AUGUST 2021 • Vol. 7 • Issue 5
MONTHLY • Pages 64
₹ 200

RNI No.: DELENG/2015/67140, Published on: Every month, Posted at Lodi Road HPO, New Delhi on 9-10th of every month

THE AWARE CONSUMER

www.theawareconsumer.in

RESEARCH FEATURE
Delving Into The Conspiracy Against Indian Generic Drugs

DRUGS & COSMETICS ACT, 1940
NEED FOR OVERHAUL

INTERVIEW
Mr. K L Sharma, Author - 'Healing the Pharmacy of the World'

OUT OF THE BOX
Legislation Boosts Illicit Trade Of Tobacco Products

PLUS ROUND UP • MY MARKET • THE PRESCRIPTION

National Accreditation Board for Testing and Calibration Laboratories

NABL grants accreditation in accordance with ISO/IEC 17025: 2017 to the laboratories testing Drugs & Pharmaceutical Products to ensure the life saving medicines adhere to the requirements.

More than 125 laboratories in Chemical discipline and more than 78 laboratories in Biological discipline are accredited by NABL in Drugs & Pharmaceuticals group.

Endotoxins Aid Veterinary Agents Oral Ointment Soluble Preservative Chemotherapeutic Powders Filtrable Substances(Active Sterility limit Pharmaceuticals Immunological except Drug Methods Hormones Chemical Non-Filterable Tablets efficacy Raw Bioassays Solutions Vitamins Preparations Above Materials Physical test Drops Antibiotics Ointments Mentioned Synthetic Drugs Substance Capsules Liquids Intermediates tests Including Microbial Pharmaceutical Physiological Gels Pyrogen material Other API Products Parenteral Ingredients Creams

NABL operates in accordance with ISO/IEC 17011: 2017.

NABL is a full member signatory to Asia Pacific Accreditation cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangements (MRAs).

Details of accredited laboratories are available on NABL website (www.nabl-india.org) under Laboratory Search -> Accredited Laboratories
Select Country: India, Field: Testing, Discipline: Chemical, Group: Drugs & Pharmaceuticals
Select Country: India, Field: Testing, Discipline: Biological, Group: Drugs and Pharmaceuticals

National Accreditation Board for Testing and Calibration Laboratories (NABL)
NABL House
Plot No. 45, Sector 44
Gurugram, Haryana - 122003
Email: info@nabl.qcin.org | Ph: 0124 4679700

VIEW  POINT

MESSAGE FROM PUBLISHER & EDITOR

Health Services Hinge On Drug Quality

QUALITY HEALTHCARE IS intricately interlinked with assured-quality medicines. Only when the medicines are reliable and effectual, can we expect safe and effective healthcare. Even the World Health Organization's (WHO) Sustainable Development Goal 3.8 supports universal health coverage by aiming to achieve 'access to safe, effective, quality and affordable essential medicines and vaccines for all'.

However, the pharmaceutical system in India is marred by variable and questionable quality in the form of misbranding, spurious, not of standard quality (NSQ) and fake medicines, unregistered medicines, inappropriate and irrational use of medicines and antibiotics and more. Therefore, strong and robust pharmaceutical governance forms an essential component of strengthening the healthcare system for achieving universal health coverage.

In reality, what we actually have is a pre-Independence legislation called Drugs and Cosmetics Act, 1940 with the accompanying Drugs and Cosmetics Rules, 1945 that define the regulatory requirements to ensure that all drugs and cosmetics are safe, effective and conform to quality standards.

Both the Act and the Rules have been amended scores of times to keep pace with the evolving landscape. However, fact of the matter is that the core primary legislation is over eight decades old now. Numerous deficiencies are staring us in the face - the regulatory infrastructure is inherently weak and is further marred by ineffective implementation; there is lack of access to safe and effective medicines for the general population that is further compounded by a proliferation of fixed-dose combination drugs; the clinical trials are badly regulated, and much more.

The legal provisions are proving to be imprecise and inefficient; the very structural design of the Act has been stretched far beyond its breaking point. Even the recent amendments have been quite lax and patch-jobs at best.

It follows that until we strengthen or overhaul the drug regulations, both the clinical outcomes and overall healthcare will continue to be poor, unsafe and ineffective!

Prof. Bejon Kumar Misra
Publisher & Editor
bejonmisra@theawareconsumer.in

fssai

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

Ministry of Health and Family Welfare, Government of India

Food Standards
To help you get the best, we ensure that it upholds the global benchmark

Business
We ensure that the food you purchase has the correct information & safe to ensure trust.

Eat Right India
We make sure that every citizen of India gets safe & wholesome food.

Food testing
We ensure that the food is adulteration free & of good quality

Inspections
We check your food to ensure safety

Citizens
You can reach out to us with your queries

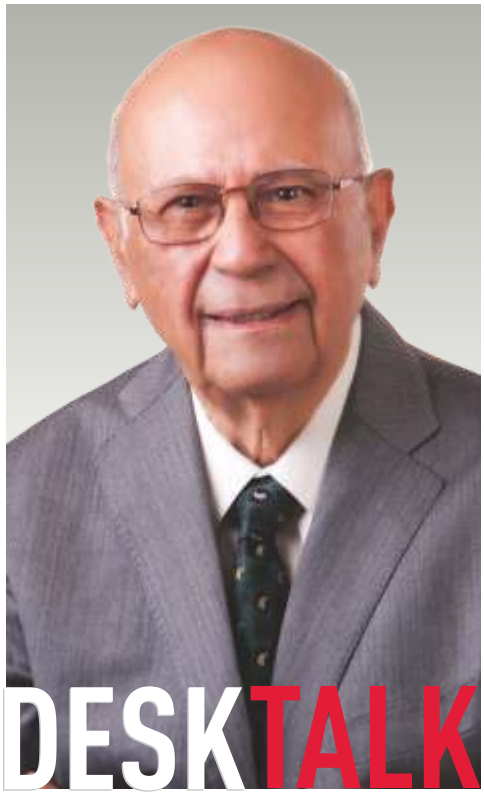
States
We work through our State departments to reach out to each and everyone of you

FARM TO FORK WE ARE WITH YOU

Connect with us:

fssai.gov.in facebook.com/fssai twitter.com/fssaiindia 9868686868

PRAFULL D. SHETH
Editorial Board Member



DESKTALK

DRUG REGULATION – HIGH TIME FOR CHANGE !

THE IMPORT, MANUFACTURE and distribution of all medicinal drugs in India is governed by the antiquated Drugs and Cosmetics Act of 1940. Given the extent to which the quality and safety of healthcare depends on a robust drug regulatory regime, it is high time that the lawmakers drafted a well-defined legislation that is both in tune with the current environment and aligned with global best regulatory requirements.

The FIP report on Pharmaceutical Sciences in 2012 projects framework based on legal and regulatory window as a continuum from drug discovery through development, manufacture and usage of medicines overlaid at all stages with regulatory and educational aspects and highlights the need for translation between science and practice (J Pharm Sci. 2012 Aug 21 doi: 10.1002/jps23295).

Even though the dependence on e-commerce is proliferating in the society, online pharmacies are still not covered by the Act. Nor there is a clear-cut regulation on telemedicine for that matter. The government is yet to notify the list of 'over-the-counter' (OTC) drugs even after repeated appeals.

The umpteen loopholes and drawbacks are compounded by an abundance of obsolete protocols and procedures that have not only outlived their utility, but end up creating unnecessary confusion. Pharmaceutical governance has gone for a toss and the market is seen increasingly dominated with NSQ and spurious medicines. The 37 regulators in our country are unable to control the menace - there is a systemic lack of transparency, delays and inefficiency – and the toothless framework allows the violators to escape scot-free.

The system is calling for a shift from this reactive, punishment-based regime to a proactive deterrent mechanism. Reframing the Drugs and Cosmetics Act alone can make India's drug regulatory system rational, safe and effective once again. Strong provisions should be accompanied by clearly drafted rules in purview of the public health perspective. They should require rigorous and transparent evidence to back the effectiveness and safety of new drugs.

Only then can our drug regulatory affairs become streamlined enough to meet the health needs of the nation and also match our contribution to global drug manufacture.

INSIDE

REGULARS

03 | VIEWPOINT
07 | ROUNDUP
37 | AFTERWORD

16

RESEARCH FEATURE

DELVING INTO THE CONSPIRACY AGAINST INDIAN GENERIC DRUGS

While pharmaceutical products are vital for our well-being and survival, we cannot ignore the lurking dangers of spurious medicines.

25

HORIZON

OVER-THE-COUNTER LIST ON THE CARDS

In USA, there are more than 80 classes of over-the-counter (OTC) drugs, ranging from acne medicines to weight loss products, amounting to up to 1,00,000 marketed products.

31

INTERVIEW

Mr. K.I. Sharma, Author - 'Healing The Pharmacy Of The World'

40

MY MARKET

WHEN WILL THE LAW OF THE LAND CATCH UP WITH ADVANCEMENTS IN TECHNOLOGY?

With the flourishing e-pharmacy market in India expected to hit a market size of US $2.7 billion by 2023, we need a well-defined legal regime to ensure safe and secure selling of medications on these online platforms that can truly add value to the consumers.

44

OUT OF THE BOX

BRINGING MEDICAL DEVICES INTO THE REGULATORY AMBIT

Modern healthcare would be incomplete with the use of various medical devices. While these enhance the quality of care, some of them have also been associated with many problems.

48

IN FOCUS

FAKE AND SUBSTANDARD DRUGS - AN URGENT AND UNRESOLVED CRISIS

Spurious, substandard and counterfeit drugs are putting health and lives at risk, not to mention the reputation of the manufacturer and the country.

THE AWARE CONSUMER
UNLOCKING CONSUMER POTENTIAL
www.theawareconsumer.in

AUGUST 2021 • Vol. 7 • Issue 5

Owner, Printer, Publisher & Editor:
Prof. Bejon Kumar Misra

EDITORIAL CONSULTANTS
Prafull D. Sheth
Bina Jain
Suman Misra
Dr. Manisha Kukreja Batla
Dr. Alka Mukne
Pyush Misra
Payal Agarwal
Shashank D. Sudhi
Srishty Jaura
Mahika Dalmia

DESIGNER: Galaxy; Yellow Palette
DESIGN CONSULTANT: Maanav Khaitan

WEB DESIGNER:
Manish Mohan
Ebrahim Bhanpurawala

MANAGER CIRCULATION
S. K. Venkatraman

Published at:
B - 306, 1st Floor,
C.R. Park, New Delhi-110019

Printed at:
M/s. Swastika Creation
19, D.S.I.D.C. Shed, Scheme 3,
Okhla Phase II, New Delhi - 110020

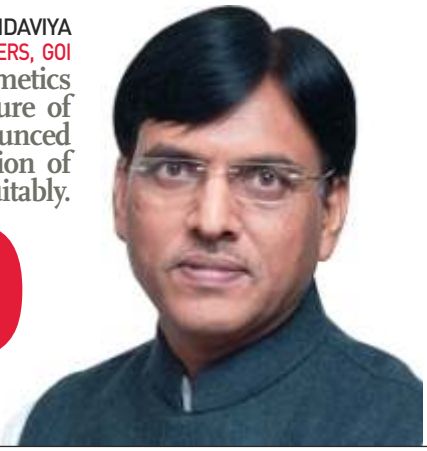
For any queries, please contact us at
contact@theawareconsumer.in
Phone: 9311044424

Total number of pages - 64, Including Covers

MR. MANSUKH MANDAVIYA

MINISTER OF HEALTH AND FAMILY WELFARE, MINISTER OF CHEMICALS AND FERTILIZERS, GOI

The Drugs and Cosmetics Act, 1940 was amended under Drugs and Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. A Whistle Blower Scheme was announced by the Centre to encourage vigilant public participation in the detection of movement of spurious drugs in the country, rewarding the informers suitably.



ROUNDUP

JAN AUSHADHI STORES

"Quality Medicines at Affordable Prices for All"

Holding Marketers Accountable For Drug Quality

Pharmaceutical companies that market medicines made by third parties will now be treated at par with the manufacturers when it comes to the quality of the drugs as well as other regulatory compliances.

DATA BRIEFING

India ranks 3rd worldwide for pharma-ceutical production by volume and 14th by value. Indian pharma export reached

US$ 24.44

Billion in FY21

The government is constantly amending, streamlining and upgrading its drug control interventions with new rules and guidelines. We take a look at some of the recent amendments and how it impinges on the stakeholders.

MANUFACTURERS ARE LEGALLY responsible for the drugs they produce - both in terms of quality and labelling - and are liable for action in case of defects. On the other hand, the marketers of these drugs have always stayed out of the ambit of the law and did not have any liability. All that they need is the right license to sell….

The Union Ministry of Health and Family Welfare (MoHFW) issued a notification on 13th February, 2020 on the implementation of the Drugs and Cosmetics (Amendment) Rules, 2020, holding the pharmaceutical companies that market drugs also responsible for ensuring the quality and regulatory compliances of the said drugs.

The amendment has inserted two new rules - Rule 84D and Rule 84E - in the Drugs and Cosmetics Rules, 1945, to define agreement for marketing and responsibility of the marketer of the drugs respectively. Another subclause to Rule 96 provides that a drug pack should contain the name of the marketer of the drug and its address, in case the drug is marketed by a marketer. If the drug is contained in an ampoule or a similar small container, only the name of the marketer can be shown.

The Effects

This move is designed to make marketers more accountable for any defects in the drugs. The increased scrutiny will ultimately boost the quality of medicines entering the market.

It will also prevent pharmaceutical companies from marketing drugs manufactured by another pharmaceutical company by labelling their own company name which leads to unnecessary and risky drug duplication. Otherwise, many standalone and region-specific marketing firms source medicines from contract manufacturers or through marketing tie-ups, only to sell their own brands by generating local prescriptions. Now, as the original product will be sold to the public, it will prevent the serious adverse events associated with drug duplication.

The amendment will further impact many big domestic and multinational pharmaceutical companies that outsource the manufacturing of their medicines to smaller companies and then pass on the blame to them when the products are found to be sub-standard.

Even the industry is in favour of this move. Ms. Malini Aisola of All India Drugs Action Network opined, “Legal accountability of marketing companies is absolutely essential for protecting patients' interests especially given a situation where large pharma companies are making healthy profits from the sale of medicines that they themselves are not involved in manufacturing”.

Ms. Kanchana TK, Former Director General of Organization of Pharmaceutical Producers of India supports, “We believe that quality should be embedded in every stage of the medicine-making process and across the delivery chain — from the R&D laboratory to the pharmacy where the patient buys the drugs. We, therefore welcome the proposal mooted by the Health Ministry to make marketing companies responsible for product quality and ensure availability of medicines with assured standards and safety”.

Telemedicine Guidelines Legitimize Remote Consultations

The government has finally empowered medical practitioners to use technology to provide remote healthcare. However, the Telemedicine Guidelines need further refining before patients can truly benefit from easy access to medical interventions sans any risks.

Remote medical consultations become legal, but the guidelines are marred by drawbacks

THE INDIAN GOVERNMENT published the Telemedicine Practice Guidelines on 25th March, 2020 making it legal for registered medical practitioners to provide diagnosis and treatment through teleconsultation over electronic media like - audio-visual media, telephonic conferences, satellite communication, internet, etc. for medical consultation, examination or remote monitoring purposes.

While many doctors have been practicing telemedicine since the past two decades, there was no statutory support and the legality was shrouded in ambiguity. The unprecedented pandemic has forced the hand of the authorities to finally allow medical practitioners to officially conduct remote consultations and prescribe medicines, provide counselling and impart health education for patients located anywhere in the country.

The rules ordain that the registration number should be displayed in all communications exchanged with the patients (emails, WhatsApp messages, prescriptions and fee receipts). A photo, scan or digital copy of a signed prescription or e-prescription can be sent through any e-medium such as email, messaging platforms, etc. without contravening the provisions of the Drugs and Cosmetics

Act and Rules. There are still some restrictions on prescribing certain classes of medications during teleconsultation while some require a video consultation.

Legalizing remote access to healthcare has been a timely move during the ongoing periods of lockdown, social distancing and quarantine in the wake of the COVID-19 pandemic. It is now becoming the first port-of-call for many patients who do not want to risk getting infected/infecting others by stepping into a clinic or hospital.

Even in regular circumstances, the quick and timely access to medical interventions enabled by telemedicine helps overcome the common limitations of large geographical distances and limited resources while also easing the burden on in-person healthcare. The way we perceive doctor visits and consultations is also set to change drastically.

The Looming Loopholes

The All India Organization of Chemists and Druggists (AIOCD) - a representative body of around 8.5 lakh chemists across the country - is of the opinion that there are glaring irregularities in the telemedicine guidelines that open the door to misuse of prescription drugs and pose a greater risk to patient health. It is seeking Prime Minister Narendra Modi's intervention to streamline the guidelines in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder as well as the Pharmacy Act, 1948.

In a letter to the PM, AIOCD President, JS Shinde pointed out that as per Rule 65 (11)(c) of the Drugs and Cosmetics Rules, 1945, when dispensing prescription medicines, the pharmacist should stamp the medicines 'as dispensed' on the prescription so that people cannot purchase the same drugs from other pharmacies. Therefore, how can the e-copies of prescriptions be considered valid when they cannot be stamped? As multiple dispensing of prescription drugs becomes possible, it will increase the incidence of self-medication and lead to antibiotic resistance.

The association has suggested establishing a national portal on which the doctors can email the prescription and the patients or the pharmacist can access it by using a unique OTP. The prescription can be defaced/marked on the portal itself to avoid reuse.

It further expressed concern over the changed classification of medicines in the Telemedicine Guidelines that is vague, insufficient, ambiguous and inadequate and will only cause confusion leading to wrongful prescription/dispensation. The body has also taken exception to doctors offering teleconsultation outside their town/city and e-pharmacies offering direct or indirect telemedicine consultation.

Health-care providers can incorporate **telemedicine** systems to reduce doctor-patient visits and help in breaking the chain of transmission of infections. Anticipating the increased need of telemedicine by health-care providers, the Medical Council of India released practice guidelines in March 2020.

Doorstep Delivery Of

HOME DELIVERY OF medicines is already a common industry practice as more and more pharmacies offer retail sale of drugs to the doorsteps of consumers. The government is now regulating this phenomenon while instituting clear conditions for delivery of prescription medications.

On 26th March 2020, the Union MoHFW issued a notification authorizing licensees holding a license in Form-20 or Form-21 under the Drugs and Cosmetics Rules, 1945 (Drug Rules) to deliver Schedule H drugs (except narcotics, psychotropics and controlled substances as defined in the Narcotic Drugs and Psychotropic Substances Act, 1985), Schedule H1 drugs (under the Drug Rules) and Schedule X drugs (under the Drug Rules) provided the prescription is given physically or through email.

Licensees have to register the email address with the licensing authority, send bills via email and maintain records of the transactions. Other mechanics also come into play, like time limitations (validity period of prescriptions) and geographic restrictions (delivery within same revenue district).

This is a necessary and expedient move, especially in the unique circumstances of the COVID-19 pandemic. It is also a step in the right direction in terms of public interest for those who are unable to step out to fill their

Amendment of Schedule K – Shortcut to Public Healthcare?

Replacing pharmacists with Anganwadi workers and community health officers not only impinges on the pharmacy profession but can also turn hazardous to public health.

Prescription Drugs Becomes Legitimate

Last mile delivery of all drugs – including prescription ones – is being expressly recognized by law as legal and acceptable. But is enabling easy access to all medicines really safe? Will this become the new norm in a post-COVID society?

SCHEDULE K OF the Drugs and Cosmetics Rules, 1945 comprises of certain substances and drugs along with their regulation. It allows registered medical practitioners to stock and dispense these medicines to the patients from their premises even without a drug license or having a registered pharmacist on the premises.

This exemption was probably allowed during the pre-Independence era when medicines were mixed and compounded by hand as 'ready-to-consume' tablets, capsules, syrups and other drug dosages were not available. Many doctors, especially in small towns and villages, now misuse this exception by practically running a medical store in their clinics with large stocks of different medicines, thus impinging on the business of the pharmacies in the vicinity.

Many pharmacists have been clamouring that this exception is no longer necessary and actually flouts the norms of ethical medical practice. Removing it is long overdue – doctors should stick to clinical practice alone while pharmacists should be allowed to practice their profession.

The MoHFW did amend the provisions of Schedule K, but in an entirely different manner. The amendment now permits even allied healthcare practitioners like Anganwadi workers and community health officers at Ayushman Bharat health and wellness centres to dispense around 80 types of drugs listed under Schedule K without a license under the Drugs and Cosmetics Act, 1940.

The Objections

This move to strengthen the healthcare infrastructure in the country can actually backfire as only qualified pharmacists know the rules of medication management and dispensing of drugs. The government is actually putting consumer lives at stake as serious consequences are in store – there will arise safety issues while dispensing drugs, ignorance of storage conditions causing deterioration of potency of medicines and possible increase in antibiotic resistance. Actually, even the WHO emphatically advocates pharmaceutical care in the greater interest of the public.

Pharmacists across the country have volubly protested against the amendment citing that it not only violates the Drugs and Cosmetics Act and the Pharmacy Act, but also contravenes with Article 16, 21 and 47 of the Indian Constitution.

It not only deprives the pharmacists of their fundamental right to practice their profession and earn a livelihood, but can effectively spell the end of the pharmacy business!

Source: Secondary research & media reports

Lapses and Drawbacks

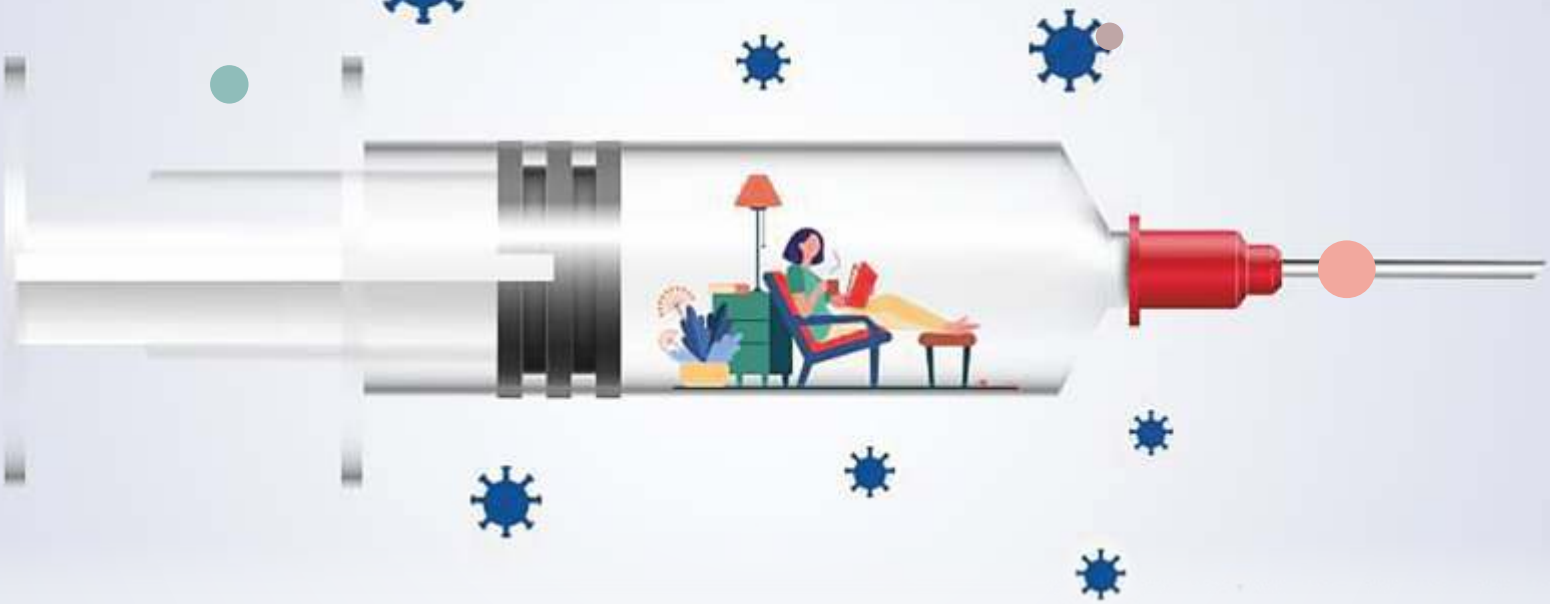
The rules still suffer from a lack of clarity from both a legal and logistical standpoint. It fails to address the issue of reusing the same prescription within the validity period. Even the ambit of delivery is very narrow and will prove to be limiting. Data privacy concerns can arise from the electronic sharing of prescriptions as they can easily be misused.

The AIOCD has again taken exception to online pharmacies affiliating with ride-hailing platforms for doorstep delivery of drugs. It is expressly highlighting that the tie-up between MedLife and Uber will derail the supply chain of medicines in the present critical situation. It is demanding that the Union Health Minister should impose a blanket ban on illegal operation of online pharmacies as they are still out of the ambit of the Drugs and Cosmetics Act, 1940. The argument is that the online drug aggregators may not hold the required license or fail to follow the norms laid out in the notification. Moreover, the guidelines do not expressly permit outsourcing of the delivery of medicines to a third party!

#LetsBeatCorona

DISPO VAN

THE TRUSTED BRAND PROMOTING PATIENT SAFETY



STAY IN, STAY SAFE!

www.hmdhealthcare.com • info@hmdhealthcare.com

Rajiv Nath

- Mg.Director@ HMD
- Forum Coordinator@ AIMED

"Not every war is won on a battlefield. Some wars can also be won sitting at home."

#Stay**Home**Stay**Safe**

Consumers, Beware

Cosmetic Regulations Overhauled

The Indian cosmetic market for personal hygiene, skincare and haircare has always been booming and continues to do so even during the pandemic. The regulatory landscape governing cosmetics is quite complex. The new rules attempt to ease and synchronize the product development, stability, safety, quality and efficacy of the cosmetic products; yet more is needed.

Self-Care – But at What Cost?

IT'S NOT JUST about drugs; cosmetics need regulation too! The latter may be designed to enhance your appearance or make you smell good, but can still affect your skin and health.

Cosmetics have been included under the Drugs and Cosmetics Act, 1940 and Rules 1945 from 1962. The Act defines cosmetics as 'any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering appearance and includes any article intended for use as a component of cosmetics'. This includes 30 different types of cosmetics from makeup, sunscreen, antiperspirants and fragrances to soaps, shampoos, hair oils, toothpastes and shaving creams.

There are stringent provisions pertaining to the import, manufacturing, sale and distribution of cosmetics. These provisions primarily deal with licenses for imports and manufacturing of cosmetics. The provisions also contain a list of cosmetics which are prohibited by law to be manufactured or imported, with penalties for contravention of any of the provisions.

The import of cosmetics is regulated under a system of registration by the Central Drugs Standard Control Organisation (CDSCO) under the Directorate General of Health Services, MoHFW while the manufacture of cosmetics is subject to a system of inspection and licensing by the State Drug Control Department. The CDSCO is also the main authority to regulate all activities relating to cosmetics and promulgate corresponding regulations to ensure safe use of cosmetics.

Cosmetics that have been tested on animals are prohibited from import into India. Furthermore, any cosmetics which are not of standard quality or are adulterated, misbranded or spurious are prohibited from manufacturing, sale and distribution.

The Bureau of India Standards is another statutory authority in India which is empowered to lay down standards for cosmetics under the Bureau of Indian Standards Act, 1986.

The New Rule Prohibits the Following:

- Manufacture, sale and distribution of cosmetics prohibited in country of origin.
- The 'use before or use by date' is less than 6 months from the date of import.
- Cosmetics containing hexachlorophene.
- Cosmetics that have been tested on animals after November 12, 2014.

The Changing Framework

The cosmetic regulations suffer from some major loopholes – the rules are multiple and complex, the process of approval of cosmetic products is cumbersome and time-consuming, the license approval criteria is marked by lack of uniformity and there is inconsistency amongst the different authorities. There is a need to harmonize the guidelines and regulations by making the CDSCO a single national authority rather than being weighed down by the confusion of different state authorities functioning under their own state guidelines.

Before March 2013, there were no requirements to register imported cosmetics. Even domestic companies did not require registration earlier.

The legislation is not only proving to be inadequate, but the guidelines are not even implemented properly by the regulatory authorities. The companies impudently release products with harmful substances in the market while the consumers continue to suffer from the side effects. Counterfeiting is rampant and the booming e-commerce is

further fuelling the incidence of unregulated and untested cosmetics.

Consumers should be aware that the MoHFW notified the Cosmetics Rules, 2020 on 15th December, 2020 to separately codify and update the protocol for import, manufacture, labelling, packing, sale and distribution of cosmetics.

Accordingly, cosmetics that are prohibited in the country of origin or feature a 'use before date' of less than six months cannot be imported into the country. Similarly, even cosmetics that contains the harmful chemical preservative hexachlorophene or have been tested on animals after 12th November, 2014 are prohibited from import. Manufacturers have to provide a declaration confirming product compliance with Good Manufacturing Practices and other guidelines.

Special attention is being accorded to the quality and ingredients of different cosmetic products. Manufacturers have to mandatorily declare all ingredients of their products, including those with concentration of less than 1%. Cosmetics containing dyes, colours and pigments (other than those specified by the Bureau of Indian Standards) cannot be imported or manufactured in India. Moreover,
if a manufacturer or authorized agent figures that a cosmetic poses a health risk, they are obligated to initiate procedures to recall the product from the market with immediate effect.

Therefore, the new rules empower consumers to make more informed choices even as it streamlines the regulatory requirements and standards.

International Regulations

Every country has a different regulatory framework for controlling the cosmetic industry. Product classification poses a major issue and product control processes can also get quite confusing. For instance, while Indian authorities do not require filing of product information, in the USA, no cosmetic can be placed on the market without filing the requisite information pertaining to the safety of the product. According to the European Union Cosmetics Directive, manufacturers should maintain product information files about each product comprising information about the quality, safety testing, proof of claims made or data of any undesirable effects. These need to be made available to the regulatory authorities upon request as evidence that the manufacturer has complied with the regulatory laws.

The International Organization for Standardization and International Cooperation on Cosmetics Regulation along with other major international organizations is working towards a harmonization model by framing a mutual and collective regulatory framework as the best example for countries around the world.

Conclusion

The regulations pertaining to control standards and safety information for cosmetics need to be further enhanced to ensure safe cosmetic products for the consumers. The regulatory experts should work hand-in-hand with the industry to determine the allowed composition and to decipher which countries are available for distribution.

Source: Secondary research & media reports

Delving Into The Conspiracy Against Indian Generic Drugs

While pharmaceutical products are vital for our well-being and survival, we cannot ignore the lurking dangers of spurious medicines. But is it fair to malign the entire Indian generic drug industry as counterfeit? Is a more sinister plot at play here?

SUBSTANDARD AND COUNTERFEIT drugs negatively impact both the consumers and the pharmaceutical industry. While poor quality and spurious medicines can play havoc with patient health, impact of treatments and even turn fatal, they also eat into the profits and branding of the pharma companies.

While the size of the global pharmaceutical market was pegged at around US $1.25 trillion in 2020, it is estimated that the global counterfeit drug market is worth almost US $200 billion. The revenue losses due to counterfeits are probably accountable for 13 new drugs not being brought to market every year. Moreover, the counterfeit drug market is growing at an alarming rate of 20% per year – twice that of the legitimate pharma market!

The WHO declared the issue of counterfeit and substandard drugs as an urgent health challenge for the next decade. In 2013, it established the Global Surveillance and Monitoring System for substandard and falsified products. 550 regulators from 141 countries were specially trained to detect and respond to this issue. Many countries are now actively reporting suspicious drugs and medical devices. Moreover, the member states agreed on a comprehensive global strategy focused on prevention, detection and response to move towards achieving increased access to quality, safe, effective and quality medical products.

The Whys and Wherefores

Globally, about 2 billion people, or one third of the global population, lack access to essential medicines and other health products. This void is most often filled by substandard and falsified products. As Michael Deats, an expert on medicine safety and vigilance with WHO, observed, “If there is insufficient product on the market, within days, the vacuum is filled with falsified versions.”

All kinds of general and innovator medicines can be counterfeited, be it regular and inexpensive drugs for pain or costly ones to treat cancer. Pfizer was shocked to discover that even its successful drug Viagra could not escape the counterfeiting menace!

The tentacles of these fake drugs have spread across the globe. No country remains untouched; between 2013 to 2017, the WHO had received more than 1500 reports of substandard/falsified medicines, vaccines and in vitro diagnostics from all regions of the world. And this is actually just a small fraction of the total problem as many cases may be going unreported.

The incidence is rising as global supply chains become more complex and the internet is becoming an easy route for counterfeit drugs from unauthorized sources to appear on the market. Many falsified medical products are manufactured in one country, assembled in another, print packaged in a third location and then shipped across the world. Moreover, online pharmacies can easily circumvent regulatory oversight.

The global threat has only been exacerbated by the current health emergency of COVID-19. Consumers not only have to cope with the new and unknown danger, but also the threat of potentially harmful fake medicines, vaccines, testing kits and other healthcare products. In March and April 2020 itself, the WHO received 14 reports of confirmed falsified chloroquine products from five countries in Africa and Europe. All reported products were identified at patient level and were confirmed as falsified. Seizure of fake COVID-19 tests and personal protective equipment such as facemasks and hand sanitizers has been reported by various countries as well as by the World Customs Organization.

low- and middle-income countries is either substandard or falsified. This study was based on more than 100 published research papers on medicine quality surveys done in 88 low- and middle-income countries involving 48,000 samples of medicines. The report concluded that Asia accounts for the largest share of counterfeit drugs in the world and that many developing south-east Asian countries like China and India – that are also the biggest drug manufacturers - may have counterfeit drugs at these levels.

This was followed by another report by the European Commission which unequivocally states that 75% of the global cases of SFFC medicines originate from India. The media even exploded with reports of the WHO estimating that 1 in 5 drugs made in India are fake and that 10% to 25% of Indian drugs are spurious. Later, the WHO clarified that it did not carry out any such study and the claims of contaminated, substandard and counterfeit drugs are baseless.

The USA has been claiming widespread counterfeiting of over 20% in Indian-origin drugs since years. The Special 301 report released by the US Trade Representative in 2019 declared that India and China were the leading sources of counterfeit medicines distributed globally. It reads, “While it may not be possible to determine an exact figure, studies have suggested that up to 20% of the drugs sold in the Indian market are counterfeit and could represent a serious

KEY FACTS

100% of therapeutic areas are affected by counterfeit medicines (WHO, 2017).
10% of medicines sold in developing countries are substandard or fake (WHO, 2017).
96% of all global online pharmacies are operating illegally (LegitScript, January 2016).

Yet, all eyes are on the pharmaceutical industry as treatment medicines and vaccines alone can help us turn our back on the pandemic!

The Glaring Focus on Asia and India in Particular

India in the Eye of the Storm

In 2017, WHO declared that 10.5% of pharmaceutical drugs (or 1 in 10 medical products) circulating in

Casting a doubt on the quality of generic drugs manufactured in India

threat to patient health and safety”. It also retained India on the 'priority watch list' for its alleged poor enforcement of intellectual property regulations. Ex-US FDA regulators further charged that Indian generic drugs are of inferior quality and Indian pharmaceutical companies overcharge the generic medicines.

The Indian Health Ministry categorically rebutted these allegations stating that its 2016 report found only

3% drugs to be not of standard quality and the incidence was as low as 0.0245% for spurious drugs. The government also demanded documentary evidence to support USTR's insubstantial claim.

Malicious Forces at Play

These are deliberate attempts to tarnish India's image as it happens to be one of the leading producers of low-cost generic medicines in the world.

A report by the Indian Pharmaceutical Alliance and global consultancy firm McKinsey ranked India at third place in volume and tenth in value in pharmaceutical sales in the world. The Indian pharmaceutical industry, dominated by generic manufacturers, was worth Rs 2.3 lakh crore in 2017 and is expected to grow to Rs 8.5 lakh crore by 2030 if it grows by 11%-12% each year, (reported by The Economic Times in June 2019).

The South Asia head of the Access campaign by Médecins Sans Frontières came out in India's defence with, “MSF supports the health ministry's position that the USTR 301 Report is an attack on affordable generic drugs”.

Fact of the matter is that many of the leading multinational drug companies are blatantly maligning Indian pharmaceuticals. They even tried using the infamous Ranbaxy debacle - that failed an FDA inspection - to cast a shadow on the entire generic manufacturing industry in India. The global media organization Fortune's leading magazine even published articles on 'the big, dark, deceitful and dirty world of the Indian drug industry' and emphasized that 'Indian generics made in dirty labs with deceitful ways are no patch on the original branded drugs'.

The Big Pharma are threatened by the quality and affordability offered by generic drugs and the powerful US lobby is going all guns blazing to undermine the growth of the Indian generic industry by creating distrust among the American public. There is a sly campaign to discredit drug industries in countries such as India.

The US FDA actually upholds a diametrically opposite view. It states that, “A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs." The FDA regularly monitors Indian generic drugs and they are continuously checked for quality. Moreover, 2.25% of India's pharmaceutical products are exported to highly regulated markets around the world.

The slur on Indian generics has compounded ever since WHO defined counterfeit drugs as “drugs that are deliberately and fraudulently mislabelled with respect to identity and/or source.” It upholds that counterfeits are a type of substandard drug, which are “genuine medicines which have not passed the standards and quality testing protocols set for them.” This opens the door to drugs not registered in a particular country to be termed as counterfeit.

9th June is observed as World Anti-Counterfeiting Day every year.

Counterfeiting impacts all industries and sectors, including consumer goods and electronics, food and drinks, pharmaceuticals and medical equipment.

World Anti-Counterfeiting Day is an attempt to raise awareness of the negative impact that counterfeit products have on our health, safety and security.

Conclusion

Generics are a lifeline for billions of people around the globe. Even though the statistics have a malicious intent, the Indian government and the pharma industry needs to pull up their socks and put an end to the menace of falsified and substandard drugs!

Source: Secondary research & media reports

Drug Quality – A Matter Of Serious Health Concern

Medicines save lives! But are they always reliable?

The National Drugs Survey 2014-16 was the largest-ever scientifically designed and professionally executed drug survey undertaken in the world for determining the quality of drugs. It identified the prevalence of spurious and NSQ drugs in the country, pinpointed possible causes of the problems and recommended strategies to address the issues.

Quality of drugs is under the scanner

IN MARCH 2014, the National Institute of Biologicals (NIB) submitted a project report to the MoHFW, Government of India to carry out a national survey to estimate the extent of the problems of spurious and NSQ drugs in the country. Post-approval, the NIB constituted a Core Expert Committee, a Consultative Expert Committee and a Statistical Design Committee to plan and undertake the "Survey of Extent of Problems of Spurious and Not of Standard Quality (NSQ) Drugs in the Country".

The survey was designed to meet the following objectives:

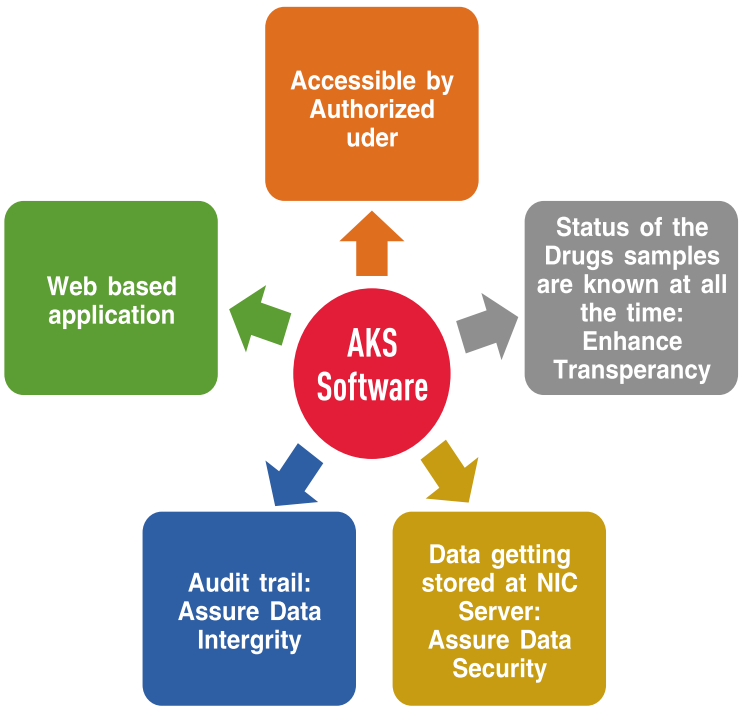
- Estimate proportion of specific critical quality standards at different points of supply chain
- Estimate proportions of spurious and NSQ drugs in the country
- Identify possible causes of findings
- Propose possible strategies and implementation plans to address the problems identified

An initial pilot study was conducted for a month which helped refine the purpose, scope, data collection forms, digital tools and even the understanding of the stakeholders. After this, the survey was rolled out across the country in April, 2015.

The survey was marked by several unique features:

- An innovative and cost-effective AKS-Drug Survey Software was exclusively developed in-house at NIB to facilitate collection, collation, segregation, analysis and retrieval of the survey data. It mapped sampling activities of the Sample Drawing Officers (SDOs) in the field and facilitated track and trace of drugs samples at various stages of the survey.
- Nationwide training in drugs survey methodology (through a specially prepared animated training module) was imparted in 28 centres to more than 1800 SDOs and representatives of civil society/Pharmacy Council of India (PCI). The latter were charged with ensuring that the process of drawing drug samples by SDOs is in accordance with the sampling methodology and maintaining highest degree of transparency and objectivity.
- The statistical survey design included 224 drug molecules belonging to 15 different therapeutic categories of National List of Essential Medicines (NLEM) 2011.
- 47,954 drug samples from 23 dosage forms were drawn in 654 districts of 36 states and union territories by 932 SDOs from states/UTs and 13 from CDSCO.
- The survey covered the legitimate supply chain which included drawing of 33,656 samples from 5717 retail outlets, 8369 samples from 1421 government sources and 4987 samples from 8 air/sea ports. 38.8% of the samples were sourced from rural areas of villages and taluk headquarters.
- The 47,012 approved samples were physically examined by trained drugs inspectors of CDSCO before being subjected to test/analysis as per pharmacopoeia requirements at 10 central/state government drugs testing laboratories accredited by NABL.

Salient features of AKS-Drug Survey Software developed in-house at NIB



A sample drawing team visiting a retail outlet

- From the total sample size, 71.6% were drawn from retail outlets, 17.8% from government sources and the rest were from ports. These samples were from 1719 manufacturing units, with 80% coming from 197 manufacturing units. The samples represented 183 molecules, with 80% coming from 46 molecules. About 80% of the samples drawn from retail outlets and government sources were tablets.

Methodology

The methodology of the main survey including the sampling procedure, sample collection, packaging, visual inspection, transport of samples to laboratories, reporting of results by the laboratories and digitization of data was carefully planned and executed.

There were 945 trained drug inspectors – 936 were assigned for drawing samples from retails outlets and government sources while 9 visited the ports. Each SDO was accompanied by a representative of civil society/PCI to ensure that the samples were drawn in an unbiased manner. Six formulations from six different molecules were planned to be drawn from each source.

The SDOs were armed with two kits comprising of the necessary items for collecting samples. Each SDO was provided with a list of sources from where the samples were to be drawn and data forms that featured a unique number specific to the SDO and colour scheme of pink for government sources and white for retail outlets. The SDOs were instructed to use only one data form for each source. They also carried a NIB Drug Survey brass seal engraved with a unique number for each SDO for tagging samples drawn by the SDO from the sources.

The sampling procedure for retail outlets/government sources was divided into three broad stages -

- Locating the source
- Drawing the samples and feeding the data of the source and sample particulars in the data form. The drawing of sampling was further split into three steps:
  - Selection of drug molecules for drawing of samples
  - Listing all available formulations of the selected molecules
  - Selection of one formulation for drawing as sample
- Packing the samples (primary packaging done at source) and posting them along with the data form to NIB after feeding the particulars in the AKS software

It was mandatory that the filled data form should be attested with the signatures of the team members along with an authorized person from the source.

For sampling from ports, samples were drawn for a period of three months by CDSCO port officers from each and every consignment imported through the notified ports in respect of finished drugs formulations and Active Pharmaceutical Ingredients (API) pertaining to the list of 224 molecules identified for the drugs survey.

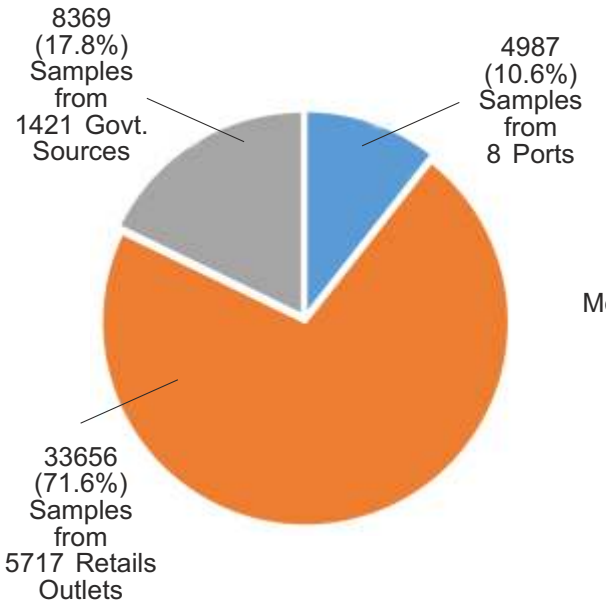
A designated NIB drug survey nodal officer received the samples, logged the details and stored them in the earmarked storage area. CDSCO drug inspectors conducted a visual inspection of the samples (as per the NIB checklist) and uplinked their observations in the AKS software. Some of the sampled formulations were found to have expired at the time of sampling and some were rejected for other reasons.

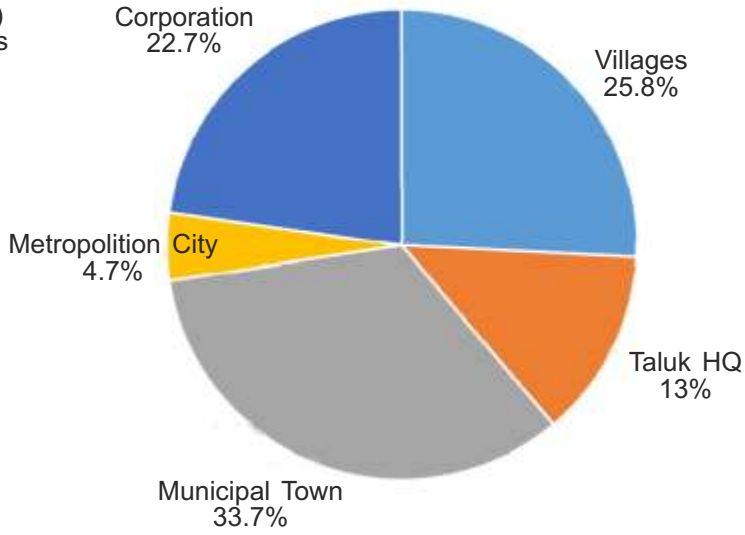
The approved samples were repacked and dispatched to the selected testing laboratories. Relevant testing details were provided to the laboratory staff in both hard copy and online format. The authorised lab personnel acknowledged receipt of samples, conducted the required tests as per the pharmacopoeia requirements and reported the results for every sample (mentioning all the specifications and compliance/noncompliance) using the AKS software.

A total of 69 different tests such as identification, dissolution, assay, etc., were performed on the samples

DRUG SURVEY

- **Total Samples drawn under Drugs Survey : 47,954**
- **Total samples subjected to test / analysis- 47,012 samples***





38.8% of samples were drawn from rural areas of Villages & Taluk Hq

*Out of 47,954 Samples drawn, 942 were not tested as they were either out of list of selected molecules or lost/damaged in transit

in the labs. Not all the 69 tests were applicable to all formulations.

Based on the results, the report stated whether the sample was of Standard Quality/Not of Standard Quality along with reasons for declaring the sample as NSQ. Samples which failed identification by respective drug testing laboratories were declared 'spurious' under section 17B(d) of the Drugs and Cosmetics Act, 1940. NIB maintained a record of all test reports and shared the details of spurious and NSQ samples with the appropriate regulatory authority with a request to take appropriate action and also to take legal samples of same batch of drugs for testing.

Lab Test Results and NSQ Proportions

Retail Sources - Out of the 33,656 samples featuring 177 different molecules drawn from 5717 retail outlets, 1011 failed in one or more of 28 out of the 69 tests and were declared as NSQ. Failure due to dissolution test contributed to 33.6% of non-compliance, failure in assay contributed to 22.6% of non-compliance and failure in description contributed to 11.9% of non-compliance. Therefore, the estimated NSQ percentage for retail outlets in India is 3% and is not expected to be more than 3.19% (the upper 95% confidence limit).

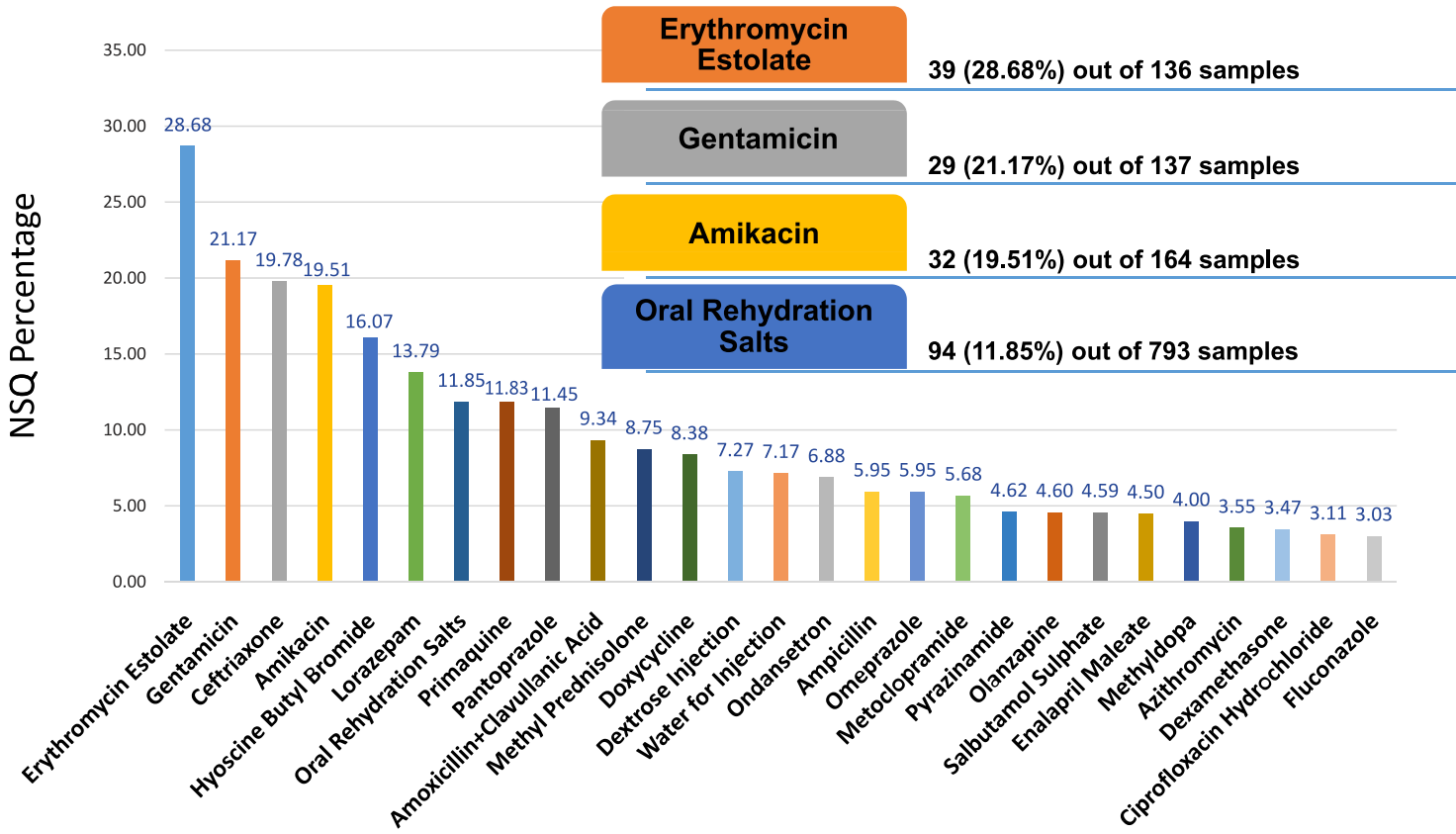
The NSQ proportions were also estimated with respect to dosage forms, molecules, states/union territories and even manufacturing units.

Government Sources - In case of government sources, of the 8,369 samples featuring 158 molecules drawn from 619 districts that were tested/analysed, 839 samples failed in one or more of 27 of the 69 tests and were declared as NSQ. Failure in assay contributed to 23.96% of non-compliance, failure in dissolution contributed to 22.18% of non-compliance and failure in related substances contributed to 13.76% of non-compliance. Therefore, the estimated proportion for government sources is 10.02% with a 95% confidence interval of 9.38% to 10.68%

The NSQ percentages were also estimated based on molecules, dosage forms, states, type of source, location and manufacturing units. Among other things, it revealed

ANALYSIS OF FINDINGS – RETAIL OUTLETS

Molecules with more than 3% NSQ samples (total samples ≥ 50)



a higher incidence of NSQs in municipal towns and taluk headquarters.

Ports - 4,987 samples featuring 57 molecules were tested from 1,708 consignments from 8 sea and air ports in Delhi, Mumbai, Chennai, Kolkata, Hyderabad and Ahmedabad.

The drugs consignments sampled at ports came from about 108 manufacturing companies - 92% from China and 2% each from Italy and France. It was observed that eight companies from China accounted for 57.7% of the samples of which two companies alone accounted for 35.19% of samples.

None of the samples drawn from ports were found to be NSQ.

Lab Test Results and Spurious Drugs Proportions

Of all the samples drawn from retail outlets and government sources, 13 were found to be spurious - 8 were from retail outlets and 5 from government sources. Therefore, the estimates of spurious drug percentages was 0.0237% for retail outlets and 0.0597% for government sources.

Collated Survey Results

Of the 47,012 samples that were tested, 13 samples were 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%.

For government-sourced drugs, Meghalaya, Mizoram, Arunachal Pradesh, Nagaland, Telangana, Uttarakhand, Uttar Pradesh and Punjab had NSQ percentages higher than the national average. As many as 22 private manufacturing units from where more than 50 samples were sourced, reported higher NSQ percentages than the retail average of 3%.

To establish the seriousness of the issue, the report quoted two examples where drug-related toxicity led to multiple deaths in India. In 1988, around 33 children died in Gurgaon after developing acute renal failure from the ingestion of cough expectorant. Again in 2014, 15 women died in a sterilization camp in Chhattisgarh from consuming antibiotic tablets contaminated with

rodenticide. On a global level, more than 1.2 million or 3.75% deaths of children under five infected with malaria were associated with the consumption of poor-quality anti-malarials.

It should be noted that the survey data was analysed while keeping various issues in view -

- Design, conduct and performance of the survey and quality of data collected
- Quality of drugs based on laboratory test results

Therefore, it also provides supplementary information on the type of issues that may arise in conducting massive surveys and will prove handy in conducting future surveys of this nature.

Recommendations

The survey results clearly indicate 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.

It put forward recommendations like:

- The government procurement agencies should revisit their procurement guidelines for qualifying the manufacturers, develop risk-based pre-inspection norms for selection of manufacturers of quality drugs and adopt quality testing of each consignment at NABL-accredited laboratories.
- Government warehouses, medical store depots and pharmacies should have adequate storage facilities and provision for temperature and humidity control, sufficient air-conditioned space, refrigerators, deep freezers etc. along with their annual maintenance contracts. These facilities, should be inspected at least once a year by a joint team of CDSCO and State Licensing Authorities. Alternatively, third party inspections by accredited bodies could be considered.
- The agencies should conduct regular skill development training for the medical store officers, pharmacists and other staff members for handling of drugs, inventory control, good storage and warehousing practices and proper documentation in digital format.
- Government hospitals should set up modern hospital pharmacies manned by an officer with appropriate pharmacy qualifications.
- Entire data of government drugs supply chain should be digitised for efficient inventory control, monitoring and surveillance.
- Government should also reduce the dependence on API imports by taking measures to upscale existing indigenous production capacity of APIs and set up new manufacturing units to enhance production to meet the country's need.

RECOMMENDATIONS FOR GOVERNMENT

1. **Minimise NSQ proportion of drugs in the Govt. Sources**
2. **Reduce dependence on imports of APIs from China**
3. **Create a National Digital Database Registry**
4. **Capacity Building laboratory infrastructure & Manpower**
5. **Establish National Drugs Regulatory Training Academy**

- A National Digital Database of all distributors, retailers/pharmacies and government sources with name and contact information of licensed pharmacists should be created at the earliest.
- There is a need to augment the existing central and state drug testing capacity besides setting up new labs to cope with the testing of large number of surveillance and regulatory drug samples. They should be equipped with sufficient number of trained analysts, latest equipment and adequate consumables while making them ISO 17025 compliant.
- A National Training Academy in Drugs Regulatory Sciences will create a national talent pool of skilled regulatory manpower that is proficient in operational functions and understands the current Good Manufacturing Practices, Good Laboratory Practices and Good Distribution Practices.

The government did institute various measures based on the survey recommendations and even amended the Drugs and Cosmetics Act in 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were made cognizable and non-bailable.

Conclusion

The percentages of NSQ and spurious drugs may seem quite small, but it should be noted that even such small amounts of poor-quality medicines are unacceptable as it leads to drug related morbidity and mortality. And the higher proportion of NSQ prevalence in drugs procured from government sources (more than 3 times that of retail outlets) is really disturbing. It raises serious doubts about the distribution of drugs in government hospitals and other government delivery channels.

This 2015-16 survey is still relevant today as there is no letting down in the proportion of NSQ and spurious drugs prevailing in the market. The incidence is proving to be especially alarming during the ongoing COVID-19 pandemic where consumers cannot even rely on the quality or efficacy of the medicines, injections and vaccines.

Source: Secondary research & media reports

Over-the-Counter List on The Cards

In USA, there are more than 80 classes of over-the-counter (OTC) drugs, ranging from acne medicines to weight loss products, amounting to up to 1,00,000 marketed products. While common in India, 'OTC' actually has no legal recognition here. But the government is taking positive steps toward formalizing this practice with an exclusive schedule of over-the-counter drugs.

The need to define OTC medicines as a separate category of drugs is evident as any medicine that is not a 'prescription-only' product is automatically qualifying as OTC

HAVE A COLD/COUGH with fever – Buy Corex or Lemolate. Suffering from acidity or constipation – take Digene or Dulcolax. Have a cut or rash on the skin – use Candid or Soframycin. We are used to walking into a medical store and purchasing general medicines like Crocin, Disprin, Avil, Lomotil, Volini, Becosules, Polybion etc. for our minor ailments.

Sale of 'Over-the-Counter (OTC) Medicines' by pharmacists without a prescription is legally recognized in most countries around the world. India is a glaring exception as OTC drugs are not legally defined or even mentioned in the Drugs and Cosmetics Act, 1940 or the Drugs and Cosmetics Rules, 1945. The legislation simply lists certain drugs under Schedules H, H1, and X that can be sold only against a prescription of a registered medical practitioner.

In practice, all other medicines outside these restricted categories are routinely sold without prescription in drugstores. This self-medication is extremely common – according to a 2015 web portal-based survey of 20,000 people across 10 cities, 52% Indians self-medicate on a regular basis. But OTCs are still not a recognized official category of medicines….

The Current Scenario

India is the 11th largest OTC drug market, valued at $6.38 billion in 2019, with a potential to reach $15.48 billion by 2024. However, the dark side of OTC is that many drugs can conveniently sidestep the regulation just because they are not listed in the prescription-only schedules.

Manufacturers often tweak commonly used formulations to bring their products out of the prescription-only category and sell them as OTC with similar sounding names. The same trick is used to dodge price control under the National Pharmaceutical Pricing Authority (NPPA).

Then there are certain important drug categories - such as diuretics and aminosalicylates – that are not included under any schedule.

Newly launched drugs also enjoy the leeway to be sold over-the-counter without prescription till the time they are expressly delegated to Schedule H or X.

What's more, even regular prescription-only drugs are commonly sold over-the-counter without prescription and strict rules are needed to prevent such illegal sale.

What is the Government Doing?

Non-prescription medicines should be clearly classified and listed to make drug regulations fool proof. Around a decade back, the primary national drug regulatory agency, CDSCO, had appointed a sub-committee to study, categorize and enlist OTC products and suggest measures for their regulations by central and state agencies. The committee specified about 200 types of vitamins, minerals, analgesics and certain anti-inflammatory, anti-pyretic drugs to be included in the list of OTCs and submitted a report to the

OTC medicine can act as a double-edged sword. To avoid abuse, there should be some mechanism to prevent the indiscriminate sale of these drugs. Surveillance for reporting of adverse effects of OTC drugs needs to be strengthened to promote safe usage.

India is the 11th largest OTC drug market, valued at $6.38 billion in 2019, with a potential to reach $15.48 billion by 2024.

central government in 2012, but no action was taken thereafter.

In 2018, the Ministry of Health formed another sub-committee - comprising of five state drug controllers - to recommend an initial list of medicines that can be considered as OTC drugs, accompanied by appropriate manufacturing and labelling regulations, classification and approval process and other conditions to be followed. In the beginning of 2019, the Drugs Consultative Committee (DCC) formed a new three-member sub-committee to review the recommendations and create a new OTC category along with a regulatory framework for these medications.

Six months later, the consultative panel proposed that the government should create two lists of OTC drugs based on evidence of their safety, availability, therapeutic index, need for accessibility to patients, non-habit forming nature, supply chain mechanism and socio-economic conditions of the country. There should also be clear provisions for regulating their quality, pricing and advertisements along with stringent regulations for the approval, distribution and sale of new OTC drugs. It even opined that certain OTC medicines can be sold at retail outlets as well.

The proposal then moved to the Drug Technical Advisory Board (DTAB), the government's highest advisory board on pharmaceutical matters for approval. R Chandrashekar, Deputy Drug Controller (India), MoHFW said that it will still take a year or two for the government to institute the rules for OTC regulations.

Along with an official OTC drug schedule of analgesics, decongestants, antacids, digestives, muscle relaxants, vitamins, anti-allergy drugs, medicated skin creams and hormonal contraceptives, the DCC is also working on other regulatory measures. It will introduce an additional 'Behind-The-Counter Medicines' category for drugs that do not require a prescription but can be sold 'only under the supervision of a qualified pharmacist'.

What Will the Future Look Like?

Once the OTC list is notified, pharmacists will be free to sell these medicines on their own and patients can purchase them even without medical consultation. The active ingredients in these medications are safe and effective for use by the general public. They can follow the instructions on the label without direction from a healthcare professional.

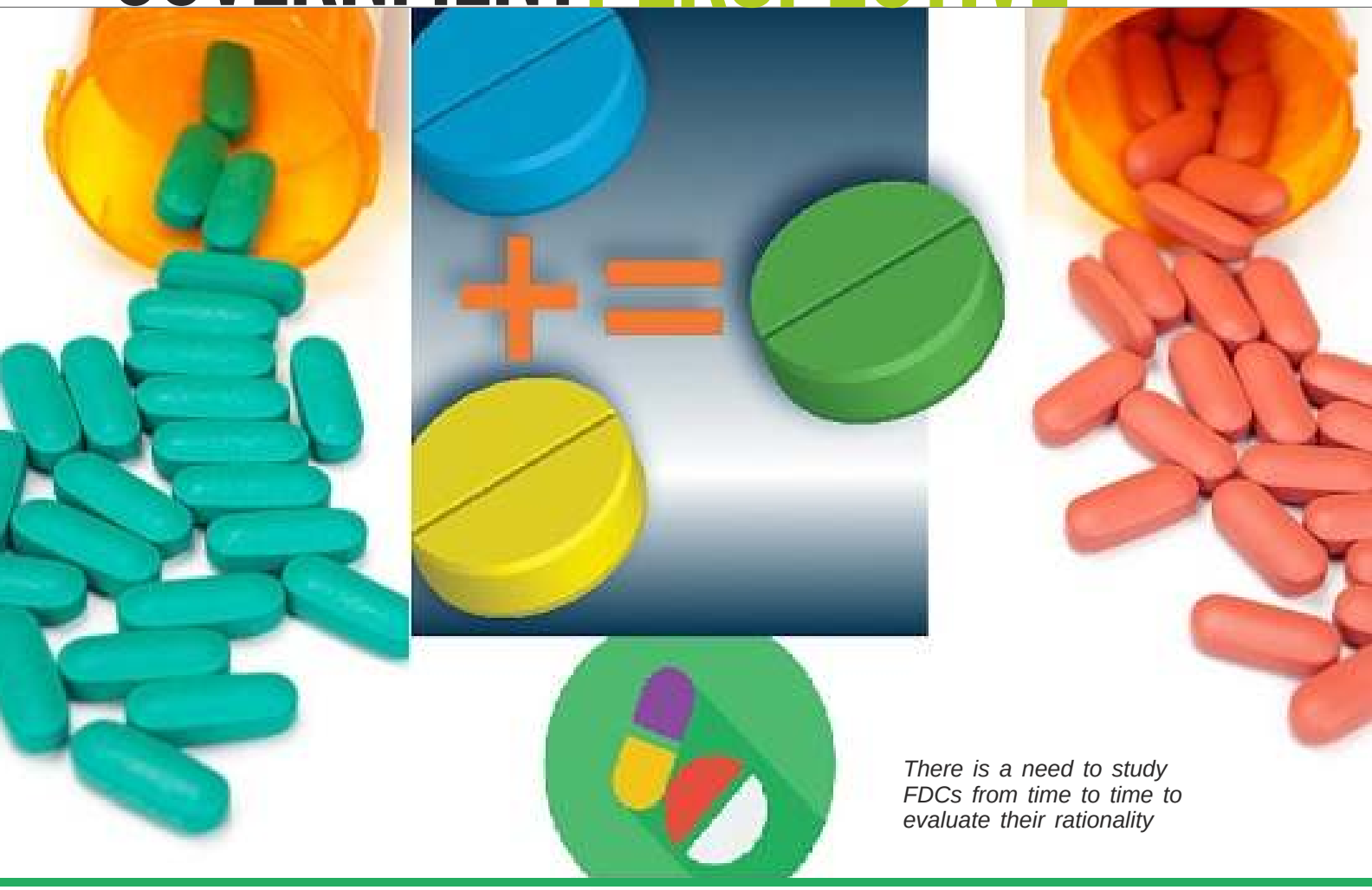
However, OTC medicine can act as a double-edged sword. To avoid abuse, there should be some mechanism to prevent the indiscriminate sale of these drugs. Surveillance for reporting of adverse effects of OTC drugs needs to be strengthened to promote safe usage.

Furthermore, it is imperative to educate the consumers about the uses and side-effects of the OTC drugs to empower them to make an informed decision. Even the labelling norms should be revised to make it easier for consumers to read and understand its contents. Pictorial descriptions will promote safe use among the uneducated folks. Only then will proper self-care set in without compromising patient safety!

Conclusion

We truly need a separate schedule for OTC medicines in the Drugs and Cosmetics Rules. This will improve accessibility and affordability of healthcare in the country – especially the underprivileged sections of the society and people residing in remote areas can get easy and inexpensive treatment for minor ailments or self-limiting illnesses. They will no longer need to visit a doctor or pay the fees every time they fall sick, as the OTC drugs can be purchased without a prescription.

Source: Secondary research & media reports



There is a need to study FDCs from time to time to evaluate their rationality

Crackdown On FDCs

Banning 'Cocktail Drugs' In India

The improvisation of Fixed-Dose Combinations (FDCs) promotes easy usage, higher efficacy and improves public health. However, the fallout of rampant use of unapproved FDCs is assuming threatening proportions in the country. The Government's ban on various FDCs is a bold decision to prioritise public health and patient safety over the interests of the pharmaceutical industry.

IN AN IDEAL world, medicines are administered as individual items – take a specific drug to get a therapeutic response for a particular ailment with maximum efficacy and minimum adverse effects.

However, many ailments and comorbid conditions involve multiple pathogens, and single drugs prove insufficient in providing effective relief. For instance, infectious diseases like tuberculosis and HIV as well as non-infectious ailments such as malaria, diabetes, hypertension cardiovascular issues and even pain and inflammation are better addressed through a combination of drugs.

When two or more active ingredients are combined in a defined composition and packed into a single dosage form, it is termed as fixed dose combinations (FDCs).

FDCs are designed to reduce the pill burden on the consumers and shorten the course of treatment while delivering effective results. They also work out cheaper than individual drugs because of reduced costs from packaging to distribution.

There are other benefits as well. At times, two or more drugs have a synergistic action, wherein the combination induces a better medicinal response than when the individual drugs are used separately. In cases where multiple oral pills are prescribed for a prolonged course of treatment, FDCs can easily reduce the incidence of non-adherence, partial compliance or intake of wrong dosages that will have an adverse effect on the patient's health. Or, one drug may even stimulate a corrective action by reducing the incidence or severity of adverse effects caused by the other. FDCs are also known to prevent the development of resistance to certain drugs.

When there is an incremental benefit in therapy, convenience or cost within the line of safety, they are deemed as 'rational' FDCs. Such rational FDCs are available in varied therapeutic categories and are recommended for use by clinical experts, government authorities and even the WHO. Many of the commonly-used cough syrups, painkillers and topical medications are multi-drug concoctions.

The Darker Side

The safety, efficacy and bioavailability of some individual active ingredients can change when combined with other drugs. In case of a mismatch between the segments, it can diminish the therapeutic benefit or alter the safety profile, contrary to what is exhibited when the medicines are used individually. The changes can make them ineffective or even turn harmful for the patients; sometimes the chemical incompatibility can reduce the shelf life too.

Pharma companies prefer to develop FDC formulations as it is cheaper and quicker to combine existing active ingredients to make new products than to discover new chemical entities and manufacture them separately.

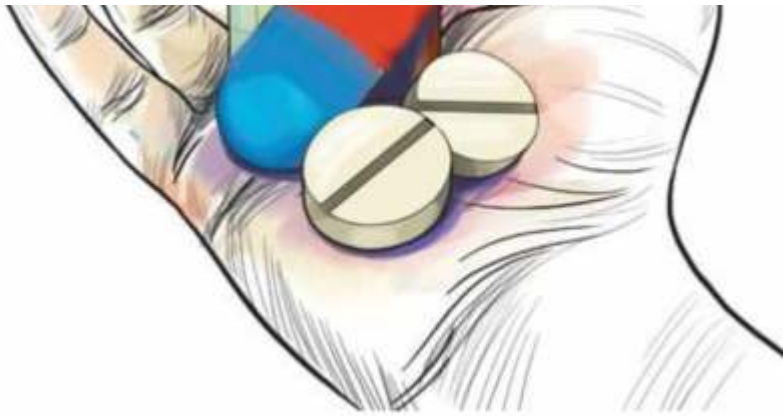
Moreover, new combinations are used as a weapon to beat the competition by marketing 'unique' and 'innovative' medicines, even if the amalgamation of drugs is actually unnecessary or ineffective. Unethical manufacturers often go the FDC route to circumvent the price control imposed on certain single-ingredient drugs by coming up with combinations that will not be subject to price control.

Actually, just a handful of FDCs figure in both the WHO List of Essential Medicines and National List of Essential Medicines of India.

Concerns about Rationality and Utility

Over the decades, there has been a proliferation of medications that have bizarre combinations of three to even five ingredients with or without validation of their presence or quality. The Indian market is flooded with many irrational FDCs that are launched without the approval of the national licensing authority, the CDSCO.

Many of the commonly-used cough syrups, painkillers and topical medications are multi-drug concoctions.



Health experts have been vociferously protesting about the unscientific pharmaceutical combinations that can cause drug interactions, dangerous side effects and even render the body resistant to treatment. What is particularly worrying is that FDCs are often prescribed to cover diagnostic imprecisions.

The presence of such irrational FDCs calls for extreme caution from the pharmaceutical companies, due diligence from healthcare providers and careful checks from the regulatory agencies. However, the pharma industry continues to be brazenly irresponsible while prescribing

doctors are befuddled by the different permutations and combinations of unlimited FDCs.

Rule 122E of Drugs and Cosmetics Act 1940 deems FDCs as 'New Drugs' that will be approved by the CDSCO after due examination of the documentation on rationality, efficacy and safety. However, in actual practice, the State Licensing Authorities (SLAs) often issue manufacturing and marketing permission without proper studies, counterchecks or prior approval from the CDSCO.

No wonder, the Indian medicine market has become a world leader of cocktail drugs. In fact, FDCs enjoyed a much higher market share over single drugs with around 2,000 cocktail combinations, four times more that what's available in the US!

There is a pressing need to cut down on fixed-dose drug mixtures and encourage single dosage forms.

What is the Government Doing?

A Standing Parliamentary Committee was constituted in 2012 to study the fiery issue of new and existing FDCs.

FDCs are accepted in international markets only after the therapeutic advantages of the combinations are clearly proved by long-term clinical studies

This led to the shocking revelation that about two-thirds of the FDCs are manufactured and marketed without a license from the Drugs Controller General of India (DCGI).

The Ministry of Health and Family Welfare constituted another Committee under the Chairmanship of Dr. CK Kokate in 2014 which studied over 6,000 combinations that had not been green-lighted by the CDSCO.

After 18 months of deliberations, the recommendations led to the ban of 344 FDCs in March 2016 under Section 26A of the Drugs and Cosmetics Act, 1940. This affected about 7000 brands including painkillers, anti-diabetic drugs, respiratory and gastrointestinal medicines. Popular medicines like Corex, D'cold, Saridon and Vicks Action 500 were ordered off pharmacy shelves causing furore among major manufacturers like Abbott, Pfizer, Mankind, Glenmark, Wockhardt and Cipla. More than two dozen domestic drug makers challenged the ban in various state High Courts until the Delhi High Court stayed the ban in December 2016 citing technical reasons.

The Government of India appealed against the verdict in the Supreme Court arguing that the FDCs are 'irrational', lack 'therapeutic justification' and risk patient health while there are enough single drug alternatives that are safer and effective. The apex court referred the matter to the Drug Technical Advisory Board (DTAB) for a fresh review, suggesting that this authority will decide whether the manufacture and sale of these drugs should be regulated, restricted or banned outright.

The DTAB committee again found that many FDCs were formulated without due diligence and had dosing mismatches that could result in toxicity. Consequently, in September, 2018, the government once again issued a ban on the manufacture, sale and distribution of 328 varieties of FDC drugs, affecting over 6,000 medicine brands. Later, the Supreme Court allowed the sale of three of these drugs including Saridon.

This proved to be a landmark decision for the development of a robust healthcare policy in India. In January, 2019, the MoHFW banned 80 more FDC drugs including antibiotics, painkillers, medicines used for treating fungal and bacterial infections, hypertension and anxiety.

Yet, many of the banned concoctions continue to be available in drugstores on account of a lax regulatory network that is compounded by the ongoing legal challenge played out by the pharma lobby.

It should be noted that the government bodies continue to review the FDCs on a regular basis. In September, 2020, three of the banned drugs were categorised as 'rational' as the combination demonstrated a proven advantage over a single-compound drug.

Conclusion

India needs to establish a strong regulatory system for the approval of FDCs based on scientific and authoritative information about whether they are rational and genuinely necessary for our health care. Both the central and state regulators must harmonize their procedures for licensing FDCs. The pharmacovigilance and enforcement mechanism should also be strengthened.

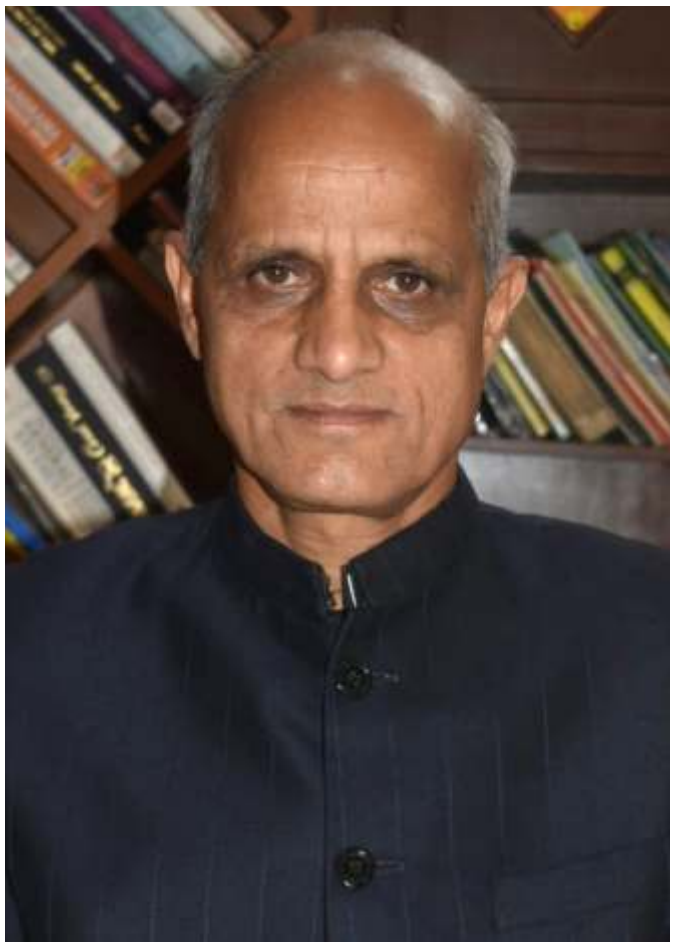
Doctors, pharmacists and other health care professionals need to be made aware about the benefits and ill-effects of FDCs to ensure sound prescription and pharmacy practices.

The pharmaceutical manufacturers, in particular, should stop perceiving the ban against irrational FDCs as an impediment, and take it as an opportunity to establish a stronger healthcare system in the country! The industry should act responsibly - use adequate rationale for developing FDCs and generate strong efficacy and safety data.

In fact, all stakeholders - from the regulatory authority, industry and physicians to the consumers and academicians - should join hands and act responsibly to curb FDC misuse.

Source: Secondary research & media reports

"The extent of the NSQ and spurious drugs was found to be 3.16% and 0.0245%, respectively which is more or less at par with what is prevalent in most developed countries"



Mr. K.L. Sharma

- a civil servant of four decades standing - has a wide exposure to policy formulation at the highest levels in the government. He has worked as Joint Secretary in the Cabinet Secretariat. In his post of Joint Secretary in the Ministry of Health & Family Welfare (2014-17), he initiated a string of reforms for improving medical products regulation.

He has authored a book, 'Healing the Pharmacy of the World' which should be available in the market by the third week of August 2021. This interview provides an insight into the contents of his trailblazing book.

Q Centralisation of drug regulatory structures and their strengthening have been identified as the possible measures for improving medical products regulation by a number of Committees including the Mashelkar Committee. It's almost two decades since the Mashelkar Committee report was submitted to the GoI. How far have the recommendations been implemented?

Quality of medical products is critical for efficient delivery of healthcare. An effective and robust regulatory oversight goes a long way in ensuring the quality of medical products. Centralization of drug regulation had been identified as a possible solution to address the vexatious issue of Not of Standard Quality (NSQ) medical products by the Pharmaceutical Enquiry Committee, as early as in 1954. The Committee had suggested that the Drugs Act may be amended for centralizing the grant of licenses for manufacturing drugs in the country.

Both the Hathi Committee (1974) and Dr. R. A. Mashelkar Committee (2003) had highlighted the lack of uniformity in regulatory practices and efficiency of regulatory structures across the country. Hathi Committee had recommended that the central government should assume the responsibility for ensuring statutory enforcement and control over manufacturing of drugs all over the country. Mashelkar Committee had pointed out that the dual system of drug control had failed to achieve the desired effectiveness and, therefore, the feasibility of bringing all aspects of licensing, including loan licensing, certification and complaint handling under the effective control of the central government, should be examined. Mashelkar Committee had also recommended creation of a Central Drug Administration (CDA) for licensing all manufacturing activities.

These recommendations had been made in light of the fact that the divided responsibility for regulation of medical products between the centre and states has proved to be one of the major weaknesses of the system. The diffused responsibility leads to poor regulation of medical products and also impedes the growth of the sector. A strong and globally competitive medical products sector cannot be visualized with decentralized, diffused and amorphous medical products regulatory structures.

The Mashelkar Committee had also suggested strengthening of the regulatory structures and had proposed a formula for fixing the strength of regulatory officials. No serious effort has been made so far to improve the regulatory framework in pursuance of the recommendations of these committees. The structures continue to operate at nearly one-tenth of the strength recommended by Mashelkar Committee.

What is more critical is that the regulators do not have domain expertise. With a view to address this, the Satyananda Mishra Committee had recommended creation of different verticals for regulating different products. It had also proposed making CDSCO an Attached office of the Ministry of Health & Family Welfare; upgradation of the post of DCGI to HAG+ level; creation of six posts of Additional Drug Controller Generals for heading different verticals; and setting up a national academy for training drug regulators. These verticals would have specialization in relevant disciplines viz. Drugs; Medical Devices; Biologicals & other Emerging Areas; Quality Control and Laboratories; and AYUSH Drugs, respectively. The issues remain unaddressed so far.

Q The Drugs and Cosmetics Act, 1940 was amended in 2008 with stringent penalties for marketing NSQ products, setting up of designated courts for speedy trials and restructuring the regulating infrastructure. Why do you think the core issue of spurious and NSQ medicines still remains unresolved?

The quality of medical products can be ensured only if the internal quality control and quality assurance systems in the manufacturing units are impeccable and an independent, strong and effective external oversight and monitoring mechanism compels the internal structures to deliver. Both put together, enhance public trust in products and services.

A strong and globally competitive medical products sector cannot be visualized with a diffused and amorphous regulatory structure. The amendments to the Drugs & Cosmetics Act in 2008 were carried out without adequate diligence. It introduced duality in the penalties for import and manufacturing of spurious and NSQ drugs. Many more piecemeal efforts were made for addressing the fundamental concerns; however, they did not fructify. As far as the special courts are concerned, these have not led to any changes at the ground level.

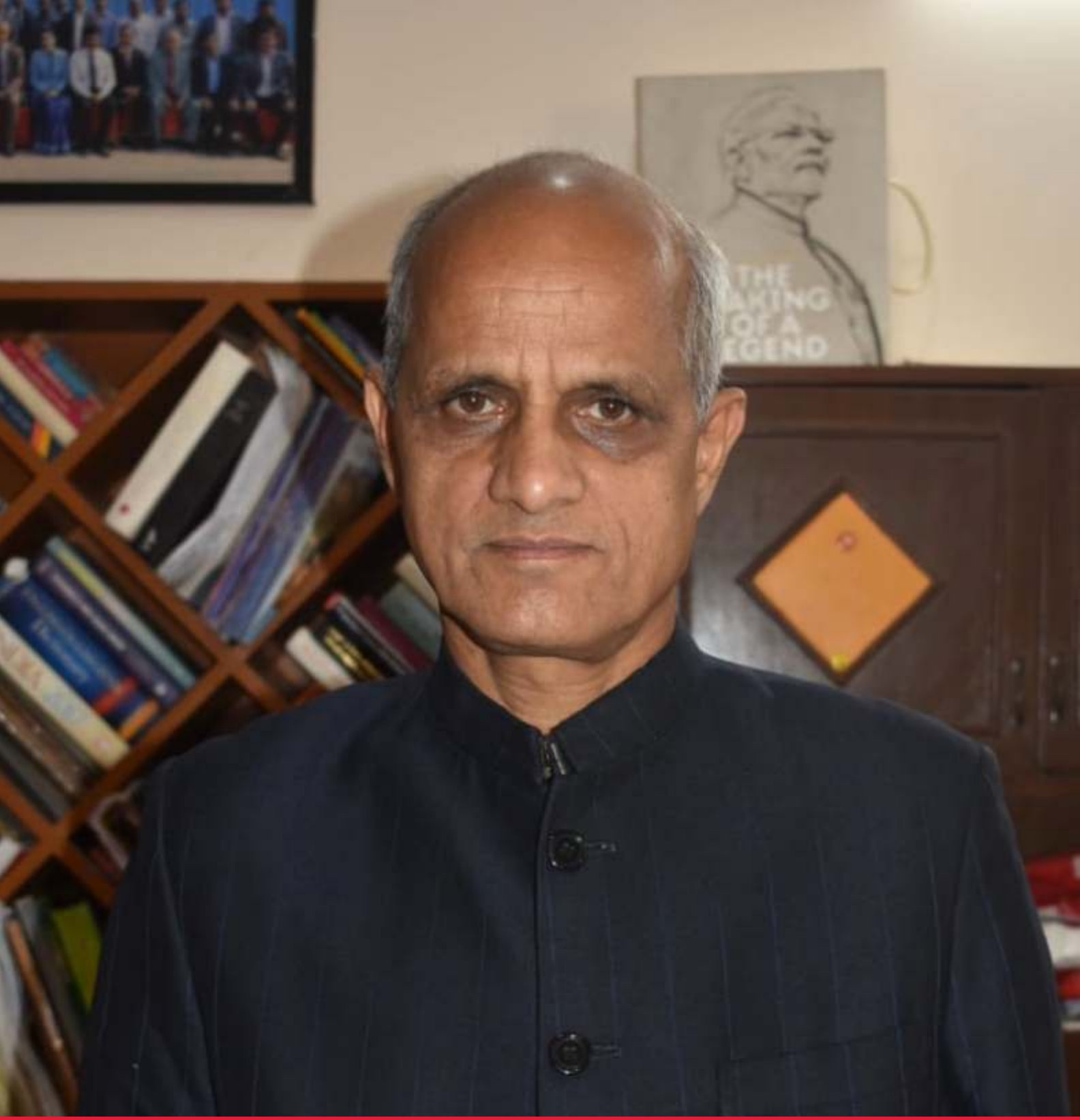
As a consequence of the diffused regulatory structures, defects seep in through the gaps and markets get flooded with NSQ medicines. Addressing concerns regarding quality of medical products will require a calibrated strategy to address systemic fault-lines.

Q What are the possible reasons for non-uniformity in drug regulation across the states and union territories?

The lack of uniformity in drug regulation can be traced largely to the constitutional and institutional fault-lines, archaic laws, absence of political will and commitment to reforms, half-hearted efforts made for strengthening and reforming drug regulatory architecture, bureaucratic inefficiency, poor implementation at the ground level and a host of other factors.

The Constitution of India, like any other constitutions of the world is not without fault-lines. Both the central and state governments are empowered to take legislative, administrative and other required steps for regulation of drugs in the country. Public health, on the other hand, is included in the state list and the responsibility for that rests exclusively with states.

There can be no doubt that the pre-independence legislation viz. 'The Drugs & Cosmetics Act, 1940' should have been consigned to history long time ago. This law



India is critically dependent on China for bulk drugs or Active Pharmaceuticals Ingredients/Key Starting Materials/ Drug Intermediates. Development of domestic capacity is critical to the sustainability of Indian pharmaceutical industry.

had been enacted keeping in view the provisions of the Government of India Act, 1935 which vested the provinces with much more authority than what has been vested in them under the Constitution of India including for regulation of medical products. The Drugs & Cosmetics Act, 1940 does not reflect the current constitutional provisions and is an anachronism of a bygone era based on the vestiges of pre-independence governmental architecture. It is a matter of great concern that even after over seven decades of India's independence, a new law to regulate medical products in the country uniformly has not been enacted and the archaic law that has outlived its utility still continues to be stretched.

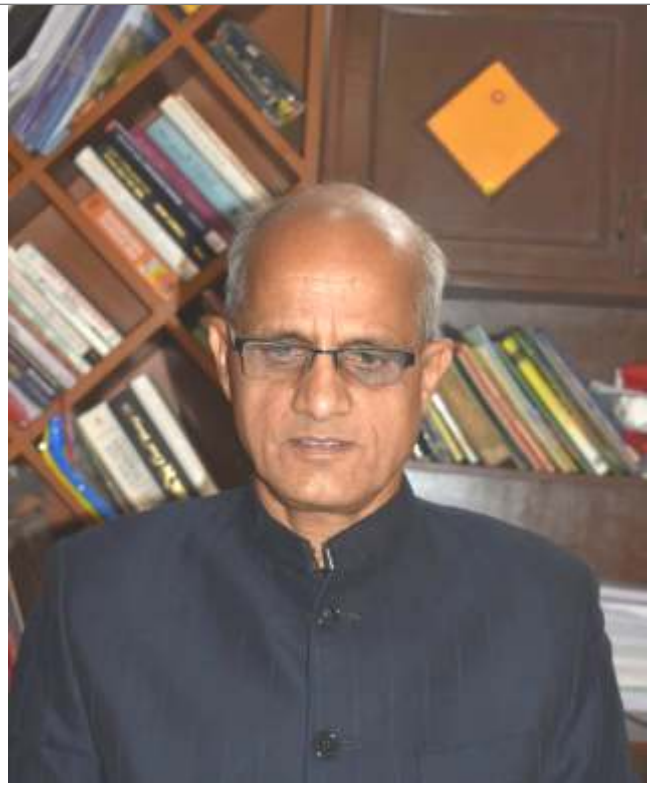
The existing mechanism of Drug Consultative Committee is incapable of ensuring effective coordination between the central and state drug regulatory authorities as the state regulators act as per directions of the state government. Many a times, the central and state regulators act at cross purposes. In these circumstances, expecting uniformity in medical products regulation is asking for the sky.

Q Why does the drug regulatory system continue to be woefully inadequate to contain the prevalence of SFFC drugs? What can be done to build more effective deterrents against violations?

The primary reason for this is the diffused responsibility in terms of the existence of three dozen-plus central and state regulators all of whom have concurrent jurisdiction in matters relating to medical products regulation. This makes it difficult to visualize any effective drug regulation. The responsibility of all is the responsibility of none. In this situation, the issues that should be accorded high priority get ignored as a consequence of the bystander effect. The confusion and chaos accompanying the diffused responsibility also creates conditions conducive for rent-seeking and other malpractices, both on the part of regulators and the regulated.

Instances such as grant of licenses for manufacturing unapproved fixed dose combinations; manufacturing medical products in non-GMP compliant facilities or even in non-licensed facilities; lack of proper inspections of manufacturing premises; non-adherence with stability or bio-equivalence and other requirements, etc., all result in proliferation of NSQ medicines. The poor storage facilities for medical products both at the wholesale and retail levels contribute significantly to deterioration in the quality of medical products. To control the proliferation of poor quality medical products, improving the quality of regulatory oversight is necessary.

Q Can you throw some light on the findings of the largest ever drug survey undertaken anywhere in the world to determine the quality of drugs sold in the Indian market? What is your opinion on how the country is faring today in terms of controlling the menace of spurious and NSQ medicines?



The country-wide survey undertaken during 2014-16 tested and analysed 47,012 samples. These had been drawn from rural areas; municipal towns/taluk headquarters and metropolitan cities. The extent of the NSQ and spurious drugs was found to be 3.16% and 0.0245%, respectively which is more or less at par with what is prevalent in most developed countries. The position in respect of retail outlets with 3% NSQ and 0.023% spurious drugs was better than what was prevalent in government supply chain where it was 10.02% and 0.059%, respectively.

The quantum of NSQ drugs in case of 40 manufacturing companies from which 25 or more samples had been drawn was more than the national average of 3%. The highest NSQ drugs were in case of a Gujarat-based company where 90.63% of the samples drawn were found to be NSQ. 11 companies had NSQ drugs in the range of 15% to 90.63% and 27 companies including some multi-national companies had NSQ drugs exceeding 5%. Some multinational companies had NSQs in excess of 50%. Presently, there is no well-calibrated strategy to address quality concerns relating to medical products. It is considered that a lot of catching up needs to be done on the quality front in India.

Q How can the regulator work towards building a data bank of manufacturers and drugs providing access to accurate and updated information?

It is not possible to have any meaningful regulation of medical products with diffused regulatory structures. The only viable solution for improving the quality of medical products in India is one law, one country and one regulator. Not of standard and spurious products will

continue to proliferate as long as the regulatory responsibilities are divided and adequate human resources are not made available.

Q Do you think that a comprehensive review of the outdated Drugs and Cosmetics Act will help enhance its efficacy? Is there a need to completely overhaul the regulation?

There is no doubt that the archaic law has outlived its utility and there is no point in stretching it. The regulation of medical products marketed in the country and also those exported to other countries cannot be treated with such disdain. It paints the so-called pharmacy of the world, poorly. Any delay in overhauling the law, improving skill-sets and creating the right ecosystem would impact the Indian pharmaceutical and medical devices industry adversely.

Q What are your views on the Production Linked scheme for medical devices and medical devices parks?

The requirement of medical devices in India is met largely by imports. Currently, over 75% of medical devices are imported to meet the domestic demand. Analysis of the PLI schemes for medical devices and medical devices parks reveals that it may still not be sufficient to attract large scale investments. The major limitations of the scheme include the very low rate of incentive offered at 5% of incremental sale, it being pegged uniformly for all target segments and no preference being accorded to priority medical devices. In its current form, this may not spur any large scale investment.

The poor storage facilities for medical products both at the wholesale and retail levels contribute significantly to deterioration in the quality of medical products. To control the proliferation of poor quality medical products, improving the quality of regulatory oversight is necessary.

Q How can we ensure uniform pharmacovigilance practices throughout the country?

All medical products have a trade-off between the benefits and the potential for harm. The drugs undergo extensive screening before approval. It is, however. not possible to capture all adverse drug reactions (ADRs) during clinical trials as these are often small, short and invariably biased. The clinical trials generally do not include patients with co-morbid diseases, pregnant women, children and elderly and most medicines are tested only for short-term safety and efficacy on a limited number of carefully selected individuals which could be anywhere between a few hundred to a few thousand. Pre-marketing trials cannot, therefore, mirror actual clinical use situations. No doubt, many adverse effects, interactions with different foods or other medicines and other unknown risks come to light years after the medicine has been in use. Such ADRs impact the quality of life; result in prolonged hospitalization and increase mortality.

Monitoring the quality, safety and efficacy of a medicine throughout its use for treatment, is therefore, important. Continuation, or otherwise, of a medical product for treatment has to be decided on the basis of a careful analysis of risks involved and potential benefits over a longer period of time.

Pharmacovigilance is an important constituent of drug development. Detection of the possible risks associated with the use of drugs through pharmacovigilance constitutes a critical element of the regulatory framework.

It is essential to address the underlying reasons for the reluctance of the physicians and industry to report adverse events. The message regarding the importance of the pharmacovigilance has to be transmitted effectively and all stakeholders taken on board to ensure that they do not ignore reporting of any adverse event that could help in improving the quality of the medical product.

Consistency of policy is one of the most critical elements for attracting long term investment. The scheme does not give an assurance of continuation beyond the stipulated period. Further, approval may not mean much as funds for each scheme are provided through annual budgets. While approved schemes will have a preferential claim, the actual availability of funds will, in most cases, vary from year to year.

The small and incremental changes or the sporadic efforts to address the concerns are not only insufficient but also directionless. The scheme fails to visualize the big picture and misses out on structural and long-term strategic issues. Some of the limitations are coming to light only now due to the developments post the onset of the COVID-19.

For the scheme to make an impact, pegging the incentives at 20-25% of the incremental sales for first ten years with higher incentives for critical/priority areas would be appropriate. After that the incentives could be progressively tapered down. The ceiling on the incentives needs to be removed to avail the economies of scale. Induction of state-of-the-art machinery and latest technology should be incentivised to enhance environmental concerns and sustainability.

Q What are your views on the Production Linked scheme for bulk drugs and pharmaceuticals?

India is critically dependent on China for bulk drugs or Active Pharmaceuticals Ingredients/Key Starting Materials/Drug Intermediates. The dependence is in the vicinity of 80%. A number of countries are now entering the formulation sector and the environmental and regulatory norms in China are being tightened.

Development of domestic capacity is critical to the sustainability of Indian pharmaceutical industry.

There are serious concerns with regard to the PLI schemes for pharmaceuticals. The first is with regard to the availability of funds for the proposed schemes as the allocation of funds is made through the annual budgets. The second is the continuity of the schemes over a longer period of time with such modifications as may be necessary to attract the investors and quality manufacturers. Thirdly, these schemes are still not ambitious enough for a country of India's size and potential. Fourthly, the apprehension is that the schemes could be jeopardized by red tape and dilatory tactics of structures. Fifthly, the schemes do not make any provisions for encouraging and setting up pharmaceutical machine manufacturing facilities in India to lower fixed costs, enable savings in Forex and reduce time to set up additional facilities. The sixth concern is that no provision has been made to bolster the logistics infrastructure for connecting key pharmaceutical hubs in the country to facilitate quick and cost-efficient movement of goods including cold chain facilities. The seventh concern is that it ignores the Brownfield projects which could have been used more effectively. Lastly, the challenge of proper storage and transportation of medical products remains unaddressed.

Q What should in your opinion be done to promote Make in India in respect of medical products and enhance the consumer welfare?

A consumer does not always look for cheap products and certainly not when the quality is compromised. Medical products of suspect quality are highly dangerous. These could have life-and-death consequences and also threaten the very existence of some of the most efficacious medicines due to anti-microbial resistance.

On the other hand, doing business is not just about minting more profits. Successful businessmen create new products and services that positively impact the lives of people. Knowing for sure that investing in new innovations or engaging in creativity for enhancing customer experience will help build a sustainable and profitable enterprise, successful businessmen take all possible steps to enhance the experience of existing customers, onboard new customers and win their trust and support. The spin-off of such a customer-centric approach is more wealth in the hands of enterprising businessmen and also increased consumer satisfaction.

India has all that it requires to leapfrog to the top league of medical products manufacturing countries. What needs to be done is fixing the nuts and bolts here and there in accordance with a well thought out multipronged strategy. These include improving the legal architecture, strengthening centralised medical products regulatory structures, better education and human resource development in pharmaceuticals and related fields, better direction through incentives and disincentives and more optimal utilisation of existing resources - the demographic dividend, public sector facilities especially for undertaking drug discovery and development.

AFTERWORD

Pyush Misra
Trustee,
Consumer Online Foundation

Is The Drug Regulator Aligned With The Industry Or The Patients?

An unhealthy collusion with the pharmaceutical companies pervades the entire drug regulation landscape

Every consumer has the right to safe, effective and quality medication. While the authorities are charged with regulating every aspect of drugs, the CDSCO seems to be operating on skewed priorities and perceptions. The hands of drug manufacturers control the strings and have the regulators dancing to their tune…...

DRUGS ARE AN integral part of healthcare – mankind depends on medicines to cure and prevent various ailments and diseases. The various stakeholders – from pharmaceutical companies, doctors and chemists to medical experts and drug regulators have the responsibility of promoting and contributing to the rational, effective and safe use of therapeutic drugs, devices, diagnostics and other substances.

Unfortunately, the Indian pharma industry has already proved to be blatantlynegligent towards ensuring proper healthcare. The Big Pharma is driven by market share and profits, even to the extent of sticking to their business-as-usual model even in the unprecedented times of the COVID-19 pandemic. They are continuing with their covert operations without shying away from making hay by encashing the misery of the public at large.

The doctors who are supposed to safeguard our health by assessing the safety of drugs, actually act as agents of the pharmaceutical manufacturers in exchange for seductive commissions and other incentives.

To add to this, the CDSCO – which is the guardian of public health – is also working hand-in-glove with the drug companies. As the primary national drug regulatory agency, the CDSCO is charged with prescribing standards and measures for drugs and other devices along with regulating the market authorization of new drugs. It also has to confirm that the pharmaceutical sector upholds Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) while ensuring a healthy supply of quality drugs at affordable prices in the country.

The Hand That Rocks the Cradle....

Alas, the 'Pharmacy of the World' is tainted by various allegations in its drug regulatory regime.

The 59th report of the Parliamentary Standing Committee on Health and Family Welfare released in 2012 made some appalling revelations. While reviewing the drug regulation in India, the committee unequivocally stated that, “There is sufficient evidence on record to conclude that there is a collusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts.”

The approval of new drugs is marred by irregularities with the authorities allowing new medicines to enter the market untested and subjecting the consumers to unsafe and dangerous drugs. There have been many cases of drugs being approved without conducting phase three clinical trials to determine if there are any ethnic differences that can alter the metabolism, efficacy and safety of the drug when administered to patients of different ethnicities living in India.

This is to the extent that the DGCI was approving one drug every month without following the requisite norms that led to 31 new drugs being approved in the period between January 2008 and October 2010 without conducting the mandatory clinical trials on Indian patients. Even drugs that are banned or withdrawn in other countries continue to be sold in India.

Then again, too much is left to the absolute discretion of drug authority officials when it comes to approving new drugs. Yet, the drug inspectors have no assurance of their safety and do not have the power of arrest.

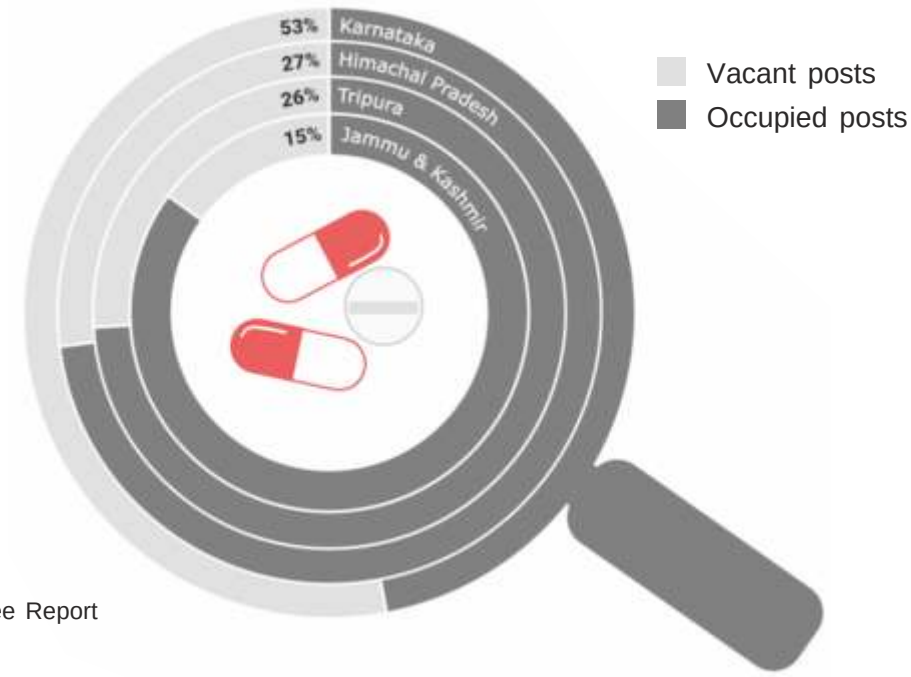
Inspections & Prosecutions By State Drug Regulatory Authorities

State / UT	inspections	Non-compliant	Prosecutions	Prosecutions (As % of non-compliant cases)
Jammu and Kashmir	27,520	0	0	0%
Jharkhand	8,966	1723	7	0.4%
Uttar Pradesh	907	0	0	0%
Odisha	6,260	876	6	0.6%
Mizoram	1,205	141	4	2.8%
Telangana	16,575	3,853	0	0%
Uttarakhand	1,858	0	0	0%
Andaman and Nicobar	120	0	0	0%
Daman and Diu	407	19	0	0%

Source: Drug Regulation in India: The Working and Performance of CDSCO and SDRAs report, 2019

Lack of Drug Inspectors Across States

In four states, many sanctioned posts of drug inspectors remained vacant



IndiaSpend

Source: Malshekar Committee Report

The committee even alleged that the practice of seeking expert consultation for deciding about new drugs is actually a farcical exercise. The so-called expert medical opinion is actually guided and written by the 'invisible hands of drug manufacturers and experts merely sign them'. This is supported by the fact that the opinions were quite subjective and failed to cite any hard scientific evidence.

Then there is the advertising of prescription drugs by pharmaceutical majors which is outlawed in India. Manufacturers like Ranbaxy, Cipla, USV and Lundbeck are blatantly flouting the law by openly marketing anti-depressant Deanxit, cholesterol-lowering Coltro, anti-epileptic agent C-Toin, Desval and Lametec DT that fall under Schedule H of the Drugs and Cosmetics Act, 1940.

In 2015, the government notified the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) but failed to curb the unethical marketing practices in the country.

Why does the CDSCO give into the industry lobbying and favour the drug manufacturers at the cost of the consumers? Why did the ministry not take action against the erring companies even after it was recommended in the panel report? Why is the government turning a blind eye to the numerous instances of pharma companies offering sops to doctors to push their drugs and cartelization of generic drug prices?

Why doesn't the CDSCO maintain a record or database of errant drug manufacturers? Why has the Medical Council of India not cancelled even a single medical practitioner's licence for unethical practices? Why were senior officials of the CDSCO and the Health Ministry allowed to participate in a meeting organised by an American biopharmaceutical industry lobbying group in the USA in 2019?

The conflict of interest in the regulatory authority is further marred by the lack of access to both physical infrastructure and human resources. For instance, the Mashelkar committee had recommended that there needs to be one drug inspector for every 50 manufacturing units and one per 200 distribution retailers to ensure improved drug regulation.

However, the number of drug inspectors in most states continues to be grossly inadequate. According to an IndiaSpend report released at the end of 2019, there was half the number of recommended drug inspectors in Gujarat and one-third the recommended number in Maharashtra and Punjab. Himachal Pradesh reported a vacancy in 27% of the 22 posts, Karnataka in 53% of the 28 posts and Tripura in 26% of the 23 posts.

Even many of the positions in the CDSCO continue to remain unfilled with 22% or 64 of the 287 positions lying vacant.

The Clock Is Ticking

The CDSCO needs to renounce its practice of hushing up or denying malpractices in the industry before it is rendered completely ineffective and is reduced to a mere figurehead. Cleaning the anarchy in the implementation of drug laws calls for a robust and spirited regulatory body that can curb the existing maladies of spurious drugs, exorbitant pricing and unsafe drug approvals.

Source: Secondary research & media reports

When Will The Law Of The Land Catch Up With Advancements In Technology?

With the flourishing e-pharmacy market in India expected to hit a market size of US $2.7 billion by 2023, we need a well-defined legal regime to ensure safe and secure selling of medications on these online platforms that can truly add value to the consumers.

THE E-COMMERCE SECTOR is witnessing a continued upward trajectory as more and more consumers shift from 'offline' to 'online' markets that spell convenience with a capital C. The unprecedented COVID-19 pandemic and the following lockdowns have proved to be a surprise catalyst that is fuelling an unparalleled surge in online shopping of everything from groceries and medicines to clothes and entertainment.

Reliance Retail has recently picked up a majority stake in the Netmeds e-pharmacy, PharmEasy has merged with smaller rival Medlife while e-commerce giant Amazon also launched its online drug delivery services in Bangalore. 1mg, Practo, Myra and Apollo Pharmacy are the other major players in the market.

Indeed, e-pharmacies had already started making their presence felt even before the outbreak of the novel coronavirus. Now, they are proving to be a boon for the distressed and petrified consumers by facilitating ready availability of medicines – all that you have to do is order the medicines on a virtual platform and they will be delivered to your doorstep via mail, courier or delivery agents.

Apart from ease of access, online pharmacies offer better pricing, lower transaction costs and greater anonymity for consumers. The convenience is a godsend for those who are too old, too sick, have limited mobility or are suffering from chronic diseases. Especially COVID patients and their families find it expedient to order medications off the internet rather than risk venturing outside.

However, like all new things, even e-pharmacies suffer from a downside. Patient safety and privacy issues are marring the horizon.

There is the looming fear that online drugstores may not maintain the quality of medicines or fail to store them properly. It is easy to deceive patients and illegal online

Rules and regulations for the e-pharmacy sector have assumed greater importance in view of the COVID-19 pandemic

pharmacies are thriving across the globe, providing spurious, substandard or even prescription/banned drugs in unregulated quantities, that too, without prescription. For instance, The Anti-Narcotics Cell unearthed the rampant sale of a new chemical drug, MD (chemical 'mephedrone') that was being sourced from online pharmacies without restriction. Then there is the risk of self-medication and re-ordering of drugs on the same prescription, leading to drug abuse and antibiotic resistance.

The Changing Face of E-Pharmacy Regulation

India still does not have a law specific to the online sale of medicines. In the absence of any prescribed rules, e-pharmacies are adopting the rules framed for retail pharmacies under the Drugs and Cosmetics Act, 1940. Actually, the Act does not differentiate between selling goods online and through physical stores. Fact of the matter is that the pre-colonial laws were framed decades before the advent of information technology and fall short of the ground-breaking developments of today!

Taking advantage of the lack of a concrete law for this segment, the brick-and-mortar chemists oppose e-pharmacies at every turn by terming them as illegal.

In 2018, the 'Tamil Nadu Chemists and Druggists Association' filed a writ petition in the Madras High Court, following which the court imposed an interim ban on online sale of drugs until a relevant legal framework is enforced. The ban was temporarily stayed after an appeal. Concurrently, the Delhi High Court also issued a nationwide ban on the online sale of medicines which was then imposed by the DCGI.

However, the owners of online drugstores skirt the ban by adopting a marketplace model and projecting themselves as 'intermediaries' that merely facilitate the online sale and delivery of drugs for registered physical pharmacies. Thereby, these online platforms are covered by the Information Technology Act, 2000. Yet, the virtual pharmacies are cognizant of the need for regulation and try to self-regulate - they framed a Code of Ethics that ensures the highest level of professional standards.

In fact, the stakeholders are well aware that the lack of regulation is causing large investors to shy away from

A clear and comprehensive regulatory network will improve the accessibility and affordability of medicines from virtual platforms. But the draft rules proposal is stalled due to staunch resistance from traditional medical pharmacists

the e-pharmacy sector and keeps it from developing into a major market player in the economy. They tendered a proposal to the Union Government and the Drug Consultative Committee instituted a sub-committee in 2015 under the chairmanship of Maharashtra's ex-Food and Drug Commissioner, Dr. HarshadeepKamble to examine the issue of regulation of the online sale of medicines through e-commerce channels.

Global Best Practices

The USA accords the Verified Internet Pharmacy Practice Sites (VIPPS) certification to pharmacy websites that comply with the defined rules and standards prescribed by the VIPPS program. They also have to be authenticated by the Drug Enforcement Administration for dispensing 'controlled substances' and should adhere to the directions specified by the Food, Drug and Cosmetic Act. The FDA Guidelines further stipulate that a legal, regulated e-pharmacy should have a valid prescription, a physical location in USA and be licensed by the State Board of Pharmacy where it has its operations.

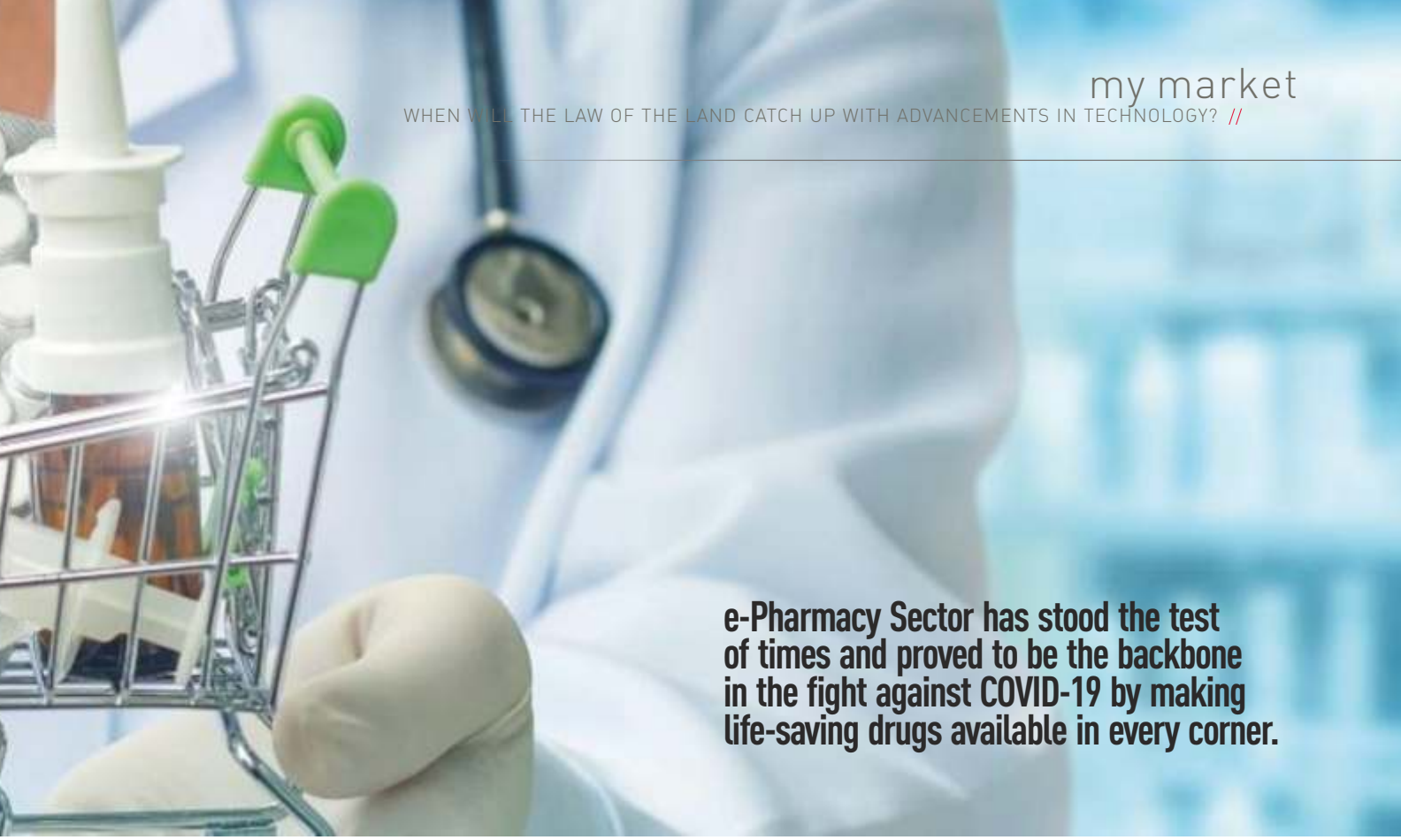
In Canada, licensed e-pharmacies must adhere to the relevant code of conduct within the bounds of its province. The licensing takes place at the provincial level instead of the national level. Therefore, e-pharmacy service providers need to offer offline services with a physical street address to be able to extend the sale of drugs online.

India's Draft Rules for Online Pharmacies

e-Pharmacy Sector has stood the test of times and proved the backbone for fight against COVID-19 in recent times, making life-saving drugs available to every corner of India. A vibrant e-pharmacy remains a vital cog in the implementation of the National Digital Health Mission, and it is a sincere suggestion that the Government should notify the final e-pharmacy rules immediately. Draft e-Pharmacy Rules published as per notification G.S.R 817(E)/2018 dated August 28, 2018) are in addition to but not in substitution of, the existing legal framework of the Drugs and Cosmetic Rules, 1945 under Drugs and Cosmetics Act, 1940 which the existing e-Pharmacies are fully compliant with.

On 28th August, 2018, the MoHFW promulgated an extensive set of draft regulations as an amendment to the Drugs and Cosmetics Rules, 1945 to regulate the online pharmacies. Some of the key proposals include:

- Mandatory registration of e-pharmacy platforms with the CDSCO for a fee of Rs. 50,000. The registration will be valid for 3 years only and renewal will be required if the pharmacy wants to continue operations.
- Compulsory 24x7 customer support facility with a registered pharmacist to respond to customer queries and appropriate grievance redressal in place.
- Drugs must be sold against a cash or credit memo only on compulsory verification of the details of the patient and the medical practitioner mentioned on the prescription. A record of the same must be maintained.
- Sale of drugs enumerated under the Narcotic Drugs and Psychotropic Substances Act, 1985 and Schedule X of Drugs and Cosmetics Rules, 1945 - essentially tranquilisers, habit-forming drugs and psychotropic drugs is prohibited.



e-Pharmacy Sector has stood the test of times and proved to be the backbone in the fight against COVID-19 by making life-saving drugs available in every corner.

- Maintaining confidentiality and non-disclosure of any customer information received through a prescription or otherwise except to the government authorities for public health measures.
- Periodic inspection by the Central License Authority to ensure follow-up with the registration conditions. In the event of non-compliance, the Authority is empowered to suspend or even cancel the registration.
- The State Drug Controllers can decide on consumer complaints pertaining to the sale of adulterated, non-standard or misbranded drugs by e-pharmacies.

Challenges In the Proposed Regulations

The draft rules seem to be silent on the registration of e-pharmacies that operate on the marketplace model. Neither do they clarify how the registered e-pharmacists should verify the details of the patient and the medical practitioner before dispensing prescription drugs from the snapshots of the prescriptions they receive. Nor do they talk about the timespan for which the e-pharmacies must preserve the electronic record of the patients and the medicines procured by them.

The restrictions on internal sharing of customer information and data localisation requirement can also throw up roadblocks in the future. Even the grounds for sharing consumer health information with the government are quite a grey area.

The authorities should step up to the plate and filter out the ambivalence and needless restrictions in the proposed rules to establish a level playing field for both offline and online pharmacies.

A nation-wide framework of Electronic Health Records can reduce privacy concerns regarding healthcare data. Similarly, a system of e-prescriptions issued by healthcare professionals can check the misuse of the prescriptions. Norms should also be put into place to standardize the process of verification. There should also be a clause for imposing a fine or penal prosecution liability on illegal websites selling medicines along with actions for generating consumer awareness among citizens.

Conclusion

It is high time the draft rules are notified and enforced, especially given the traumatic medical demands of the COVID-19 pandemic. The regulated digital sales will increase transparency and price competition in the pharmacy market, that will eventually make medicines affordable for the final consumers.

In fact, in October 2020, the association of Indian internet pharmacies, Digital Health Platforms penned a letter to the Prime Minister Modi to notify the final e-Pharmacy Rules stating that, “A vibrant e-pharmacy sector continues to be a key element in successfully implementing the National Digital Health Mission, and governmental support and motivation to the sector is critical to enable the continuation of service to the nation”.

“To create a national digital health ecosystem that supports universal health coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, that provides a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards based digital systems, and ensures the security, confidentiality and privacy of health-related personal information.”

Source: Secondary research & media reports

Payal Agarwal
Editorial Consultant

Bringing Medical Devices Into The Regulatory Ambit

Regulatory framework for medical devices retrofits them as drugs under the Drugs and Cosmetics Act

THE CASE OF faulty hip implants by the multinational pharmaceutical giant, Johnson & Johnson has been making waves for over a decade. It was way back in 2010 that the company was forced to order a global recall of its Acetabular Surface Replacement (ASR) implants after doctors in the U.K. and Australia reported an extremely high failure rate for the implant.

The metal in the implant was apparently degenerating when the prosthetic ball and socket rubbed against each other. This not only damaged the bone and tissue, but also caused dangerous metals like cobalt and chromium to leech into the bloodstream of the patient.

By then the ASR had already been implanted in around 93,000 patients worldwide. Many of them reported serious adverse reactions like pseudo tumour, metallosis, cysts in the kidneys, pain while walking and general excruciating pain that confined them to the bed. Some even had to undergo revision surgery to replace the ASR implant with another kind.

Australia was the first to take regulatory action based on the higher-than-average replacement rate and removed the implants from the Australian market in 2009. In the USA, the National Institutes of Health in 2014 recommended continued clinical surveillance and laboratory monitoring of patients due to the highest all-cause revision rate of the ASR Hip Resurfacing System among resurfacing brands. By 2013, the company had to announce a $4 billion settlement to cover the claims raised by 12,000 patients in the USA.

In India, these ASR implants were manufactured and sold by Deputy International Limited (DePuy), UK, a subsidiary of Johnson & Johnson. The first red flag was raised by Maharashtra Food & Drug Administration (FDA) when a patient suffered a serious adverse reaction, leading to the CDSCO cancelling the product's import and marketing in 2012. A medical device alert on ASR implants was issued three years after the global recall!

Meanwhile, individual patients filed cases against the company in consumer courts. The matter dragged on for years with the company taking the stand that it had not received any reports of adverse events in India. Even the government maintained a stony silence for years when it came to prosecution and compensation.

It was only in 2017 that the DCGI set up an expert committee of experts to probe the issues arising out of faulty ASRs implanted in an estimated 4,700 Indian patients between 2004 and 2010 as well as review the actions taken by the company to replace the faulty ASR implants and compensation provided to those who had suffered.

Following this, the RK Arya committee devised a formula to determine the quantum of compensation based on the percentage of disability, age and risk factor (ranging between Rs.30 lakh to Rs.1.2 crore) which was approved by the court. However, Johnson & Johnson filed a lengthy rejoinder in court stating that there are no legal provisions by which the government can compel it to compensate. Finally, the pharma major agreed in court to pay Rs.25 lakh each to 67 people who had to undergo revision surgeries.

Isn't this a paltry sum going by the gravitas of the case and the extent of people involved? Has justice really been done to the patients? What's more, the company was literally sitting on the details of 254 more patients who had revision surgery without paying any compensation.

This headline-making case exposed the regulatory loopholes as no prosecution could take place without a legal basis to prosecute intentional wrongdoing in the law. Johnson & Johnson could easily exploit this regulatory deficit and got away without paying most of the suffering population, especially those who suffered health complications without requiring a revision surgery.

Modern healthcare would be incomplete with the use of various medical devices. While these enhance the quality of care, some of them have also been associated with many problems. Ensuring quality, efficacy and safety of medical devices at all levels of the supply chain calls for government regulation. While all medical devices have now been brought into the fold of regulation, does defining them as drugs and extending the same laws actually make sense?

The History of Medical Devices Regulation in India

Medical devices are defined as 'devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals'. The import, manufacture, sale and distribution of notified medical devices are regulated in India under the provisions of the Drugs & Cosmetic Act 1940 and Rules 1945. The regulatory authority is the DCGI under the CDSCO. Only disposable syringes, needles and perfusion sets were notified in 1989 followed by 10 sterile devices in 2005. In 2007, the DCGI formulated a new set of

guidelines for the import and manufacture of medical devices in the country.

These regulations were in the aftermath of the JJ Hospital controversy, where unapproved and untested stents were used on 60 patients. Subsequently, the Mashelkar Committee had recommended the creation of a specific Medical Devices division to address the management, approval, certification and quality assurance of medical devices.

Again, following the embarrassing Johnson & Johnson debacle, the Health Ministry notified the Medical Device Rules, 2017 using the powers under the Drugs & Cosmetics Act, 1940. These rules lay down comprehensive quality requirements and other special regulations to be followed by marketers/importers/ manufacturers/sellers of notified medical devices. An online licensing process was initiated for this purpose. However, even till then only 37 categories of medical devices were notified in the country.

Finally, the MoHFW released the Medical Devices (Amendment) Rules, 2020 to notify that all medical devices sold in the country will be treated as drugs under the Drugs and Cosmetics Act with effect from 1st April, 2020 to ensure they maintain safety and quality standards. The definition of 'drugs' was expanded to include all devices intended for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; diagnosis, monitoring, treatment, alleviation or assistance for any injury or disability; investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining life; disinfection of medical devices; and control of conception. This includes software and accessories covering all wearables boasting health features.

Everything from hypodermic syringes, sutures, staplers, catheters, digital thermometers and condoms to cardiac stents, knee implants, prosthetic replacements and sophisticated machinery for CT scans, MRIs and dialysis are now placed within the framework of the Medical Device Rules, 2017 and will be regulated as drugs for quality control and price monitoring.

Along with this, the government also introduced two changes in the Medical Device Rules - a new chapter for registration of newly notified medical devices by their respective manufacturers and importers and an exemption for the 37 categories that are already regulated/notified medical devices from the requirement of registration introduced by the new chapter.

For the purpose of registration, the manufacturers/importers of the medical devices have to upload the generic name, model number, intended use, class of medical device, material of construction, dimensions, shelf life and brand name on the dedicated online portal called 'Online System for Medical Devices' established by the CDSCO.

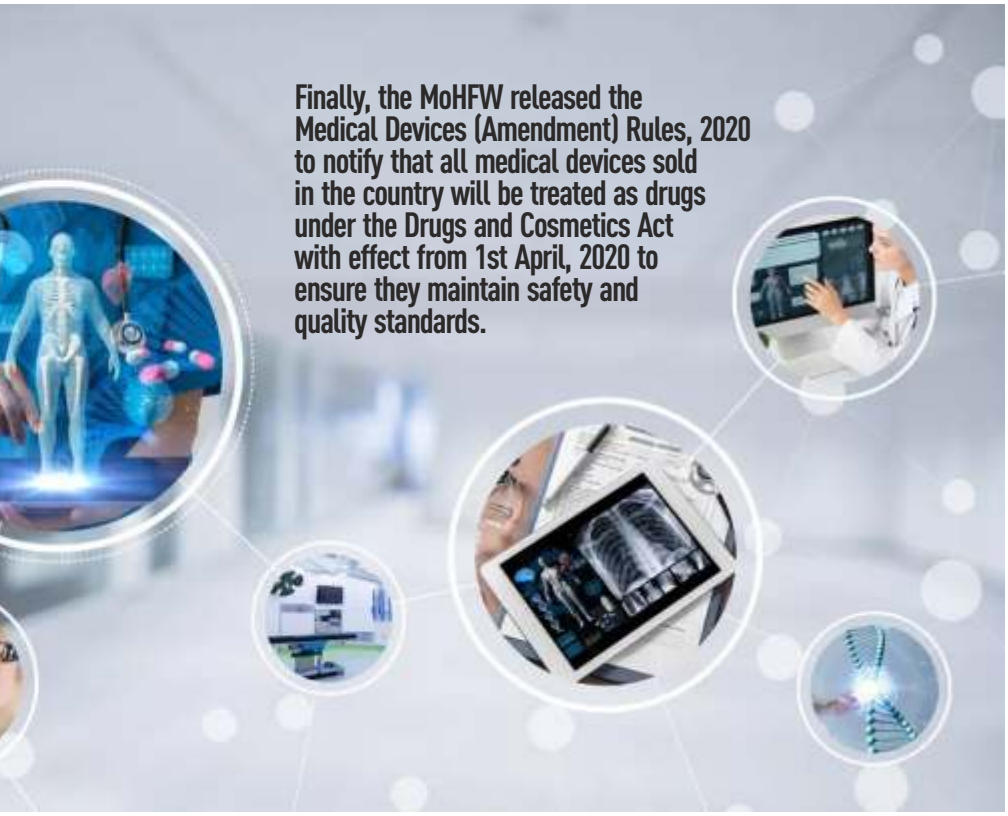
The manufacturers also have to upload the name and address of the company or firm or any other entity manufacturing the medical device along with the name and address of the manufacturing site and certificate of compliance (ISO 13485 standard) accredited by the National Accreditation Board for Certification Bodies or International Accreditation Forum. Once the device is registered, a registration number will be generated which has to be mentioned on the label of the device.

In addition to registration, the manufacturers/importers have to obtain a license from the Central or State Licensing Authority through an online portal. A license is issued only after considerable quality checks. The license holder is required to maintain detailed records of the purchases/sales and ensure traceability in case of a quality or safety-related failure or complaint. The business premises are also subject to periodic inspection. Even the supply chain of medical devices (including marketers) will have to obtain an appropriate license for distribution or retail sale and also observe other compliances stipulated under the rules at all times.

The voluntary registration should be completed within 18 months from April 2020 and manufacturing/import licence should be obtained within 36 months for some devices and 42 months for others. Upon the expiry of these time periods, all provisions of the Medical Devices Rules 2017 will apply to the respective devices.

Medical devices that are not registered before 1st October, 2021 cannot be marketed or sold in India until a registration is obtained. Failure to obtain a license may result in criminal prosecution resulting in imprisonment and fine. Any stock of medical devices that are sold without registration or license could also be confiscated. The CDSCO will be the nodal authority to investigate complaints related to the quality and safety aspects of medical devices and can suspend registration or cancel licences.

Therefore, all medical devices – whether manufactured in India or imported - will now have quality assurance and be subject to oversight from the regulator.



Regulating all medical devices and ensuring they meet certain standards of quality will make the companies accountable for quality and safety of their products.

To address the needs of the industry, the DCGI on 18th April 2021 proactively allowed that in case an existing importer/manufacturer has submitted an application for grant of licence, it shall be deemed valid and the applicant can continue the import/manufacture up to 6 months from issue of the order or till a decision is taken on the said application, whichever is earlier. This is done to ensure supply chain continuity and access to medical devices during the ongoing pandemic, while implementing a smooth transition into the new regulatory regime.

The Looming Drawbacks

Does creating a regulatory framework out of notifications and rules make any sense? The Medical Device Rules 2017 lack penal provisions as the ministry only has the authority to create rules and not new offences or penalties through its rule-making authority. Even though the Drugs and Cosmetics Act contains a penal provision for the manufacture of sub-standard drugs, it cannot be extended to manufacturers of poor-quality medical devices because the Second Schedule to the Act covers only pharmacopeias for drugs.

It follows that manufacturers of substandard medical devices can never be prosecuted under the law. While the regulatory authority can prohibit the manufacture and sale of certain medical devices or cancel a license, there will not be any penalties or prosecution to punish for the harm already inflicted on patients due to negligent/intentional wrongdoing by the manufacturer.

So, will the offenders never be held accountable for their actions? Moreover, owing to the poor surveillance and lack of political will, defective products will be recalled from foreign markets while continuing to be marketed in India.

It's not just about the lack of regulatory teeth under the Act. The authorities should also keep in mind that medical devices are far more complex which makes it much more difficult to standardise them as compared to drugs.

Then again, even if the government wants to deliver justice to those who have suffered from the use of a faulty medical device, how will it get a list of the patients? The devices are mostly sold to hospitals and doctors who may refuse to divulge the patient details because of the fear of legal liability. In the face of the information deficit, many of the patients never even realize that a device implanted in them has malfunctioned and that they have a right to compensation. For instance, in the hip implant scandal, 3600-odd of the patients could not even be traced!

Conclusion

Legally defining medical devices as drugs opens a new minefield as the same regulatory framework will not work here. Rather than riding on animpotent framework, the government should take a targeted approach like enacting a carefully-drafted new law in the Parliament to regulate the unique and complicated issues of the medical device industry. The regulators should engage in an effective dialogue with the stakeholders to develop a robust and dynamic regulatory system to ensure development of safe and efficacious medical devices in India, that will be globally reliable.

As MaliniAisola from the All India Drug Action Network observes, “We urgently need comprehensive reforms to strengthen the regulatory mechanism in relation to patients' safety. These may include guidelines for the approval of devices including clinical investigation requirements, oversight of marketing and promotion, putting in place a robust and functioning system of adverse event reporting accessible to the public, rules for voluntary and statutory recalls, and patient compensation scheme”.

Source: Secondary research & media reports

Fake And Substandard Drugs

– An Urgent And Unresolved Crisis

Spurious, substandard and counterfeit drugs are putting health and lives at risk, not to mention the reputation of the manufacturer and the country. It calls for serious attention and concerted action by strengthening the laws and implementing them efficiently.

IN JULY 2015, the Punjab drug control authorities flagged the sale of hydroxyprogestronecaproate injections - a hormone prescribed to lower the risk of preterm delivery - at just Rs. 10-12 per dose, roughly one fifth of the actual price. A raid on the manufacturer and seller revealed that the medicine was being unscrupulously produced without any active ingredients! Nobody knows how many unsuspecting consumers bought and used the spurious drug expecting it to deliver results, only to be faced with treatment failure. And this is just one of the scores of fake drug peddling cases abounding in the country.

Indeed, what happens when you fall ill, get injured, contract a disease or suffer a serious medical condition? The first recourse is to visit a doctor who will prescribe the required treatment and medications. You purchase the medicines and take them regularly, expecting them to do their job and set you on the path of recovery.

Drugs are lifesaving entities and account for around 60% of healthcare costs. Considering their crucial role in the medical treatment, patients willingly dole out the money in a bid to 'get well soon'.

Now, what if the medicines that you are relying on turn out to be of poor quality, adulterated or even fake? As they will fail to treat the disease for which they were intended, the health condition can get prolonged, cause financial loss to the patient and may ultimately require a new treatment. In the case of antibiotics, this can increase antibacterial resistance too.

Alas, the instruments that are meant to treat the sick and save lives, often end up increasing the risk of illness or even death. Ultimately, there is a loss of trust in the pharmaceutical industry and the health system at large. And the impact on the national clinical and economic burden due to the healthcare failure cannot be stressed enough.

Getting to Know the Menace

Substandard medicines are genuine drugs (either branded or generic) that suffer from poor manufacturing practices, inadequate quality control processes, inappropriate packaging or incorrect storage/contamination due to which they may fail to match the specific quality standards or specifications. The negligence can take the form of incorrect drug formulation or even the presence of impurities that cause the medicine to work less effectively, not work at all or even lead to an adverse reaction and other health consequences.

On the other hand, misbranded, spurious and fake drugs are intentionally designed to appear identical to the genuine product, but the ingredients may not match the label. These are usually imitations of drugs from popular brands - the packaging is slick and cleverly labelled with the names of legitimate companies in a way that makes it difficult to tell them from the original. At times, even time-expired drugs are relabelled and sold in the market. The WHO defines counterfeit medicines to include 'products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging'.

In other words, substandard medicines are a result of unintentional carelessness whereas spurious or falsified ones spring from a deliberately fraudulent and criminal intent. Substandard products can be attributed to lack of expertise, unfair manufacturing practices or insubstantial infrastructure; however counterfeit drugs are a clear case of blackmarketing. But the consequences of both are equally grave in terms of both morbidity and mortality.

In fact, these poor-quality drugs are often grouped together as spurious, falsely-labelled, falsified, counterfeit (SFFC) drugs.

Consumers are not only unaware of the quality or reliability of various medicines, but many actually accept, prefer and buy counterfeit/substandard products over genuine/branded ones because of their cheap price, easy accessibility and availability in the market.

When medicines save lives, can they be allowed to be flawed? Why is a parallel world of fake, misbranded and substandard medicines still flourishing?

The Alarming Incidence

Hardly 1% of the medicinal products in streamlined countries like USA, Canada, Japan, Australia, New Zealand and most of the European Union are counterfeit. On the other hand, Russia, China, India, Brazil, Mexico, Pakistan, Southeast Asian and Middle Eastern countries are considered the hub of fake drugs. According to the 2017 WHO report, around 10.5% of medicines sold in low and middle-income countries, including India, are substandard and falsified.

India happens to be the world's largest manufacturer of generic drugs. But this feat is marred by the fact that it is considered a beehive for SFFC drugs that are not only sold within the country, but also exported

to nearly 200 other countries across the globe.

There are rising concerns about the quality of drugs manufactured in India. www.downtoearth.org.in reports that – 13 of the 38 notices issued by the U.S. Food and Drug Administration (FDA) between January and August 2019 were sent to Indian pharmaceutical companies over issues pertaining to quality, active pharmaceutical ingredient contamination, data management and cleanliness.

Closer home, in June 2018, the Bureau of Pharma Public Sector Undertakings of India reported that 25 batches of drugs from 18 pharmaceutical companies supplying low-cost generic drugs under the Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana since January of that year were found to be of substandard quality.

This kind of prevalence of SFFC drugs not only impinges on the health of the citizens but also mars the credibility of drug products from India.

Driving The Fight Against Poor-Quality Drugs

Section 17, 17A and 17B of the Indian Drugs and Cosmetics Act, 1940 deal with misbranded, spurious and adulterated drugs respectively. Not of Standard Quality (NSQ) products have been further classified into A, B and C categories to aid with the quality evaluation.

The government is constantly stepping up its game with several important initiatives and preventive steps to curb the incidence of SFFC drugs and also ensure public access to quality-assured medicines. For instance, both central and state authorities are instructing physicians and hospitals to prescribe generic medicines as far as possible – these generic formulations offer low-cost and reliable options for many drugs.

The Mashelkar Committee was set up in 2003 to conduct a comprehensive examination of the problem of spurious and substandard drugs in the country. It recommended rigorous measures to strengthen the drug regulatory system at central and state levels. Accordingly, the 2008 amendment instituted more stringent penalties for manufacture and trade of spurious and adulterated drugs, like enhancing the period of imprisonment to a minimum of ten years and extending to lifetime, along with penalty of Rupees ten lakhs or three times the value of the drugs confiscated, whichever is more. The illegal practices related to adulterated and spurious drugs were deemed cognizable and non-bailable. It also provided for the accredited establishment of special designated courts for the trial of such offences. Since then, many additional posts have also been generated to further strengthen the regulatory mechanism.

Prof. Bejon Misra
a consumer policy expert and founder - Safe Medicines India

"Without digitised lists of manufacturers, licenses granted and inspections, annual sampling by the CDSCO is too limited and unstructured. Nor can consumers ask for the name of the licensee for a particular pharmacy, or when the chemist was registered or last inspected."

The CDSCO randomly tests drug samples for ingredients, dissolution, sterility and toxicity among others, as chemical analysis in a laboratory is the only reliable tool for identifying whether a drug is substandard or counterfeit. It publishes monthly drug alerts enumerating the drugs, medical devices and cosmetics that were evaluated and declared as not of standard quality/spurious/adulterated/misbranded. The regulatory authority is further enhancing the central drug laboratories with sophisticated testing equipment and also setting up new laboratories in different parts of the country.

To encourage attentive public participation, a 'Whistle Blower' scheme has been initiated that awards people for providing accurate information on the movement of spurious drugs. When doctors or patients raise a complaint against a drug, the drug controller raids the medicine shop and sends samples for testing. If found lacking on any parameters, the medicine is banned and the DCGI releases a memorandum that the drug is found to be NSQ. In case the manufacturer fails to correct the process or repeats the non-compliance, the product license may be suspended or even cancelled.

A recent notification on the implementation of the Drugs and Cosmetics (Amendment) Rules, 2020 holds both marketers and manufacturers responsible for ensuring quality and regulatory compliances of the marketed drugs in the country.

Not Enough at All

The determined efforts at drug regulation have definitely yielded good results - A series of surveys reveal a falling prevalence of substandard and spurious drugs in the Indian market - from about 9% in 1990s to 4.5% by 2015.

However, any level of spurious or substandard medicines remains unacceptable. Moreover, India continues to be defined by unregistered medicines, lack of transparency in licensing procedures, lenient penalties and inadequate enforcement of laws. It is particularly distressing to see unscrupulous elements having a heyday with spurious drugs and playing with innocent lives even during the ongoing COVID-19 pandemic.

Our punitive laws are grossly inadequate to cover the seriousness of the crime. There is an urgent requirement to create strong regulatory control and monitoring with more rigid regulations, stringent enforcement of laws, efficient vigilance and vigorous legal actions to safeguard the interests of the

consumers at large. Strong, empowered and well-funded national drug regulatory agencies with well-defined policies and requirements can serve as effective deterrents. The FDA in USA with its minimal Good Manufacturing Practice standards that drug makers must strictly adhere to is a case in point.

Moreover, it should be noted that deliberately falsified drugs are considered an alarming threat and legislation is also focused on the control of fake medicines. But it is a fact that poor-quality legitimate drugs are more common and pose a greater threat to patient health. Even the National Drugs Survey 2016 highlights that while only 0.2% to 0.5% of the Indian pharmaceutical market is marred by spurious drugs, substandard medicines happen to be in the range of 8% to 10%!

Another startling reality is that while pharmaceutical companies export high quality drugs to meet the required standards of the importing countries, they flood the domestic market with substandard products that easily meet the subordinate local quality standards. It is also noted that on many occasions substandard drugs have to be recalled from foreign markets, but can be easily sold in India. Lack of political will combined with gross corruption saves the manufacturers from legal prosecution and they often escape scot-free.

Even when some pharmaceutical companies are penalised with short-term suspensions of a single product license, they continue to produce other drugs on their other production lines with the same unscrupulous intentions. To add to this, the timeline of testing samples, issuing lab reports to the authorities, ordering recalls and the orders reaching the retailers takes months, by when countless people would have already risked their lives by using the medications.

Better pharmacovigilance programmes with fast and efficient techniques are the need of the hour. This will facilitate constant monitoring of the safety of different drugs and communication of perilous issues to manufacturers, retailers, healthcare providers and patients in a timely manner.

The government must tighten the noose on SFFC drugs to ensure that public health and safety takes precedence

The authorities are facing numerous loopholes in the process. For instance, we had only 47 drug testing facilities under the National Good Laboratory Practice programme as of 2019. Merely 6 central labs are testing just about 8,000 samples per year. Moreover, only 20 to 30 test laboratories are equipped to decipher whether a drug is counterfeited, substandard or of good quality.

It goes without saying that the laboratories are overloaded. On the other hand, the various state drug regulatory authorities continue to dole out manufacturing licenses. The minimal expansions in testing capacity are no match to the rise in the number of manufacturing units and products.

This is further compounded by the fact that the authorities do not have a consolidated national list of drug manufacturers, their status on Good Manufacturing Practices and total number of licenses granted. Lack of data limits their ability to properly regulate the pharmaceutical sector or even devise a concrete national or state policy in this context.

As Prof. Bejon Misra, a consumer policy expert and founder, Safe Medicines India, an industry watchdog commented, “Without digitised lists of manufacturers, licenses granted and inspections, annual sampling by the CDSCO is too limited and unstructured. Nor can consumers ask for the name of the licensee for a particular pharmacy, or when the chemist was registered or last inspected.”

There is a systemic lack of both infrastructure capacity and manpower. Cases become long-drawn out affairs with hardly any penalties. Convictions rarely, if ever, enter the picture. What we need is more drug inspections, better equipment and additional laboratories.

But what do we actually get? The Mashelkar Committee had recommended death penalty, but this was watered down to life imprisonment. In 2018, the DTAB recommended that the top 300 Indian pharmaceutical brands should mandatorily incorporate an anti-counterfeiting solution – a unique code on each product with SMS-based authentication code. This was made voluntary which has slowed down the adoption process.

The government should carefully conduct surveys and standardized testing to ensure systematic, accurate and transparent collection and documentation of data on SFFC drug manufacture and dissemination. Properly defining the extent of the problem will aid in better surveillance over clandestine activities like manufacture, sale and movement of spurious drugs.

Drug detection technology has to be quickly upgraded. Quality has to be ensured at every stage of the supply chain. Even generic drugs should be tested for quality to ensure proper regulation and safety.

Conclusion

We cannot allow poor quality drugs to compromise public health anymore. An effective and efficient regulatory environment with proper drug quality monitoring is imperative.

Source: Secondary research & media reports

Adv. Srishty Jaura
Editor –
"SPEAK UP!"

The Route Of Clinical Trials For Testing And Approval

Clinical trials link pre-clinical discovery to the use of new medicines and vaccines. After all, we cannot put innocent human lives at risk with untested drugs, no matter how promising they may seem to be. What is needed is fair regulation that will promote clinical research through a transparent process while ensuring the safety and well-being of the participants.

Modern medicines are powerful tools to fight against diseases and ailments. But proper testing and approval is crucial.

THE RIGHT TO Health is a fundamental right of the citizens. It has been enshrined in the Indian Constitution and is recognized by statutory laws as well as international laws. New drugs are constantly being developed by medical research organizations in the fight against both existing and emerging diseases. However, these cannot be directly used on the patients.

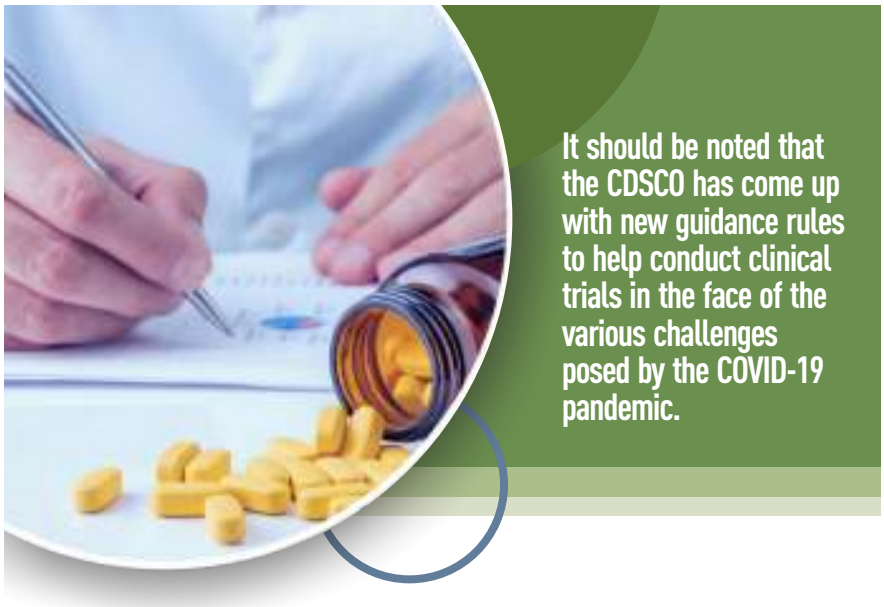
Research into new therapeutic agents entails clinical trials to assess the safety and efficacy of the newly discovered drugs. In the wake of the COVID-19 pandemic, we can no longer turn a blind eye to the potential of clinical research for new therapies, especially in emergency situations.

Yet, clinical trials on human 'guinea pigs' gives rise to many an ethical issues like protecting the rights, ensuring the safety and well-being and maintaining the privacy of the subjects. Informed consent and voluntary agreement of the research participants is crucial. It is equally important that the clinical research organizations should maintain accountability and transparency while conducting trials and release the research details in the public domain.

Regulation in India

The regime for testing and approval of drugs and vaccines is governed by the Medical Council of India Act, 1956, the Central Council for Indian Medicine Act, 1970 and Schedule Y of the Drugs and Cosmetics Rules, 1945 that lays out a set of guidelines and requirements for clinical trials. Considering the looming gaps in the legislation, the ICMR issued the Ethical Guidelines for Biomedical Research on Human Subjects in 2000 followed by the CDSCO releasing the Indian Good Clinical Practice (GCP) guidelines in 2001 in line with the WHO guidelines.

Over the next decade, India emerged as a fertile ground for clinical research due to the lack of language barrier, availability of appropriate infrastructure, relatively lower costs, large pool of patients, diverse ethnic subjects and wide variation of disease which is further topped by the fact that the government itself was keen on facilitating clinical research. More and more foreign pharmaceutical companies were making inroads into the country. However, lack of proper co-ordination between the various regulatory agencies led to as many as 31 new drugs being launched without the necessary approvals between 2008 and 2010.



It should be noted that the CDSCO has come up with new guidance rules to help conduct clinical trials in the face of the various challenges posed by the COVID-19 pandemic.

While multiple regulatory initiatives were introduced over the years mandating registration of clinical trials and research organizations, inspections of the clinical trial sites, pharmacovigilance programme and more, these were actually only stop-gap measures without any clarity or synchronization. 2013 witnessed a major amendment listing out the conditions for the conduct of clinical trials along with providing compensation to victims of the trials.

The prerequisites for conducting clinical trials in India are:

- Permission from the Drugs Controller General of India (DCGI)
- Approval from respective Ethics Committee where the study is planned
- Mandatory registration on the ICMR maintained website

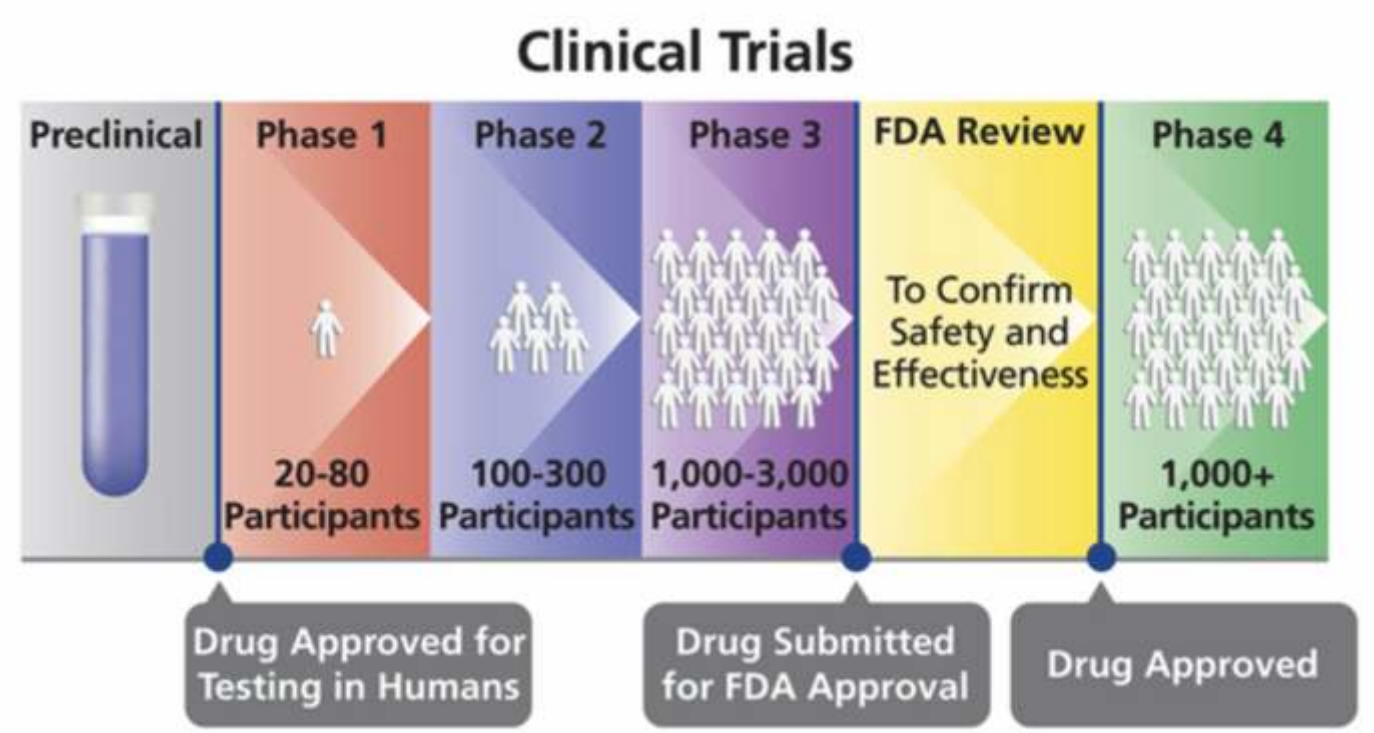
However, clinical trials continued to be badly regulated with ambiguous language, lack of transparency, complicated approval mechanisms and missing compensation for research-related adverse effects. There was a gaping regulatory failure and unethical clinical trials riddled with malpractices were the norm rather than the exception.

Moreover, the biggest problem plaguing clinical research is inadequate informed consent and unethical treatment of human subjects. The harsh fact is that clinical research organizations primarily recruit low-income groups among trial subjects to exploit their ignorance and financial needs. They are persuaded by the monetary rewards and most often, their official consent also goes unrecorded.

The over-hyped instance of the Bill and Melinda Gates Foundation-funded Programme for Appropriate Technology in Health (PATH) violating the norms for conducting the HPV vaccination trials on tribal girls in Andhra Pradesh and Gujarat is a case in point. The government could only halt the unethical trials and issue warnings without imposing any penalties as the Act did not provide any specific penalties for violating provisions relating to clinical trials.

The Wave of Regulatory Change

In March 2019, the MoHFW finally stepped up for codifying the clinical



trial rules by notifying the New Drugs and Clinical Trials Rules, 2019 (NDCT Rules) under the Drugs and Cosmetics Act, 1940 to replace Schedule Y. The primary objective was to address the concerns related to patient safety and compensation in case of clinical trial related injury, disability and death.

The new rules empower the DCGI to decide the compensation in cases of death, permanent disability or other injury to a subject during clinical trials or bioavailability or bioequivalence studies of new drugs or investigational new drugs. The quantum of compensation will be calculated on the basis of the formula specified in the Seventh Schedule of the NDCT Rules. In case of injury, medical management should be provided as long as required as per the opinion of the investigator.

The organization conducting the research is required to set up an Ethics Committee to monitor the trials and coordinate with the regulatory agencies.

The time for approval of applications for clinical trials has been reduced and in case the applicant does not receive any communication from the Central Licensing Authority within the stipulated time, it will be deemed that permission to conduct clinical trial has been granted. A local clinical trial can even be waived for approval of new drugs that have been approved and marketed in certain countries.

However, many loopholes still remain. For instance, it is still difficult to prove that an injury is on account of the clinical trial and this opens the door to manipulation. Even the monopolistic tendencies in clinical research have not been addressed. There is also a need for bridging trials to check drug suitability in the ethnically-diverse population of India.

Moreover, the Drugs & Cosmetics Act is silent on the issue of compensation. Therefore, the compensation formula contained in the NDCT Rules actually surpasses the scope of the Act.

It should be noted that the CDSCO has come up with new guidance rules to help conduct clinical trials in the face of the various challenges posed by the COVID-19 pandemic. While reiterating that patient rights, wellbeing and safety continue to be of paramount importance, the sponsors of any ongoing clinical trials should coordinate with investigators and respective Ethics Committee to decide whether to continue the trial or not in the interest of the trial subjects. It even allowed for protocol amendment, deviation or modification in the procedures of the clinical trials while ensuring the rights, safety and wellbeing of trial subjects, and the integrity of clinical data remaining uncompromised. Records of all changes in the clinical trials, including the reasons for any amendments or deviations in the study should always be maintained.

Conclusion

It is imperative to maintain high standards in clinical research to ensure patient safety and accuracy of data. Only then can we ensure public confidence and participation in the clinical trials while providing for the availability of safe and effective products. Else, the industry will lose its way and we will be left clutching at straws in the pandemics to come!

Source: Secondary research & media reports

Improving Quality Healthcare And Accessibility, Equity And Patient Safety In India

Improving quality of care in the healthcare sector in view of COVID-19

Mr. RAJESH BHUSHAN (IAS)

Union Health Secretary, Ministry of Health & Family Welfare, Government of India has introduced several reforms in the medical regulatory landscape as the Chairman of the Regulatory Reforms Committee. We present an overview of his efforts, directions and opinion based on his comments at the launch of the Monthly Virtual Dialogue Session of Patient Safety & Access Initiative of India Foundation (PSAIIF) on 28th October, 2020.

Multi-Stakeholder Collaboration and Consultation

The one thing that has come into sharp focus while battling the pandemic is that one has to adopt a wholesome approach from within the government, while a wholesome societal approach needs to be assumed from the outside. This strand of thought must guide us while looking at safe and quality healthcare along with access and equity. Multiple Ministries of the Centre and State need to work together in close collaboration. All entities should work in harmony to make any progress. Various stakeholders in the society must jointly come together wherein the government shall be the facilitator, in order to deal with issues in the healthcare sector and also with transparency in healthcare pricing.

Optimal Utilization of Resources

Resources, both in terms of human and capital resources, should not be thought of as a limiting factor. In actuality, the restraining factor is the optimal utilization of such resources. The pandemic has rightly highlighted the scattered allocation of resources in the healthcare sector and the need to optimally utilize our resources.

Digital Infrastructure

While importance must be given to strengthening and augmenting physical infrastructure, attention should also be diverted to digital infrastructure in a way that complements the existing physical infrastructure. These hierarchies of infrastructure are so closely related that one cannot exist in isolation from the other. A unique feature of India is that in any zone of digital infrastructure, particularly dealing with healthcare, the foundation stone is provided by the union government. The private entrepreneurs or promoters can thereafter build on that groundwork.

National Patient Safety Implementation Framework

In 2018, the union government introduced the National Patient Safety Implementation Framework that was extremely comprehensive but fell short of providing an enabling environment across public and private sectors during the implementation phase. It is strongly believed that the introduction of Multi-Stakeholder Consultation will fill the gap in this field of work too.

Uniform Implementation of Government SOPs & Guidelines

The Union Health Ministry issues comprehensive and contemporary documents such as SOPs and Guidelines from time-to-time, for various health facilities both in the private and public sectors – like, on prevention and control of infection. These should be implemented in a uniform manner, particularly at the grassroot levels in the health and wellness centres.

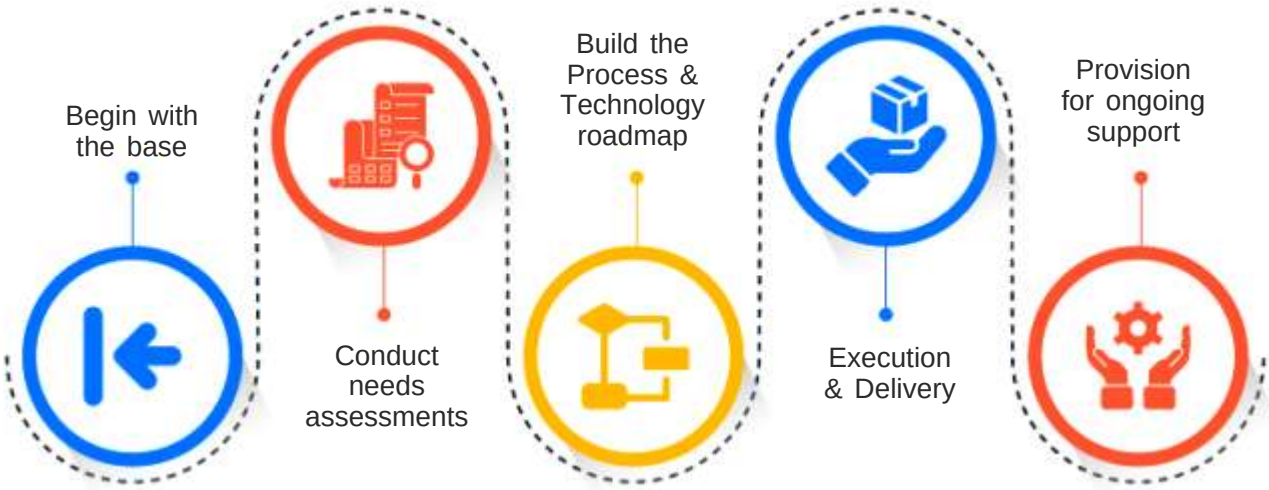
National Quality Assurance Standards

The Union Health Ministry has successfully launched the National Quality Assurance Standards for every single level of healthcare facility in the country to familiarize the concept of Multi-Stakeholder Collaboration that is still to be worked on and taken to its logical conclusion.

Safety of Healthcare Workers

The safety of our healthcare workers such as doctors, nurses, paramedics and the like are of crucial importance as without their safety, the safety of the patients will always remain solely an

The Era of Healthcare Digitalization is Here



objective to be achieved instead of becoming a reality to applaud. This takes us back to the key concept of Multi-Stakeholder Collaboration & Consultation, the target being to orient, reorient and upgrade the skills of our healthcare workers.

National Digital Health Mission - Moving towards Access & Equity

In consonance with the established requirement of physical and digital infrastructure to move in tandem, our Hon'ble Prime Minister recently introduced the National Digital Health Mission on Independence Day. It essentially envisions a digital platform along with a digital ecosystem that would incorporate a Doctors' Registry, a Health Facility Registry, Health IDs for every citizen of the country and a Consent Manager. These registries and consent mechanisms together create an ecosystem that forms the building blocks of a Digital Healthcare System. Individual private entities and promoters can also enter to support and further build on the foundation of the scheme.

It should be noted at this point that healthcare data is extremely critical and valuable. Accordingly, data privacy and security concerns have to be addressed simultaneously wherein, once again, Multi-Stakeholder Collaboration & Consultation becomes necessary because private promoters offer rich experience in the space.

Confluence of Conventional & Classic Medicines

With reference to the physical infrastructure in the healthcare sector, the Government has started looking into the potentially beneficial confluence of conventional medicines like allopathy with the Indian system of medicines. For the first time, during the pandemic, in the space of Standard Treatment Protocol for treating the infection, the GoIchannelled a separate chapter for a protocol on Indian system of medicines.

Before this chapter was formulated, it was decided that any remedy or system of treatment that is incorporated in the Protocol must undergo a rigorous system of trial. To further this, one of the Retired DGs of ICMR was requested to head a Committee of AYUSH doctors to ensure validation in terms of providing scientific and empirical evidence. Similarly, the Post Recovery Protocol that the Union Government issued for COVID-19 also has a separate section for Indian system of medicines which, in reality, is the way forward.

Incidentally, the Government is targeting that by the end of this financial year, the country will have 70,000 health and wellness centres while by December 2022, there will be 1,50,000 health and wellness centres, out of which 48,000 are currently functional. They will be staffed with not only conventional allopathic practitioners but also practitioners of classic Indian system of medicine.

Mahika Dalmia
Asst. Editor

COVID-19 Testing To Vaccines To Cure

- How Are The Regulations Playing Out?

The Indian legal regime has no choice but to expedite the licensing process for testing, importing and manufacturing COVID-19 test kits, drugs and vaccines by processing the applications on a high priority basis. It is equally imperative to ensure that the drugs and vaccines are safe to use. Can the regulatory body balance these two needs?

THE WORLD IS in the grip of the COVID-19 pandemic for the last 18 months and counting. Ever since the SARS-CoV-2 virus that causes upper-respiratory tract illnesses first originated in Wuhan, China, countries have been racing against time to find speedy detection, cure and prevention solutions for this new disease.

The regime for testing and approval in India is governed by the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 that are administered by the CDSCO through the DCGI.

Right from the start of the unprecedented pandemic, the CDSCO has been at the centre of things as it plays out its role of the national regulatory body for pharmaceuticals and medical devices. The DCGI, headed by Mr. V.G. Somani, is responsible for approving licenses for testing kits, drugs and vaccines to fight the COVID-19 disease.

In the face of the emergency situation, the CDSCO is now taking on a dual role – assisting pharma companies in developing drugs and vaccines as quickly as possible on the one hand and ensuring that the regulations are properly followed to ensure safety and effectiveness on the other. It is constantly facilitating faster approvals of applications for vaccines and treatments by setting out shorter timelines.

A Dekko at the Regulatory Pathways

Test Kits - From a regulatory standpoint, testing kits fall under the category of 'in-vitro diagnostic' kits and are regulated as 'medical devices' under the Drugs and Cosmetics Act, 1940 read with the Medical Devices Rules, 2017. Companies that want to develop or manufacture COVID-19 testing kits have to obtain a license from the DCGI to manufacture prototypes for conducting clinical investigations, tests, evaluations, examinations, demonstrations or training. While the license is usually issued within 30 days from the date of the application, the regulator has cut down the approval period to less than 7 days.

Furthermore, the CDSCO is using its discretion to defer, abbreviate or waive off data requirement for clinical performance evaluation on a case-to-case basis. Once the review is cleared, the developer has to again apply for a licence to import/manufacture the test kits for sale or distribution within India. The standard timeframe of 105 days for issuing the license has also been reduced considerably.

The CDSCO's Public Relations Office is providing guidance on the expedited regulatory pathway and accelerated approval process. There are reports of reviews completed within 36 hours, site inspections, completed within a day and approvals granted within 24 hours of a positive evaluation report!

Treatment Drugs – Dedicated research and development efforts are ongoing to both repurpose previously used drugs that show promise and also develop new treatment protocols for the COVID-19 disease. However, an existing drug that has already been approved for the treatment of other diseases is still deemed as a “new drug' and has to be tested again since no scientific data exists to demonstrate the drug's effectiveness on the new disease.

The approval pathway for new drugs is governed by the New Drugs and Clinical Trial Rules, 2019 (NDCT Rules) and the regulator's permission is required at multiple stages of the testing, review and approval of the drug. Getting a license for the manufacture/import of new drugs for the purpose of sale or distribution in India itself can take up to 90 working days.

However, the NDCT Rules provide for an accelerated approval mechanism for drugs intended to be used in life-threatening or serious disease conditions, rare diseases, diseases of special relevance to the Indian scenario or unmet medical need in India, disaster or special defence.

The government is committed to quickly finding effective and safe treatments for the COVID-19 disease. But regulatory roadblocks and uncertainty still persists….

Preventive Vaccines – Biotech companies are steadfastly involved in isolating the SARS-CoV-2 virus, studying its genetic structure and finding the best way to neutralise it. Virus vaccines also require detailed trials before they can hope to get regulatory approval.

Vaccines are considered as drugs and have to comply with provisions of the NDCT Rules that set out the benchmarks and timelines for testing and approval of the vaccines. However, the CDSCO is trying to expedite the trials on the grounds of the unmet medical need by using 'non-standard end-points' which ought to be 'reasonably likely' to predict clinical benefit. It is even waiving off phase III of the human clinical trials (to be confirmed later in post-marketing studies) in case phase II shows 'remarkable efficacy' by achieving an effect relatively close to what is desired.

In April, the DCGI has already watered down the process for foreign vaccines to gain access to the Indian

Fighting with diseases is an ever-evolving frontier of clinical research. Discovery of new drugs and devices is always the way forward!

market by allowing them to skip local clinical trials and apply directly for Emergency Use Authorisation, subject to certain conditions. The authorities are also simplifying the application, documentation and testing requirements as much as possible.

A Dekko at the Fast-Tracked Approvals in the Past Few Months

The DCGI approved the emergency use of the anti-COVID drug, 2-deoxy-D-glucose (2-DG) as an adjunct therapy in moderate to severe cases for aiding faster recovery of hospitalised patients and reducing supplemental oxygen dependence. The regulator had earlier expedited all three phases of the clinical trials in the country.

It has given a quick nod to phase II and III trials of various promising drugs like Molnupiravir from Optimus Pharma that can be administered orally to treat mild and moderate infections.

This was followed by the exemption of foreign-made COVID-19 vaccines from post-approval bridging trials in the country, if they have restricted use permissions from the regulators of US, UK, Europe, Japan or those listed by the WHO for Emergency Use. It has also done away with the need to test every batch of the vaccine at the Central Drugs Laboratory (CDL) in Kasauli.

Even the antibodies cocktail drug (Casirivimab and Imdevimab) has recently got approval for restricted emergency use based on the clinical trial data suggesting that it can reduce risk of hospitalisation and mortality by 70%.

The DCGI has even granted permission to the Serum Institute of India to manufacture the Russian Sputnik COVID-19 vaccine in India for examination, testing and analysis with certain conditions.

While the regulatory body is in favour of relaxing the norms, the government is firmly opposing the industry demands for compulsory licensing provisions and waiver of patent rights to produce vaccines.

A Dekko at the Legal Ambiguity

Yet, the pandemic is highlighting the glaring holes in the Indian drug regime. While the regulations allow for expediting the protocols, they do not provide clear details on how to actually move quickly to ensure the availability of a safe and effective treatment. The processes also call for definite measures to ensure safety and transparency.

For instance, the laws and rules do not set out detailed standards of appropriateness or guide on how to determine appropriate new endpoints or even 'remarkable efficacy'. There is no clarity on which clinical or animal trials can be abbreviated and by how much, which can be deferred and until when, and which can be omitted altogether. Nor do they specify how these decisions will be taken, who ought to staff the committees or provide a direction on ensuring transparency on the committee decisions.

In this national health emergency situation, we need to quickly rush the testing kits, drugs and vaccines to the hospitals. Unnecessary delays need to be eliminated as far as possible. A delayed action can become an Achilles' heel in the fight against the pandemic.

But, in the face of such ambiguity, what if a test is unnecessarily deferred or omitted? We cannot afford to panic and cut corners in the race to achieve quick response times. The need for speed should never ever compromise on the safety of the consumers by approving ineffective, or even worse, unsafe drugs.

Conclusion

The authorities seem to be operating on a reactive approach, when only a pre-emptive and proactive approach can empower us to face the situation head-on and emerge victorious on the other side of the pandemic!

Afterall, we need a cure soon, but not at the cost of safety!

Source: Secondary research & media reports

Where can consumers have their say about policies and legislation, about their needs and requirements, about products and services, about genuine and fraud companies? We provide you the platform to share with our readers your experiences.
Write to us: bejonmisra@consumerconexion.org

Drawbacks In The Provisions From A Public Health Perspective

We need a new law that supports the effectiveness and safety of new drugs in the context of public need.

Medicines are lifesaving entities and play a crucial role in preventive and remedial medical protocols. They need better regulations per se.

THE DRUGS & Cosmetics Act was first introduced to regulate the import, manufacture, distribution and sale of drugs in British India. It was enacted by the Department of Health under the Ministry of Health and Family Welfare after receiving the assent of the Governor General on 10th April, 1940 and came into force on 1st April, 1947.

Today, it is obvious that this colonial-era legislation has outlived its utility. It's not just the industry and consumer organizations that are clamouring for an entirely new law with clearly drafted rules that put effectiveness, safety, rationality and need at the heart of India's drug regulatory system. Even consumers themselves are cognizant of the flagrant snags in the existing legislation.

Is assured access to safe and effective medicines too much to ask?

We are conditioned to rely on medicines to improve our health and maintain our well-being. I pop a pill whenever I feel a headache brewing, drink some cough syrup for sore throat; all my aches and other ailments have a specific drug for them. However, at times, no matter how many tablets I take, they don't seem to work at all. It makes me wonder, is my faith in the medicine misplaced? Or is there something more sinister at work here? Why doesn't the disease or infection go away? It is scary to think that the medicine I ingest may be fake! What if it is doing more harm than good to my body?

My question is – why doesn't the government do anything to correct the maladies plaguing the world of drugs and medicines? Is asking for strict, focused and vigilant legislation too much?

– Kiara Dias, Goa

As a practicing pharmacist for two decades, I don't merely dispense medicines. I have in-depth knowledge and expertise on medicines and am aware of the safety, efficacy and economic dimensions of various drugs. I can confidently advise my customers about the drug dosage, drug-drug interactions, drug-allergy interactions and drug-food interactions.

Make the drug laws more well-defined and aligned with global regulatory requirements

The law should treat us as an important cog in the wheel of healthcare management and prevention of diseases. We have been seeking many regulatory changes to be able to provide a more effective and expanded model of pharmaceutical care. The government has introduced some of these measures now to support the COVID-19 public health emergency efforts. There is a need to push other changes through and also keep them in place even after we are done with the pandemic!

– Palkesh Mor, Surat

The increasing availability of NSQ drugs in the market is quite appalling. How can they escape detection by the regulators? How can we trust the health system when it does not protect us from substandard and fake drugs? The government's competence and expertise is in question now. Given the dismal track record, are the authorities even committed to patient safety?

– Pavan Boorada, Hyderabad

We hear about so many drug recalls in USA and Europe. Why does India still lack a cohesive policy governing the recall of pharmaceutical drugs? Without any effective system of issuing recalls, they are often delayed and become mostly useless.

Why don't we institute some solid checks and measures to catch and punish the violators and save the public from the nuisance of unreliable drugs? Why doesn't the government work on maintaining a national database of errant manufacturers and warn the consumers to be wary of them? What kind of wake-up call are you waiting for? Aren't the drug fiascos playing out in the present health emergency a dire warning of things to come?

– Manoj Sharma, Pathankot

The government's drug procurement policy reeks of drawbacks and loopholes that have been highlighted by domestic and international legal and health experts. The problem of poor-quality drugs is already very serious and steadily growing in India. Left unchecked, it will cause grave damage in the near future.

Even industry stakeholders are pushing for a regulatory overhaul. Are the policymakers game to the challenge of reframing the Drugs & Cosmetics Act?

– Anant Mukherjee, Purulia

Our obsolete drug regulations are hampering governance and creating unnecessary confusion. The regulatory infrastructure is also weak and we lack the capacity to execute even simple laws. The government should streamline the drug regulation in India by increasing central control and also involving the consumers in making the new law. They should also look into extending the regulatory system to cover exported medicines.

– Srinivas Gutta, Machlipatnam

People say that we have the toughest drug legislation that extends to life imprisonment. What we lack is proper implementation that will infuse fear among the errant parties. A comprehensive review will win over lax amendments and should also enhance the ease of doing business in the industry.

– Feroz Sheikh, Lucknow

Source: Secondary research & media reports

SOURCES / REFERENCES

https://nabl-india.org/
https://en.wikipedia.org/
https://www.who.int/
https://www.ncbi.nlm.nih.gov/
https://www.researchgate.net/
https://www.thelancet.com/
https://www.europeanpharmaceuticalreview.com/
https://www.downtoearth.org.in/
https://www.mondaq.com/
https://www.drishtiias.com/
https://scroll.in/
https://www.latestlaws.com/
http://www.pharmabiz.com/
https://journals.plos.org/
https://www.expresspharma.in/
https://www.lexology.com/
https://arogyalegal.com/
https://economictimes.indiatimes.com/
https://www.indiaspend.com/
https://www.businesstoday.in/
https://www.livemint.com/
https://www.firstpost.com/
https://www.athreva.com/
https://blog.ipleaders.in/
https://www.jurist.org/
https://caravanmagazine.in/
https://corporate.cyrilamarchandblogs.com/

National Accreditation Board
for Hospitals and Healthcare Providers

QUALITY COUNCIL OF INDIA
Creating an Ecosystem for Quality

NABH AYUSH ENTRY LEVEL CERTIFICATION PROGRAM

TAKING QUALITY TO OUR ROOTS

NABH
is a constituent board of Quality Council of India (QCI).
It is playing a pivotal role at the National level in propagation, adoption and adherence to healthcare quality standards in AYUSH healthcare delivery systems.

With an objective to bring more light to AYUSH related treatments, the Government of India in 2014, formed the Ministry of AYUSH and consequently brought in the National Accreditation Board for Hospitals & Healthcare Providers (NABH) to start implementing quality healthcare standards for hospitals providing AYUSH treatments as well.

In the recent years, there has been a paradigm shift from allopathy system to traditional healthcare. To support this trend, health insurers have started offering AYUSH treatment covers as part of their health insurance policies. NABH Ayush Entry Level Certification Standards provide an objective system of empanelment by insurance and other third parties. These standards also address the need for quality control and quality monitoring in AYUSH healthcare as required by the Pradhan Mantri Jan Arogya Yojana (PM-JAY) under the Ayushman Bharat Scheme.

NABH AYUSH Entry Level Certification standards are easily downloadable from NABH website.

www.nabh.co
nabh@nabh.co

THE AWARE CONSUMER

India's Most Credible
Consumer Monthly

Save upto 50% on subscription

Subscribe today!

Save ₹3,600/- FOR 36 ISSUES

Please accept my subscription of **THE AWARE CONSUMER**

NAME _____

ADDRESS _____

PH. NO. _____ E-MAIL _____

PAYMENT ☐ CASH ☐ CHEQUE CHEQUE/DD NO. _____

DRAWN ON _____

DATE _____ SIGNATURE _____

No. of Issues	News Stand Price	Discount	You Pay	You Save
12	₹ 2,400/-	20%	₹ 1,920/-	₹ 480/-
24	₹ 4,800/-	30%	₹ 3,360/-	₹ 1,440/-
36	₹ 7,200/-	50%	₹ 3,600/-	₹ 3,600/-

Cheque / DDs should be drawn in favour of **HAMARA CONSUMER DOST PVT. LTD.**
Send your subscription to: The AWARE CONSUMER, F-9, 2nd Floor, Kailash Colony, New Delhi-110048
Contact: 9311044424 • E-mail: bejonmisra@theawareconsumer.in

Posted at Lodi Road HPO, New Delhi on 9-10th of every month
Published on 6th of every month

RNI No. DELENG/2015/67140
REG. NO. DL (S)–17/3523/2017-19