A Three day Short Course on

Challenges to Access to Medicines: Patents, Pricing and Drug Research in India

August 16th-18th, 2017

Sama – Resource group for women and health

Introduction

Sama is a Delhi based resource group that works in the area of public health and women rights. Sama has been engaged in various issues around access to medicines, intellectual property, ethics in drug research, reproductive technologies and surrogacy, health of marginalized communities (such as adivasis and dalits) and gender based violence through research, advocacy and capacity development**.**

In the context of access to medicines, over the past few years, Sama has been focusing on a spectrum of ethical issues with regard to drug research in India; on the affordability and accessibility of medicines for which research has been conducted in India; on patents, drugs pricing etc. To strengthen knowledge and understanding on these critical issues relating to access to medicines, Sama has been organizing short courses and capacity building workshops for researchers, health activists, NGO representatives, health professionals, ethics committee members and students. The previous capacity building courses were conducted in Bhopal, Delhi and Mumbai.

Taking forward this initiative, Sama organized a three day short course on Challenges to Access to Medicines: Patents, Pricing and Drug Research in Delhi from 16th to 18th August 2017. This short course was expected to provide key inputs on some of the most critical issues in the domain of access to medicines in India.



The short course broadly covered the following issues:

a) Access to Medicines in the framework of Public Health and Human Rights: Focus on the access to medicines as a key component of the right to health; health as a human right

b) Ethical Issues in the context of Access to Medicines and Drug Research: The significance of ethics in the conduct of health research; the national and international standards and regulations for research involving human participants

c) Access to Medicines - Connecting with ground realities; sharing experienced realities of the systems of health delivery / access to medicines; costs to access medicines/healthcare incurred by patients

d) Access to Medicines and Drug Research: The shift in research and development of medicines from synthetic/chemical to bio-therapeutic products; technological, intellectual property and regulatory barrier in accessing bio-therapeutic products

e) Access to Medicines and Drug Pricing: Historical overview of pricing policy for medicines in India; links between the essential drugs list and the pricing policy; recent changes in the national pharmaceutical pricing policy in India

f) Access to Medicines and Patents: Overview of international legal frameworks and national regulations on patents and its impact on access to medicines

g) Access to Medicines and Trade Agreements: Bilateral, regional and plurilateral trade agreements and their impact on access to medicines. New challenges to access to medicines brought about by trade agreements such as provisions under TRIPS Plus etc.

The broad objectives of the course were to develop a shared understanding on the current scenario around access to medicines in India. One of the major objectives was to identify and assess the critical barriers and challenges related to the health systems and drug research around access to medicines in India. Also, to understand the role of pharmaceutical industry, patents and policy and legal issues in ensuring universal access to medicines in India was one main objective.

Rationale

Sama, for past several years, has been consistently engaged with issues related to the conduct of clinical trials in India, post trial access to medicines, patented drugs and access to medicines by the general population. This short course was in continuation of this initiative.

The poor availability of quality medicines in the public health care sector as well as the lack of affordable treatment in the private health care sector, with minimal or no insurance coverage, have caused India to be one of the countries with highest out of pocket expenditures for health care services. A large part of out of pocket expenses consists of money spent on medicines.

There are several factors that determine access to essential medicines. Inadequate budgetary provision for health along with the lack of a comprehensive policy on medicines in India and a weak regulatory framework allows medicines to be produced, promoted and prescribed without assurance of their quality, rationality or reasonableness of the price.

Looking at the present statistics, out of all the efforts to lower healthcare costs for people, access to quality, effective, safe and affordable medicines is primary. Furthermore, for any reasonable health care system availability of medicines for the priority health care needs of the population is imperative.

It was in this context that Sama organized the three day short course on challenges to access to medicines while also discussing about patents, pricing and drug research in India.

Day 1

Session 1: Universal Healthcare and Access to Medicines

Speaker: Dr. Amit Sengupta

The three day colloquy on challenges to access to medicines began with an introductory session on universal healthcare and access to medicines by Dr. Amit Sengupta. The speaker started with a rousing note that society and especially public health professionals should remember that health and healthcare is not just about data but about people. A fact which is generally being forgotten for long time in the midst of all numbers and targets to achieve as far as health status of people is concerned.

He requested everyone present to take out two minutes before we begin and think about the deaths of innocent children in a recent mishap in Gorakhpur hospital due to apathy of government hospital administration. He emphasized on keeping this incident in mind while he conducts this session which will introduce the house to the issues around access to medicines.

Talking about healthcare in India, it was highlighted that how development of healthcare services has always been unsatisfactory and has never been given the much needed impetus in the public policy and planning in India. Healthcare has never ever become a game changing social and political issue in India unlike in other countries which is one of the major reasons responsible for the poor public health systems in the country.

In the first Five Year Plan, the budget allocation for healthcare was only 0.22%. Since early 1990s 'withdrawal of the state' from the social sector became a part of the public policy in consonance with overall economic policies of the country. Post economic reforms country saw huge cuts in the health budgets and thus the public health expenditure as part of GDP fell from 1.4% to 0.9% by 2002 which led to virtual dismantling of public health services.

The public outcry against the declining government interest in healthcare led to the National Rural Health Mission in 2005. The NRHM strengthened public health services in some areas but access to these services still remained inadequate and far from reality. By this time, there was a huge deficit in the infrastructure of the public health systems.

Statistics show that growth of infrastructure has lagged behind demand and creation of new infrastructure has lagged well behind the set targets. The conditions of the primary health centers (PHC) and community health centers (CHC) is poor and there is an infrastructural deficit including a shortage of trained medical personnel such as unavailability of anesthesiologists in CHCs in Haryana without whom most of the surgeries cannot take place.

The state of Indian public sector encourages growth of the private sector in the field of health care and one of the many dangers of the proliferation of the private health sector is that it is largely unregulated and thus unaccountable. As a consequence of all the above factors, around 70% of the health care costs are borne by the people through 'out of pocket expenses' which is very high as compared to other developing countries.

Discussing about other developing countries, it was mentioned that Sri Lanka has a well developed public healthcare system. Thailand with a universal healthcare system, which is often cited as a successful example of public-private partnership in healthcare, was in fact preceded by years of strengthening of public health systems. Even today, up to 90% of hospital beds are in public hospitals in Thailand. Meanwhile in India, out of pocket expenses that are paid at the point of the care by the persons not covered under any health insurance bears major part of medical costs in India.

Public-Private Partnerships (PPP) is projected as 'win-win' situation for all those involved which primarily means public services outsourced to the private sector. There is a transfer of resources from public to private healthcare sector. This brings up a question as to why such a situation exists in which vital services in public healthcare are contracted out to private health sector? It includes outsourcing of both clinical and non clinical healthcare services to the private sector.

The common argument given to promote increased private provision of health services is that it can bring in desperately needed additional capital and capacity in low-income countries. But private sector provisioning of health care requires huge public subsidies to thrive which are given in the form of cash subsidies, subsidized medical education, subsidized or free infrastructure (land, etc.) and tax breaks.

One of the major concerns is that the private sector also competes to provide care mainly in the urban areas and not in underserved areas which gives rise to a situation where private sector does not complement public services but competes with it. Private sector competes also by drawing human and technical resources away from public sector.

Before understanding the debate around Universal Health Coverage (UHC), speaker explained what universal health coverage is and how it was conceived as a health financing system that would progressively move towards the coverage of the entire population. It will include an increasing range of services and seek to increase the share of pooled funds as the major source of funding (in relation to co-payments by those accessing health-care).

UHC was promoted by WHO as a health financing system which while saying that governments should spend more on health care also leaves to the individual countries on how this money is utilized. It says healthcare should be public funded but services can be outsourced to the private sector and the role of government can be more of managing this system.

System envisaged is of a clear 'provider/purchaser' split which entails that the issues of financing services are entirely divorced from provisioning of the services. However, one needs to understand that public and private sector logic is different. While Public sector will spend a certain amount of money to treat the largest number of people, private sector will use the same amount of money and invest it to get a larger amount of money as returns.

Essentially, one of the stark features of UHC is that of being a model of health insurance where the population covered is entitled to treatment by certain pre-defined service packages. In other words, UHC concerns itself with the cost-effectiveness and efficiency and thus does not differentiate between public and private services. Schemes such as Rashtriya Swasthya Bima Yojana launched by government

in 2009 and several other state health insurance schemes with some already rolled out and some in pipeline are entirely funded by public sector to provide hospital care to people in certain accredited institutions for a certain list of procedures.

Thus, the insurance has been masquerading as universal health coverage for a while. The social health insurance schemes provides public funds to private health facilities thus denuding public health care facilities further and build health care priorities in favor of tertiary care rather than primary care. Yet they are being seen as the model to implement UHC in India. So, it is important that for long term benefit of achieving 'health for all' public health services are reclaimed and work is carried forward to bring in transformations not just in the area of healthcare but related to other social determinants of health too.

Different sources estimates that majority of the population has no access to all the medicines that they need. Poorer population spent a larger proportion of their health expenditure on medicines with many being pushed below poverty line every year due to high out of pocket medical expenses.

Pharmaceutical manufacturing industry is one of the few success stories of manufacture in India as India has become one of the largest manufacturers of drugs in the world and exports medicines to over 200 countries thus, availability of medicines and local production of medicines are not major concerns in case of India. Some of the identified factors that determine access to medicines include:

- Rational selection and use
- Affordable prices
- Sustainable financing
- Responsive health system
- Reliable supply system

Though affordability is one of the factors for access to medicines, it stands out to be a critical factor as far as Indian health system scenario is concerned. Pattern of Indian pharmaceutical market is different from most of the markets. In most cases, a bulk proportion of consumption of drugs is through supplies by large institutional mechanisms such as hospitals, health insurance both in public and private sector where as in India a very large proportion of drug consumption is through retail sales (85%).

Intellectual Property Rights are temporary monopolies given by the government to a manufacturer and thus are important tools used to control access to medicines. The 1970 Patent Act did not allow monopoly in pharmaceutical sector and this allowed Indian brands to make medicines for the domestic and even international market. In 1988, Uruguay round of negotiations related to trade started. In 1989, the resistance by the developing countries to the inhibiting IPR laws was broken down.

In 1995, rules set by WTO or TRIPS became applicable to almost all the countries of the world. Same set of rules of patents were applicable to all the countries in the world. Thus, we had to change the patent law and allow companies to have monopoly. Momentum of the earlier patent act has led us through most of the 2000s and impact was not felt of the new situation but now we are witnessing the effect of change in patent law in terms of research and development and access to medicines with a number of new medicines not accessible to majority due to change in law.

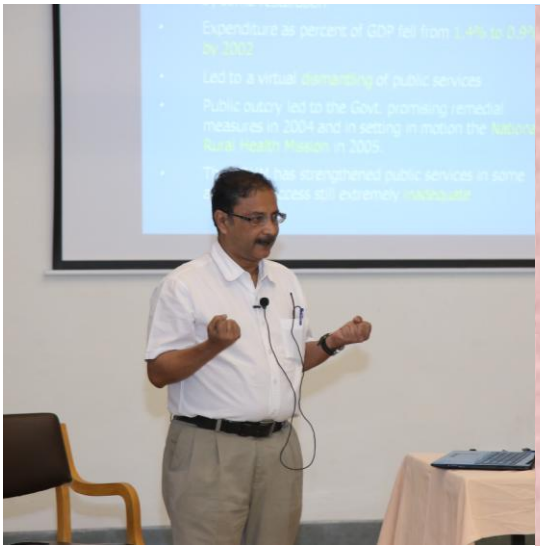
Issues of patents has also become linked to the rights of human being and survival of HIV/AIDS patients as it was the first group of patients forced to organize themselves and speak up for themselves. Now, patents affect access to medicines for all patients suffering from diseases such as HIV/AIDS, cancer and others.

Discussion

During post session discussion, some interesting facts came up. One of the basic arguments given in favor of monopoly over drugs by a specific company is that the cost of research and development is really high and that any attempts to block it might affect the discovery of new drugs. Most of the research on development of new drugs will be affected and if we don't give monopoly to corporations how they will have money to develop new drugs albeit companies need money to invest thus monopoly should be given.

This has been a traditional and classic industrial argument given by companies even after the genocide in Africa justifying high price of drugs due to high costs involved. In Africa, situation changed in the year 2001 and 2002 as that was the time when 90% of drugs for HIV/AIDS were supplied by Indian companies. Drugs are salts procured by companies in large amount and then manufactured in desirable forms at a very low cost.

Companies tend to make profits on drugs within a short time but patents give them an extra advantage to earn much more profits for years. Ridiculousness of the claim on R&D lies in the myth that the private companies esp. in US discover new medicines. Drug discovery is a very complex task which involves trial and error to look at and examine a range of compounds which might be useful for the treatment of the disease and almost this entire research is done in public funded institutions or most researches are done in public universities.



Today, science has constantly been able to come up with the new solutions but at the same time human greed and commerce is trying to hold back the advantages of human endeavor from reaching all.

- Dr. Amit Sengupta

Instead, multinational companies are the ones who get license to manufacture those drugs on large scale and thus invest in putting them into clinical trials. Therefore, there is no actual reason to believe

that the drugs are discovered by the companies. They only take the commercial risks involved in manufacturing and marketing the drugs.

There are certain drugs known as blockbuster drugs which gain more than a billion dollar in sales. One such example is zintec which within a small time frame of three months started making profits keeping in mind the cost of manufacturing involved and a monopoly given to it resulted in extended profits for the company for a long time. Thus, companies are the ones who actually gain from patents not the one who discovers them.

Another scenario is when a small company is bought by a large company and thus the latter one enjoys the benefits of the patent where as the former gets onetime payment for their discovery. On being asked, how the list of essential medicines and price control on drugs has actually changed over the years and why in spite of 645 drugs on essential medicines list, they are not accessible and affordable for all Dr. Sengupta explained that how the nature of the list has changed.

Earlier, there were 343 drugs on the national list of essential medicines in 1979 which included all forms of the listed drugs whereas now in the new list of 645 drugs only dedicated formulations are listed and under price control. Thus, a drug with different fixed dose combination and different formulation can be exempted from price control even if it exists in the NLEM.

Day 1

Session 2: Access to Medicines – In the framework of Human Rights

Speaker: Vivek Divan

Mr. Divan kicked off the session by stirring a question in front of the house as to why do we need human rights at all? Do we actually need them or not? To which the participants had interesting answers such as there is a need of human rights to prevent the incidences of oppression of one entity, company or human being by another. Another participant spoke about the need of human rights to prevent denial of basic rights of an individual. Also, human rights are needed so that there should not be any kind of exploitation based on any class, caste or gender.

Clearly, speaker highlighted that there is a power equation often existing in the society which could be in terms of a smaller company against a bigger company, a corporation against a state, an individual against a state or based on class, caste, gender and sexual orientation etc. Thus, something is needed which protects those who are exploited or marginalized to the maximum extent and see that as much as equality is possible in the society.

Human rights are needed to ensure a dignified life to a human being. Talking about human rights, he shared how the framework for human rights came into being over the years after the Second World War. He also asked the participants if they knew where the Human Rights are listed or present and the participants were aware of that they are written in declarations, conventions, and international agreements and in the Indian Constitution as well. He discussed different human rights values that could possibly be a part of any rights framework.

Certain human rights and freedoms are core to any free society. Speaker then discussed different rights and freedoms one should essentially have along with right to standard of living that includes health, well being and medical care as included in United Nations declaration on human rights. Human rights are absolute where as fundamental rights are not absolute. Right to health and medicine are essential to all.

India has many international commitments to human rights in healthcare such as ICESCR (International Covenant on Social, Economic and Cultural Rights) and several national commitments such as those in Constitution which are listed under Directive Principles of State Policy. When it comes to enforcing ICESCR, international agreements signed by India do not automatically become law here as it has a dualist system of international law in which it has to be passed by the parliament before it becomes law. However, the Indian courts do take the international agreements in consideration while making judgments, provided that these agreements do not clash with the domestic law.

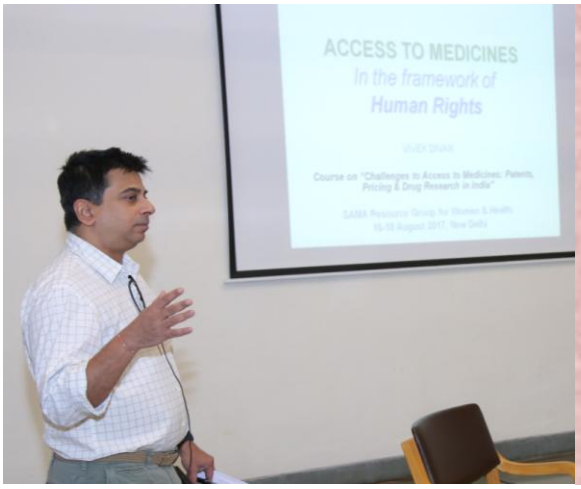
Constitutional courts have interpreted Right to Health as within the Right to Life, referring to Directive Principles and there have been various instances when Supreme court has looked at human rights of individuals and directed government to work accordingly, such as ensuring access to 1st and 2nd line of HIV treatment and directing government to monitor the implementation of its order on access to

medicines. So, the right to health even if not written exclusively has been articulated by the courts as right to life in terms of access to medicines in many instances.

Most judgments regarding access to health are mostly concerned with government workplaces, government hospitals etc. and are thus, enforced against the state. Also, the courts have come against private healthcare facilities in certain instances and ensured accomplishment of right to health in such cases. Consumer Protection Act is one such protection offered against malfeasance by private healthcare providers. Thus, implementation and enforcement of such laws is prime responsibility of government to realize right to health in terms of access to medicines.

Under the Sustainable Development Goals of the UN, Goal 3 is about ensuring healthy lives and promotion of well-being for all at all ages but the statement has been left more open ended for the states to interpret. He also pointed out that the goal even in its existing form emphasized on about how public health should be considered more valuable than Intellectual Property Rights.

Mr. Divan ended the session with a few questions for us to ponder upon such as whether we need a clearly spelled out Fundamental Right to Health which also includes access to medicines in clear terms, whether we should have a Human Rights Legal Framework that applies to private sector and how can the state be held accountable for international commitments so that they are more effective for us. Do we need more laws or better implementation of the existing ones?



Public health should be considered more valuable than the Intellectual Property Rights and therefore access to medicines should be facilitated to the extent possible.

- Vivek Divan

Discussion

One of the participants asked, that in Indian context what is holding us back to come up with an act of parliament bringing a fundamental right to health and if at all Is it important that all of us should have right to health? To this, Vivek responded that many in country thought that their right to health should come from private sector. He discussed how Netherlands model is one wonderful example of how people can be given good health and access and that the American model is actually one faulty health system when it comes to access.

Also, the need of the hour is that instead of looking at the constitution of more laws steps should be taken to ensure realization and implementation of existing laws. Courts are already overburdened and became last resort for the people thus preventing people to come up to realize their rights.

Another question by Dr. Yogesh Jain triggered a discussion on whether its right to have a regulation which would have otherwise prevented someone's right to access to medicines such as in the case of blood for transfusion due to various guidelines to be followed or ultrasound facility restricted by PCPNDT act. To this, Vivek responded that we have actually failed to have good implementation and regulatory mechanism of existing laws and thus compromise on the issue of access to medicines.

Day 1

Session 3: Access to Lifesaving Drugs

Speaker: Dr. Yogesh Jain

Third session started with the screening of a short documentary movie 'In the name of medicines'. Post screening Dr. Jain opened the session with speaking about marginalized India which he has been serving for few years now as a physician. He emphasized on the fact that drugs may not be only part of health but an important part of health. Talking about issues around access to essential medicines he requested all to take up this movement at any level possible.

He then acquainted the house with the basic nomenclature related to drugs viz. essential medicines, drug list etc. The last essential drug list came out in 2015 and each state is then supposed to have its own drug list tailored to the specific health problems faced by the population of that state. Certain lifesaving drugs are needed by some states and are often required at lower volume and thus companies do not show interest in manufacturing them.

Explaining about the three tier level of health care he explained the services available at these public health facilities at different levels viz. primary, secondary and tertiary level of care. Some of these lifesaving drugs are also niche medicines and are not cheap but companies do not see any incentive to manufacture them unless forced to do so. Thus, all lifesaving drugs may not be included in essential drug list. And similarly all essential drugs are not life saving drugs.

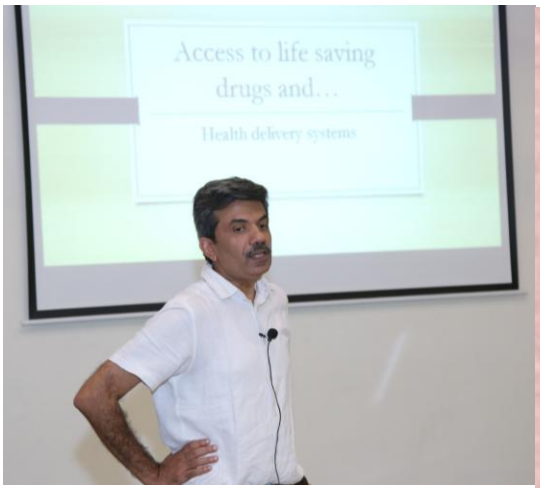
There are certain drugs which are under price control even if not under essential drug list. This was mandated by the Supreme Court 2003 judgment that essential and life saving drugs should not fall out of price control and price control should apply to all strengths, doses and chemical analogues of the essential and lifesaving drugs.

Generally, the reasons to poor access to lifesaving and essential drugs can be classified broadly into three reasons. A major reason which controls access to drugs is the mistaken notion about branded drugs always being superior to generic drugs. There is major drug misinformation such as multiple brands by the same company. Big companies often source drugs from smaller companies and wholesale price is much lower than retail price. Fixed dose combination makes generic prescription difficult. Another reason for poor access to drugs is poor drug approval and regulatory system.

Inaccessibility of drugs has a terrible impact on the Indian population out of which the worst has to be a large number of deaths resulting from it. For example, for someone in rural India suffering from diabetes an average of 34% of income is spent on diabetes care. With no money to buy medicines, majority of the people stop the treatment in between and do not care about their diabetes resulting in morbidity and mortality.

When it comes to state spending on all the essential drugs keeping in mind correct methods of procurement, 100% utilization of essential drugs would take 17,000 crore rupees. He showed with statistics the number of wage days required to meet the out of pocket expenditure on certain essential

drugs for certain diseases and how the cost of procuring these drugs can be reduced to 10% of market price if state provides these drugs to people. He emphasized that the issues with drug inaccessibility can be brought up using case based advocacy or through media and if needed, as a last resort, the legal route can also be taken.



Drugs may not be the only part of health but it is definitely an important part of health and responsible for major part of out of pocket expenses.

- Dr. Yogesh Jain

Discussion

Post presentation, the house was divided into groups and asked to discuss the incidences of non access to essential medicines in their professional and personal experiences. Everyone in the house came up with their personal experiences and a list of drugs was made with the name of the drug, disease, reason for inaccessibility and effects of that inaccessibility as seen.

It was identified that there were a number of essential drugs which should be available something as basic as ORS solution but were not available at the public health care facility or inaccessible to larger population for some or the other reason. There were drugs with short shelf life and required in small quantity because of utilization in small area for certain niche disease which were not manufactured looking at the low volume and low sales.

Looking at the list most of the participants understood the problem and the need to take necessary steps of action especially in terms of efforts highlighting case based advocacy, health movements and writing about the issues on a larger scale so that the voice is heard.

Day 2

Session 1: Drug Pricing, DPCO – 2013 and Related Issues

Speaker: S. Srinivasan

After introducing himself to the house, the speaker began the session with a discussion on various issues in access to medicines in India today and how this is further exacerbated due to the nature of the Indian economy which further leads to businesses hoarding essential commodities like medicines.

To begin with he explained drug price control order issued under essential commodities act. It consists of a certain set of drugs from essential and lifesaving drug list put under price control. Highlighting problems he mentioned that the problem is simple average formula, DPCO excludes many lifesaving drugs and that it overlooks a large number of irrational fixed dose combinations and excludes patented drugs from price control.

National pharmaceutical pricing authority (NPPA) is the government agency that implements DPCO. Taking the presentation forward he discussed about the India's pharmaceutical industry and how Indian pharmaceutical companies are dominating and growing above the market. He also highlighted the situation of pharmaceutical companies now and the difficulties being faced by them.

While the USPTO(United States Patent and Trademark Office) argues that "India has no ease of access of trade because of extreme price control measures", only 10.56% of India's pharmaceutical Industry is under price control which greatly affects affordability of medicines for the majority of the population and this is how Drug Price Control Order (DPCO) becomes of great significance. Most of the drugs available in Indian markets, especially bulk drugs, are imported from China. The Indian pharmaceutical industry is also a 'top-heavy' sector in which top 10 companies have 42.8% of the total turnover of the industry and the top 25 have 65-70%. Many small entrepreneurs and family businesses in the industry are also closing up due to difficulty of running a smaller pharmaceutical industry in India.

Medicines are a unique commodity as unlike other commodities, the buyer i.e. the patient has often no choice to buy another medicine as s/he is made to believe that the choice of medicine is a matter of life or death. There is also an information asymmetry between the patient and the doctor/pharmacist as the seller has more information than the buyer and the buyer is making an uninformed choice.

Thus, there is a general market failure in the Indian pharmaceutical industry which can be explained as a 'market for lemons' where even useless goods or those not required by the buyer or 'lemons' are sold to the buyer. Competition in the free market in this case has not managed to reduce the prices of the medicines.

The current DPCO uses market pricing to fix the prices of medicines covered by the order. Before DPCO 2013, the ceiling price of drugs was fixed using cost based pricing. While Market Based Pricing (MPB) was supposedly introduced to lower the prices of drugs, the Simple Average Formula has been criticized

as it results in the opposite since the market is skewed to higher prices leading to a higher average which is used to set the ceiling price. The decision to follow MBP in the pharmaceutical sector has further been questioned as no other major sector follows this.

The revised National List of Essential Medicines (NLEM) has come under fire as only 376 drugs in specifies strengths and not when in combination with other drugs is under price control. Many essential drugs and a majority of anti-diabetes drugs have been excluded from NLEM 2015 and this is despite the fact that in terms of absolute numbers, India has the largest number of diabetes sufferers in the world.

When DPCO 2013 ceiling prices are compared to Rajasthan Government procurement prices, we find that there is a difference of 10 to 12 times between the two which shows the failure of the average pricing formula of DPCO. Patented drugs are also not included under price control and are thus exorbitantly priced. Next step should be weeding out of irrational FDCs and bringing patented drugs under price control too.

Discussion

The session was followed by a round of questions by the attendees in which the first question was of a situation regarding some essential drugs which companies might stop producing if there is little profit for the companies. The answer to this question was that while the government cannot compel any company to manufacture any drugs, it can issue a Compulsory License (CL) to a company on a contract basis in the case of overpriced or inaccessible patented drugs.

Through the next question, we learnt that the Ayurveda or other traditional medicines do not come under price control and neither it is strictly regulated which should be addressed as soon as possible. Mr. Srinivasan also explained how the newly rolled out GST, a source of much confusion has affected medicinal drugs which is 12% on most formulations and 5% on some others which has resulted in all drugs becoming dearer by 2-3%.

For drugs under price control, ceiling has only marginally increased but for others, the population is expected to bear the losses. The session ended on a comment on how both the left and the right oriented political groups agree on the failure of the pharmaceutical market but the government wants to curb the powers of the National Pharmaceutical Pricing Authority (NPPA) as it feels it is controlling the prices of too many drugs and medical equipment much to the chagrin of the government.

> Medicines are a unique commodity as unlike other commodities and the buyer i.e. the patient is often given no choice to negotiate buying these commodities.
>
> - S. Srinivasan

Day 2

Session 2: Experiences from Free Medicines Scheme of Rajasthan

Speaker: Chhaya Pachauli, Prayas/JSA

Ms. Pachauli opened the session by posing a question to the house: Should medicine be free for all? Is this the only way to make medicine accessible to the marginalized? One of the participants pointed out that it should be a targeted intervention only meant for the underprivileged while another argued that the medicines should be free for all as it is essential to maintain the dignity of human life. Another one said in further addition to this argument that free medicine for all will lead to gradations in quality of the medicine with only the worst available as free of cost.

Jan Swasthya Abhiyan(JSA) argues that if there is targeted intervention for providing free medicines, the onus for proving eligibility through identity documents like Aadhaar Card falls on the patient which they are often lacking and thus, it hinders their access to these medicines. Free medicines for all will also help break the nexus between the medical care providers and the drug manufacturers. Doctors getting commission from drug companies for prescribing their medicines would mean they would needlessly prescribe unnecessary and expensive drugs, thus the scheme would rationalize treatment. The status of the Free Medicine Scheme in India is different across different states. Tamil Nadu was first to introduce the scheme in 1995. Rajasthan replicated the model in 2011 with slight variations. There are variations in success and manner of implementation of the scheme across the states.

The Rajasthan model of the Free Medicines Scheme was discussed by the speaker. The first phase was the campaign by civil society. It started with a scheme in Chittorgarh in which drug stores were opened by Cooperative departments and Life Line Drug Stores run by Medical Relief Societies which provided medicines at a cheaper cost. There were some difficulties in convincing even civil societies for the campaign as two questions were commonly asked which were firstly, why did everyone require free medicines and secondly, how could the government bear such immense expenses to provide medicines free of cost to everyone? The first step of campaign was to mobilize civil society to resolve such aforementioned doubts, clear misconceptions about generic medicines plus engage in building consensus among community. This was followed by activities at district level with dharnas, protests and effective use of the media. With a major help from sensitive bureaucrats and political willingness due to the approaching elections, the scheme was launched on 2nd October, 2011.

The Rajasthan Medical Services Corporation Limited (RMSCL), an autonomous centralized procurement body was established to procure and supply medicines. The work flow begins with an annual demand which is received and then sent to headquarters. From here on, it is sent to the lab for quality testing of drugs and it then enters public distribution. The quality testing ensures no spurious drugs are being distributed. A website, e-Aushadhi, can be used to enquire about availability of drugs in any particular health facility and makes exchange of drugs possible between health centers in case of shortages. The department can also monitor what kind of medicines are prescribed through use of carbon copies of

prescriptions made by doctors which patients hand over to the drug distribution facility. There is also a provision of SMS based daily monitoring and feedback system which sends a daily summary of logs of patients, medicines, etc to doctors and officials involved. The scheme overall led to increased availability of medicines at health facilities across Rajasthan.

However, the scheme has suffered a few reverses post state elections in Rajasthan and a change in the government. During its campaign for elections, the then opposition party, BJP criticized this very successful scheme and after it won elections, the new government gradually sabotaged the scheme. It removed key officials involved, the able leadership was removed and the role of the RMSC was relegated to only procurement and supply of medicines unlike earlier when it also used to perform the role of orienting health service providers and creating community awareness.

To combat all these challenges, the Save Free Medicines Campaign has emerged in which Ms. Pachauli is also involved. It is conducting memorandum campaigns, conducting public hearings and mobilizing community members in its attempts to save the scheme. There have also been talks about a 'National Free Medicine' scheme in which essential and life saving drugs will be guaranteed to all irrespective of existence of scheme in the particular state.

Day 2

Session 2: Free Medicine "Niramaya" Scheme in Odisha: Field Reality

Speaker: Gouranga Ch. Mohapatra, State Convenor JSA, Odisha

In the state of Odisha, 70% of medical care costs are out of pocket expenses and 70% of these costs are spent on buying medicines. The free medicine scheme adopted in Odisha was a business model in which, in the initial years, the responsibility of running the scheme was given to corporations. The budget which was a miniscule 15.29 crores in 2001-02 was increased to 253 crores in 2016-17 with a massive jump in 2013 which is at present the highest per patient budget out of all states.

However the ground reality is vastly different and very disheartening. Drug distribution centers have not been established in most areas of the state. The government has not procured all the medicines on the Essential Drug List of Odisha which covers most requisite molecules. Most medicines are not available in the public health facilities and all of them are not available at even the medical colleges in the capital which are expected to be well stocked. Despite dedicated transport vehicles, there is poor availability of medicine. Some medicines are found to be of inferior quality despite regular and rigorous testing.

Doctors at public health facilities are still not prescribing generic versions of the medicine and are instead prescribing branded ones which are not available at the drug distribution centre and are highly priced. Many of them are still uncertain of the quality of the medicines available for free under the scheme and many others are involved in unethical practice. The software for managing procurement and supply logistics is not functional. There is a shortage of doctors, staff in project management and pharmacists.

Hence there is a lot of action required to overcome these challenges and it has to start with grass-root level campaigning and sensitization. Mr. Mohapatra remarked that this scheme has actually been launched thrice till now, timed carefully right before elections at various levels and finally started the third time.

Discussion

Ms. Pachauli and Mr. Mohapatra had a joint question session in which the first question was addressed to both of them which asked why there was no political will to make the scheme successful in both Odisha and Rajasthan.

Chhaya shared that in Rajasthan, after the change in government, the new government has launched a health insurance scheme, Bhamashah Swasthya Bima Yojana which is only for those families covered under Food Security act and has a food security card with them. Thus, the government wishes to promote the scheme launched by them instead of the scheme launched by the previous government. There was also a time when the previous Rajasthan government planned to increase the budget for Free Medicines Scheme but the current government was planning to slash the budget.

Through other questions, we also found out that out of the entire budget for the scheme in Odisha, a very small percentage is allocated for the procurement of the medicines. Thus, both the speakers were skeptical of the will of the respective governments to ensure the success of free medicines scheme in their respective states.

Day 2

Session 3: Drug Research and Ethical Issues

Speaker: Dr. Amar Jesani

This session by Dr. Jesani was one of the most interactive sessions of the workshop with him choosing not to go for presentation but a soul stirring short documentary followed by case studies and discussion on drug research, clinical trials and ethical issues around the same.

In the beginning of the session, a documentary was shown with the name of 'A matter of trust' filmed by doctors in Karachi who have looked into how ethics are forlorn when clinical trials are done. The documentary compelled everyone to think about the way clinical trial is conducted and how patients fall prey to certain foul practices in a normal routine medical setup. Dr. Jesani then discussed the learning from the short documentary in which participants gave their inputs on how ethics were compromised in the documentary. How the trust of patient was broken by doctor and how doctor was given all sorts of enticements to compel her to conduct clinical trial in her clinic. The documentary showed how inaccessibility of drugs after clinical trials affects patients or clinical trial participants at large.

Later, Dr. Jesani discussed various issues around ethical considerations in drug research, ethical considerations while conducting clinical trial, individual rights of participants of clinical trials and human rights violations of the individuals in the whole process of discovery and approval of a new drug. The house discussed how in the case of some medical emergency anywhere across the world the samples or swabs are shared between the countries to come up with some new drug or vaccine against the cause of the disease. But what is the guarantee that the vaccines or medicines discovered will be available to those who sent their biological samples. Thus, a question of ethics and conduct of ethical practices arise in the whole discovery cycle of the vaccine or a new drug.

The discussion further ensued stating various examples in the past and present where ethical guidelines were partaken just for sake and not followed in the process of drug research. After that, the house was divided into groups and a case study was given to each group. Each group was required to think about the answers to the questions in the end. All groups used chart and colors to jot down their thoughts related to the case study. The groups participated in the learning activity very enthusiastically.

In the end all the case studies were discussed in front of the house and issues around ethics, ethical considerations and drug research were deliberated upon such as informed consent, recruitment of participants for the clinical trial research, difference between intervention and control group and how during the study control group should not be at a disadvantage. Discussion was an enriching experience for all those present.

Day 3

Session 1: TRIPS, Patents and Patent Law

Speaker: Veena Johari

The Agreement on Trade-Related Aspects of Intellectual Property Rights(TRIPS) and Patent Law, the speaker argues, is not based on rights of the people but is based on greed of the big corporations. The speaker started the discussion with an explanation of the fundamentals of the legal terminology involved. What does a patent do? It gives ownership and monopoly of producing a product that is gives a monopoly right, it gives exclusive rights to the monopoly holder and allows them to put it before the patent authority.

There are two domains of the patent from the point of view of public involvement. The Public, which is the information available in the public and thus known to all already from beforehand, that is prior art. The private domain that is once one gets a patent, one should make it available to the public. The pre-requisites of patentability are novelty, non obviousness and utility. A pharmaceutical patent is valid for 20 years and gives sweeping rights to the patent holder.

Historically, the dangers of patents did not go unseen as according to the State Monopolies England 1624, one could not arbitrarily raise prices of patented items. The TRIPS Agreement was passed in 1994 where the key players were the CEOs of the big pharmaceutical companies working towards their own self profit. It gave a 10 year transition period from 1996 from their earlier patent laws to TRIPS to the developing countries like India and a longer period to the least developed countries.

The 1970 Patent law in India only had process patents and did not give product patents and made patents inapplicable to pharmaceutical drugs. In 2002, India extended the patent term to 20 years from the earlier 4 years. In 2005, the Indian patent laws were completely overhauled to conform to TRIPS regulations. It also ensured publication of patents after 18 months.

Ms. Johari then went on to elucidate us about the articles of TRIPS which work as safeguards against the indiscriminate power of the multi-national pharmaceutical companies. Article 7 and Article 8 talk about balancing obligations, benefit to users as well and also more importantly, about public health. Article 27 states that methods of treatment like ways of performing a surgery or how a drug is administered may not be patented. Article 31 talks about the provision of compulsory licenses in which a government can authorize a party to use or produce a patented product without the authorization of the patent holder. It also provides the provision of bypassing patent laws in cases of extreme emergency.

There are two kinds of dates vital to a Patent. One is Priority Date, which is the period for claiming a patent. The other is Filing Date which is the date of filing a patent application and is the date from which the patent term applies when granted.

After TRIPS was enforced in most countries of the world, there were a lot of concerns about how people are not getting medicines and led to HIV movement in particular in response to the millions of deaths as a result of lack of access to drugs to HIV/AIDS patients especially in Africa. These were instrumental in

the passing of the Doha Declaration in 2001. It declared that TRIPS does not prevent member countries from taking measures to protect public health. However, it is well known that developing countries oftentimes cannot employ these safeguards as they are under pressure from dominant countries and international bodies not to use the same.

To understand the intricacies of the TRIPS agreement, it is important to be well versed with certain definitions. The first is invention which refers to an inventive step or a new invention. The section 3 of Indian Patent Act talks about patentability. Section 3(d) states that mere discovery of a new form of a know substance which does not result in enhancement of known efficacy or is simply discovery of a new property or the use of a known process is not patentable.

Efficacy refers a therapeutic efficacy that one which produces an effect at the cellular level and patentability requires proof of efficacy. So while in the Novartis case, Novartis argued a wider understanding of efficacy, the courts and the law calls for a narrow definition. Section 3(e) further states that mere admixtures or combination of known substances cannot be patented.

On this point, Mr. S. Srinivasan argued that increased bio-availability is a legitimate reason for patent but the counterpoint was that while such adaptations may be useful and also difficult to obtain, if the process is known and the chemical form is not altered, then a patent cannot be granted.

There is a very important provision of the Third Party Intervention in which one can oppose the granting of a patent either before or even after the granting of a patent. A pre-grant opposition can be filed by any interested party but is seldom used and comprises less than 1 % of the total number of oppositions. A post-grant opposition which is more commonly used can only be filed by someone personally affected by the granting of the patent.

This presentation was followed by a mock case study activity in which the participants were divided in groups and each were given a case in which they had to decide on the basis of prior art and Patent Laws whether they would have granted the patent.

Day 3

Session 2: Case Study - Gleevec Case

Speaker: Pratibha Sivasubramaniam

The speaker started the session with a question on what is 'evergreening' in relation to patents. Someone rightly answered that it meant extending patent life by the mere addition of a few molecules or a change in the form and thus applying for a new patent on the basis of it.

Novartis, one of the biggest pharmaceutical companies in the world, did not hold a patent for an anti-cancer drug in India and thus generic versions of it were available. This was during the transition period before TRIPS was fully applicable and thus no product patent laws applied in India.

In 2005, post amendment in patent law, Novartis filed a patent application for the beta-crystal form of Imatinib Mesylate, the anti-cancer drug. 50 generic drug manufacturers and CPAA, an NGO filed a pre-grant opposition in the Chennai High Court as Imatinib Mesylate was a known substance and Novartis was simply offering it in a different physical form with no difference in efficacy proved. Novartis filed a constitutional challenge to Section 3(d) under which the pre-grant opposition was filed; it also appealed against the rejection of the patent application.

The defense of Section 3(d) given by the court was that Domestic Court cannot examine TRIPS compatibility and this section does not violate the Constitution of India. The judgment given by the court was that it recognized that the state has the obligation to provide good healthcare to citizens. Following this judgment against Gleevec, it filed a case in the Supreme Court which Gleevec lost in Supreme court as well and the Supreme Court maintained the standing definition of 'efficacy' which Gleevec had challenged.

Following this presentation, a two minute video clip was played which captured the protests against Novartis during the same case. The protesters in the video argued that the Novartis will kill India's pharma industries and such mega pharmaceutical companies do not care about the poor and "put profit above people". This was followed by a question which was regarding the extra-legal action in the Novartis and Gleevec case i.e. what these companies did to put pressure on those opposing them aside from filing legal cases. There was also a comment about a deeper curiosity about the people's movement against such pharmaceutical giants and what went on 'behind the scenes'.

Day 3

Session 3: Free Trade Agreement Negotiations

Speaker: Kajal Bharadwaj

The speaker started with an example of HIV treatment drugs to show how the MNCs operate and their impact on the lives of people across the globe. From 2001-2012, generic competition severely brought down the price of MNC manufactured HIV drugs which were so overpriced that millions of people in poorer parts of the world such as sub-Saharan Africa perished because they could not afford the treatment before generic companies started manufacturing the drugs as well. Such sky rocketing high prices also existed for cancer treatment, Hepatitis C pills and many others.

These generic companies, majority from India were able to manufacture the patented drugs without suffering legal consequences as they were based in developing countries which were still in their transition period before TRIPS had to be enforced. Thus, the '3 in 1 AIDS pill' with a fixed dose combination could also be launched in India as there were no product patent laws at the time.

Thus, there was an increasing use of TRIPS flexibilities and developing countries argued that the 20 year monopolies granted by TRIPS were contrary to WTO which wished to open markets and promote market competition. Thailand with a universal health care system also issued compulsory licenses to many generic companies to bring down their healthcare budget which was inflated due to the high price of the patented drugs of MNCs.

However, implementing TRIPS flexibilities comes with a reality check that is every time one of these flexibilities or safeguards is used, it is challenged legally by the pharmaceutical companies. The US patent office and pharma companies train Indian judges and patent office officials which leads to a bias towards them. This proved itself in the Novartis case when the high court judge in the case had been taken to training conferences in Europe by pharmaceutical companies and thus had to withdraw from the case as there could have been a possible personal bias.

The US Government brings out a 'Special 301 Report' which is a list of all those who violate their Intellectual Property laws and India has been on the 'Priority Watch List' since the very beginning. The US government applies or threatens to apply trade pressures on these 'guilty' countries in order to make them comply.

Lately, the Indian generic industry is going through a lot of mergers with MNCs and so there are also no oppositions filed against the patent applications by MNCs anymore as they all want to be in the good books of the MNCs or they will not get acquisitioned. The Free Trade Agreement (FTA) also hampers a lot of safeguards of the WTO TRIPS. FTA also depletes government revenue which leads to privatization of healthcare and it has also increased the IP clauses at present.

The TRIPS-Plus which has now been adopted by many countries has a clause on Data Exclusivity which allows monopolies without the use of patents. It also provides for patent enforcement by tax payer money through police cases making it a criminal offence to infringe upon a patent right.

This was followed by a group activity in which 5 groups were created each representing a different stakeholder in passing of an inclusion or amendment to FTA which proposed that the patent holders should be compensated with an extension of term for the delays incurred in granting of the patent and in approval for marketing rights.

The different stakeholders were the Health Ministry of India, an organization representing Indian pharmaceutical companies, an organization representing multinational pharmaceutical companies operating in India, the Indian Patent Office and the network of patient groups in the country. All had to present their case before the Minister of Commerce who had to make the final call on whether India should go for or against the inclusion of the clause based on the arguments presented by each group.