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COMMON CAUSE

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ACCESS TO AFFORDABLE HEALTHCARE GENERIC MEDICINES

And their wider implications for the health of the nation

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COMMON CAUSE VISION

An India where every citizen is respected and fairly treated

MISSION

To champion vital public causes

OBJECTIVES

To defend and fight for the rights and entitlements of all groups of citizens

LIFE-SAVING DRUGS AND DEMOCRACY

What is Needed is Change, not Charity

The road to prosperity is through saving capitalism from capitalists, argue economists Rajan and Zingales.¹ Perhaps nothing represents the distortion of capitalism better than the global drug industry which flourishes on privileges of power such as secrecy, lack of transparency, rule-bending and denial of knowledge to others. Ironically, all this happens in the name of fair play while grave injustice is done to the poor patients who cannot afford life-saving medicines.

"The corrupt version of capitalism...generates economic inefficiencies and social injustice, thereby undermining political support for the free-market-based system..." the authors suggest about what will work for human society. The governments, they recommend, need to fix the rules of the game through the "right dose of regulation and alleviation of social costs." The drug business proves the point by leveraging its dominance at the expense of public interest at a time when health policies are already skewed in favour of the expensive drugs and big private hospitals

The debate takes us to what kind of relationship we want between science and democracy. For instance, democracy deepens when the fruits of modern science reach the last person but then scientific research thrives in an ecosystem which provides a reasonable return on investment. It is on this principle that the global Intellectual Property (IP) regime protects IP-rich industries like the entertainment, ICT, software or pharmaceuticals. Consequently, multilateral agreements under WTO and TRIPS make IP central to the world economy. Even the judiciary is unable to intervene as the new agreements tend to be beyond domestic laws.

According to Doctors Without Borders (or the MSF in French), such agreements follow one-size-fits-all-approach and make healthcare prohibitive for the world's poor. They also severely limit provisions like the use of Compulsory Licenses (CL) which some developing countries use to make unaffordable medicines available to their citizens.³ But in the end, questions like whether a person would live or die become a matter of her country's capacity for negotiations with global fat cats and their glib advocates. India's production of generic medicines is already affected adversely by harmful provisions included in recent trade negotiations between India and EU.

The MSF was given Nobel Peace Prize as a recognition for its work on affordable healthcare for the poorest across the world. In his Nobel acceptance speech, the organisation's President, Dr James Orbinski, put the issue in perspective:

"More than 90% of all death and suffering from infectious diseases occurs in the developing world. Some of the reasons that people die from diseases like AIDS, TB, sleeping sickness and other tropical diseases are that lifesaving essential medicines are either too expensive, or not available because they are not seen as financially viable, or because there is virtually no new research and development for priority tropical diseases...It is also for governments, International Government Institutions, the Pharmaceutical Industry and other NGOs to confront this injustice. What we... demand is change, not charity..."

Obviously, India is not alone in this battle. But our challenges are enormous since a large segment of our population is extremely poor and vulnerable. Even those who are relatively well off can fall below the poverty line due to a single medical emergency. Expenditure on health care is rural India's second most important cause of indebtedness, according to a Parliamentary Standing Committee Report on Health and

Family Planning. The expenditure on medicines constitutes anything between 40 and 80 per cent of the total cost of treatment, the report notes.

The committee also notes that use of the generic drugs, which are substantially cheaper than branded products, need to be promoted both in the public and private sectors to reduce the prices and availability of drugs. It applauds the efforts of the IAS officer Dr Samit Sharma who, as Collector of Chittorgarh district of Rajasthan, transformed the health services by making cheaper, generic drugs available and for building awareness among the people. He has shown that an alternative system is possible. Similar experiments have also worked in many other states.

However, a particularly weak link is the doctors who avoid prescribing generics because of a deep-seated belief that these are inferior in quality. The assumption is that the manufacturers of generic drugs don't follow the same, stringent procedures as their branded counterparts. However, agencies like the Food and Drug Administration (FDA) in the US mandate rigorous tests to prove that the generic drugs are equivalent to the name-brand originals. Incidentally, the Indian pharma companies are among the biggest suppliers of generic drugs in the US.

It is obvious that the doctors' fears can be dispelled by benchmarking the best manufacturing practices and quality control. However, it is shocking that the branded medicines produced by multinationals, which are known to splash big money on brand-building and promotion through incentives to doctors, are also found to be lacking in quality. A recent report of a study on sub-standard and spurious drugs conducted by the National Institute for Biologicals for the National Drugs Standards Control Organisation found many branded medicines to be sub-standard.⁵

Of late, the Medical Council of India has issued new guidelines to doctors after the Prime Minster Narendra Modi said that the government was considering a legal framework for prescribing generic drugs. The All India Drug Action Network (AIDAN), which works on rational and people-oriented drug policies, has been quoted as saying that things are unlikely to change without phasing out all branded drugs except the patented ones. The government has also announced setting up of 3000 Jan Aushadhi stores by the end of 2017 for dispensing cheaper drugs but that is not even half a per cent of the country's total number of chemists estimated to be around 9 lakh.

It is no brainer that the government spending on health-care needs to increase to at least 3 per cent of the GDP. However, the need is to not only to spend more money but also to change the way the money is spent and create innovative institutional mechanisms for delivery of low-cost medicines and health services.

This issue of Common Cause journal discusses the availability and accessibility of low cost medicines for all. The idea is that medicines should not be a luxury and the society and the state must step in if the life-saving medicines cost several times a citizen's earning capacity.

Vipul Mudgal

¹RajanRaghuram G and Zingales L (2003) Saving Capitalism from the Capitalists: Unleashing the Power of Financial Markets to Create Wealth and Spread Opportunity

²RajanRaghuram G and Zingales L (2003) Transitions, the World Bank Newsletter about reforming economies,

July/August/September 2003 • Volume 14, No. 7-9 (http://www.worldbank.org/transitionnewsletter)

³MédecinsSansFrontières. "TRIPS, TRIPS Plus and Doha." July 11, 2011. http://www.msfaccess .org/content/trips-trips-plusand-doha.

⁴http://www.doctorswithoutborders.org/news-stories/speechopen-letter/nobel-prize-acceptance-speech

⁵Can doctors judge best qualities in medicines? By Jyotsna Singh http://www.thehindu.com/sci-tech/health/can-doctors-judge-best-quality-in-medicines/article18447835.ece

THE TRUTH ABOUT GENERICS

What You Must Know

India is known as the 'pharmacy of the developing world', with 25 per cent of the world's generic drugs in terms of volume being produced by the country¹. Medicines produced by generic companies in India are among the most affordable. Our pharmaceutical industry is a major source of generic medicines worldwide. Despite their widespread use, misapprehensions about generics remain. In the following Q&A we have tried to compile some answers from authoritative sources:

Q: What are Generic Drugs?

Generic drugs are essentially an exact chemical replica of their branded counterparts and they function within the body in the same way as a branded drug would. Alternatively, they can be described as a bioequivalent version of the original drug, identical in dosage, form, safety, strength, route of administration, quality, performance characteristics and intended use. The generic versions of drugs become available after the expiration of the patent of the original drug.

Q: Why do Generic Drugs Cost Less?

When a company develops a new drug, they are granted a patent for exclusive use of the same. But after the expiration of the patent other drug manufacturers can also produce the same drug at lower prices because they didn't invest the same amount of money for research & development as the original company would have and thereby they don't have to recover those costs.

Q: Are Generic Drugs Always Cheaper?

Usually. In the United States, however, when a generic drug is first approved and marketed, costs may remain high (although less than the brand name drug) for six months because the Food and Drug Administration (FDA) will give the first generic manufacturer a "180-day exclusivity period". It is assigned to the generic manufacturer who is the first to file an Abbreviated New Drug Application (ANDA)² and has done the additional work to get the generic drug to the market. This exclusivity allows the company to be the first and possibly only - generic on the market for six months. In India, even with high profit margins for some branded generics, they are usually cheaper than the original branded medicines.

Q: Are Generic Drugs as Safe as Brand Name Drugs?

Yes. All drug manufacturers have to conform to the Schedule M, Good Manufacturing Practices, prescribed under the Drugs and Cosmetics Act, 1940. Any drug that fails to meet the specified criterion is recognised as spurious and is prevented from being sold in the market.

Q: Does Every Brand-Name Drug have a Generic Equivalent?

No. New drugs are developed under patent protection, and most drug patents are protected for 20 years.

¹http://www.pharmabiz.com/NewsDetails.aspx?aid=94600&sid=9

²ANDA contains data which when submitted to FDA's Center for Drug Evaluation and Research, Office of Generic Drugs, provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public.

Multiple companies can manufacture and sell generic versions of the brand-name product. However, some drugs may never have a generic because manufacturers may deem these products unprofitable or too difficult to manufacture.

Q: Why do Generic and Brand-Name Drugs Look Different?

Often trademark laws do not allow generic drugs to look exactly like the brand-name drug. However, the generic drug must have the same active ingredients. Colors, flavors, and certain other inactive ingredients may be different, but the effectiveness of the drug remains the same. Also, the same generic drug, made by a different manufacturer, can look different too.³

Q: Do Generics Lead to a Fall in Brand Prices?

Yes, once these generics are allowed, then automatically the price of the branded drugs also reduces because there is an increased competition.

Q: What is a Branded Generic?

Branded generics are just like they sound - generic drugs that have a brand name and a generic molecule. These drugs are developed, either by a generic drug company or the original manufacturer after the patent expires for the original product. This product must be bioequivalent to the innovator and must be physically, chemically, and biologically stable. The branded generic name is proprietary to (owned by) the company. IMS Health⁴ defines a branded generic as: • Prescription products that are either novel dosage forms of off-patent products produced by a manufacturer that is not the originator of the molecule, or • A molecule copy of an off-patent product with a trade name.⁵

Q: Can You Give Some Examples of Branded Generics?

Asprin tablet is a generic and Disprin tablet is branded generic.

Q: Are Branded Generics More Expensive than the Generic?

Branded generics are not always as affordable as a true generic. By sporting a brand name, some consumers may incorrectly assume that the branded generic is a higher quality product than a true generic, but that is not usually the case. While there is some evidence to suggest extremely high profit margins of branded generics, yet they are almost always less expensive than the original branded medicine. In addition, multiple versions of a branded generic may be available, causing differences in the prices of different branded generics.

Q: What is the Difference in Price of Generic Drugs and Branded Drugs?

One of the main reasons for advocating generic drugs by the government was due to the significant price difference between generic and branded drugs. According to a report published in 2010, some price

³https://www.drugs.com/generic_drugs.html

⁴IMS Health is an American company that provides information, services and technology for the healthcare industry. It is the largest vendor of U.S. physician prescribing data; https://en.wikipedia.org/wiki/IMS_Health

⁵https://www.drugs.com/generic_drugs.html

⁶http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/retail-margin-on-generic-drugs-may-be-as-high-as-1000-claims-study/articleshow/58252850.cms

differences in some of the popular drugs under their generic names and branded names were as follows:

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Painkiller

Generic drug paracetamol: Price ₹2.45; Branded drug Crocin: ₹1, Calpol: ₹0.70

Generic *paracetamol* syrup: ₹9.00; Branded Crocin syrup: ₹5.00

Generic diclofenac sodium+ paracetamol: ₹4.4; Branded Diclogesic: ₹9.40

Antibiotic

Generic *Amoxycilin*: ₹13.2; Branded LMX: ₹0, Remox: 38.7

Generic Azithromycin: ₹41.8; Branded Azee: ₹07, Azithral ₹28.55

Vitamin

Generic folic acid: ₹2.8; Branded Folivite: ₹1.8 Generic B-complex: ₹1.8; Branded Becosul: ₹1.0

Cancer Drug

In the case of brain tumours, the current cost of treatment using *Temozolomide* is ₹2.16 lakh for the innovator brand and ₹20,000 for its generic variants.

Again, for *Irinotecan*, which is used in treating a range of cancers including those in the lungs and ovaries, the cost ranges from ₹1.87 lakh for innovator brands to ₹25,000 for the generic ones.⁸ These are just a few examples indicating differences in prices of generic and branded drugs.

Q: How are Generic Drugs Approved?

The Drug Controller General of India (DGCI), under the gamut of Central Drugs Standard Control Organisation (CDSCO) is responsible for the approval of all the drugs, including generic. All drugs are subject to identical statutory requirements, inspections and approvals.

Q: Why should Preference be on Generic Drugs?

One prime reason to popularise generic drugs is to make drugs and medicines affordable for people who cannot otherwise afford the expensive branded medicines and the private hospitals. India has a significantly higher out-of-pocket expenditure by households on health than several other developed and developing countries, with health expenditure causing a major brunt in the household budget. Another reason for the use of generic drugs is to reduce the unethical practices of doctors who deliberately prescribe branded drugs over generic drugs. This could be due to incentives or kickbacks from the pharmaceutical companies. The use of generic drugs will reduce the rising cost on healthcare.

Q: Do Generic Drugs Take Longer to Work in the Body?

No. Generic drugs work in the same way as brand name drugs.

⁷http://www.mapsofindia.com/my-india/society/generic-drugs-in-india-more-awareness-required

http://indianexpress.com/article/india/india-others/12-cancer-drugs-may-come-under-price-control/

⁹http://data.worldbank.org/indicator/SH.XPD.OOPC.ZS

¹⁰http://www.mapsofindia.com/my-india/society/generic-drugs-in-india-more-awareness-required

Q: What are the Advantages of Using Generic Drugs?

The biggest advantage is the price. You can save as much as 90 per cent over the cost of brand-name medications. Generics cost on an average 40 to 60 per cent less than brand-name drugs. That's a real plus for older adults on a fixed income who take numerous medications.

Q: Do Hospitals and Doctors Support Use of Generic Drugs?

Unfortunately, no. Within the US generic drugs account for 88 per cent in terms of dispensed retail prescriptions, according to a 2015 report. The position is similar in a number of European countries. In India, however, the share of generics is merely 8 per cent of the ₹80,000 crore domestic pharmaceutical market.¹¹

Q: Is a Generic Medicine Right For Me and Can I Ask My Doctor To Prescribe Them?

In most cases the answer is yes, but you should always discuss changes in your medication with your doctor or pharmacist first. This includes making sure that you do not have an allergy to any of the inactive ingredients in the generic medicine. The Medical Council of India (MCI) has stipulated that doctors will face action if they fail to adhere to its guideline on prescribing the drugs only in generic names and writing prescriptions legibly. The Medical Council of India (MCI) has stipulated that doctors will face action if they fail to adhere to its guideline on prescribing the drugs only in generic names and writing prescriptions legibly.

Q. In India Why aren't Generic Drugs Prescribed Even Though They are Cheaper and Effective?

There is a lack of awareness among people about generic drugs. Generic drugs have the same chemical composition as branded drugs, but because they are sold under their chemical names, the general public is not familiar with these. For example, for popular branded drugs like Crocin and Calpol, their generic name is Paracetamol. Even doctors are more sure about the availability of the branded drugs rather than the generic ones as there is no advertising and marketing of generic drugs in India. Another reason is that the branded pharmaceutical companies spend enormous amounts on marketing. Their medical representatives bribe doctors with commission on prescription of their products. Hence, the pharma companies brainwash the people with continuous marketing of their branded medicines. The only way to stop this is to educate the people about generic drugs.

Q. How can I Get a Generic Medicine?

Easy — just ask your doctor to write your prescription using the medicine's active ingredient, or, unless your doctor has said that substitution is not permitted, ask your pharmacist to dispense the generic version. The *Jan Aushadhi* programme is an initiative of the government to provide essential medicines at reasonable rates at specially established shops.¹⁵

Q. Where are Generic Drugs Available?

Generic drugs should be available in almost all chemist shops, but they often do not keep a stock of all generic medicines. To buy a generic medicine, the patient has to ask for generic version of a branded drug.

¹¹http://pharmaleaders.tv/the-branded-generics-market/

¹²http://www1.apotex.com/au/products/generic-medicines-faqs

¹³http://timesofindia.indiatimes.com/india/doctors-to-face-action-unless-they-only-prescribe-generic-drugs-mci/articleshow/58314973.cms#

¹⁴http://www.mapsofindia.com/my-india/society/generic-drugs-in-india-more-awareness-required

¹⁵http://www1.apotex.com/au/products/generic-medicines-fags

It is the responsibility of the Department of Pharmaceuticals of the government for promoting generic drugs. But sadly, promotion and marketing have not been done properly or have not been done at all.

Q. What is Jan Aushadhi (JAS) Programme?

To promote affordable drugs, the government had in 2008 set up a scheme called *Jan Aushadhi*, whose objective was to open generic drug stores around the country. The Department of Pharmaceuticals has in 2017 launched a campaign called '*Pradhan Mantri Bharatiya Janaushadhi Pariyojana*' to provide quality medicines at affordable prices to the masses through special *kendras* known as *Pradhan Mantri Bharatiya Jan Aushadhi Kendra* (PMBJK). These provide generic drugs, at lesser prices but equivalent in quality and efficacy as expensive branded drugs. In a recent development, the railway minister has announced the opening of *Jan Aushadhi* stores at railway stations, dispensaries, workshops and on rail premises.

Q. How Many PMBJKs Have Been Opened and What Are Their Locations?

More than 850 PMBJKs are presently functional and spread over 28 States/UTs. List of state-wise/district-wise JAS along with their locations are available under the heading "PMBJK" of the website of *Jan Aushadhi*.

Q.What are the Medicines Available at PMBJKs and Their Prices?

The endeavor of Bureau of Pharma Public Sector undertakings of India (BPPI) is to make available all therapeutic medicines at the PMBJKs. A list of medicines with their MRPs which are presently available are given under the heading "Price List of PMBJP medicines" on the website: janaushadhi.gov.in. More medicines are being added to this list.¹⁹

Q. What Exactly Has Prime Minister Narendra Modi said on Generic Drugs?

Speaking in Surat on April 17, Modi referred to the *Pradhan Mantri Bharatiya Janaushadhi Pariyojana* (PMBJP), which aims to provide cheaper medical drugs to the people. "In the coming days, the government will bring a legal framework under which doctors will have to prescribe generic medicines which are cheaper than equivalent branded drugs, to patients," the Prime Minister said. "...If a doctor writes a prescription, he has to write in it that it will be enough for patients to buy a generic medicine, and he need not buy any other medicine," he added.

Q. Is This a Completely New Intervention?

Not exactly. After seeking approval from the central government, the Medical Council of India — which registers doctors to ensure proper standards of medical practice in the country — had on September 21, last year, notified an amendment in Clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. This clause now reads: "Every physician should prescribe drugs with generic names legibly and preferably in capital letters and he/she shall ensure that there is a rational prescription and use of drugs". The words "legibly and preferably in capital letters" were not there originally. Also, the UPA government had from time to time, issued circulars and instructions to government hospitals and Central Government Health Scheme (CGHS) dispensaries to "prescribe generic medicines" to the "maximum extent possible". ²⁰

¹⁶ http://www.mapsofindia.com/my-india/society/generic-drugs-in-india-more-awareness-required

¹⁷http://ianaushadhi.gov.in/faq.html

¹⁸http://www.newindianexpress.com/nation/2017/jun/13/janaushadhi-outlets-on-railway-stations-hospitals-soon-1616247.html

¹⁹http://janaushadhi.gov.in/faq.html

²⁰http://indianexpress.com/article/explained/cheap-generic-vs-costly-branded-issues-in-picking-right-drug-in-india-4620165/

Q. Have There Been Recent Initiatives in Making Cancer and Other Drugs Cheaper?

Yes, in March 2017, the drug pricing regulator National Pharmaceutical Pricing Authority (NPPA) has slashed the prices of some cancer drugs by up to 86 per cent. The price of a drug called Iressa, which is manufactured by Astrazeneca Pharma India Limited and is used for the treatment of lung cancer, was around ₹29,259, which has now been slashed to ₹3,977. The price of another expensive drug for targeted cancer therapy Biceltis, manufactured by Emcure Pharmaceuticals, which is an antibody used to target cancer cells, has been reduced by over ₹10,000.

Price of chemotherapy drugs like Doceaqualip, manufactured by Intas Pharmaceuticals Ltd, has been reduced by 37 per cent – from ₹16,890 to ₹0,560. Bhupendra Singh, chairman of NPPA said that more cancer drugs will soon come under price control. The price of Dr Reddy's tablet Levin used to treat blood cancer has been cut by 25 per cent. "Apart from cancer, important medicines used in the treatment of diabetes, bacterial infections and blood pressure have been capped by the government, thereby reducing the cost by an average of around 25 to 50 per cent," he said. Since March 2016, prices of around 800 drugs have been slashed by the government.²¹

Q. Is There an Ugly Side to the Manufacture of Generic Medicines in India?

Yes. Though India is now placed fourth in the global generics market, it leads the race in the global burden of counterfeit medicines. At least 75 per cent of all such drugs traces its roots to India, followed not very closely by Egypt (7%) and China (6%). The greed for cashing in on the foreign developed markets has resulted in reputed Indian pharma giants like Ranbaxy, GVK Biohealthcare, Dr. Reddy's Laboratories being proven guilty of submitting fabricated BA/BE (Bioavailability/Bioequivalence) studies to push generics into the international markets. They pleaded guilty in the courts and had to give millions of dollars in settlements. Currently, only 0.01 per cent of the drugs in the Indian market are even tested. Some of the generics are not even tested on basic effectiveness, so they don't even have to put in an active ingredient, which gives retailers sometimes 1,000 per cent profit margins. Due to such lax rules and regulations, substandard, contaminated and sometimes toxic drugs end up even in government generic medicine supplies.²²

Q. What Steps Have the Successive Governments Taken in This Matter?

The government in April 2017 has enacted amendments to the Drug and Cosmetics Act, 1940, making it mandatory for manufacturers to submit BE/BA reports for approval of generic medicines into the market. The earlier regime only required BE/BA reports for generics of those patented drugs approved by the Drug Controller General of India (DCGI) within the first four years of introduction of the original drug. Beyond that no generics manufacturers are required to submit any BE/BA reports to sell their drugs in the markets. Only the finished drugs are sometimes submitted for testing at the Central Drugs Standard Control Organisation (CDSCO) and there is no regulation for ensuring good manufacturing practices presently.²³

Q. What is 'Evergreening'?

Through this mechanism the companies continue to retain their dominant market position by obtaining multiple secondary patents, often by making inconsequential modifications to the original product. Companies as a result are able to protect their product for decades, preventing production of cheaper generic replicas.

²¹http://mumbaimirror.indiatimes.com/mumbai/other/prices-of-cancer-drugs-slashed-by-up-to-86/articleshow/57487124.cms

²²http://www.firstpost.com/india/why-branded-drugs-cost-way-more-than-their-generic-counterparts-3412922.html

Q. Can You Cite an Indian Example?

Yes. The Novartis Vs Union of India judgment had disallowed pharmaceutical companies in India from evergreening their patents. This was a landmark judgment that set an important precedent for the global pharmaceutical industry and sought to improve access to cheaper medicines to people in India. It precluded pharmaceutical giant Novartis AG from "evergreening" their patents.

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Herein, Novartis was denied a patent as the drug that it sought a patent for (Glivec) didn't constitute an 'invention' that was patentable under the Indian law. In effect, patents can only be granted for major innovations, not updates to existing compounds — legitimising domestic manufacturers to make generic versions of drugs at vastly lower costs. It made clear that the patient's well-being supersedes any commercial interests.24

Q. What is Compulsory Licensing?

Compulsory licensing is when a government authorises a party other than the patent-owner to produce the patented product or process, without the patent owner's consent.²⁵ The Indian Patent Office in March 2012 issued its first compulsory license to a domestic generic drug-maker. This decision effectively ended German pharmaceutical company Bayer AG's monopoly over an anti-cancer drug and authorised the production of a low-cost version for the Indian market.²⁶ This is the only compulsory license that has been granted in India so far.

Q. What is the Generic Medicine Pricing Situation in Europe?

With respect to pricing, recent evidence has emerged that European generic medicine manufacturers face competition from Indian manufacturers; that the price level of generic medicines varies substantially between European countries; and that generic medicine manufacturers engage in competition by discount rather than price competition in France, The Netherlands and the United Kingdom (UK). These trends suggest that there may be scope for further reducing the prices of generic medicines in several countries.²⁷

Give a Sense of the Contribution of Generics in the European Pharmaceutical Market

Generic medicines considerably contribute to European drug supply. In most European countries, the market share of generic medicines in volume terms exceeds 40 per cent. In Germany, the biggest pharmaceutical market in Europe, the volume share is much higher and has reached 73 per cent. In the pharmaceutical market in the UK, which ranks fourth in Europe, the generic medicines' volume share was 66 per cent. However, the volume shares differ noticeably among the European countries: In Italy (second largest European pharmaceutical market) it was only 41 per cent, in France (third largest) it was 52 per cent.

That market penetration of generic medicines in terms of volumes varies widely among the European countries is attributable to their different institutional settings and policies to promote generic substitutions or INN (international nonproprietary name) prescribing. The share of generic medicines in value is in most European countries distinctly lower than in volume (except Greece). The discrepancy between volume and value share was largest in Denmark and Sweden.21

²³http://www.firstpost.com/india/why-branded-drugs-cost-way-more-than-their-generic-counterparts-3412922.html

²⁴Supreme Court of India, http://supremecourtofindia.nic.in/outtoday/patent.pdf, accessed on 10 March 2016

²⁵http://economictimes.indiatimes.com/news/politics-and-nation/india-has-right-to-grant-compulsory-licences-under-wtogovernment/articleshow/51517108.cms ²⁶http://www.ictsd.org/bridges-news/bridges/news/india-grants-first-compulsory-license-to-generic-drug-producer

²⁷https://www.ncbi.nlm.nih.gov/pubmed/19450118

²⁸Value of Generic Medicines; Study Report for the European Generic Medicines Association Berlin, 5 October 2015 http://www.progenerika.de/wp-content/uploads/2015/11/IGES-Study-Report_Value-of-Generics_Oktober-2015.pdf

WHEN MEDICINES CAUSE MISERY

Public Health Services - An Overview

Indranil Mukhopadhya*

Every family in India dreads a medical emergency. When a family member falls ill, we pay from our pocketeither we draw from our savings, sell assets or borrow. If one is poor, the options are either to forego care and die, or to get pushed to further destitution due to the costs. Children are taken out of school, women work longer hours to earn a little more, and make do with meagre meal(s). As families cope with health shocks, the vicious cycle of poverty and ill-health continues. Annually 55 million people in the country are pushed to poverty just to meet health bills - this is more than the population of 177 countries.

High Out-of-Pocket Medical Expenses

A health system dependent on household out-of-pocket (OOP) spending and market is iniquitous as access depends necessarily on affordability. Poor and marginalised are typically underserved in such situations. Further, as individuals we don't know the health care requirements for us - a phenomenon known as 'information asymmetry'.

This leads to inefficiencies in the form of irrational care, over-medicalisation and exploitations of various kinds. Moreover, good health is essential for complete development of society, to have capable citizens and a healthy work force - which in turn creates conditions for speedy growth. Moving away from a system dependent on OOP, governments recognise health as a merit good and bear the responsibility of providing health care in most countries. Access to health care is seen as a basic right of citizens. In many countries, tax money is used to provide services directly. In others, healthcare is organised through social insurance.

In India, government bears little more than a fourth (28.6%) of health spending; while households spend more than two-third (67.7%). Public spending on health is particularly low in India compared to many neighbouring countries like Sri Lanka, China, Thailand and Malaysia. All the BRICS (Brazil, Russia, India, China & South Africa) countries spend more than 3 per cent of GDP on health, while spending in India is only 1.15 per cent. Almost entire household expenditure is in the form of direct payments at the time of availing services, which is known as OOP. Households spend very little on purchasing insurance - it remains limited to the richer sections of the society.

Table 1: Health Care Expenditure in India: 2004-05 and 2013-14

Indicators	2004-05	2013-14
Total Health Exp. (THE) as % of GDP	4.2	4.0
Total Govt. Health Exp. as % of GDP	0.96	1.15
Total Govt. Health Exp. as % of THE	22.5	28.6
Household Health Exp. as % of THE	71.1	67.7
OOPE as % of THE	69.4	64.2

Source: National Health Accounts India 2004-05 and 2013-14

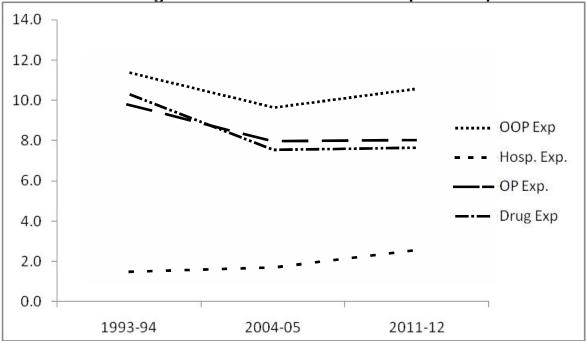
¹National Health System Resource Centre. (2016). National Health Accounts Estimates for India (2013-14). New Delhi: Ministry of Health and Family Welfare, Government of India

Health expenditure causes a major brunt in the household budget. Evidence from the National Sample Survey (2011–12) suggests that on an average, OOP constitutes approximately 6 per cent – 7 per cent of the total household consumption expenditure. This proportion is significantly higher in India as compared to a few developed and many developing countries (Xu et. al, 2003², 2005³, Doorslaer et. al., 2006⁴).

Health Expenditure: Some Figures

Existing studies have indicated that the poor in India are quite often required to borrow and sell off household assets to finance their healthcare needs (Mahal et al. 2001⁵; Peters et al. 2002⁶). As depicted in Figure 1, between 2004-05 and 2011-12, greater part of the household expenditure is being spent on health. A major part of this expenditure is on medicines.





Source: Author's Estimate Based on NSSO Unit Records, Various Rounds

²Xu K, Evans DB, Kawabata K, Zeramdini R, Klavus J, Murray CJL. 2003. Household catastrophic health expenditure: A multicountry analysis. The Lancet; 362(9378):111-7

³Xu K, Evans D B, Carrin G and Aguilar-Rivera. 2005. Designing Health Financing System to Reduce Catastrophic Health Expenditure. Technical Briefs for Policy Makers, Number 2, WHO/EIP/HSF/PB/05.02, Geneva

^{*}van Doorslaer E, O'Donnell O, Rannan-Eliya RP, Somanathan A, Adhikari SR, Garg CC et al. 2006. Effect of Payments for health care on poverty estimates in 11 countries in Asia: An Analysis of households' data. The Lancet; 368; pp.1357-64 *Mahal, A, Singh J, Afridi F, Lamba V, Gumber A, and Selvaraju V. 2001. Who Benefits from Public Health Spending in India? New Delhi: National Council of Applied Economic Research.

⁶Peters DH, Yazbeck AS, Sharma RR et al. 2002. Better health system for India's poor: findings, analysis and options. Human Development Network, Health, Nutrition and Population series. Washington DC: The World Bank.

Expenditures on medicines have historically constituted a significant proportion of OOP, especially in low and middle-income countries (McIntyre *et al.* 2006⁷; Saksena *et al.* 2006⁸; Niens *et al.* 2010⁹). Numerous studies from India also demonstrate that medicine expenditure is a major driver of OOP, and consequent catastrophe and household poverty (Berman *et al.* 2010¹⁰, Karan *et al.* 2014¹¹; Garg and Karan, 2009¹²).

The most recent Indian study found that the poorest 20 per cent of households experienced a faster increase in the proportion reporting any OOP for outpatient care than the better off 20 per cent households. The study concluded that the financial burden of OOP increased faster among the more underprivileged groups, in comparison to their more privileged counterparts (Karan *et al.* 2014¹³). Another Indian study recommends that expenditures on drugs need special focus, expressly for the poor. As depicted in Figure 2, the share of medicines in total household health expenditure is higher among poorer households. This makes a strong case for greater attention towards protecting poorer households from the ill effects of medicines.

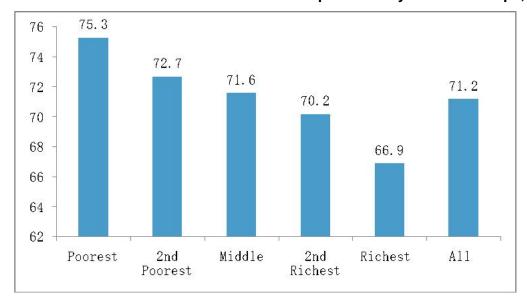


Figure 2: Share of Medicines in Households' OOP expenditure by Quintile Groups, 2011-12

Source: Extracted from Unit Level Records of 68th CES Round, NSSO

⁷McIntyre D, Thiede M, Dahlgren G, Whitehead M. 2006 What are the economic consequences for households of illness and of paying for health care in low- and middle-income country contexts? Social Science and Medicine 2006;62(4):858-65.
⁸Saksena P, Xu K, Durairaj V. 2010. The drivers of catastrophic expenditure: outpatient services, hospitalization or medicines? World Health Report (2010) Background Paper, No 21

⁹Niens LM, Cameron A, Van de Poel E, Ewen M, Brouwer WBF, et al. 2010. Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross Country Comparison of the Affordability of Medicines in the Developing World. PLoS Med 7(8): e1000333. doi:10.1371/journal.pmed.1000333

¹⁰Berman P, Ahuja R, Bhandari L. 2010. The Impoverishing Effect of Healthcare Payments in India: New Methodology and Findings. Economic & Political Weekly EPW April 17, 2010 VOL XLV NO 16

[&]quot;Karan A, Selvaraj S, Mahal A. 2014. Moving to Universal Coverage? Trends in the Burden of Out-Of-Pocket Payments for Health Care across Social Groups in India, 1999–2000 to 2011–12. PLoS ONE 9(8): e105162. doi:10.1371/journal.pone.0105162

¹²Garg CC, Karan AK. 2009. Reducing out-of-pocket expenditures to reduce poverty: a disaggregated analysis at rural-urban and state level in India. Health Policy and Planning 2009;24(2):116-28

¹³Karan A, Selvaraj S, Mahal A. 2014. Op cit.

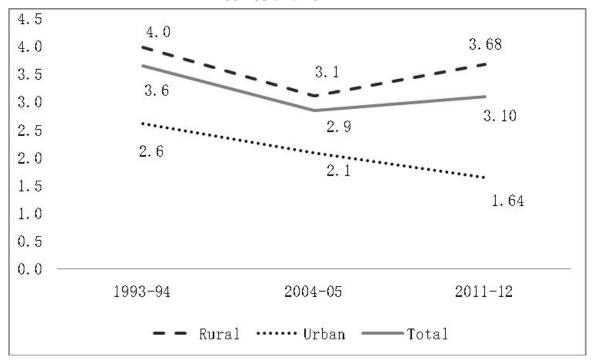
There is adequate evidence to indicate that because of the unpredictable nature of expenses on healthcare, also many non-poor households are plunged into poverty and those who are already poor are pushed further down (known as 'poverty deepening'; Doorslaer *et al.* 2006¹⁴). Using the nationally representative data from the consumer expenditure survey (CES) of the National Sample Survey Organisation (NSSO), Doorslaer *et al.* (2006) and Garg and Karan (2009) report that OOP caused approximately a 3.2 per cent increase in the poverty ratio in the year 2000. Shahrawat and Rao (2011¹⁵) report similar findings with additional information on higher increase in poverty among lower expenditure quintiles of households.

Using the health and morbidity survey data of the NSSO, Berman et al. (2010¹⁶) decomposed the poverty impacts of OOP into inpatient and outpatient expenses separately and reported that increase in poverty due to outpatient expenditure is significantly higher than what is due to inpatient expenditure.

Rampant Poverty in Rural Areas

As per NSSO data there is a considerable increase in impoverishment due to medicines between 2004-05 and 2011-12, particularly in rural areas. In rural areas around 3.7 per cent people fall below poverty line in order to pay for medicines.

Figure 3: Households Falling Below Poverty Line Due to OOP on Medicines (%): 1993-94, 2004-05 and 2011-12



The best way to provide financial protection from OOP on medicine is to provide free medicines from public facilities. Earlier it was a norm that whoever visits a government hospital gets prescribed medicines free. As part of the health sector reforms public spending was cut in the early 1990s. This resulted in sustained neglect of public health services and above all, a gradual withdrawal of medicine

¹⁴van Doorslaer E, O'Donnell O, Rannan-Eliya RP, Somanathan A, Adhikari SR, Garg CC et al. 2006 op cit.

¹⁵Shahrawat R, Rao KD. 2011. Insured yet vulnerable: out-of-pocket payments and India's poor. Health Policy and Planning, doi:10.1093/heapol/czr029, April 12, pp.1-9

¹⁶Berman P, Ahuja R, Bhandari L. 2010. Op cit.

supplies in the government health system, which has driven people away from public services.

People are forced to either access the private retail market for purchasing medicines or to opt out due to financial barriers (Baru 2003¹⁷; Selvaraj 2011; Mukhopadhyay 2012¹⁸). Medicine budgets shrank across the states since the early 1990s with the exception of Tamil Nadu, which recognised the importance of enhancing medicine supplies through the public health system.

Low levels of public spending have correspondingly led to a high OOP on medicines, which constitutes twothirds of total spending on medicines. Across the states in India we find that the share of medicines decreases with the level of monthly per capita expenditure (MPCE).

However, Tamil Nadu remains an important deviation with lowest share of medicines. The OOP on medicines also cause significant impoverishment and intensity and its extent has increased significantly over the decades.

While the evidence is limited, available data from several India states demonstrates significant variations in the availability and stock-outs of essential medicines. For example, a survey of public facilities in Tamil Nadu and Bihar showed that the mean availability of a selected basket of essential medicines for Bihar was about 43 per cent as compared to 88 per cent for Tamil Nadu (Selvaraj, S et al 2011¹⁹).

On the other hand, a study by Cameron et al. noted that the median availability of critical medicines in the public health system was about 30 per cent in Chennai, 10 per cent in Haryana, 12.5 per cent in Karnataka, 3.3 per cent in Maharashtra (12 districts) and 0 per cent in West Bengal.

Several factors can influence the provision and use of essential medicines via the public health system, such as poor and incomplete stocking due to inadequate budgetary support; poor supply chain management leading to frequent stock-outs; prevailing prescription practices leading to inessential and costlier prescriptions for medicines from outside the public health system; and a lack of confidence in the quality of medicines supplied through the public system.

Tamil Nadu Model of Procurement and Distribution of Medicines

The various models of procurement and distribution of medicines and other medical supplies observed in different states of India are a function of the state's prioritisation of the issue, institutional capacity, demography and other factors. The Tamil Nadu Medical Services Corporation (TNMSC) established in 1995 is a model of centralised procurement and decentralised distribution through an autonomous procurement agency.

Though TNMSC has emerged as a model for many states, its replication was beset with hesitation in several states, hampering its full potential. Some state governments, and more recently the Union Government, have recognised the need to ensure availability of medicines through the public system.

¹⁷Baru, R. 2003. Privatisation of Health Services: A South Asian perspective. Economic and Political Weekly, 38(42) pp. 4433-

¹⁸Mukhopadhyay I. 2012. Public Health Care Expenditure in India: a Study of Kerala, Tamil Nadu and West Bengal, JNU, New Delhi, unpublished PhD thesis

¹⁹Selvaraj S, et al. Improving governance and accountability of India's medicine supply system. New Delhi: Public Health Foundation of India;2011

Though several states attempted to duplicate the Tamil Nadu model, only a small number of states could succeed. Kerala and Rajasthan were among the few states which could successfully replicate the Tamil Nadu model in the past three years. Rajasthan has put in place a system of centralised procurement and decentralised distribution with the creation of the Rajasthan Medical Services Corporation (RMSC). Rajasthan has also institutionalised the Chief Ministers Free Medicines Scheme in 2011, to provide access to free medicines in the public health system.

An evaluation study of free medicine initiative in Rajasthan showed that the introduction of the scheme resulted in rapid increase in utilisation of public hospitals (Selvaraj S. et al. 2014²⁰). The study also demonstrates that availability of medicines in all the facilities have increased significantly due to the revamped procurement and distribution system.

As per the results, public facilities in Rajasthan were dispensing on an average 100 essential medicines, while in a CHC (Community Health Centre) and district health facilities, the number of essential medicines are 180 and 300 respectively in the year 2013. While the median percentage availability is about 61 per cent in a PHC (Primary Health Centre), and in a district hospital it is as high as 75 per cent. This is substantially higher than the number of medicines found at PHC or higher levels of public health facilities in other studies.

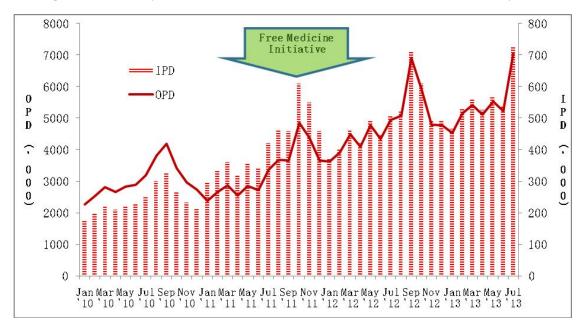


Figure 4: Monthly Trends in OPD-IPD visits in Public Facilities of Rajasthan

Source: Selvaraj S. et al. (2014)

Conclusion

Access to essential medicines is a crucial driver of quality of health care and it is interlinked with access to healthcare. General constraints in access to healthcare affect access to medicines (ATM) and viceversa. Essential medicines play a major role in primary health care performance and medicines

²⁰Selvaraj S, Mukhopadhyay I, Kumar P, Aisola M, Datta P, Bhat P, Mehta A, Srivastava S, Pachauli C. Universal access to medicines: Evidence from Rajasthan, India. WHO South-East Asia J Public Health 2014; 3(3-4): 289–299.

availability is used as a measure of quality of care (Bigdeli et al. 2012²¹).

ATM works as a catalyst in strengthening other components of the health system, and in the process enhances overall system capacity. Results from the Chief Ministers Free Medicines Scheme in Rajasthan show a significant improvement in utilisation of public facilities. Since the introduction of the scheme in 2011 out-patient visits in public facilities in Rajasthan have increased several times (Selvaraj et al. 2014). Rajasthan could achieve this increase in utilisation with an additional annual investment of ₹300 crores, which is less than a tenth of total health budget of the state. On the other hand, in the context of fiscal conservatism and retreat of state from healthcare delivery, Tamil Nadu remains an exception in providing reasonable quality of care, anchored through its ATM initiatives. It has to be noted however, that success of Tamil Nadu cannot be seen only through ATM but as a part of a plethora of other initiatives rooted in a health systems strengthening.

Rather than treating it as a one-off project-based initiative, free medicines initiatives should be institutionalised. Improvement in drug availability must go in tandem with the availability of health workforce. Critical shortages of health workforce, particularly specialist doctors and pharmacists, needs to be addressed. The recent drive to appoint pharmacists permanently at various levels, including at the primary level in Rajasthan, shows that access to medicines puts pressures on governments to strengthen other elements of the system in order to provide good quality of care. The other important element is to make it mandatory for government doctors to prescribe generic medicines. This in itself can do away with a lot of malpractices, where doctors prescribe branded medicines rather than available generic substitutes and in this process push patients to purchase medicines from private pharmacies.

The experience of Rajasthan and other states suggest that there would be a lot of resistance from medical fraternity on compulsory generic prescriptions. The success of Free Medicine Initiatives would depend on how effectively governments respond to such challenges and enhance overall investment in filling critical gaps in service delivery.

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²¹Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, Van Damme W. Access to medicines from a health system perspective. Health Policy and Planning. 2012;1–13. doi:10.1093/heapol/czs108. http://heapol.oxfordjournals.org/content/early/2012/11/21/ heapol. czs108.full - accessed 15 December 2014.

ACCESS TO CHEAPER DRUGS

International Trends & Developments

Shreerupa Mitra*

In May last year, leaked diplomatic cables of internal communications between the officials at Columbian embassy in Washington and their headquarter revealed an interesting fact. These officials feared that their government's decision to produce a generic version of Novartis' cancer drug *Gleevec* could lead to the US withdrawal of financing for the war-torn country's peace process. A staffer with the Senate Finance Committee, which is led by Orrin Hatch, the Republican Senator of Utah, warned Columbia of repercussions if the drug *Imatinib* (sold under the brand name *Gleevec* among others)—that figures in World Health Organisation's (WHO's) Essential Medicines List (EML)—for treating chronic myeloid leukemia was produced in cheaper versions. The drug was unaffordable for most Columbians.

It was reported by the media that Hatch has close ties with the pharmaceutical industry. The Pharmaceutical Research and Manufacturers of America (PhRMA)—the industry's trade group—had spent \$7,50,000 funding an organisation that backed Hatch's re-election in 2012 and donated to the family's charity. One of the senator's son was employed with the lobbying group.

The WHO defines access as having medicines that are "affordable and available" within one hour of walking distance. Lack of access to healthcare, including medicines, is a complex issue that sometimes involves flailing health systems, inequalities within countries, regulatory barriers, discrimination, health insurance and social safety networks, intellectual property (IP) rules and exclusive marketing rights, among other determinants. Though pharmaceutical companies like to point out that crumbling social systems are the cause for patients not getting the medicines they need, but patent laws also play a huge role in achieving this undesired end. It is estimated that even if 95 per cent of the drugs on the EML are unpatented, the five per cent would still be a huge burden for a national health budget. At least a third of the world's population has no regular access to medicines. The ethical argument for drug availability is one that confronts the developed countries as much as the poorer ones.

Not a North/South Issue

On June 23, a bicameral letter addressed to US President Donald Trump, that included the signatures of well-known senators like Elizabeth Warren, Bernie Sanders and Al Franken, said that they were "particularly troubled" that his administration's draft healthcare reform bill "includes policies that, perversely, would make prescription drugs more expensive here and abroad" and gives the pharmaceutical industry "much of what it wants". This is in spite of Trump's declaration that the drug industry "is getting away with murder".

The Trump administration plans to extend the patent life of drugs in foreign markets to "provide for protection and enforcement of intellectual property rights." This will ensure "that American consumers do not unfairly subsidise research and development for people throughout the globe." Foreign governments "pay too little" for medicines, it says. Also, it shows that the Trump administration plans to review and revise all multilateral and bilateral agreements "to promote greater IP protection and competition in the global market".

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This essentially translates to more bilateral and plurilateral trade texts that contain provisions which lie beyond, and even violate international trade laws of the (WTO), as well as arm-twisting weaker nations and generic-producing countries, like India and Thailand, to accept more expansive monopoly protections for biopharmaceutical patents. "Shamefully, the order even blames developing countries and outlines a plan to intensify the patent abuses that already cost lives and entrench unaffordability around the world," Peter Maybarduk, Director, Public Citizen's Access to Medicines Programme, which helps developing countries overcome pharmaceutical monopolies, said in a press statement about the draft reform healthcare bill.

Pharma Industry Invests Hugely in Lobbying, Election-Campaign Coffers

The pharma industry spends twice as much as other business sectors do on lobbying—and the numbers go up every year. The New York Times (NYT), quoting from the Center for Responsive Politics' data says that the pharmaceutical and health products industry has already spent \$78 million on lobbying in the first quarter of this year, a 14 per cent jump over last year, and "has billions in profits on line".

The drugs industry poured more than \$58 million into the election-campaign coffers of members of Congress and presidential candidates in the 2016 election cycle, the Center for Responsive Politics data shows. "That was the biggest investment in the industry's history and a 20 per cent jump from the last presidential election cycle in 2012," says the NYT.

PhRMA increased its dues by 50 per cent this year, which generated an extra \$100 million. The extra cash was used to flood the social media, television and newspapers. Also, ads were used to peg the blame for steep prices on health insurers and other actors to dodge the spotlight on itself.

Lack of Transparency on R&D Drug Spending

Though the Big Pharma argues that the high drug prices are needed for investing in research and development (R&D), there is a complete lack of transparency on how much the industry actually spends on R&D and what percentage goes in advertising.

Advertisement spending on health products in the US was \$5.2 billion in 2016, which is a 60 per cent increase between 2011 and 2015, according to a Stat analysis. Meanwhile, only one antibiotic—Teixobactin—has been discovered in the last 30 years because antibiotics have a low return on investment unlike, say, medicines for blood pressure that need to be consumed on a daily basis. Similarly, there is no investment on "orphan diseases"—that affect small numbers of individuals-- and neglected tropical diseases (NTD) -- that mostly strike poor populations-- for the lack of profitability in such ventures.

Drugs Developed on Public Funding Sold at Exorbitant Prices

Additionally, many pharmaceutical companies develop drugs and vaccines on public funding but sell them at exorbitant prices—something currently being witnessed in the US with the Zika vaccine. Unaffordable for the public, this vaccine was developed at the US' Walter Reed Army Institute for Research, and the Department of the Army funded its development. But now the US Army plans to grant exclusive rights to this potentially groundbreaking vaccine—along with as much as \$173 million in funding from the Department of Health and Human Services—to the French pharmaceutical corporation Sanofi Pasteur. They want a

monopolistic license without any commitment to keep prices affordable, says Knowledge Ecology International (KEI), an award-winning American non-profit that works on patent issues, and had leaked the Columbian diplomatic cables. Sanofi manufactures a number of vaccines, but it has also faced repeated allegations of overcharges and fraud. "It's a familiar, if tragic, pattern: A medical breakthrough is discovered at public expense, only to be licensed to a private corporation that earns billions of dollars by making it unaffordable for ordinary people," Richard Eskow wrote in the Nation on June 20 in the context of the Zika vaccine licensing.

The Fight at Multilateral Forums

The US and some other rich countries, like the United Kingdom (UK) and Japan have taken the pharma lobby's battle to multilateral forums like the WHO, UN Human Rights Council (UNHRC) and the WTO.

At the centre of this battle lies the UN Secretary General's High-Level Panel on Access to Medicines (UNHLP) whose report was released in September 2016. The UNHLP has concrete recommendations for reining-in price-gouging strategies used by pharma companies. Some of these are: WTO members must respect the flexibilities included in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), also in the context of the right to health; that there must be no more undue political and economic pressure from states and corporations on countries who evoke compulsory licenses (CL) to counter 'evergreening' and "other misuse of market practices"; and to create a database of medicines showing how much a brand costs across countries, the dates of expiration of patents and the results of clinical trials.

A CL is evoked when a government allows someone else to produce a patented product or process without the consent of the patent owner. India has used this provision only once in its history to manufacture Bayer's drug Sorafenib Tosylate (Nexavar) used for the treatment of kidney and liver cancer.

"Procurement decisions and generic manufacturing are often delayed by the absence of clear, accurate and up-to-date information on existing and expired patents," the report states.

Developed and Developing World at Loggerheads

The EU, the US, the UK, Japan, among other countries, discredited the UNHLP even before the report could be published, calling it a "flawed premise" of assuming incoherence between IP rights and access to medicines. References to the UNHLP were removed from resolutions during negotiations at the UN, if these countries were to support a text.

India, along with Brazil, Iran, South Africa and some other countries had urged the WHO's powerful Executive Board (EB) in January this year for a discussion on the UNHLP report. It was turned down by the former Director-General Margaret Chan and the EB. It later turned out from leaked emails by KEI that US representatives were opposed to its inclusion as an agenda. Several health activists from across the world were enraged with the decision and wrote to Chan.

The discussion on the UNHLP was then moved to the WTO for discussion. It was also added as a sub-item at the last World Health Assembly (WHA) held in May this year under an agenda item on shortage of medicines, though delegates pointed out that shortage and access to medicines were two separate issues.

"If the EB140 (WHO Executive Board) does not discuss the report, WHO risks losing its leadership on such a vital global health issue. This would be a serious setback to its credibility and integrity, particularly when it

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is trying to justify an increase in its programme budget," an Indian official said at the beginning of the EB meet in January.

India, again, raised the issue with a group of countries a month later during the UNHRC session in March at a general debate on a resolution on the right to health sponsored by India, Brazil and South Africa, among other countries (curiously, India did not join the right to health resolution at the Council's session in June this year).

"It's unfortunate that some members and even WHO are undermining any discussion on the report," India had told the Council in March.

Rich Nations Too Wary of High Drug Prices

However, although the EU as a constituency does not support the UNHLP report, many countries like Netherlands and Portugal, and some other rich nations, are wary of medicines and vaccines being unaffordable for their citizens.

Michael Kirby, a former justice in the Australian High Court and a member of the UNHLP, told the UNHRC on March 8 that at the public hearings of governments, industry, civil society, and patients held in London, Johannesburg and Bangkok during the investigation for drafting the UNHLP report "curiously the voice that was most haunting" was that of an ambassador from the Netherlands.

"Don't assume this is just a problem of poor countries or poor people. This, he said, is a challenge for us all – a challenge for Netherlands, a rich and inventive country. The cost of essential drugs is now excessive for our budget," the Dutch ambassador told the UNHLP members.

"In recent times, the dramatic increase of prices of new and innovative medicines made them unaffordable to large segments of the population also in rich countries while threatening the sustainability of healthcare systems. In too many countries, prices of new medicines (to treat Hepatitis C and cancer, for instance) are particularly shocking," a senior Portuguese delegate told the Council in March.

"A recent study by EY Poland of 30 important cancer drugs found that only 2 of the 30 were routinely available for reimbursement in Poland and the Czech Republic, while 30 of 30 were routinely reimbursed in the Netherlands, and 28 of 30 were reimbursed in Switzerland. In the UK, just half were routinely reimbursed. The 2016 ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe provides additional evidence of the vast disparities in access among 48 countries in greater Europe and Central Asia," Jamie Love, the director of KEI and a well-known American health advocate, wrote in Medium on June 17.

Protest in Spain over High Drug Prices

Salud por Derecho, a Spanish non-profit, launched a campaign called 'Sick, Sick, Sick' in June that has a fake talent show to denounce the high prices of medicines and pharma industry practices. They also wrote a letter with a signature campaign addressed to Farmaindustria- the association of pharmaceutical companies in Spain-- asking them, among other things, to lower the prices of medicines, to cease pricing secrecy, reveal percentage of public funds invested in research, and to stop the barriers for generics' entry into the market.

After the Netherlands assumed presidency for the EU this year the issue of access to medicines has been

gaining some traction. On September 26, members of the European Parliament will host two days of meetings on delinkage, where the proposal for a Cancer Innovation Fund will be discussed.

Canada has also said in UN forums that medicines are becoming too expensive even for their own relatively rich population, though a June 30 decision of the Supreme Court of Canada has made it easier for biopharmaceutical companies to gain patents--perhaps succumbing to years of American pressure.

Outrage Against US Drug Companies

The US-based Interfaith Center on Corporate Responsibility (ICCR) reported that long-term shareholders are "outraged" that major American drug companies, including AbbVie, Amgen, Biogen, Bristol-Myers Squibb Company, Eli Lilly, Gilead Sciences, Johnson & Johnson, Merck & Co., Pfizer, and Vertex Pharmaceuticals, have scuttled shareholders' proposals for greater transparency around excessive price increases on critical drugs. A recent Kaiser poll indicated that 74 per cent of the American public believes that the pharmaceutical industry puts profits before the needs of people. At least 16 American states have introduced legislation calling for greater drug pricing transparency. Some 22 million Americans could lose insurance by 2026 under Trump's health bill to replace Obamacare, a Congressional report says.

Over and above, price gougers are at liberty to raise costs of drugs whimsically— as in the case of Martin Shkreli, who spiked the price of an AIDS and cancer medicine by 5,000 per cent overnight.

Cancer Resolution at World Health Assembly

The fractious nature of the issue of access was exposed, again, recently at a cancer resolution debated at the last WHA (World Health Assembly).

On May 31, the WHA adopted a landmark cancer resolution proposed by Brazil, Canada, Colombia, Costa Rica, France, Netherlands, Nigeria, Panama, Peru, Russia, Thailand and Zambia (India and some other countries later co-sponsored the resolution), to improve prevention, diagnostics, treatment, and implement evidence-based protocol for cancer management, including palliative care for cancer.

Among other things, it asks the UN health agency chief "to prepare a comprehensive technical report to the Executive Board at its 144th session [January 2018] that examines pricing approaches, including transparency, and their impact on availability and affordability of medicines for the prevention and treatment of cancer, and options that might enhance the affordability and accessibility of these medicines".

About 29 civil society organisations and 33 health professionals, activists, and economists, including Nobel laureate Joseph Stiglitz, had written to the WHA for governments to support a feasibility study for progressive delinkage of costs of research and development (R&D) from cancer drug prices, and bringing greater transparency in cancer drugs cost.

This emerged as the most contentious part of the resolution and the text had to be removed due to objection by some governments that included the US and the UK, though European countries like Portugal and France supported the idea.

On May 24, in a side-event at the WHA on addressing access barriers and affordability challenges for cancer medicines organised by KEI, Oxfam and Health Action International, Brazilian deputy permanent representative to the UN Guilherme Patriota said that it is increasingly difficult to get negotiators to agree on anything beyond, malaria, AIDS and tuberculosis, and that "you are dealing with investors directly sitting on

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the decision-making rooms". Patriota said that the final shape of the resolution was not what people had hoped for but it was "a great beginning".

Drugs make \$1 trillion Business

Manon Ress, founder and acting director of Union for Affordable Cancer Treatment (UACT) said that the drug industry is a whopping \$1 trillion business that includes getting \$100 billion from cancer drugs every year. "We are dealing with a beast," Ress said.

In South Africa, the annual price charged by Swiss multinational company Roche in the private sector for *trastuzumab* (T-DM1) is about \$38,365. The few South African public facilities that have been able to procure the medicine have done so at \$15,735 per year. Analysis by health economists, however, has shown a year's worth of *trastuzumab* can be produced and sold for merely \$240 and that includes a 50 per cent profit over the cost of production.

There have been, however, some positive movements recently on the access issue that could potentially strengthen the back of health advocates.

On June 13, South Africa's Competition Commission announced that it has launched an investigation examining alleged over-pricing of cancer drugs by three pharmaceutical giants which includes, Africa's biggest generic drug maker Aspen Pharmacare, Roche Holding and American drug maker Pfizer.

Also, in a rare instance of partnership at the WHO, a proposal by India that the issue of access to medicines be included as an agenda item in the EB for January 2018 was supported by the US. However, a stronger proposal by South Africa that the issue be made a standing agenda item at the WHA – a suggestion supported by many developing and developed nations – "was discarded by the secretariat somewhat abruptly at the end of the discussion today [May 27 at WHA]," reports IP Watch.

Litigations to Keep Medicines Costly

Though the landmark TRIPS agreement allows flexibilities in the way of allowing signatories to tailor national IP regimes so that countries could fulfill their human rights and public health obligations, governments have often found themselves being dragged to courts for exercising these flexibilities.

In Brazil and Argentina, Roche is one of the pharma companies litigating against those governments for their attempts to use TRIPS flexibilities.

Roche holds multiple evergreen patents -- referring to strategies through which pharmaceutical patent owners use the law and related regulatory processes to extend their high rent-earning IP rights particularly over highly profitable "blockbuster" drugs--on *trastuzumab*, indicating market misuse in many parts of the world, including South Africa where its patents could block biosimilars from entering the market until 2033.

Lawsuits in India, Argentina for Slashing Life-Saving Drug Prices

Five lawsuits have been filed in India and Argentina in February alone this year for slashing the cost of lifesaving medicines for treating Hepatitis C. The latest class of antiviral drugs does not merit the 20-year patent monopoly that the drug manufacturers have asked for in the two countries, litigants have argued. The treatment, which runs over three months, currently costs more than the average annual salaries of people from middle-income countries. In another instance, the Delhi High Court in May this year asked the central government to explain the basis on which the Indian patent office has rejected a patent of the University of California's prostate cancer drug Xtandi (the university claims to have invented the drug). Astellas Pharma, a Japanese pharmaceutical company that has marketing rights for the drug, charges Rs. 3.35 lakh for a month's supply.

Generic competition for the drug could drive down prices to well less than \$0.50 cents per pill or about \$2 for a day (from the current rate of \$44.77 a pill), says KEI. "I think the University of California needs to explain why it licenses a cancer drug to a company that charges \$186 per day, in India," Jamie Love said in a blog.

"The high price of Astellas branded *Xtandi* in India is shocking to anyone who thinks cancer drugs should be accessible and affordable, regardless of where you live," reads a letter, written by more than 50 health advocacy groups, including UACT, KEI and Oxfam, to the University of California President Janet Napolitano. Moreover, the university developed the drug with federal funds currently sold in India at an "exorbitant" price.

"Generic competition in India has historically driven down prices and significantly improved access to cancer drugs in India and other countries that are currently sourcing from India, and this will also apply to [Xtandi] as it goes into production and registration," the letter further said.

International activists are hoping that successful litigations in poorer countries may trigger off similar lawsuits in the developed parts of the world.

In June, a petition by Chilean lawmakers asked the government to use CL to lower the high prices of *enzalutamide* (brand name *Xtandi*) and HCV drugs, and ensure affordable access. *Xtandi* costs about \$45,000 per patient per year in Chile, which is three times the average income of \$14,100.

Anti-Consumer Measures

The ongoing negotiations for the Regional Comprehensive Economic Partnership (RCEP)—a massive trade deal between south-east Asian nations and their trade partners—has its IP chapter being closely followed by health advocates.

"There are proposals (in RCEP) for patent extensions, restrictive rules on exceptions to copyright, and dozens of other anti-consumer measures, illustrating the power of right-holder groups to use secret trade negotiations to limit democratic decisions that impact access to knowledge, the freedom to innovate and the right to health, in negative ways," Love had said last year.

Also, the re-started negotiations on India-EFTA (European Free Trade Association) trade deal is making health activists jittery where Swiss negotiators want more extensive patent protection and want to include 'data exclusivity,' a form of monopoly that prevents the marketing of generic formulations, even when a medicine is not patented or no longer patented.

Pressure on India to Wind-Down Generics

"Through this deal, Swiss pharmaceutical corporations are working to erode India's ability to produce and supply generic medicines for people across the developing world," Médecins Sans Frontières (MSF) said in a statement on May 30.

"By pushing for so-called 'data exclusivity,' pharmaceutical corporations are trying to get a backdoor route to a monopoly, even when a drug doesn't merit a patent under India's law," MSF further said urging the

Indian government "to stand strong and reject any provision that will be harmful for people's access to the medicines they need to stay alive and healthy."

These demands which violate WTO rules are called TRIPS Plus provisions. Leading US Congressmen had written to Trump before the visit of Indian Prime Minister Narendra Modi asking him to pressure Modi to remove barriers-- like the "inadequate" protection of IP rights, and "inconsistent and non-transparent" licensing and regulatory practices-- to American trade and investment.

The US Trade Representative's Special 301 report -- a Congressionally-mandated annual report that has been issued every year beginning in 1989—already puts India under its 'Priority Watch List' for its IP regime and directs its chief trade negotiator to hold foreign governments 'accountable' for IP-related trade practices that go against the interests of American innovators and creators. There is tremendous pressure on India both from the US and European countries to wind-down its generic industry.

"The United States is paying too much, and so does everyone else, just not to the degree that the US gets ripped off. What Trump and Modi should focus on is a new trade framework that focuses on sharing the costs of funding research and development as a public good," Love told me during an interview for Firstpost.

Conclusion: All Eyes on WHO

Much depends upon the leadership of the new WHO DG Tedros Adhanom Ghebreyesus and the people he chooses to surround himself with. Margaret Chan was particularly unhelpful with pushing the UNHLP report's recommendations and, therefore, the conversation on enhancing access. Tedros, who goes by his first name, will find himself in a tight spot given the fact that the top two finance-contributing countries to the cash-strapped global health body—the US and Japan-- support the agenda of the Big Pharma. Moreover, 80 per cent of WHO's finances come from voluntary contributions that are often earmarked, like Bill and Melinda Gates Foundation—the second largest financier of WHO when the private sector is counted—who contribute finances for eradicating polio, while assessed contributions from governments that the WHO is free to prioritise are painfully slow to increase.

"The issue before us (access to medicines) is not only a matter of ethics, though it is also that. It is also a matter of law – international law," Kirby told the UNHRC on March 8. He called the UNHLP report "the minimum, prudent package" to address the prevailing global situation of unaffordable health products, shortage of drugs and stimulating innovation systems on delivering drugs for "non-profitable" diseases.

"We will never forget the voices of those who are left behind, many of them women or girls, families forced to beg for charity for patented medicines...," Kirby told the Council. "Unless the world and the UN, and this Council (UNHRC) act now... millions will be left behind and millions will die."

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AFFORDABLE HEALTHCARE AND JAN AUSHADHI SCHEME An Overview

Swapna Jha*

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

A report published in May 2017 by Global Burden of Disease, has revealed that India has recorded a poorer healthcare index as compared to the neighbouring Asian nations of Bangladesh, Bhutan, Sri Lanka and China in the last 25 years.¹

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

First Drug Policy formulated in 1978

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

Jan Aushadhi Scheme (JAS) launched in 2008

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

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

The campaign failed to achieve its desired results. The Parliamentary Standing Committee on Health and Family Welfare, in its 58th report² pointed out the reasons for the scheme's failure, and a few international organisations in their respective studies also arrived at similar conclusions.

http://indianexpress.com/article/india/india-ranks-below-bangladesh-sri-lanka-bhutan-nepal-in-healthcare-index-report-4663079/

Why Did the Scheme Fail to Take Off?

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

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

Pricing of Medicines

From the policy perspective, it raised serious questions regarding the pricing of medicines in the JAS and its overarching goal. Since patients were dependent on physicians for medicine prescriptions with little knowledge of the price variations among branded and generic medicines, the JAS did not provide the cheapest alternative for the patients. Hence, there was a need to urgently review the JAS prices to achieve its goal of providing low-cost affordable medicines. Furthermore, strong supply-side regulations such as prescription audits were necessary to prevent the widespread prescription of costly branded medicines. In the absence of such steps, the JAS policy did not meet its objective of providing low-cost affordable medicines and financial risk protection to households from the cost of medicines³.

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

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

"One of the suggestions put forth before the Committee was to make it mandatory for all doctors to write all prescriptions in generic names only. However, the Committee feels that going for a "generic only" prescription policy has its flip side. Even if the doctor prescribes a drug by generic name, the chemist will be free to dispense any equivalent. Thus the power will shift from doctors to the chemists. The pharma companies would unethically start wooing the chemists instead of doctors. This will be worse than current situation. If the patient does not get any relief, doctor will blame the chemist. Moreover, while the doctor has some interest in the continued patronage from the patients, chemists could not care less. For them profits will be the only criteria of selling medicines." Taking clue from this, immediate steps are required to provide cheaper medicines to the poor people, as envisaged under the government programme.

²Department-related parliamentary standing committee on health and family: welfare fifty-eighth report on action taken by the government on the recommendations/observations contained in the forty-fifth report on issues relating to availability of generic, generic-branded and branded medicines, their formulation and therapeutic efficacy and effectiveness ³Kanchan Mukherjee, A Cost Analysis of the Jan Aushadhi Scheme in India

Major Bottlenecks in Implementation

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

Jan Aushadhi Scheme 2.0

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

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

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

categorisation is as follows:

- **a)** Branded Medicines contain one or more ingredients marketed under brand-names given to them by their manufacturers in India. These are normally promoted to doctors. [In western countries, brand-name medicines are defined differently: the term refers to new drugs developed by the innovator patent holding companies].
- **b)** Generic Medicines are those which are marketed under their chemical/salt names. [In western countries "generic" medicines are defined differently i.e. products that contain the same ingredient(s) as brand-name medicines but are manufactured after the expiry of patents by companies other than innovators. These are marketed under new brand names]
- c) Branded-Generics is an exclusively Indian terminology and refers to branded products [same as category (a) above] but not promoted to the medical profession and marketed through heavy incentives to retail chemists. Obviously such products are unethically and illegally sold either without prescriptions or by substituting prescribed brands.⁴

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

To make matters worse, even the so-called generics typically have specific brand names and the name of the "Active Pharmaceutical Ingredient", although given the prominence required by law under the Drugs & Cosmetics Act, is not popularised in the manner that it should. This state of affairs tends to obscure the fact that true generics have no role to play at present in the Indian drug scene, as was observed by the Task Force in 2005.⁵

Suggestions on Making the Scheme a Great Success

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

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

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

⁴Department-related parliamentary standing committee on health and family welfare; forty-fifth report on issues relating to availability of generic, generic-branded and branded medicine, their formulation and therapeutic efficacy and effectiveness ⁵Task force to explore options other than price control for achieving the objective of making available life-saving drugs at reasonable prices

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

Code of Pharma Marketing Practices

The government has also introduced the voluntary Uniform Code of Pharmaceutical Marketing Practices (UCPMP) released by the Department of Pharmaceuticals in January 2015. This is to be replaced by the mandatory UCPMP. The mandatory code, which is in the preparatory stage, is aimed at making the drug supply chain, involving pharmaceutical companies, distributors, retailers and doctors, accountable to the proposed marketing code. The code will be binding and its violation will attract punishment and penalty under the Essential Commodities Act, the Indian Medical Council Act as well as the Drugs & Cosmetics Act. The seriousness of the government in making medicines available at cheap prices can be gauged by the fact that the drug pricing regulator, the National Pharmaceutical Pricing Authority announced provisional ceiling prices of 761 medicines, including anti-cancer, HIV, diabetes and antibiotics, with a majority being reduced ahead of the GST implementation. It plans to notify them as formal revised ceiling prices immediately after the GST notification. On June 30, 2017, it was clarified that the prices of around 78 per cent of 'actively used' drugs will remain unaffected after the rollout of the GST from July 1, 2017.

Conclusion

The Jan Aushadhi campaign is expected to make a great contribution by way of achieving the socioeconomic goal of affordable healthcare, by ensuring availability of quality drugs at affordable prices for all. The scheme is also expected to reduce expenditure on medicines, thereby extending patient coverage under the public health scheme. Popularisation of the use of unbranded generic medicines will reduce outof-pocket expenses on medicines for the common man, thereby making healthcare affordable and safe. Jan Aushadhi Scheme will prove to be an effective market intervention strategy to bring down the prohibitively high prices of medicines, and will create market for drugs manufactured in Central Public Sector Undertakings (CPSUs), other state PSUs and private sector, particularly small and medium enterprises

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

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GENERIC PHARMA INDUSTRY IN INDIA

Intellectual Property Rights and Global Markets

Prof. T.C. James*

Indian generic pharma industry had in the past been lauded for its yeoman service in providing access to affordable zmedicines throughout the world. This had become possible consequent on the development of the generic pharma industry in India through sustained policy and legislative support by the government over a long period. One of the most significant factors in that has been the innovative patent regime that India had introduced in the 1970s. As in the case of many other developing countries which were under colonial rule for long, India also inherited on its independence in 1947, the Patents and Designs Act, 1911, which was patterned after the Patents and Designs Act 1907 of the United Kingdom.

Commissions & Committees for Pharma Industry

After Independence, the country appointed various commissions and committees to explore ways to develop domestic pharmaceutical industry and also make modern medicines available to people of the country. The most prominent of the committees was the Ayyangar Committee (under the chairmanship of Justice N. Rajagopala Ayyangar) This committee explored the situation in the background of status of pharma industries in other countries. It also went in detail through the draft Patents Bill which had earlier been introduced in the Parliament. On the basis of the committee's recommendations, the Parliament enacted the new Patents Act, 1970. The most significant aspect of this act was that it had extended only process patents to pharmaceuticals and food products and that too for a period of seven years only. The new act was brought into force in 1972. The next three decades saw the phenomenal rise of the generic pharma industry in India.

Patent Protection

Manufacture and sale of generic drugs become possible when the original product is not protected by a patent. Since, as per the Patents Act, 1970 (till its amendment in 2005), pharmaceutical products could not obtain a product patent in India, the Indian companies which were at a nascent stage, could manufacture new generic drugs by finding out their chemical composition through reverse engineering. They could also export their products to those countries, particularly in Asia and Africa, where also most of these products did not have any patent protection. Further, since in those days, period of patent protection even in developed countries was for 14 years only, the medicines came out of the patent regime faster and the Indian generic industry found good market in the developed countries also.

Share of Generics in Global Market

Today, about 50 per cent of all the drugs in the global market are generics. About 88 per cent of the prescriptions dispensed in the United States in 2014 were generics.¹ In India, the 'branded generics' account for 90 per cent of the rupees one lakh crore pharmaceutical market.² India accounts for 20 per cent of global exports in generics.³ Countries have separate legislations for regulating them, like the Hatch-Waxman Act, 1984 of US. Governments have been attempting to popularise more generics because of the high cost of the 'branded' medicines. The difference is clear when one realises that although generics

http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf

²http://www.business-standard.com/article/economy-policy/govt-s-generic-push-will-dent-rs-90-000-cr-branded-pharma-market-117042400066_1.html.

³https://www.ibef.org/download/Pharmaceutical-January-2017-D.PDF

account for 50 per cent of all medicines, the value in financial terms of these is only about 17 per cent. As per the Generic Pharmaceutical Association, generic drugs were responsible for \$254 billion savings in health system in 2014, reflecting the price advantage. The transnational pharmaceutical industry, however, was and still is not happy with the growth of the generic industry. There have been sustained efforts by the industry to push for delays in the entry of generics. The most potent of the tools for this is the patent, since patent rights exclude all competitors, even independent researches resulting in an identical or similar product. Many of them developed in regimes which had provided favourable conditions either through nongrant of patents to foreign inventions or, in certain cases, to pharmaceutical products. Now the approach of big pharmaceutical firms has been towards extension of the monopoly rights, both spatially and temporally.

Intellectual Property Rights (IPRs)

Intellectual Property Rights (IPRs), which include, among others, patents, trademarks, industrial designs, copyrights, geographical indications and so on, were within the remit of the World Intellectual Property Organisation (WIPO) based in Geneva. The agreements and conventions of WIPO were not directly impacting trade and commerce and had limited enforcement provisions and also provided very wide flexibilities in their implementation to the countries. The General Agreement on Tariffs and Trade (GATT) was the one which was regulating trade and commerce. The only provision under this agreement that affected Intellectual Property (IP) was the one relating to protection of geographical indications. While this protected many denominations of wines and spirits and also some food items, it did not affect pharmaceutical products. Towards the end of the Tokyo Round of GATT negotiations (1973-79), the US proposed a plurilateral agreement on trade in counterfeit goods, a trade mark issue but limited to border measures. However, the proposal did not receive general support and was not adopted. The Uruguay Round of negotiations commenced in the year 1986. The pressures of the pharmaceutical industry for inclusion of IPRs within the negotiating mandate were intensified.

Meanwhile, the US was losing international competitiveness in manufacturing and service industries. At the same time, it was leading in research outcomes and, therefore, enhanced IP protection throughout the world was in its interest. Countries like Switzerland and Japan who also had large research-based industries also joined the US in pushing for inclusion of IPRs in the GATT negotiations. The concerted efforts of these countries and international lobbying of big corporations finally led to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1994, at the time of the conclusion of the Uruguay Round. 5 This comprehensive treaty covering almost all IPRs was included as one of the basic treaties of World Trade Organisation (WTO) with mandatory dispute settlement mechanisms and detailed enforcement provisions. The pressures from the industry that 14-year patent period was not sufficient for them to recoup their research expenditure, particularly for pharmaceuticals where the drug approval process was time-consuming leading to introduction of the new drugs in the market much later than the commencement year of the patent, led to the extension uniformly across all countries and technologies to a 20 year patent protection regime. The TRIPS Agreement also provided for patents for all inventions across technology and for both products and processes. Developed countries had a one-year window to make their IPR regimes TRIPS compliant and developing countries a 10-year window. From January1, 2005, all WTO member-countries, with the exception of the least developed countries, had to have IPR laws and enforcements which were as per their obligations under the TRIPS Agreement. The new regime has resulted in many constraints on the generic industry in India which had thrived under the special regime that was in existence since 1972.

Huge Challenge for Developing Countries to Access Affordable Medicines

A major concern of developing countries like India during the TRIPS negotiations was access to medicines. The newly patented medicines were always highly priced and were beyond the reach of common people in almost all these countries. With inadequate public healthcare systems and virtual lack of any social security or insurance, the ordinary people in these countries would find it difficult to access medicines was the fear of the negotiators from these countries. These concerns were addressed in the TRIPS Agreement through various provisions. The articles on objectives and basic principles specifically stated that the protection and enforcement of intellectual property rights should be "in a manner conducive to social and economic welfare, and to a balance of rights and obligations" (Article 7), and that members may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development" (Article 8). It also recognised that "appropriate measures may be needed to prevent the abuse of intellectual property rights by right holders" (Article 8). It also included provisions which have come to be generally known as TRIPS flexibilities.

Doha Declaration

Although the TRIPS Agreement incorporated flexibilities, which included compulsory licences, specifically to address public health crises, when countries initiated steps for exercising those flexibilities, doubts were raised by pharmaceutical companies over the same. This led to restatement of the public health provisions in the Doha Declaration on the TRIPS Agreement and Public Health (2001), which stated in unambiguous terms that "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health", and that the "Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." It also made special provisions for countries that do not have manufacturing capacity in pharmaceuticals to avail of those facilities in other countries under the Compulsory Licence provisions. This declaration has made it possible for the generics to enter the access to medicine area in certain circumstances. However, the provisions have been used in a very limited number of cases by developing countries.

Envisioning Access-Oriented IP Strategies

Some of the challenges in the IPR area that the generic industries are facing are increased pressure by big pharmaceutical companies who generally thrive on new innovative drugs, on governments to introduce certain provisions which are beyond the mandate of the TRIPS Agreement, usually referred to as the TRIPS plus provisions in the IPR, and drug regulations and use of litigation as a pressure strategy on generic pharmaceutical manufacturers. Some of the major pressure areas for India in this case are: (a) easing of patentability norms to provide for patents for minor improvements, (b) introduction of data-exclusivity regime for clinical trial data, (c) non-use of the Compulsory Licence and similar pro-public health provisions in the Patents Act, and (d) patent linkage. We may explore how these provisions affect the pharmaceutical industry in India and access to medicines. The TRIPS Agreement does not get into any elaborate definition of the patentability of an invention. It incorporates the general norms of the Paris Convention on Industrial Property (1883) that an invention should satisfy the criteria of novelty, inventiveness and industrial application. That means the exact contours of inventiveness are left to national legislations. The Indian Patents Act provides that inventiveness is a "feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art." [Section 2(1)(ja)]. When, in 2005, India amended the Patents Act

to provide for product patents for pharmaceuticals, in order to prevent patenting of minor innovations, a provision, essentially a clarification on patentability, was added to the then existing Section 3(d) to the effect that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" will not be eligible for a patent. This coupled with the already existing provision to the effect that the mere discovery of any new property or new use for a known substance was meant to prevent 'evergreening' of a pharmaceutical patent.

Evergreening and Its Impact

The practice of evergreening is that of obtaining a patent for a minor enhancement or a new use of the patented product, when the patent period is about to expire. Since mostly it is a product patent, this prevents manufacture of generic versions, although the patent on the original invention has expired. This phenomenon is mainly in the area of pharmaceuticals because of the particular nature of the market. Unlike in the case of ordinary consumer goods like a refrigerator or a television set or a mobile phone handset, the decision on which a particular medicine should be purchased by the customer (patient) is made by a third party, that is, the prescribing physician. Ordinarily, a physician is not bound by the affordability of the patient; he is concerned about prescribing the latest or what is perceived as the most effective medicine in the market. Secondly, if it is a new use or a new property, the product remains the same and a competitor cannot manufacture the same, being within the rights of the patent owner. This shuts off generic versions till the last of the patent on the product expires. Sometimes, the generic company would have done basic research and development for the generic version, such as the bioequivalence studies, but that investment also will become infructuous when on minor improvement, a patent is granted. The branded pharmaceutical producers have been demanding the scrapping of Section 3(d) of the Patents Act on one pretext or the other. The provision was challenged on the ground that the word 'efficacy' is not defined and, hence, may lead to arbitrariness, but the Supreme Court clarified that efficacy in the context means therapeutic efficacy and rejected the argument.

Clinical Trial Data and Market Approval

Another demand of non-generic pharmaceutical companies is that the clinical trial data submitted for obtaining marketing approval for a new drug should not be relied upon for grant of marketing approval for a generic version of the drug. They argue that Article 39 of the TRIPS Agreement makes it obligatory for member countries to protect undisclosed test, or other data submitted for obtaining marketing approval, against disclosure. In India, such data is submitted to the Drug Controller under the Drugs and Cosmetics Act. The data remains confidential and is not revealed. But the Drug Controller relies on this data for grant of marketing approval for a subsequent drug which is a bioequivalent and does not demand fresh data. Insistence of submission of fresh data by each applicant will tantamount to unnecessary clinical trials subjecting human beings for trial again and again, not to say about making the generic versions costlier, by defeating the very purpose of bringing inventions into the public domain on expiry of the patent period.

Compulsory Licence for Patented Anti-Cancer Drug Nexavar

As far as Compulsory Licences (CLs) are concerned, India has so far used the provision only once in 2012. This was the case of an application by Natco Pharma for a CL for the drug Nexavar patented by Bayer Corporation. The relevant provisions of the Patents Act stipulate that on an application by a party a CL can be granted by the Controller of Patents, three years after the grant of the patent on any of the following grounds: that the reasonable requirements of the public have not been satisfied, or that the patented invention is not available to the public at affordable prices, or that the patented invention is not worked in the territory of India. Natco Pharma was granted the CL to make a generic version of the drug Nexavar used in

⁷Novartis AG v. Union of India (UOI) and Ors. 2013

the treatment of liver and kidney cancer on the grounds that the drug was not available in adequate quantity in the country even through imports, that the price of the drug was unaffordable to most Indians, being ₹2.8 lakh for one month's requirement of 120 tablets, and that the invention was not worked in the territory of India since the grant of the patent. Natco was to manufacture and sell the product at a price of ₹8,800 for one month's supply and to pay a royalty of 6 per cent to Bayer Corporation.

The decision was initially challenged in the Intellectual Property Appellate Board (IPAB) and later in the higher courts with no avail, although the IPAB raised the royalty percentage to seven from six. So far this remains the only CL granted by India, but a scare was created in the media and business circles that India has been contemplating issuing of large number of patents, although there has been no further instance. Now that a full-fledged TRIPS compliant patent regime is there in India and Indian economy has opened to global competition, and Indian market is considered as of high value, almost all new drugs are patented here unlike in the past and the generic industry will have to wait for the expiry of the patent before launching their generic versions. It is also interesting to note that Indian companies are not coming forward with fresh applications for CL. India has also not used other provisions, such as for government use.

Patent Linkage

A fourth demand by the large pharmaceutical companies is for what has come to be known as patent linkage. This means that when application for approval of a generic version of an already marketed drug is submitted to the Drug Controller, he should check with the Patent Office as to the existence of any patent in the medicine and, if so, inform the patentee. This often serves as delaying or harassment tactic and not anything to do with the drug quality or safety, the two issues with which the Drug Controller is concerned. Patents, like other intellectual property rights, are private rights, and it is for the patent owner to take action against infringements. The law provides for civil remedies such as damages, accounts, etc. The Drug Controller should not be made a tool to enforce private rights. Countries which are recipients of the benefits of royalties on patented pharmaceuticals push for such measures through bilateral and regional or other treaties. The progress in the TRIPS Council or in the WIPO for the demand for such provisions is very tardy. Countries like India while negotiating need to assess the balance of benefits before entering such treaties.

Conclusion

While generic companies by encouraging competition helps in keeping the prices in check, the country also needs innovative pharmaceutical companies. Without R&D newer drugs will not become possible and India, with widespread vector-borne diseases and new challenges of lifestyle diseases badly needs new medicines, particularly in areas like TB and Malaria. Even when basic research is done in public-funded institutions, much investment is needed in the clinical trial sector for bringing the drugs to the market. The private companies need reasonable assurance that they will have conditions that enable them to make profits to recoup their investment. They also need enough incentives to introduce new drugs in the Indian market. It is essentially about industry perception. R&D and competition are two essentials to make healthcare affordable, accessible and universal, and without which India cannot achieve the goal of health and well-being of all. The IPR regime will have to balance both the requirements for new drugs and the public interest of easy availability and affordability. It will also have to make periodic changes in the regulations to address new economic and social challenges. Policies and legislations will have to be made keeping in mind the ultimate well-being of the citizens from a long term perspective.

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THE NATIONAL HEALTH POLICY 2017

Reluctance to Push the Boundaries

Pallavi Sharma*

Our public health system is bursting at the seams as it struggles to accommodate millions of people, especially those who have no other alternative. With health insurance a rarity, over 62 per cent of the family health expenditure goes from the personal savings¹ of an average Indian household. This is abysmally high when compared to 13.4 1 per cent in the US and 10 per cent in the UK, and just above 54 per cent in China.²

In a recent study on Global Disease Burden, India ranked 154th among 195 countries surveyed.³ One would expect a nation so deep in a health crisis to be driven by an urgency - both in terms of a speedier response and better financial resources. The National Health Policy (NHP), released early this year, is in many ways a step forward. It imagines a robust health system in tune with the constitutional aspirations contained in Article 47 to raise the standard of living and improve public health."

This NHP comes nearly 15 years after the previous major health policy of 2002. Much has changed in the years passed. This article examines some of the key proposals of the NHP, including its emphasi on generic medicines, to assess whether it fares well on the international standards of economic and social rights.

Availability, Accessibility and Acceptability Standards

International economic and social rights jurisprudence delineates a three-fold criteria of *Availability, Accessibility and Acceptability* (AAA) to gauge states' action to secure economic and social rights for their subjects. ⁴ The AAA criteria entails that the goods, services and facilities provided by the state pursuant to its covenant obligations should be *Available, Accessible,* physically, economically and without discrimination, and *Acceptability* of the way this right is being upheld for the population it is being provided to.

1. Availability

With the focus on a 'comprehensive primary healthcare' system, the policy gives its fair share to the concern of availability of quality health facilities in the country. There is an honest assessment of the state's capacity to fulfill all the health needs of the country's vast population.

Acknowledging that our public health delivery systems may be sub-par, it introduces the idea of 'strategic partnerships' with private commercial and charitable institutions in multifarious ways for a short-term solution to the problem of availability of medical care facilities. For instance, in a welcome move, implicitly acknowledging the deplorable state of public infrastructure on mental health, the policy envisages 'mental health' as one of the collaborative spheres where private expertise and reach may be utilized to develop

¹Nayan Kalnad, Niranjan Bose and Hari Menon, India's Great Healthcare Challenge—And Opportunity, http://www.indiaspend.com/cover-story/indias-great-healthcare-challenge-and-opportunity-46858, accessed June 30, 2017.

http://www.indiaspend.com/cover-story/indias-great-healthcare-challenge-and-opportunity-46858, accessed June 30, 2017 ²lbid.

³India Ranks 154 Among 195 Countries in Healthcare Index ,https://thewire.in/137902/india-rank-healthcare-index/, accessed June 30, 2017.

⁴I draw this criteria from the work of the Committee on Economic and Social Rights, in particular their General Comments and communication with states.

⁵Mental health care system in India in tatters, only 1 in 5 getting treatment, Oct 25, 2016, http://www.hindustantimes.com/india-news/mental-health-care-system-in-india-in-tatters-only-1-in-5-getting-treatment/story-2Xa41PbR2q5tC36Xk9ms5L.html, accessed June 23, 2017.

sustainable networks in community.6

The policy undertakes the obligation of ensuring 'comprehensive primary healthcare system' upon the state, while leaving the window open for PPP models of partnership and purchase to fill in the gaps in secondary and tertiary care services until the public health system is equipped to bear the burden. The policy does not however shed more light on what services are to be expected from this 'comprehensive' package.

Collaboration with Public Sector Hospitals, Non-Profit Entities

Preference for such collaborations would be given to public sector hospitals, followed by non-profit entities and lastly to private commercial ventures to minimise 'moral hazards'. Collaboration with private providers already working in remote and underserviced areas has also been suggested as an immediate and temporary measure to fill critical gaps in primary care services and address demands for specialised personnel or domain-specific organisational experience.

This said, the devil lies in the implementation of these strategic partnerships. Public-private partnership (PPP) models have in the past been notorious for flouting the standards of quality, exploiting contractual workers for profit maximisation as well as raising questions about extent of state and private accountability. Health rights advocates have expressed deep concerns over this 'strategic partnership' against the backdrop of a weak regulatory and deeply litigious environment for such partnerships to operate in a sector as sensitive as health. A breakdown of relationship between state and private provider may have catastrophic consequences on the health delivery systems they operate in. It may lead to delays and glitches in availability of health services as well as additional fiscal burdens on the state.

Failure of PPP Models in Rajasthan, Karnataka

If anything, recent experiences from Rajasthan and Karnataka reflect the failure of over-reliance on PPPs, especially in primary healthcare. Last year, in Karnataka, the government abruptly scrapped the *Arogya Bandhu* scheme of collaboration with various NGOs, charitable trusts and private medical colleges to run and administer 52 Public Health Centers (PHCs), with financial assistance from the state, for their inability to meet the requisite quality and resource standards. ¹⁰

This year, health rights activists in Rajasthan have expressed deep displeasure at the PPP model in primary healthcare¹¹ and challenged it before the High Court for being exploitative.¹² They are concerned that reliance and expenditure on PPPs to deliver healthcare in PHCs is chipping away from the state's capacity to build and strengthen its public health delivery system in the long run.

The NHP further suggests independent mechanisms with institutional autonomy at state and central levels for regulating need-based purchase of secondary and tertiary care from empanelled private sector-in

⁶AnooBhuyan, Centre Shifts Health Policy Focus from 'Private' to 'Non-Governmental' Sector, https://thewire.in/117398/health-policy-private-nonprofit/, accessed June 23, 2017.

⁷AnooBhuyan, Centre Shifts Health Policy Focus from 'Private' to 'Non-Governmental' Sector, https://thewire.in/117398/health-policy-private-nonprofit/, accessed June 23, 2017.

Sujatha Rao, India's New National Health Policy is Ambitious on Paper But Lacks Clarity, https://thewire.in/118615/indias-new-national-health-policy-is-ambitious-on-paper-but-lacks-clarity/, accessed June 23, 2017.
Sujatha Rao, ibid.

¹⁰PPP in public health suffers setback, http://www.thehindu.com/news/national/karnataka/ppp-in-public-health-suffers-setback/article8253276.ece, accessed June 30, 2017.

[&]quot;Stop privatization of healthcare in Rajasthan', April 7, 2017, http://timesofindia.indiatimes.com/city/jaipur/stop-privatization-of-healthcare-in-rajasthan/articleshow/58067983.cms, accessed June 30, 2017.

¹²HC admits PIL on giving health centres to private players, May 9, 2017, http://timesofindia.indiatimes.com/city/jaipur/hc-admits-pil-on-giving-health-centres-to-pvt-players/articleshow/58581361.cms, accessed June 30, 2017.

priority from public, not-for-profit and lastly, commercial establishments, subject to due standards of quality. This is where scepticism for the policy creeps in. The merits of such independent purchase commissions cannot be denied in the interest of transparency and fairness. However, without a roadmap into a legislation and regulations governing this authority, we may be pushing the PPPs on health into muddy waters.¹³

Over-Reliance on Private Sector

Furthermore, even though strategic partnership seems a plausible answer to the immediate demands of our public health system, crumbling under population burden and inadequate infrastructure, the policy is eerily silent on what this 'short-term' is. ¹⁴ In absence of clear attainable targets, we may be moving towards a model of over-reliance on private sector, where addressing the inadequacies of the public health system takes a backseat.

It is to be borne in mind that moving towards a purchase model/insurance-based system for secondary and tertiary services makes sense only as far as adequate parallel attention is given to building and strengthening the state-supported infrastructure. Hospitalisation and other tertiary care related services are those which compel people to break their banks, and beyond a point, the expenditure towards insurance and buying services from private sector would rather be invested in the state hospitals to strengthen and upgrade their services.¹⁵

The policy also speaks of compulsory rural postings for doctors, the viability of which as a sustainable solution is yet to be established. ¹⁶ Even though the Policy discusses 'financial and non-financial' incentives, medical colleges in rural areas, preferring students from under-served areas and bringing 'rural needs' to the centre of the medical curriculum, it seems to be leaning towards either "measures of compulsion" or voluntary "giving back to the society" initiative to service the rural healthcare needs of the country. This may be an answer to the immediate manpower crisis in primary healthcare sector, but may not do much to create a sustainable and fair system of incentive to encourage doctors to service rural sectors, unless exhaustive infrastructural improvements are made.

2. Accessibility

Physical Accessibility

The WHO understands physical accessibility as "the availability of good health services within reasonable reach of those who need them and of opening hours, appointment systems and other aspects of service organisation and delivery that allow people to obtain the services when they need them". ¹⁷ It also extends to "a safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS, including in rural areas". ¹⁸

¹³See generally G Pramod Kumar, http://www.huffingtonpost.in/2017/03/17/why-modi-governments-new-health-policy-is-fraught-with-problems_a_21899577/, accessed June 23, 2017.

¹⁴Bijoya Roy, Why Public-Private Collaboration is Bad News For Healthcare in India, https://thewire.in/117527/ppp-healthcare-health-policy/, accessed June 23, 2017

¹⁵G Pramod Kumar, http://www.huffingtonpost.in/2017/03/17/why-modi-governments-new-health-policy-is-fraught-with-problems a 21899577/, accessed June 23, 2017.

¹⁶For a basic understanding of the debate on compulsory rural secondments for fresh graduates, see Soham Bhadhuri, Why Compulsory Rural Service For Fresh Doctors Is A Terrible Idea, http://www.huffingtonpost.in/dr-soham-d-bhaduri/why-compulsory-rural-service-for-fresh-doctors-is-a-terrible-ide_a_22026342/, accessed June 23, 2017.

¹⁷Universal health coverage and universal access, Bulletin of the World Health Organization 2013; 91:546–546A, as quoted in Accessibility, http://www.who.int/gender-equity-rights/understanding/accessibility-definition/en/, accessed June 30, 2017.

¹⁸The Human Rights definition of 'accessibility', WHO, ibid.

In terms of physical accessibility of health services, the policy aspires for districts to be the centres for quality secondary care, and basic secondary services like caesarean sections and neonatal care to be made available at least at sub-divisional levels in a cluster. Identifying human resource as integral to developing secondary care sector, it speaks of a scheme to develop human resources and specialist skills. Though the policy does not categorically lay out a blue print for this scheme, suggestions can be found in the document concerning systematic improvement of medical education and examination process in the country as well as developing a special public health cadre for management, among others.

The policy expects to set up medical colleges and institutions like All India Institute of Medical Sciences on the model of regional, zonal and apex referral centres to increase the access to health services. It also makes a special case of partnership with empanelled private commercial and charitable institutions and integration of AYUSH¹⁹ as well as indigenous medicinal practices of quality to diversify the health portfoliowhich has obvious positive implications on accessibility of health facilities to all.

The policy is also conscious of the serious gaps in access to health services in the tribal regions of the country. It suggests increase in outreach through special 'mobile medical units' to mitigate the geographical and infrastructural challenges faced by the 100 million tribal population.

It suggests that decision making should be decentralised and community be involved in health planning. It emphasises on the special role of Panchayati Raj Institutions and echoes the viability of Community-Based Monitoring Systems which were brought into place through the National Rural Health Mission in 2005.

Economic Accessibility

WHO understands 'economic accessibility' as "a measure of people's ability to pay for services without financial hardship. It takes into account not only the price of the health services but also indirect and opportunity costs (e.g. the costs of transportation to and from facilities and of taking time away from work)." Affordability is influenced by the wider health financing system and by household income". 20

In terms of affordability, the policy speaks of affirmative action to bridge the gap due to gender, poverty, caste, disability, social exclusion and other geographical barriers by bringing in systems for better investments and financial protection. India currently faces an excessive out-of-pocket expenditure on health constituting nearly 40 per cent of the monthly non-food household expenses. The policy speaks of ambitious targets of not only increasing the health budget from the current 1.8 per cent to 2.5 per cent by 2025, but also the states increasing their health expenditure to the north of 8 per cent. It also aims to reduce the out-of-pocket health expenditure of households by one fourth by 2025.

The policy envisages a strong National Health Accounts System to bring efficiency in resource allocation in public sector in health. It urges that standards for treatment of patients be the same for public and private hospitals and patients not be denied their right to information about their treatment and process.

Though much has been spoken about continuing insurance schemes like *Arogyashree* and *Rashtriya Swasthiya Beema Yojana* (RSBY), providing cashless insurance for hospitalisation in public and private hospitals and bringing India's BPL population under a state-sponsored insurance mandate, critical and immediate attention needs to be given to the implementation of these schemes. Making these schemes

¹⁹Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy

²⁰Economic Accessibility, WHO, ibid.

workable requires addressing the deep chasms of class, caste and gender that cut through our health delivery system.²¹ Further, information asymmetry between hospitals and patients can open soft-spots for patient exploitation for claiming insurance by public or private service providers.²²

For any insurance scheme to be a success in making health care 'affordable', it would have to be acknowledged that real access goes beyond enrolment and into empowerment - where patients with a RSBY card can claim insurance as a state sponsored right and not gratis at the hands of care-givers.

Drug Pricing and Affordability²³

The policy picks up on the flavour of 'generic drugs' and 'Make in India' in the 2017 budget. It suggests streamlining the drug procurement systems and bringing in strong purchase policy to procure drugs in bulk. *Jan Aushadhis*, or the low cost medical stores housing generic variants of expensive branded drugs, are to be opened in larger numbers across the country for access to affordable drugs.

The National Health Policy 2002 advocated the use of generic drugs only in the rubric of essential medicines - the idea was to limit the use of proprietary drugs both by private and public establishments and ensure that basic treatments used only price-controlled essential drugs to keep the cost of healthcare low. The new policy, however, substantially departs from this approach and focuses on generic variants of all drugs, and not just those in the essential lists. It also goes a step beyond infrastructural support for low cost drugs, into educating masses about branded and non-branded drugs and busting myths about quality of the latter, if they meet all prescribed standards.

The movement for integrating low-cost generic drugs to the very fabric of the public health delivery system has seen traction with the incumbent government. Previously known as the *Jan Aushadhi* Scheme, the *Pradhan Mantri Jan Aushadhi* Yojna has currently opened nearly 700 *Jan Aushadhi* stores, though it is still far from its ambitious plans to open 3,000 stores as declared in the 2016-17 Budget.²⁵ In fact, recently a potential collaboration with Indian Railways was explored²⁶ and it was decided that railway's broad geographic catchment would be utilised to open such stores and make them more accessible to all.

The ambitious scheme of flooding the market and the minds of the patients alike with generic drugs can go a long way in decreasing the expenditure of medicines other than essential medicines, whose price is already statutorily regulated. However, adequate advertisement/information, clarification of doubts, sufficient supply to meet the increase in demand²⁷ and a water-tight system of quality control²⁸ are prerequisites to

²¹See generally Vani S. Kulkarni, Where is the 'Public' in Public Health?, https://thewire.in/139212/public-public-health/, accessed June 23, 2017.

²²Vani Kulkarni, ibid; Also see Shubhashish Bhadra, Jaitley is Carrying Forward a Deeply Flawed Health Insurance Program, https://thewire.in/23796/jaitley-is-carrying-forward-a-deeply-flawed-health-insurance-program/accessed June 23, 2017.

²³See Pragati Mitta, 'Evolution of Jurisprudence: Right to Health' in this issue of the Common Cause Journal

²⁴2002 National Health Policy, pp 28.

²⁵Budget analysis-Jan Aushadhi Scheme, http://unionbudget2017.cbgaindia.org/health/jan_aushadhi_scheme.html, accessed June 23, 2017.

²⁶Soon, Jan Aushadhi stores to open at railway stations, June 19, 2017, http://www.business-standard.com/content/b2b-chemicals/soon-jan-aushadhi-stores-to-open-at-railway-stations-117061900622_1.html, accessed June 23, 2017.

²⁷Govt's cheap medicine scheme falls sick, June 25, 2017,

http://www.newindianexpress.com/thesundaystandard/2017/jun/24/govts-cheap-medicine-scheme-falls-sick-1620516.html, accessed June 25, 2017.

²⁸See generally for concerns regarding mass-pushing generic drugs in the market, Zia Haq, Popping the Right Pill, http://www.outlookindia.com/magazine/story/popping-the-right-pill/298975, accessed June 23, 2017.

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generic drugs being accepted as a viable alternative for patients and doctors in the country.²⁹ There are also initiatives in the pipeline to mandate doctors to compulsorily prescribe generic drugs. Such initiatives would have to ensure that they are structured in such a way that they are not a mere lip-service to the cause and the decision-making power is not passed on from the doctors to the pharmacist, and the patient continues to bear the heavy cost burden. The state also needs to be cognisant that the generic drugs policy cannot be an isolated attempt at making health accessible. It needs to be coupled with an increase in allocated health expenditure and timely policy interventions for strengthening the public health delivery system.

3. Acceptability

The policy also speaks of a pluralistic public health system by integrating, where appropriate and chosen by the patients, AYUSH care into mainstream health delivery practices. It also pushes for research on tribal medicinal practices to broaden the health service basket. This is an optimistic acknowledgement of indigenous health practices, which, if of the requisite standard and quality, can suit the unique health needs of the community in a trusted way.

In another significant move to increase acceptability of treatment, the policy expresses its discomfort with camp-based sterilisation services, given the dubious concerns of quality, safety and dignity of women and to make sterilisation services available generally in public facilities. Similarly, it aims to increase male sterilisation from the current 4 per cent to at least 20 per cent.

Conclusion

The NHP is generally optimistic about building a public health system which will be able to tackle the heavy disease burden in India. It also advocates increasing the health expenditure from the current 1.8 per cent to 2.5 per cent of the GDP by 2025, which, though much below the global average of 5 per cent, will still a progress, provided it gets done.

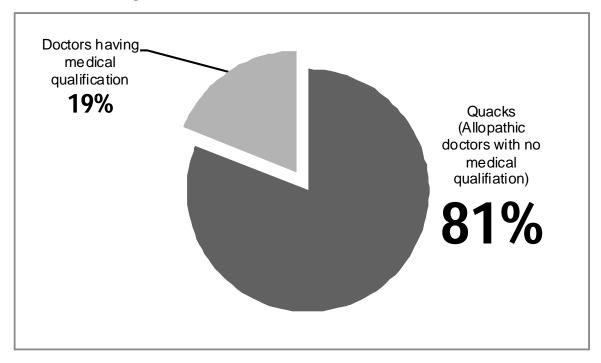
It talks about putting in place by 2020 a district level data systems as part of the Health Management Infrastructure. The focus is on a preventive and promotive healthcare. The policy is also unclear about many crucial areas, like a hesitant reference to adolescent and sexual health education, bunching it with recommendations for prevention of common chronic illnesses, ambitious targets of disease elimination. Its divisions of responsibility between the centre and the states is at best vague. The fact that the policy follows an incremental assurance-based model instead of giving 'health' its due status as a 'right' leaves much to be desired.

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²⁹India will soon have assured quality system for generic medicine: Dr Y K Gupta, http://health.economictimes.indiatimes.com/news/industry/india-will-soon-have-assured-quality-system-for-generic-medicine-dr-y-k-gupta/59215215, accessed June 23, 2017.

The Epidemic of Quacks in Rural India

April-June, 2017



^{*}According to 'The Health Workforce in India, 2001' by WHO

Medically Qualified Allopathic Doctors in India

Females Doctors	67%
Male Doctors	38%

Density of Doctors in India (Per Lakh Population)

All Doctors (allopathic, ayurvedic, homoeopathic and unani)	80
Allopathic doctors with medical qualification	36

Density of Nurses and Midwives in India (Per Lakh Population)

All Nurses & Midwives	61
Nurses & Midwives with medical qualification	6

EVOLUTION OF JURISPRUDENCE:

Right to Health

Pragati Mitta*

While India has made significant advancement in boosting economic growth and has lifted millions out of poverty, progress in improving health outcomes has been slow. There is a critical lack of access to affordable, quality healthcare. The high cost of healthcare often pushes the underprivileged into further impoverishment. For a significant portion of the population their health expenditure threatens the household's capacity to maintain a basic standard of living. The absence of adequate investments in preventive public health facilities such as sanitation and waste management in this densely populated country adds to the problem, as it leads to rampant spread of infectious diseases and raises health costs.

In its recent assessment of the Indian economy, the Organisation for Economic Co-operation and Development (OECD) identified India's poor health outcomes as one of its major developmental challenges. In 2012, as per the OECD study, India witnessed 253 deaths per 100,000 persons due to communicable diseases alone, much higher than the global average of 178. This high disease burden saps the productivity of Indian workers and lowers their earnings. According to a 2010 World Bank estimate, India loses 6 per cent of its gross domestic product (GDP) annually because of premature deaths and preventable illnesses.²

Low Level of Public Investments

A key reason behind the poor health of the average Indian is the low level of public investments in medical care facilities such as primary health centres (PHCs) and health professionals. Even when public health facilities are available, they are often of poor quality. The lack of reliable public health services and the absence of health insurance compel the poor to spend heavily on private medical care. According to a 2011 research paper, out-of-pocket health expenditures account for nearly one-sixth of India's poverty burden. The high costs of healthcare also act as a deterrent for poor people in seeking treatment, leading to delays and aggravating health problems.

Thus the recognition of healthcare as a fundamental right, and its subsequent enforcement is crucial to developing India. Below, the evolving jurisprudence of this right in Indian courts is discussed.

International Recognition of Right to Health

Internationally, the right to health was first articulated in the 1946 Constitution of the World Health Organisation (WHO), whose preamble defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". The preamble further states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."

¹http://www.livemint.com/Opinion/DSH1OnDr2LG0zAcHhl29XJ/The-growing-burden-of-healthcare-costs.html ²http://www.livemint.com/Politics/pHCS4KW8ZnFqlUqRIILVFN/Five-charts-that-explain-Indias-healthcare-crisis.html ³Soumitra Ghosh, Catastrophic Payments and Impoverishment Due to Out-of-Pocket Health Spending: The Effects of Recent Health Sector Reforms in India (http://aparc.fsi.stanford.edu/sites/default/files/AHPPwp15.pdf)

In 1948, Article 25 of the United Nations' Universal Declaration of Human Rights (UDHR) codified health as a human right as part of the right to an adequate standard of living. The Indian Constitution, adopted two years later, did not expressly recognise the fundamental right to health. However, the judiciary has, over the course of several decades, expanded the meaning of right to life (given in Article 21) to include right to health – including affordable care, immediate medical care, clean environment and workers' right to healthcare among others. By reading the fundamental right to life with several Directive Principles of State Policy, the Supreme Court has implied a fundamental right to health.

In a series of cases dealing with the substantive content of the right to life, the court has found that the right to live with human dignity includes right to good health. Although several of these landmark cases are in the context of right to health of workmen, the right may be extended to include the general population given the language of the judgments.

Judicial Rulings on Right to Health in India

In 1981 in Francis Corallie Mullin⁴, the Apex Court for the first time declared that right to life meant more than mere animal existence and included the basic right to food, clothing and shelter. It was stated that right to life includes the right to live with human dignity and all that goes along with it. While noting that the magnitude and content of the components of this right would depend upon the extent of the economic development of the country, the court asserted that it must, regardless, include the right to basic necessities of life. This judgment paved the way for future benches of the court to include several qualitative rights under right to life.

Three years later in *Bandhua Mukti Morcha*⁵, Justice PN Bhagwati observed that right to live with human dignity involves right to "protection of health". The court declared that no government has the right to take any action which will deprive a person of the enjoyment of the basic essentials such as protection of health, just and humane conditions of work and education facilities. In this case, concerning the living and working conditions of stone quarry workers and whether these conditions deprived them of their right to life, the court held that humane working conditions are essential to the pursuit of right to life.

Vincent Panikulangara v. Union of India⁶ is considered an important step towards recognising the fundamental right to health by declaring that "a healthy body is the very foundation of all human activities". The court invoked the adage "Sharirmadyam Khalu Dharma Sadhanam", which means the body is the foremost instrument of doing good deeds. In a welfare state, it declared the obligation of the state to ensure the creation and sustenance of conditions congenial to good health. The court observed that maintenance and improvement of public health should be a top priority of the state.

The Supreme Court in the landmark medico-legal case of *Paramanand Katara*⁷ ruled that every doctor, whether at a government hospital or otherwise, has the professional obligation to extend his services for protecting life. It was held that no law or state action can delay the discharge of the paramount obligation that is cast upon members of the medical profession. The Apex Court thus established beyond doubt the utmost importance of preservation of life.

Francis Corallie Mullin v Union Territory of Delhi 1981 (1) SCC 608

⁵Bandhua Mukti Morcha & Ors v Union of India & Ors AIR 1984 SC 802

Vincent Panikulangara v Union of India AIR 1987 SC 990

⁷Paramanand Katara v Union of India 1989 AIR 2039, 1989 SCR (3) 997

In CESC Ltd v. Subhash Chandra Bose⁸ the court further expanded its interpretation of Article 21 regarding the right to health of workmen. It held that the health and strength of a worker is an integral facet of the right to life. It further observed that health is not merely absence of sickness. The court held that medical facilities to workmen are part of social security and would yield immediate returns in increased production.

This judgment cited the International Covenant on Economic, Social and Cultural Rights (ICESCR) 1976, to which India is a party. This multilateral treaty adopted by the UN General Assembly includes provisions on the right to health. The CESC case relied on Article 7, which recognises the right of everyone to just and favourable conditions of work which includes, among other things, safe and healthy working conditions. Article 12 of ICESCR outlines the responsibilities of state parties to ensure "right of everyone to the enjoyment of the highest attainable standard of physical and mental health".

Right to Health is Integral to Right to Life

In 1995, for the first time, the Apex Court explicitly held that the right to health is an integral fact of right to life in *Consumer Education and Research Centre*°. Here the court read Article 21 with the relevant Directive Principles of State Policy and held that the right to health and medical care is a fundamental right as it makes the life of the workman meaningful and purposeful. Article 21 was held to have a wider meaning which includes right to livelihood, better standards of life, hygienic conditions of workplace, and leisure.

The directive principles relied on to form this interpretation are those directing the state to secure the health and strength of workers, men, women and children (Article 39 (e)), to protect the right to work in cases of old age, sickness and disablement (Article 41) and a living wage and conditions of work to ensure a decent standard of life (Article 43). Other directive principles have been used by courts to uphold right to health – Article 38 directs the state to secure a social order in which social and economic justice promotes the welfare of the people, and to strive to eliminate inequalities in facilities; Article 39 (f) directs the state to give children facilities to develop in a healthy manner; and Article 42 bids for provisions for just and humane conditions of work and maternity. Most directly implying a right to health is Article 47 which enjoins the state to raise the level of nutrition, the standard of living and to improve public health.

In *Kirloskar Brothers Ltd v. Employees' State Insurance Corpn.*¹⁰ the Supreme Court held that the fundamental right to health of workmen is not only available against the state and its instrumentalities but even against private industries to ensure that workmen are provided facilities and opportunities for their health and vigour, as assured in the Constitution.

Violation of Right to Life under Article 21

The issue of adequacy of medical health services was addressed in *Paschim Banga Khet Mazdoor Samity*. The Supreme Court delineated the scope of Article 21 of the Constitution, and held that it is the fundamental right of everyone in this country, assured under the interpretation given to Article 21 in Francis Mullin's Case to live with human dignity, free from exploitation. The question before the court was whether the non-availability of services in the government health centres amount to a violation of Article 21. The court, while widening the scope of Article 21 and the government's responsibility to provide medical aid to

CESC Ltd v. Subhash Chandra Bose AIR 1992 SC 573

⁹Consumer Education and Research Centre & Ors v Union of India AIR 1995 SC 42

¹⁰ Kirloskar Brothers Ltd v Employees' State Insurance CorpnJT 1996 (2), 159 1996 SCALE (2)1

Paschim Banga Khet Mazdoor Samity & Ors v. State of West Bengal & Ors AIR 1996 SC 2426

every person in the country, held that in a welfare state, the primary duty of the government is to ensure that medical facilities are adequate and available to provide treatment. The government discharges this obligation by providing medical care to the persons seeking to avail of those facilities. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21. The court recognised that substantial expenditure was needed to ensure that medical facilities were adequate. However, it held that a state could not avoid this constitutional obligation on account of financial constraints.

The Supreme Court, while examining the issue of the constitutional right to health care under Articles 21, 41 and 47 of the Constitution of India in *Ram Lubhaya Bagga*, ¹² observed that the right of one person correlates to a duty upon another, individual, employer, government or authority. Hence, the right of a citizen to live under Article 21 casts an obligation on the state. This obligation is further reinforced under Article 47 which directs the state to secure health to its citizens as its primary duty. The court held this to be one of the most sacrosanct and valuable rights of a citizen, and urged the state to perform this obligation with top priority to secure the rights of its citizens to their satisfaction.

Denial of Maternal Healthcare is Violation of Constitutional Rights

The Delhi High Court issued a landmark ruling in the *Consolidated Laxmi Mandal/Jaitun*¹³ case in June 2010 holding that the denial of maternal health care is a violation of constitutional and human rights. Justice Dr. S. Muralidhar emphasised that the government is obligated to ensure maternal health services under the judicially recognised fundamental right to health. The court cited India's international legal commitments, including Universal Declaration of Human Rights (UDHR), the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and ICESCR. It was reiterated that the right to health and reproductive rights are part of the right to life under Article 21 of the Constitution. It was emphasised that the right to health includes access to and minimum standards of treatment and care in public health facilities.

More recently, in the case of *Devika Biswas*,¹⁴ the Supreme Court confirmed that the misconduct at sterilization camps, as a result of which several women underwent severe pain and anguish, was in gross violation of right to health and reproductive rights of the affected women. The court noted that it is well established that the right to life includes the right to lead a dignified and meaningful life, of which right to health is an integral facet.

To summarise, the Indian Supreme Court has in the course of the past three decades steadily expanded the meaning of right to life to imply a fundamental right to health under Article 21. This judicial approach has led to the spectacular result¹⁵ that many directive principles which, as such, are not enforceable, have been activated and have become enforceable. The Supreme Court has introduced a qualitative concept into Article 21 by holding that whatever promotes the quality of life falls within its parameters.

Promotion of Generic Drugs to Protect Right to Health

The well-established right to health encompasses the right to affordable healthcare when read with Articles 47 and 38, which bid the state to improve public health, secure a social order in which social and economic justice promotes the welfare of the people, and to strive to eliminate inequalities in facilities. Among the methods to provide affordable healthcare for all is for the government to provide and promote generic

¹² State of Punjab v Ram Lubhaya Bagga(1998) 4 SCC 117

¹⁹Laxmi Mandal v Deen Dayal Harinagar Hospital &Ors WP 8853/2008 & Jaitun v Maternity Home MCD, Jangpura & Ors WP 10700/2009

¹⁴Devika Biswas v Union of India &Ors WP © 95/2012

¹⁵Pg. 1160, Indian Constitutional Law – 7th Edition, M.P. Jain

drugs, as these are low-cost versions of branded medicines.

The Medical Council of India (MCI) in the Professional Conduct, Etiquette and Ethics Regulation 2002 (amended in 2016) has stipulated under Clause 1.5 that every physician should prescribe drugs with generic names, and ensure that there is a rational prescription and use of drugs. As per the Supreme Court ruling in *Medical Council of India v. State of Karnataka & Ors*¹⁶ regulations of the Medical Council of India are binding and mandatory. Therefore, the compulsory prescription of generic drugs by practitioners is enforceable.

The National Health Policy (NHP) 2017 of the Ministry of Health and Family Welfare has included provisions on drug regulation which encourages the streamlining of the system of procurement of drugs and facilitates the spread of low-cost pharmacy chains such as *Jan Aushadhi* stores linked with ensuring prescription of generic medicines. It further recommends education of public with regard to branded and non-branded generic drugs. NHP prescribes timely revision of National List of Essential Medicines (NLEM), along with appropriate price control mechanisms for generic drugs to decrease costs of care for all those patients seeking care in the private sector. NHP also encourages innovation in medical technology to make good quality, free essential and generic drugs available at public healthcare facilities.

The Rajasthan High Court in *Vijay Mehta*¹⁷ emphasised the statutory enforceability of the Regulations of 2002 framed by the MCI on the issue of doctors failing to prescribe generic names of medicines. In 2012 the same court in *Wagar Seva Sansthan Trust*¹⁸ reiterated the need for promoting the use of generic medicines despite repeated government failures in implementation. The court acknowledged that generic medicines are available at much lower rates than branded medicines. It was held that the right to obtain treatment is a fact of Article 21 of the Constitution of India and the right to obtain treatment at affordable prices of medicines is concomitant of the same. The court thus declared that not prescribing the medicines in generic names may tantamount to violation of Article 21 of the Constitution of India.

Conclusion

The jurisprudence on 'right to health' as an extension of 'right to life' has evolved over the past three decades. It has moved from ensuring more than a mere animal existence to a fundamental right guaranteed under the Constitution. Recent cases have affirmed the responsibility of the state to uphold this right. However, as evidenced by the poor state of the Indian healthcare system, the state has violated this right of the people by failing in its duty to provide quality, affordable healthcare.

With the recent judicial rulings and government initiatives calling for compulsory prescription of generic drugs, India could well be moving towards providing low-cost medicines to all. Promotion of use of generic drugs could go a long way in the state discharging its duty to provide affordable healthcare and upholding the right to health.

*Pragati Mitta was a legal apprentice at Common Cause

¹⁶Medical Council of India v State of Karnataka &Ors 1998 (6) SCC 131

¹⁷Vijay Mehta v State of Rajasthan WP (C) 3031/2007

¹⁸ Wagar Seva Sansthan Trust v State (Medical and Health) & Ors WP (C) 4456/2011

COMMON CAUSE UPDATES

Supreme Court:

Challenging the Lokpal Search Committee Rules: The court, on April 27, 2017, held that there is no justification to put the appointment of Lokpal on hold. The matter was earlier tagged with two other cases. The writ was allowed by the court and the matter was disposed on April 27, 2017, stating that the Lokpal Act as it stands is enforceable, turning down Center's argument to keep the Lokpal Act in suspension till the relevant laws are amended. The Court observed that if the Leader of the Opposition is not available, the chairperson and two other members of the selection committee may proceed to appoint an eminent jurist as a member of the selection panel.

Inquiry against Ex-Chairman, NHRC, KG Balakrishnan: Petition was filed for an enquiry against and removal of Shri K.G. Balakrishnan, the then Chairman, NHRC, for transgressions while holding the public office. The prayer for his removal became infructuous as he demitted office on May 2015, and an application was filed to amend the prayer. In February 2017 the court directed the Centre to file a response to our plea seeking a probe into the alleged disproportionate assets amassed by Shri Balakrishnan. The matter is likely to be listed in July, 2017.

Coal Block Allocation: On April 25, 2017, the CBI filed an FIR against its former director Shri Ranjit Sinha in the coal block scam probe. In the hearing on July 10, 2017, the court criticised the CBI for transferring DIG Shri Ravi Kant, the officers investigating the coal scam cases since 2012, without the Court's permission. While the Court abstained from passing any order on the transfer, it directed that no CBI officer, who is investigating the coal scam cases, would be transferred without the explicit permission of the Court. The Court said that the present CBI director would head the SIT that would look into the report of the ML Sharma panel, which had prime facie indicted Shri Sinha in the matter.

On July 13, 2017, the Supreme Court held that the pleas challenging any interim order passed by a special court during the pendency of the trial will be entertained only by it, and refused to revisit its July 25, 2014 order in the matter. The three-judge bench noted that the coal block allocation scam needed to be treated in a manner different from the usual cases dealt by the court. Hence it rejected the plea of industrialist Naveen Jindal, one of the accused in the case, seeking permission to approach the High Court to challenge the trial court's order.

Writ against Illegal Mining in Odisha: This petition was filed to curb the rampant illegal mining in Odisha, following which the operation of 26 illegal mines was stayed in May 2014. The court in 2016 directed the states to consider applications of miners filed before January 2015 or 12 months before the expiry of the lease. The court held that mining leases will not lapse automatically unless the state governments hear the companies and pass orders to that effect. Judgement on the matter was reserved on May 8, 2017.

Corruption in Management of Defense Lands: The PIL seeks systemic reforms and court-monitored CBI investigation into illegalities and irregularities in management of defense lands. It was filed in the wake of CAG reports highlighting mismanagement noticed in audit of defense lands. On February 20, 2017, the court issued a notice to the Center directing it to evict encroachers from the defense lands. On July 11, 2017, submissions were made by the petitioner pertaining to computerization of land records, removal of encroachment on the defense lands, establishment of

an independent regulator, etc. The Court noted that there was a need to consolidate the position regarding actions already taken by the government and actions which are supposed to be taken. The matter is likely to be listed on August 23, 2017.

Criminalisation of Politics: The PIL was filed for debarring persons charged with serious criminal offences from contesting elections and expediting the disposal of pending criminal cases involving MPs and MLAs. The constitutional validity of Section 8(4) of the Representation of Peoples Act 1951 was challenged. A landmark order was obtained in March 2014 for concluding criminal cases against lawmakers within a year of framing of the charges. The matter was tagged with two other cases with similar prayers and was referred to a Constitution Bench on March 8, 2016. In a hearing on July 12, 2017, the Court criticised the Election Commission for retracting its earlier position supporting a plea for lifetime ban on convicted lawmakers. The matter is likely to be listed again on August 18, 2017.

Allahabad High Court:

Audit of NOIDA, Greater Noida Authority and Yamuna Expressway Authority by CAG: The writ was filed in the light of the serious allegations of misconduct and corruption in the acquisition and disposal of land meant for public purposes and the need for auditing of accounts by CAG. As has been recently reported, the Government of Uttar Pradesh decided to conduct CAG audit of the three industrial development authorities- Noida, Greater Noida and Yamuna Expressway. This was reportedly stated by UP Industrial Development department principle secretary Alok Sinha, in a letter to the Accountant General of the Economic and Revenue Sector Audit department on July 11, 2017. The matter was listed on May 29, 2017, and is likely to be listed again on August 18, 2017.

APPLICATION FORM	FOR MEMBERSHIP OF CO	OMMON CAUSE.
. Name:		
Father's Name:		
. Mother's Name		
. Date of Birth:		
Educational Qualification:		
. Occupation:		
. Permanent Address:		
. Mailing Address:		
(a) Email ID :		
(b) Phone :		
. Next of Kin (Name & Address):		
0. Membership Sought. (Tick any c	one block):	
Categories	Ordinary	Life
Individual (with voting rights)	Rs. 500.00 P.A.	Rs. 5000.00
Associate (without voting rights)	Rs. 100.00 P.A.	Rs. 500.00
I. Why do you wish to join COMM	ON CAUSE (up to 80 words	s)
2. Your expectations from COMMC	ON CAUSE (up to 40 words)
Place & Date:		Signature

HEALTH IN INDIA: SOME FACTS

- India ranks 154 out of 195 countries in terms of access to healthcare, which is worse than Bangladesh, Nepal, Ghana and Liberia, according to medical journal Lancet. It also ranks India at last position, along with Ghana, in neonatal mortality in a list of 15 backward and developing countries.
- The doctor-patient ratio in the country stands at 1:2000, falling considerably below the WHO norm of 1:1000, according to 45th Parliamentary Committee report on generic medicines.
- Doctors are inequitably concentrated in the urban areas, with about 80 per cent of doctors serving in urban India, which constitutes just 28 per cent of the country's population, according to a 2016 report by KPMG and Organization of Pharmaceutical Producers of India.
- In terms of health expenditure, India is among the highest in the world, with 72% in rural and 68% in urban areas expenditure incurred for buying medicines for non-hospitalized treatment, according to 'Health in India' report, which draws data from the 71st round of the National Sample Survey (January to June 2014).
- India has one of the lowest percentages of public health expenditures as a percentage of GDP, at 1.4 per cent, according to 2014 WHO estimates. India ranks below its neighboring states of Nepal and Sri Lanka, and much below US, which stands at 8.3 per cent.
- Eighty-six per cent of India's rural population and 82 per cent of the urban population is not covered under any scheme of health expenditure support, as revealed by NSSO 71st round data, 2014.
- More than 80 per cent population is dependent on private medical care, according to 45th Parliamentary Committee report on generic medicines, 2010, which recommended a blanket cap on profit margins of all medicines across the board.
- There are only 1.3 hospital beds per 1,000 people as of 2011 (WHO estimates), which are much lower than the WHO guideline of 3.5 beds.
- According to a FICCI report, India has about 850,000 pharmacies. The 2016 government proposal of the introduction of 3,000 generic drug stores will constitute less than 1 per cent of the total pharmacies, and will hardly improve public access to cheap drugs. Currently there are over
- 1,00,000 brands of medicines are sold in India by just over 8,500 drug companies, as noted by the 45th Parliamentary Committee Report.