National Workshop on

Pharmaceutical Policies in India: Balancing Industrial and Public Health Interests

Workshop Agenda
March 03–05, 2014

Venue: **Conference Hall, ISID Complex**

Time	Theme	Chair/Speakers/Facilitators
	Day 1: 3 March, 2014	
08:00-09:30	Registration	
09:30-09:40	Chair	Prof. S.K. Goyal, Vice-Chairman, Institute for Studies in Industrial Development (ISID)
09:40-09:45	Welcome Address	Prof. M.R. Murthy, Director, ISID
09:45-09:50	About the Workshop	Prof. Dinesh Abrol, Professor, ISID
09:50-10:00	About the Workshop	Dr Sakthivel Selvaraj, PHFI
10:00-11:30	**Access to Medicines: Availability, Affordability, Public Procurement and Financing** (Class Lecture)	Chair: Amitava Guha Speaker: Dr Sakthivel Selvaraj, PHFI
	Tea/Coffee Break	
12:00-13:30	**Access to Medicines: Competition, Pricing and Rationality** (Class Lecture)	
	Competition and market structure	Chair: Dr Gopal Dabade Speaker: Amit Sengupta
	Promotion and rationality	Chair: Dr Gopal Dabade Speaker: Amitava Guha
	Lunch Break	
14:30-17:30	Group work on **Access to Medicines Chair: Mira Shiva and Richard Cash**	
	1. Availability and stock outs	Facilitators: Shaffi Mohammed and Shankar Prinja
	2. Affordability	Facilitators: Anita Kotwani and Habib Hasan
	3. Financial risk protection	Facilitators: Shailendra Hooda, Swadhin Mondal and Soumitra Ghosh
	4. Rational use	Facilitators: Mira Shiva and Gopal Dabade
	5. Public Procurement	Facilitators: Maulik Chokshi and Arun Nair
	6. Price Ceiling	Facilitators: Malini Aisola and Aashna Mehta

Time	Theme	Chair/Speakers/Facilitators
17:30-19:00	Group presentations	Chair: Mira Shiva and Richard Cash
	Dinner	
	Day 2: 4 March 2014	
09:30-11:00	**Production, Trade and Quality** (Class Lecture)	
	Production structure	Chair: Prof. Dinesh Abrol, ISID Speaker: Prof. Biswajit Dhar
	Pharmaceutical trade	Chair: Prof. Dinesh Abrol, ISID Speaker: Prof. Reji Joseph
	Tea/Coffee Break	
11:30-12:00	**Role of public sector in R&D and innovation** (Class Lecture)	Chair: Prof. Biswajit Dhar Speaker: Dr Satyajit Rath
12:00-13:00	**Foreign and Domestic Investment in Pharmaceuticals** (Class Lecture)	Chair: Prof. Biswajit Dhar Speakers: Prof. Chalapati Rao Prof. Ranganathan and ISID team
	Lunch hour meeting on **Patient Access**	Kalyani Menon Sen
14:00-17:00	Group work on **Pharmaceutical Market Structure, Investment, Trade and Regulation**	
	1. Pharmaceutical market structure – concentration	Facilitators: Malini Aisola and Aashna Mehta
	2. Pharmaceutical production – growth and profitability	Facilitators: Pritam Dutta and Mahua Paul
	3. Pharmaceutical FDI	Facilitators: Prof. Chalapati Rao and Prof. Ranganathan
	4. Pharmaceutical trade	Facilitators: Prof. Reji Joseph and Smitha Francis
	5. Changing industrial structure	Facilitators: Amitava Guha, Promod Prajapati, Bilqeesa Bhat and Nidhi
	6. Pharmaceutical regulation – spurious/counterfeit questions	Facilitators: Dr Gopa Kumar and Kajal Bhardwaj
17:00-18:30	Group presentations	Chairs: Prof. Biswajit Dhar and Narendra Gupta
18:30-20:00	Documentary film show	
	Dinner	
	Day 3: 5 March 2014	
09:30-11:00	**Pharmaceutical R&D and Innovation: System and Strategy** (Class Lecture)	
	Drug discovery, development and pharmaceutical innovation	Chair: Dr T.C. James; Speaker: Prof. Dinesh Abrol
	Global strategy and plan of action on	Chair: Dr K.M. Gopa Kumar

Time	Theme	Chair/Speakers/Facilitators
	public health innovation and intellectual property	Speaker: Prof. Dinesh Abrol
	Tea/Coffee Break	
11:30-13:00	**Pharmaceutical R&D and Innovation: Financing and Intellectual Property** (Class Lecture)	
	Patent	Chair: Dr Sakthivel Selvaraj Speaker: Dr K. Gopakumar
	IP and Competition	Chair: Dr Sakthivel Selvaraj Speaker: Prof. YogeshPai
	Foreign Trade Agreements	Chair: Dr Sakthivel Selvaraj Speaker: Kajal Bhardwaj
	Lunch hour meeting on **scientific writing for peer reviewed journal**	Anita Jain; BMJ India
14:00-17:00	Group work on **Pharmaceutical R&D, Innovation and Patents**	
	1. Pharmaceutical R&D and innovation	Facilitators: Prof. Dinesh Abrol, Nidhi Singh and Bilqeesa Bhat
	2. Free Trade Agreements	Facilitators: Kajal Bhardwaj and Pramod Prajapati
	3. Intellectual property protection – compulsory licensing	Facilitators: Prof. Yogesh Pai and Dr Sakthivel Selvaraj
	4. Intellectual property protection – working and pre & post grant opposition	Facilitators: Leena Menghaney
	5. Intellectual property protection – Section 3d	Facilitators: Malini Aisola and Kajal Bhardwaj
	Group presentations	Chair: Prof. B.S. Chimney
17:00-18:30	Documentary film show	
	Dinner	

Day 1

Inauguration

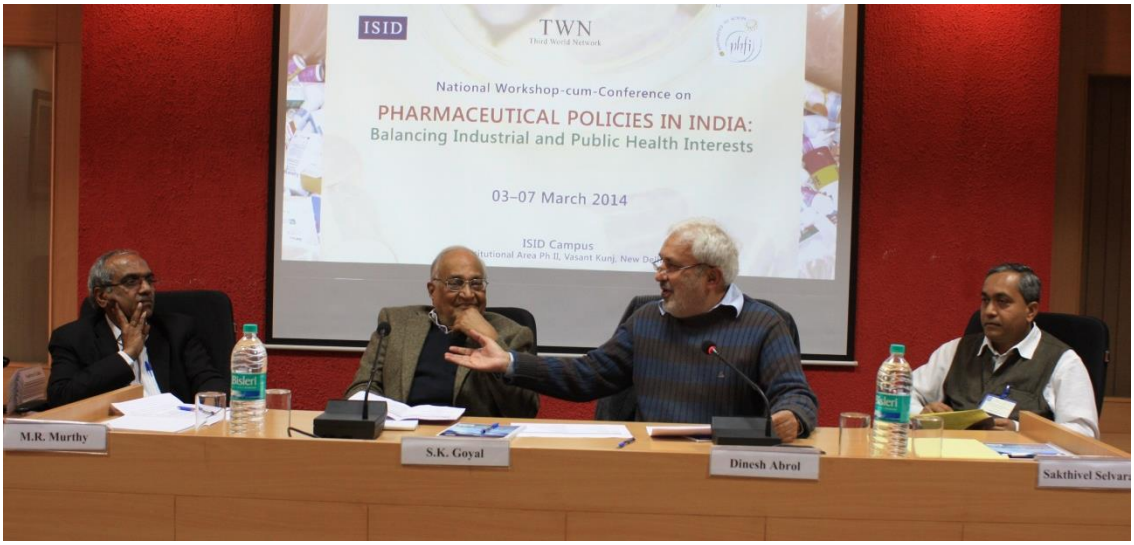
Theme: Access to Medicines

Chair: Prof. S.K. Goyal (Vice-Chairman, ISID)

Speakers: Prof. M.R. Murthy (Director, ISID)

Prof. Dinesh Abrol (Professor, ISID)

Dr Sakthivel Selvaraj (PHFI)



Key Messages:

- Since India became independent, the pharmaceutical industry has been core to the national strategies for healthcare, industrial development and general development. The pharmaceutical industry grew in prominence and capabilities to become one of the largest in the world and supplies drugs to many developing economies as well as wealthier nations. However, recent changes have led to new threats that currently face the industry, and it is in this context that ISID, PHFI and Third World Network organized a workshop and conference on the theme of 'Pharmaceutical Policies in India,' with participants coming from all over the country and displaying a wide variety of functional capabilities.
- The workshop was structured to feature lectures from leading experts in the field in the morning sessions, followed by group exercises on a range of topics relevant to the given day's theme, ending with presentations by the groups on the cases they had worked on.

- With a focus on combining theoretical learning with 'hands on' work, the emphasis of the workshop lay in training participants not just to think and learn about the issues and functional areas in the pharmaceutical sector but also to understand how to use the tools available to investigate, analyse and present policy recommendations to deal with the issues at hand.

Theme: Access to Medicines – Availability, Affordability, Public Procurement & Financing
Chair: Amitava Guha (Jan Swasthya Abhiyan)
Speaker: Dr Sakthivel Selvaraj, PHFI

Key Messages:

- The key objectives of a sound health system involve achieving the highest possible standards of Health Status, Risk Protection and Consumer Satisfaction. The intermediate goals in the process of attaining these are Access, Quality, and Equity& Efficiency.
- There is a distinct lack of access to medicine for many people around the world (1.3 to 2.1 billion people), with a particular lack of access in India and Africa.
- Key barriers to enabling access to medicines include: Unfair health financing mechanisms; Unreliable supply systems; Unaffordable pricing; Irrational Use of medicines; Inadequate funding for research in neglected diseases; Stringent product patent regime
- Much of the healthcare expenditure in India comes from personal finances, with 'out of pocket' expenditure accounting for more than 6 per cent of the average Indian household's expenditure in 2011-12, of which approximately two-thirds went into purchasing drugs, and which would have left many households facing catastrophic expenditure on healthcare.
- State expenditure on healthcare (including drug provision) varies widely
- Tamil Nadu typically displays high performance when it comes to drug availability and maintenance of minimum levels of stock, while Bihar performs far less satisfactorily on that front. It is crucial that the pooled procurement models of high performing states such as Tamil Nadu and Rajasthan serve as

blueprints for health provision systems across the country in order to improve the overall system.

- Drug price control remains a contentious issue between the government and the industry. Proper implementation of the various policy instruments on hand is needed in order to enable fair pricing.
- Due to the TRIPS agreement, a shift from a process to product patent regime was necessitated in India. This has been more favourable to large multinational firms, with India's position as a primary exporter of cheap drugs to many developing drugs coming under threat as a result.
- Rational Use of drugs relates to patients receiving appropriate medication in suitable doses for an adequate period of time, without causing excessive expenditure. Unfortunately, irrational prescription has been on the rise, leading to numerous health and financial problems.

Theme: Access to Medicines – Competition and Market Structure
Chair: Dr Gopal Dabade (All India Drug Action Network)
Speakers: Amitava Guha (Jan Swasthya Abhiyan)
Key Messages:

- The majority of the Healthcare providers in the country are in the private sector, with 64.8 per cent of the population relying on the private sector for health services
- As a result, more than 80 per cent of the medical care expenditure are in the form of 'out of pocket' (OOP) payments and many ailments go untreated due to high healthcare costs, much of which can be attributed to the expenditure on medicines, prices of which vary greatly
- A series of policy initiatives contributed to the growth of the Indian pharmaceutical sector, e.g., Indian Patents Act, New Drug Policy, 1978, and the establishment of public sector manufacturing units like HAL and IDPL
- Many Indian companies are partnering with or being acquired by multinational companies, leading to the emergence of an oligopolistic market dominated by a few large firms
- At present, there is a heavy reliance on Retail Sales – profits come from the sale of formulations and not from basic manufacturing
- India is witnessing an increasing reliance on imports, particularly of bulk drugs due to a liberalised import policy coming to dominate after acceding to WTO agreements
- Despite this, there has been an overall growth in exports as a percentage of pharmaceutical sales as the industry has continued to grow

Theme: Access to Medicines – Promotion and Rationality
Chair: Dr Gopal Dabade, All India Drug Action Network
Speakers: Amitava Guha (Jan Swasthya Abhiyan)
Key Messages:

- In recent years, there has been an increase in the promotion of non-essential (and more profitable) medicines in order to create artificial demand and fuelirrational prescription.

- Marketing expenditure by pharmaceutical companies is now far greater than R&D expenditure, which is cause for concern in the area of drug development.
- Direct marketing to healthcare practitioners is now a cornerstone of pharmaceutical marketing strategy, with increased expenditure on targeting healthcare professionals who then serve as trusted sources of prescriptions/recommendations for patients.
- The practice of giving free samples, gifts and other perks and forms of remuneration to doctors is ethically (if not legally) questionable, but has become standard procedure and effectively turns prescribing physicians into sales representatives.
- Legislation has been enacted in USA to curb such practices, but they continue to be in place at large pharmaceutical firms despite the imposition of penalties.
- In India, this continues to be an unregulated domain. A code of marketing practice was drafted in 2011, but by keeping it voluntary the government has effectively allowed pharmaceutical companies to continue with their existing practices.

On the first day, group work was on the topic 'Access to Medicines'. Groups worked and presented on the following sub-topics: Availability and stock outs, Affordability, Financial risk protection, Rational use, Public Procurement and Price Ceiling

Day 2

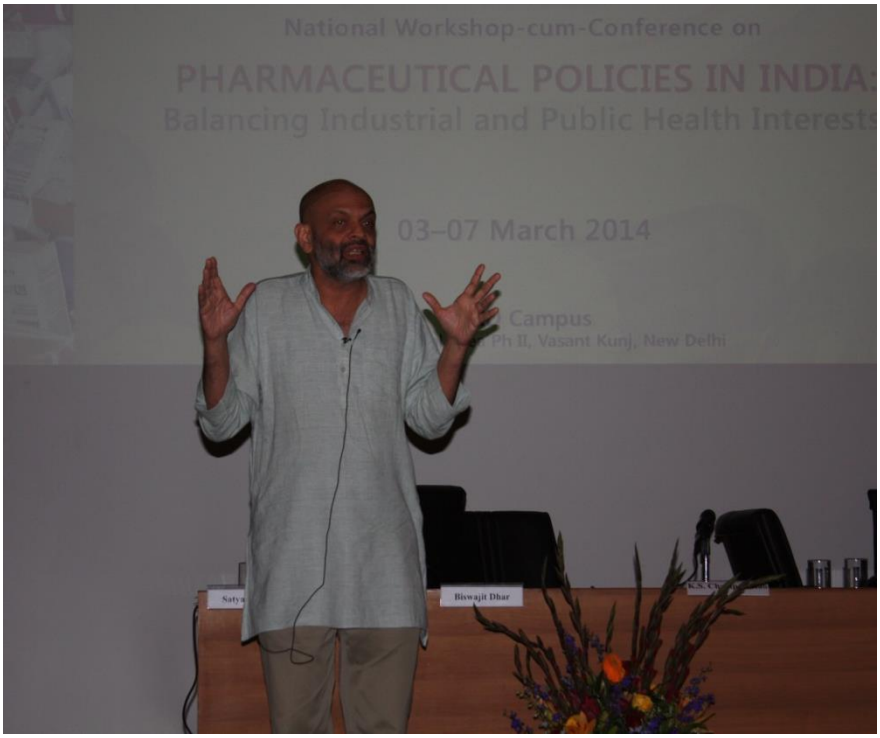
Theme: Production, Trade and Quality
Chair: Prof. Dinesh Abrol, ISID
Speaker: Prof. Biswajit Dhar
Prof. Reji Joseph

Key Messages:

- The speaker initiated the discussion by throwing light on the pre and post-independence pharmaceutical market structure. The shift from high dependence on foreign firms before independence to self-sufficient pharmaceutical industry post-independence due to policy interventions was discussed.
- The impact of various committees like the Hathi Committee (1975) and policies such as the 1970 Patents Act, MRTP Act, FERA and Industrial Policy 1977 was highlighted. The production of formulations and bulk drugs increased manifold as a result. Prices of medicines in India came to be amongst the cheapest in the world.
- In 1991, the economy was liberalised which attracted inflows of foreign investment in India.
- India's Commitments under the TRIPS Agreementled to amendments to the Indian Patents Act, 1970. India transitioned to product patent regime from the process patent regime in 2005.
- India became the 14th largest exporter of pharmaceuticals globally and 4th larger producer of pharmaceuticals (volume).
- Concerns on dependence on a single country for imports (China) and exports (US) were expressed. The quality of API imports is also questionable. The decline in production of bulk drugs as a result of the increasing focus on import

of APIs is also an area of concern. Immediate focus on revision of policies is the need of the hour.

Theme: Role of public sector in R&D and innovation
Chair: Prof. Biswajit Dhar
Speaker: Dr Satyajit Rath (National Institute of Immunology)



Key Messages:

- The role of the public sector in recognizing and engaging with the changing contours of innovation with regard to drug development was highlighted.
- The process by which new drugs are discovered was clearly stated. It was emphasised that most innovation processes are retrospective in nature.
- Many drugs have been innovated not by looking at the molecular target but rather by focusing on the physiological processes. The screening test to categorize whether a potential molecule can become a drug or not was explained. It was stated that structure/activity-based or knowledge-based discovery terms are meaningless if the screening test is not a molecular screening test.
- In most situations we do not know the exact biochemical mechanism, or there may be multiple biochemical mechanisms. Hence, using physiological essay screening instead of molecular screening becomes important. In these situations an alternative method is used by pharmaceutical companies where the whole library of chemicals is used in one screening test. This is not an intellectual activity and instead becomes a resource-intensive activity. So the question is whether pharmaceutical companies should have intellectual property rights for a process that lacks imagination and innovation in its true sense.
- Over the past three decades the conventional drugs innovation pipelines have been shrinking, which is an area of concern.

- The process of development of biologicals and the corresponding impact was also discussed. The shift in focus from chemical pharmaceutical innovation to biological pharmaceutical innovation was highlighted.
- It was stressed that public-funded academic scholarship (research) can actually bring in new innovation. But the role of private sector is important in performing the screening test as it is resource intensive and a highly reproducible activity, and cannot be done very successfully by the public sector.

Theme: Foreign and Domestic Investment in Pharmaceuticals
Chair: Prof. Biswajit Dhar
Speaker: Prof. Chalapati Rao
Prof. K.V.K. Ranganathan and ISID team

Key Messages:

- The issue of foreign investment in the pharmaceutical sector is a complex one.
- In 1991, as a result of the liberalisation policies India opened up its economy to foreign investment. Investments were either in the form of equity capital or in the form of reinvested earnings. The impact of this was analysed in the Indian scenario.
- Initially, the focus of opening the Indian economy to the world was manufacturing. In 2006, however, it was seen that only 20 per cent of total reported inflows were in the manufacturing sector.
- The pharmaceutical sector is one of the largest recipients of FDI inflows in India. Of this, 85 per cent is due to acquisitions which have not resulted in any addition to the production capacities, an area of great concern. In fact, most of the FDI inflows in India are in the form of Brownfield investment.
- The need to improve the information system for tracking actual foreign inflows in pharmaceutical sector was emphasised.

Group work topic for day 2 was 'Pharmaceutical Market Structure, Investment, Trade and Regulation'. The groups worked and presented on the following topics: Market concentration, Pharmaceutical production – growth and profitability, Pharmaceutical FDI, Pharmaceutical trade, Changing industrial structure, Pharmaceutical regulation – spurious/counterfeit questions


The day ended with a screening of the documentary 'DYING FOR DRUGS'.

DAY 3

Theme: Pharmaceutical R&D and Innovation: System and Strategy

Sub-theme: Drug discovery, development and pharmaceutical innovation

Chair: Dr T.C. James

Speaker: Prof. Dinesh Abrol, ISID

Key Messages:

- Since 1991, innovation in India has undergone several changes. It was expected that R&D investment by both the private and public sectors would go up, but overall research intensity has instead decreased since 1991.
- The private sector accounts for approximately two-thirds of gross expenditure on R&D in pharmaceuticals while the role of the public sector has declined.
- Indian innovation has been concentrated in the field of IT services (largely by MNCs) and pharmaceuticals (largely by domestic firms).
- Many Indian companies that were making substantial investments in R&D have been acquired by foreign companies.
- Technological innovation and industrial upgrading could not have taken place without state intervention and stimulation. Indian pharmaceutical R&D sector gets tax reductions, export incentives, support from government, and grant loans in a variety of forms including equity, etc.
- But none of these policies had any conditions to be fulfilled by the companies attached to them. Moreover, firms that took benefits of these instruments and governments schemes have now been acquired.
- Investment in process innovation started declining as the focus shifted to product innovation – this is reflected in the gaps we see today in manufacturing technology and process innovation.
- Public-private sector linkages were very disappointing. Private sector prioritised strategic alliances and collaborations with foreign firms for marketing rather than R&D or at the most for production.
- Problems in the Hyderabad cluster would have been solved through green manufacturing and green technology. This would have made the industry more cost effective and efficient.
- Actions created as part of the 12th5 year plan include attempts to create new clusters that are governed by PPPs, which tend to be dominated by the private sector and not the state. Huge concessions and subsidies are being given without conditions being put forth.
- Alternative pathways to technological innovation need to be explored.

Sub-theme: Global strategy and plan of action on public health innovation and intellectual property

Chair: Dr K.M. Gopa Kumar

Speaker: Prof. Dinesh Abrol

Key Messages:

- Companies are interested in developing profitable drugs, with particular emphasis on those having high market potential in developed countries (e.g. medicines used in diabetes, cancer etc.) rather than drugs useful in the context of a developing country.

- A commission that looked at health research and development in 1990 noted that of USD 30 billion spent on R&D in 1985 only USD1.6 billion was used for medicines for the treatment of diseases prevalent in developing countries. The term 'neglected diseases' was coined to describe such diseases that do not attract R&D funding.
- The Global Forum for Health Research noted the allocation problem of '10/90' - only 10 per cent of R&D funding is available to meet the needs of the 90 per cent of population of the world's population residing in developing countries.
- The TRIPS agreement was a result of pharmaceutical companies pushing for IP regime, with the substantial R&D investment being the stated reason. Studies have shown that not enough investment has been made in developing drugs for neglected diseases.
- In 2003 WHO established the Commission on Intellectual Property Innovation and Public Health (CIPH). The commission noted that the patent system is good, but is not working for developing countries and not meeting their R&D needs.
- GSPOA recommended prioritising R&D needs, promotion of R&D in developing countries, building and improving innovative capacities in developing countries, transfer of technology, management of intellectual property rights, improving delivery and access, promoting sustainable financing mechanisms and establishing monitoring and reporting systems.
- Guiding principles identified by CEWG were: (i) delinking cost of R&D from the price of the product; and (ii) open innovation, i.e. R&D outcomes should be available for everybody to take them forward.

Theme: Pharmaceutical R&D and Innovation: Financing & Intellectual Property
Sub-theme: Patent
Chair: Dr Sakthivel Selvaraj, PHFI
Speaker: Dr K.M. Gopa Kumar, TWN
Key Messages:

- The current state of research and development in developing countries was discussed.
- The pre and post-independence scenario of the Indian pharmaceutical sector in relation to patent law was discussed. The Patent Act,1970, along with drug price control policies, sectoral reservations and reduction of limit of foreign capital to less than 40 per cent have contributed to make the Indian pharmaceutical market not only self-sufficient but also a leading global exporter of drugs. Generic competition has markedly reduced drug prices.
- Patent laws have shifted from process patent to product patent under the TRIPS agreement and the impact of this transition on pricing and access to medicines was discussed. Though some flexibilities were given to the developing countries under the TRIPS agreement, their use was difficult owing to the complexity of procedures and global pressure. It was argued that it is better to not issue the patent in areas of public health importance rather than granting a patent first and then issuing a compulsory license.
- The phenomenon of 'Evergreening' of patents was discussed. Section 3(d) provides a list of items which cannot be patented. Efficient use of Section 3(d)

can be made to reduce unnecessary patents along with preventing evergreening of patents.

Sub-theme: IP and Competition
Chair: Dr Sakthivel Selvaraj, PHFI
Speaker: Prof. Yogesh Pai (National Law School)
Key Messages:

- The speaker initiated the discussion with concepts of neo-liberal economics. The speaker argued that if Intellectual Property leads to market exclusivity, then it is important to see its impact on competition law globally as it leads to market failure.
- The market-based theory of intellectual property was based on product differentiation. However, patents have instead diluted product differentiation. This raises questions about intellectual property as the only means for innovation.
- The difference between dynamic efficiency and knowledge, which is a public good, was explained. The question regarding the efficiency of monopolising knowledge was raised.
- Patents have two important groups of rights viz. the Right to exclude and the Right to transfer. The difference between property rules and liability rules was explained. Some provisions like compulsory licensing are built in as liability rules in the patent system.
- Ex ante and ex post facto competition policies were discussed. An analysis of remedies under Patent Law versus Competition Law for abuse of monopoly was done. The effect of acquisitions in the pharmaceutical market was outlined. The speaker recommended that the Competition Commission of India carefully evaluate strategic acquisitions and Brownfield investments.
- The speaker argued that patents block the path for further innovation and discovery.

Sub-theme: Free Trade Agreements
Chair: Dr Sakthivel Selvaraj, PHFI
Speaker: Kajal Bhardwaj (Independent Legal Consultant)
Key Messages:

- The role of Free Trade Agreements (FTAs) and their impact on access to medicines was discussed.
- The history of FTAs was touched upon. HIV treatment was used as an example to show how generic competition led to reduced prices of ARVs during the 1990s. But today the situation has changed; prices are increasing incessantly as patent laws have been changed.
- Flexibilities are provided in the TRIPS agreement but in practice their use is very difficult for developing countries due to global pressure.
- FTAs have even more restrictive laws on patents and intellectual property rights than TRIPS. FTAs require more products to be patented, and according to them Section 3(d) should be removed. FTAs place limitations on compulsory licenses to protect patent rights, necessitating TRIPS Plus provisions.

- FTAs having provisions for Investor protection give the companies the right to sue the Government in private secret international arbitration against their pro-health policies, thereby restricting the use of health safeguards,
- FTAs have no mechanisms for providing protection to domestic firms from takeovers. Moreover, they have decreased revenue for Government health programs.
- TRIPS Plus provisions demand a longer patent period (greater than the 20year period under TRIPS) as it advocates compensation for delay in granting patents. Looking back, the same reason has been used repeatedly for increasing patent periods.
- Data exclusivity is also a crucial criterion in FTAs, leading to monopolization of clinical trial data. It impacts all patented and non-patented medicines.
- According to the TRIPS agreement patents are private rights. However, TRIPS Plus involves the Government in patent protection. Thus, in the event of any infringement of patent laws, taxpayers' money would be used to enforce the patent rights, causing a significant burden on people.
- Though the idea behind these agreements was to provide better access to foreign markets, this aspect has been missing and has become an area of rising concern.

Lunch hour meeting on Scientific Writing for Peer Reviewed Journal. A presentation was made by Anita Jain from BMJ India

Group work topic for the third day was 'Pharmaceutical R&D, Innovation and Patents'. Groups worked and presented on the following sub-topics: Pharmaceutical R&D and innovation, Free Trade Agreements, Intellectual property protection – compulsory licensing, Intellectual property protection – working and pre & post grant opposition, Intellectual property protection – Section 3(d)

Highly acclaimed documentary film FIRE IN THE BLOOD was screened at the end of the day which was followed by a stimulating discussion on various issues of access to medicines with the director Dylan Mohan Gray.