be expected to come out with practical outcomes.

*– **Dr.D B A Narayana,** Trustee, DPT • drandba50@gmail.com*

The Right to Repair edition is enlightening and empowering. The articles are not just informative but thought-provoking. I have gained some valuable insights into the importance of our right to repair the products we own.

Indeed, there are critical issues surrounding electronic waste and the freedom to repair the things we buy. We should also demand our consumer rights and become advocates for the right to repair. What's more, this right will enhance the employability and affordability towards the nextgeneration.

I now feel motivated to make more conscious choices about the products I purchase. I appreciate the need for responsible consumption and environmental preservation.

Kudos to the dedicated team behind this magazine for their outstanding work in promoting this vital cause. I highly recommend this magazine to anyone who is passionate about sustainability and consumer rights.

*– **Hrusikesh Panda,** Jajpur, Odisha*
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I have a Fitbit watch which was working absolutely fine for over a year. One day it slipped and fell and the glass screen cracked. After that, it became difficult to see the display clearly and I wanted to replace it. I approached the authorised service centre and was surprised when they told me that the screen cannot be changed! They simply told me to discard this watch and buy a new one! I tried looking for details online, but there is nothing on the company website or other forums about changing the screen glass.

I tried filing a complaint with the company and to my utter bewilderment, I actually got an email with detailed instructions on how to dispose the smartwatch in a safe manner. While having standards for disposal is commendable, does it make financial or even environmental sense to discard an expensive gadget which is working absolutely fine except for the screen issue. Why doesn't the company design the product in such a way that the screen can be replaced?

This magazine struck a chord with me as it champions our Right to Repair. I can frankly state that I was not even aware of such a concept and assumed that I have no choice but to abide by the brand's prerogative to repair/not repair their products as they wish. This is a call for action and I sincerely hope something materialises in the near future!

*– **Rimple Sharma,** Hyderabad*
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WATCH OUT!

Watch out for the next issue in January dedicated to 'Building Consumer Awareness of Need for Comprehensive Insurance Coverage'

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