

# **Proceeding Report**

**National Workshop**

**Patent and Public Health: Addressing the Future  
Imperatives of Health Security in the Post-TRIPS Era**

**Monday, 11<sup>th</sup> April 2005  
India Habitat Centre, New Delhi**

**Organised by  
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Ministry of Health and Family Welfare  
Government of India**

**In collaboration with the WHO India Country Office**

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## Acronyms

AIDS	Acquired Immuno-Deficiency Syndrome
AMTC	Affordable Medicines and Treatment Campaign
ARV	Antiretroviral
AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
AZT	Zidovudine
CCI	Competition Commission of India
CDSCO	Central Drugs Standard Control Organisation
CL	Compulsory License
CSGTSD	Centre for Study of Global Trade System and Development
CSIR	Council of Scientific & Industrial Research
CUTS	Consumer Unity & Trust Society
DCG(I)	Drug Controller General of India
DCP	Department of Chemicals & Petrochemicals
DIPP	Department of Industrial Policy & Promotion
DPCO	Drugs Price Control Order
EMR	Exclusive Marketing Rights
EU	European Union
FDA	Food and Drug Administration
FTC	Federal Trade Commission
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practices

GOI	Government of India
HIV	Human Immunodeficiency Virus
IBSA	India, Brazil and South Africa
ICMR	Indian Council of Medical Research
IDMA	Indian Drug Manufacturers' Association
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
MNCs	Multi-national Companies
MOHFW	Ministry of Health & Family Welfare
MRP	Maximum Retail Price
MRTP	Monopolistic and Restrictive Trade Practices
NACO	National AIDS Control Organisation
NCE	New Chemical Entity
NDA	National Democratic Alliance
NGO	Non-governmental Organisation
NPPA	National Pharmaceutical Pricing Authority
OPPI	Organisation of Pharmaceutical Producers of India
PCT	Patent Cooperation Treaty
PHARMA	Pharmaceutical Research and Manufacturers of America
PLT	Patent Law Treaty
R&D	Research and Development
RIS	Research and Information System for Developing Countries
SAARC	South Asian Association for Regional Cooperation

SEARO	South-East Asia Regional Office
SMEs	Small and Medium-sized Enterprises
SPLT	Substantive Patent Law Treaty
SPS	Sanitary and Phyto-sanitary
TBT	Technical Barriers to Trade
TRIPS	Trade Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UPA	United Progressive Alliance
US	United States
USPTO	United States Patent and Trademark Office
VHAI	Voluntary Health Association of India
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WRI	WHO Representative to India
WTO	World Trade Organisation

## Preface

As per obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO), from 1<sup>st</sup> January 2005 onwards the product patent regime has been introduced in India vide the Patent (Amendment) Act, 2005. Now product patent is enforced in all sectors, including the pharmaceutical and agro-chemical sectors, which so far had been out of such provisions.

There is an impression that the prices of some drugs may increase, as there may be limitations on the manufacture and trade of generic drugs. There is another impression that the introduction of the product patent regime would provide a new opportunity for research and development of new drugs, and manufacturing of off patent drugs. From the perspective of access to health, the questions that arise are: whether the new patent regime is really a cause for concern or is it an opportunity? Is India prepared to deal with the changed situation? What should be the future course of action with respect to manufacture, trade and procurement of generic drugs?

There are laws and policy tools that are available with the Government to deal with adverse situation vis-à-vis access to medicines, which may arise due to the introduction of product patent regime. The TRIPS Agreement, read with Doha Declaration on TRIPS and Public Health and subsequent WTO General Council Decisions, provide certain flexibility, which can be used by the nation states to address public health concerns. “What are those flexibilities? How far India has addressed these flexibilities in its domestic patent law? And how the given flexibilities/safeguards should be implemented in India?” are some of the key questions in this regard.

Apart from the given safeguards in the Patents Act, some help in addressing the concerns related to the access to drugs, can also be obtained from the judicious use of competition law and policy. In theory, Patent Law grants monopoly rights, whereas the primary aim of competition law and policy is to engender competition in the market. Competition regime can particularly be useful in dealing with anti-competitive Patent Licensing Agreements. The questions that need to be looked into are: How India should use competition law and policy to tackle adverse conditions with respect to access to drugs which may arise due to introduction of product patent regime? Does the new competition regime have such a scope?

The issue of drug price control also gains importance in the present context. Is the existing price control system effective? Will it be able to control the prices of patented drugs? Should the system be strengthened? These are some of the pertinent questions that would require answers. Regulation of the prevailing exemplary gap between the manufacturing costs and the retail prices of certain drugs may also help in increasing access to drugs. How far is the concept feasible in liberal economic environment in India, is a matter of further discussion and debate. It is to be noted that the Department of Chemicals and Petrochemicals, Government of India has also initiated a national consultation in this regard.

Therefore it is clear that if at all the post-TRIPS scenario does have an adverse affect on the access to drugs, there are tools that are available with the Government to tackle such a situation.

This Workshop titled “Patent and Public Health: Addressing the Future Imperatives of Health Security in the Post-TRIPS Era,” is being organised by the Ministry of Health & Family Welfare under WHO-GOI Biennium 2004-05, to analyse all the above-said issues and suggest the way forward through multi-stakeholder dialogue that could mitigate the potential threat on access to medicines due to recent international and national trade/IP policy developments.

## Highlights

### Shri B.P. Sharma, Joint Secretary, MOHFW

- Major concerns that were raised over the Patents (Amendment) Ordinance, 2004, got addressed in the Patents (Amendment) Act, 2005.
- The concerns that were addressed are:
  - Narrowing of the patentability criteria
  - Continuance of the manufacture of generic drugs of the claims pending in the Mailbox
  - Restoration of grounds of pre-grant opposition
  - Time-limit for compulsory license (CL)
  - Para 6 of Doha Declaration on TRIPS & Public Health
- The success of the new regime will depend upon the institutional mechanism that would be put in place

### Dr. Salim J. Habayeb, WHO Representative to India

- WHO recognizes access to essential medicines as Human Rights and treats the issue as a part of the Right to Health.
- WHO played major role during the WTO Doha Ministerial Meeting in obtaining the Doha Declaration on TRIPS & Public Health.
- WHO's concerns over the Ordinance was communicated to the Indian Government and the new Act addresses many of such concerns.
- WHO India Office collaborated with the MOHFW by establishing a WTO Cell in the Ministry. WHO will continue to provide support to monitor health impacts of new trade agreements.

### Shri P. Hota, Secretary, MOHFW

- In order to address the issue systematically, the task ahead is continuous monitoring by adopting multi-agency approach. In this regard, an independent authority may be considered.
- We will have to find sustainable budget for creation and anchoring of such an authority, apart from other resources, such as manpower.
- We will have to demonstrate that the regulation would be in the interest of all stakeholders, including industry.

### Shri Ujjwal Kumar, National Consultant, MOHFW

- During the Uruguay Round concerns were raised with respect to TRIPS and its adverse effect on access to medicines. India being a global leader in generic drug production was also a concerned party.
- The TRIPS Agreement, which finally emerged through the negotiations, contained certain flexibilities to address health concerns of the member states. These flexibilities are:
  - Objective & Principles enshrined in Articles 7 & 8 respectively
  - Minimum patentability criteria and exclusions thereof

- Conditions under which CL can be granted and no mention of grounds for CL. This is an effective tool to address a number of public health concerns, including affordability and availability of medicines.
- Recognition of parallel imports, Bolar doctrine and research & experimental use exceptions.
- Doha Declaration on TRIPS & Public Health of 2001 reaffirmed rights of the member states to address public health concerns that may arise due to implementation of TRIPS.
- There have been three amendments (in 1999, 2002 and 2005 respectively) in the Indian Patents Act, 1970 to make it TRIPS-compliant.
- The Patents Act, as it stands now, addresses almost all the TRIPS flexibilities and provides sufficient safeguards to address public health concerns.
- Future agenda are:
  - Implementation of the safeguards provided under the Patents Act, 1970 as amended till now.
  - Development of a suitable mechanism for monitoring and control of prices of the patented drugs.
  - Engendering fair competition in the pharmaceutical market and removal of anti-competitive practices prevalent in the healthcare delivery system.
  - Developing newer strategies for prevention of diseases and focusing more on prevention rather than cure of diseases.

#### Shri Gajanan Wakankar, IDMA

- The growth of domestic pharmaceutical sector took place because of policy change, such as the enactment of Patents Act, 1970.
- The main fear in the post-TRIPS scenario is that the domestic pharmaceutical sector, particularly the SMEs will be crowded out by MNCs.
- The hope, however, because of the cost-efficiency advantage and good entrepreneurship, the Indian drug sector may adjust to the changed scenario. Opportunities are there, such as outsourcing of R&D, manufacturing, clinical research, clinical trials etc, provided government policies are to supportive the Indian companies.
- Although safeguards are available in the Indian Patents Act, they are mostly qualified, which in effect nullify the advantages. CL provisions are also extremely lengthy and cumbersome.
- Being competition driven, generic drugs should be exempted from routine price control, while price control on patented drugs should be there, as the same being monopolies.

#### Shri Narendra Zaveri, Advocate

- The August 30 Decision is unworkable, and India should oppose this.
- The CL system should statutorily be very clear. In an uncertain law and policy environment with respect to CL, there may not be much investment by generic drug producers, who would also have to carry out research on process of such drug manufacture and for obtaining market approval. Before a generic

- manufacture invests in preparatory steps, s/he should be reasonably clear on the grant of CL.
- In the US, there are at least 25 Bills pending in the Congress and all of them emphasises the FTC finding that big pharmaceutical companies adopt lots of malpractices to delay the competition at the cost of consumers. All the pending Bills provide only one solution that to control the prices the best way is to introduce the generic versions of drugs as soon as possible. Therefore to achieve this end, the CL provisions should be realistic, clear, workable and self-operating.
  - Guidelines should be provided for fixing terms & conditions for CL in the context of Para 6, which should *inter alia*:
    - Provide for repeat supplies for the same product to the same party under the same CL, and
    - Prescribe reasonable royalty, which should not exceed 2% of net ex-factory value
  - If the corresponding amendments in Rules of the amendments done in 1999, 2002 and 2004/05 are looked into, there is a marked tendency of Rules favouring the MNCs.
  - TRIPS does not require “data exclusivity” or “data protection”, and hence India should not accept it.

Shri B.K. Keayla, Secretary General, CSGTSD

- The Patent (Amendment) Act, 2005 has certainly shown improvement over the Ordinance from public health perspective, but still there are scopes for improvements.
- There are still problems with the patentability criteria:
  - The definitions of “invention” in S. 2(j) of the Patents Act and “pharmaceutical substances” in S. 2(ta) are both broad in nature and should have been narrower.
  - An important exclusion from patentability that should have taken place is microorganisms, because these are a part of mandated review of the TRIPS provision.
  - The formulation of the explanation given under S.3(d) of the amended Act may pose interpretative problems in future.
  - All the above expands the scope of patentable subject matter.
  - Instead of omitting S.5 of the Principal Act, the same should have been reformulated to define narrowly the scope of patentability.
- Article 31(b) of the TRIPS is one of the most important provision that has been left out in the Indian Patents Act, which have been incorporated by many countries including UK, Germany, France, Argentina and Brazil.
- Pre-grant opposition, although, has been restored, but there is no appeal for it. This is problematic.

Shri Anand Grover, Advocate, Lawyers Collective / AMTC

- Now that full-fledged patent system is becoming operational, an effective competition law is required to achieve a right balance and to enhance the interests of the public and consumers.
- Even though the US is extensively using anti-trust laws for CL, still the FTC report of 2002 talks about the lack of synergy between US anti-trust law and patent law.
- In South Africa, Competition Act has been invoked and the Competition Commission has succeeded in the grant of CL.
- TRIPS Agreement recognizes adverse impacts of anti-competitive practices.
- There are gaps in the new Competition Act of India, which mandates amendments.

Dr. K. Weerasuriya, WHO-SEARO

- WHO position is that “medicines should be available on the basis of need rather than ability to pay”.
- TRIPS Agreement comes under “constructive ambiguity”. On the one hand, there could be very strong industrial perspective, on the other, it can be interpreted in terms of public health becoming more important.
- The big question is the whether the particular model that we are using – of allowing the pharmaceutical companies, the private sector, to decide on the priority of research – is an efficient way for dealing with diseases of the global community.
- Because of the prevalent prescription practices by medical doctors, medicines are not a perfect market.
- It is difficult to foresee what is going to happen in the post-TRIPS scenario.

Mr. Z.H. Charna, Director, OPPI

- There are several myths that are being propounded by the anti-patent lobby, most of which are contextures and are not supported by facts.
- There are many reasons that will check rise in prices of patented drugs. (He gave 12 such reasons).
- NPPA has power to control prices of even decontrolled drugs, if found excessive.
- The number of new drugs registered worldwide each year is only 25 to 35.
- Patented medicines are not *per se* a cause for healthcare problems of developing countries.

Shri Ashiwini Kumar, DCG(I)

- The positive side of TRIPS is that it will provide some incentives to innovation, which may lead to better drugs in future. The negative side is that because of the monopoly, there may be adverse impact on prices of new drugs. There has to be balance between the two, because public health needs both.
- The likely impact of the new patent regime would not be felt before 2009.
- There is a vast local market for existing drugs, therefore the generic producers will not be wiped away.

- The research-based Indian pharmaceutical industry is growing and investments in R&D are rising. The Indian biotechnology sector, which is going to be very important sector with respect to drug industry, has seen a good growth in last few years.
- The regulatory system has gone tremendous change in the last 4-5 years, and is now of international standard.
- The developments in last few years have not only set a favourable environment for take off in the post-TRIPS era.
- Government has Vision 2010 for the people of India. The idea is to create a Brand India.

Shri Gurdeep Singh, Director, Department of Chemicals & Petrochemicals

- Although NPPA under DPCO has power to control prices of decontrolled drugs (which will include patented drugs), it is not effective even for those categories of drugs that are under price control.
- NPPA suffers from lack of clear-cut implementation mechanism, lack of resources, lack of information, lack of data and lack of support.
- A new mechanism to control prices of patented drugs is needed. The new mechanism should be developed through a multi-stakeholder consultation.
- A Task Force has been constituted by the DPC, which will look upon options other than price control to keep the prices of medicines at a reasonable level.

Shri Sunil Nandraj, NPO, WHO India Office

- Access to drugs in the context of patents is one of the key technical issues, for which WHO is providing support. WTO Cell in the MOHFW is part of this process.
- The WTO Cell is also looking at the issues of GATS, SPS & TBT and competition policy from the public health perspective.

## Inaugural Session

### **Welcome address by Shri B. P. Sharma, Joint Secretary, Ministry of Health & Family Welfare**

Welcoming the eminent guests, Joint Secretary Shri B. P. Sharma set the pace of the Workshop by briefly talking about the recent concerns that were raised with respect to the Indian Patents regime, particularly that related to the Patents (Amendment) Ordinance, 2004 and how these were addressed in the Patents (Amendment) Bill, 2005 that was finally passed by the Parliament and which has now become the part of the law of the land. **“All is well that ends well,”** he commented.

The main concerns was with respect to the patentability criteria, which it was felt was too broad and would allow frivolous patents to be granted and could also allow “evergreening” of the patents. According to him, the definition of the “invention” and “inventive step” in the new Act has narrowed down the scope of patentability significantly. Further, restrictions have been made through the Patents (Amendment) Act of 2005 on the patentable subject matter, which now excludes isomers, polymers, salts etc. of the known substances, unless they differ significantly in properties with regards to their efficacy.

Shri Sharma also welcomed the introduction of provision that would allow generic manufacturers to continue manufacture of generic drugs, of which patent applications are pending in the “mail box”, after paying royalty to the patent holder (if patent is granted). This was not possible under the provisions of the Ordinance of 2004.

Shri Sharma appreciated the restoration of all the grounds of Pre-grant opposition in the Amendment Act of 2005 and refinement of the provision pertaining to the Para 6 of Doha Declaration. Under the Ordinance of 2004 compulsory license in India could have been granted only when the importing country has also given a compulsory license. This could have been difficult to countries without a patent law, particularly the Least Developed Countries, which are exempted under the TRIPS Agreement from enacting a patent law till 2016. Now, under the new Act such countries need not grant compulsory license, just an authorization could solve the purpose. Specification of time limit for the grant of compulsory license is also a welcome change in the Act of 2005 over that of the Ordinance. Now, voluntary license has to be granted within 6 months, failing which compulsory license could be granted.

In the end, Shri Sharma, commented upon the working of the new regime. **“How exactly the new regime will work for the public will depend upon the institutional mechanism that we put in place,”** said Shri Sharma. He once again welcomed the participants and hoped that the discussions would be fruitful for everybody.

## **Address by Dr. Salim J. Habayeb, WHO Representative to India**

Taking the cognisance of the timing and significance of topic of the Workshop, Mr. Habayeb said that the **WHO recognises access to essential medicines as Human Rights and treats the issue as a part of the Right to Health**. The WHO Medicines Strategy has four major thrusts:

- Strengthening national medicines policy
- Improving access to essential medicines
- Improving the quality and safety of medicines, and
- Promoting their rational use

All these are implemented by the member governments, WHO provides the support and facilitation.

WHO has been in the forefront in supporting countries to address issues related to various international agreements related to trade. It played a major role during the Doha Ministerial in obtaining the Doha Declaration on TRIPS & Public Health in November 2001 and seeking to limit to some extent the negative effects of the TRIPS Agreement. It should be noted and stressed by all that the Declaration affirms that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health.

In 2003 the World Health Assembly called for WHO to establish a time-limited body to “produce an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately effect developing countries.” Subsequently, the WHO Director-General established the Commission on Intellectual Property Rights, Innovation and Public Health” in February 2004. India’s Director General of CSIR is the Vice-chairman of the Commission.

WHO had written to the Indian Government about its concern with the Ordinance of 2004, before it was enacted by the Parliament. The Patent (Amendment) Act, 2005 addresses many concerns that were highlighted in the WHO submission. WHO now believes that there are safeguards in the amended patents law, which can mitigate adverse effect on the drug prices. Only time will show the real impact.

WHO has provided technical support on TRIPS to over 70 countries mainly to support their efforts to improve access to medicines, monitor and provide data on pharmaceuticals and public health and their relation with relevant international trade agreements, and promotion of innovation based on public health needs, especially for neglected diseases in a given region.

Furthermore, the 21<sup>st</sup> Meeting of Ministers of Health of the South-East Asian Countries, held in September 2003, recommended that WHO should strengthen collaboration with member countries to undertake impact studies on implementing multilateral trade agreements. The WR India office has collaborated with the MOHFW, India by

establishing a WTO Cell. The WHO will continue to provide support to develop mechanisms to monitor health impact of new trade agreements, review and update new legislation, conduct studies on related implications, facilitate dialogue with partners, promote awareness and advocacy workshops and public debates, support regional and national training for strengthening institutional capacities, and enhance networking of expertise and institutions.

**This meeting is an important initiative to involve various stakeholders.** He congratulated the officials of the International Health Division of the MOHFW and the National Consultants for taking up this issue and wished the best for a productive meeting.

## **Inaugural Address by Shri P. Hota, Secretary (Health & Family Welfare), MOHFW**

The Secretary (Health) began by stressing the need for a brainstorming exercise involving all stakeholders, including representative from the Department of Chemicals and Petrochemicals and then to intercede with the Department of Industrial Policy and Promotion, who will take the outcome further to the WTO and other international agencies.

According to the Shri Hota, **the task ahead is continuous monitoring on an intellectual level by adopting multi-agency approach and creating a mechanism whereby qualified personnel track the system and others who empower it are drawn in as a task force, so that all the issues that come are addressed systematically.** Otherwise, there could be a situation where things unintentionally may get out of hand. There could be some group of drugs, where prices could rise sharply and it could cause some deep impact on public health. Anticipating this and preventing this in time is more important than taking measures after this has happened. Hence, the task has to be approached in a very systematic and professional manner.

In this regard, **an independent authority**, say a Central Drug Authority, may be considered, which would require investment in terms of manpower, money and other resources. The Mashelkar Committee Report does recommend in this direction, but it has to be carried to a logical conclusion. We will have to find sustainable budget for the creation and anchoring of such an authority. Such regulatory authority would also have a component of professionalisation of the whole sector. An infrastructure has to be created, in terms of its posts creation, additional expenditure, sustainability etc. As instead of downsizing government, we are here proposing extra manpower, this may have to be negotiated with stakeholders in the sector and that most of the activities would have to be done with charge of fees etc. We will have to demonstrate that the regulation would be in the interest of the industry and all stakeholders.

He thanked WHO for the support and creating an ambience within the Ministry on the issue.

**Shri Rajesh Bhushan**, Director, MOHFW presented the **vote of thanks** to the distinguished speakers in the session.

## **An overview of recent law/policy developments on patents & public health**

**Shri Ujjwal Kumar, National Consultant, MOHFW** presented an Overview of the Recent Law Policy Development on Patents and Public Health and in doing so he illustrated on the following topics:

- From GATT to WTO
- TRIPS Agreement (with focus on flexibilities)
- Doha Declaration on TRIPS & Public Health
- Indian Patents Act, 1970, including amendments (with focus on safeguards and relevant changes)
- Addressing the future imperatives

### From GATT to WTO

After Second World War, in 1947 a General Agreement on Tariffs and Trade (GATT) was signed by 23 countries, which included India. India was the original signatory of GATT. The focus of GATT was tariffs and was meant to deal only with respect to goods. The Uruguay Round, the Eighth Round of the multilateral trade negotiations, introduced services, agriculture and intellectual property rights in the GATT framework and also established the World Trade Organisation with 128 members as original signatories. Unlike GATT, the new WTO System also focused on non-tariffs barriers to trade. One major improvement that the WTO system made over the earlier GATT System was that WTO has a Dispute Settlement Mechanism of its own, while the GATT was neither organisation nor a court of justice.

### The TRIPS Agreement

The Agreement Establishing WTO contains as Annexure the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS provides for minimum standard for protection and enforcement of intellectual property rights (IPRs) that a Member country has to adhere to on a non-discrimination (National Treatment and Most Favoured Nation) principle. TRIPS Agreement obliges members to align their national laws within stipulated timeframe, which includes product patent in all fields of technology for 20 years. In case of India, the stipulated timeframe for providing product patent was 01.01.2005.

During the Uruguay Round negotiations, concerns were raised with respect to TRIPS that it may adversely affect access to drugs, because it will put hurdles on the generic drug manufacture, which keeps the prices of drugs down. India being a global leader in generic drug production was also a concerned party. The final draft of the TRIPS Agreement provided certain flexibilities to address health concerns of the member states. These flexibilities can be read into its objective (Article 7), principles (Article 8), and other provisions described below.

The Objective of the Agreement includes, technological innovation as well as technology transfer and diffusion. It further says that the IPRs be protected and enforced in a manner conducive to social and economic welfare. The Article 8 of the Agreement allows Members the adoption of measures necessary to protect public health & nutrition. It further allows promotion of public interest in sectors of vital importance to socio-economic and technological developments.

As far as the patentability criteria is concerned the TRIPS Agreement says that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. The Agreement expressly allows exclusion of the following from granting patents:

- To protect public order or morality, including public health
- Diagnostic, therapeutic and surgical methods
- Plants and animals (but not micro-organisms)
- Essential biological processes (but not non-biological and micro-biological processes)

The TRIPS Agreement provides the following conditions under which compulsory licenses can be granted:

- National emergency
- Circumstances of extreme urgency
- Public non-commercial use
- Where a user has made efforts to obtain authorisation from patentee on reasonable commercial terms but has failed to obtain the same within a reasonable period of time
- Where the practice of the patentee has been declared to be anti-competitive through a judicial or administrative process

TRIPS, although, provides for conditions under which Compulsory License can be granted, it leaves on nation states to decide the grounds on which it shall be granted. However, the TRIPS Agreement restricts the sale/use of products made through compulsory license in/for predominantly domestic market/purpose. Compulsory License as a policy mechanism can, therefore, be used to address a number of public health concerns, such as,

- The high prices of medicines (affordability)
- Failure by the patent holders to sufficiently supply the market with needed medicines (availability)
- To correct anti-competitive practices adopted by pharmaceutical companies
- Emergency public health situations, etc.

There are other flexibilities that TRIPS Agreement recognises, such as parallel imports, Bolar provisions and research & experimental use exceptions. Article 6 of the TRIPS Agreement, which is concerned with parallel imports, precludes the application of the WTO Dispute Settlement Mechanism for disputes related with exhaustion of intellectual property rights. Exhaustion of IPRs means that the titleholder has no right to control the

use or resale of goods, which he has put on the market or has allowed the licensee to market. In other words, if any IPR-protected products are imported from one country (where it has been lawfully placed in the market) to other country it will not come within the purview of the dispute settlement mechanism of the WTO. The TRIPS Agreement has left this issue open ended, leaving Member states to decide.

Article 30 of the TRIPS Agreement establishes the general basis for exceptions to the exclusive rights envisaged under the Agreement. The rule is that exceptions to the patent rights must be limited; should not unreasonably conflict with the normal exploitation of the patent; and should not unreasonably prejudice the legitimate interests of the patent holder, taking into account the legitimate interests of third parties. The research and experimentation and early working exceptions (Bolar provisions) are the two widely accepted exceptions under Article 30 with implications for public health.

The research and experimental use exception ensures that scientific research aimed at generating new knowledge is fostered and is not impeded by patents. It also fits in with one of the main aims of patent laws, which is to facilitate the dissemination of knowledge, promote innovation and thereby facilitate the advancement of science. The early working exception, on the other hand, relates to a situation where an invention is used without the authorization of the patent holder to undertake acts necessary for obtaining regulatory approval and registration of a generic product before the expiry of the patent term. The exception is intended to ensure that generic versions of the product are available on the market immediately or within a reasonable time of the expiry of the patent.

#### Doha Declaration on TRIPS & Public Health

The issue of implications of the TRIPS Agreement for public health was also discussed at the Fourth Ministerial meeting of the WTO at Doha in November 2001. Taking the cognisance of the public health concerns, Ministerial meeting came out with a separate declaration on TRIPS and Public Health. The Doha Declaration on TRIPS & Public Health clearly affirms the rights of the member countries for taking full measures to protect their public health. The declaration reaffirms the rights of WTO members to use all the flexibilities provided under the TRIPS Agreement. The Doha declaration also provides that each member would have the freedom to choose the grounds upon which a compulsory license could be granted. Similarly, each member would have the right to determine what constitutes a national emergency or other circumstances of extreme urgency. It also lays down that in applying the TRIPS agreement, each of its provisions would be read in the light of the objectives and purposes of the Agreement, which are enshrined in Article 7-8 of the Agreement.

Prescribing one substantive deviation from the TRIPS Agreement, the Para 6 of the Doha Declaration on TRIPS & Public Health removed the barrier for import-export of generic drugs. The Para tends to nullify the TRIPS requirement that the products (in this case drugs) manufactured under compulsory license should be “predominantly for the supply of the domestic market”. On how to implement the Para 6 of the Doha Declaration, a decision of the WTO General Council was reached on 30<sup>th</sup> August 2003.

### Indian Patents Act, 1970

Subsequent to the TRIPS Agreement, the Patents Act, 1970 has been amended thrice – in 1999, 2002 and 2005. All these amendments have now brought the Indian law in compliance with the TRIPS obligations. Before the promulgation of the Patents (Amendment) Ordinance in December 2004, the Indian patents law provided only process patents in the pharmaceuticals, chemicals and food sectors. This allowed “reverse engineering” or “constructive copying”, which in turn strengthen the Indian domestic drug manufacturing capacity. This was a deliberate plan that can be termed as a success story. But this provision had to change to meet TRIPS obligations.

The NDA government introduced the Patents (Amendment) Bill, 2003 in Lok Sabha. However, before the House could pass it, it got dissolved. Subsequently, in December 2004 the UPA Government promulgated an Ordinance to amend the Patents Act. The Ordinance was more or less same to the Bill of 2003. There was major public debate over the Ordinance. The Ministry of Health & Family Welfare also had some concerns over the Ordinance. These concerns, however, were addressed in the Patents (Amendment) Act, 2005.

The Act, as it stands now, provides the following safeguards, which can be useful in addressing public health concerns.

- To ensure availability of products at reasonable price through compulsory license {Section 84}.
- To deal with emergent situations or cases of public non-commercial use {Section 92}.
- The provision relating to parallel import of patented product will ensure the availability of patented products at a cheaper price to the consumers {Section 107 A (b)}.
- To ensure import of medicines by Government {Section 47(4)}.
- The Bolar provision pertaining to act of making, constructing, using or selling a patented invention merely for the purpose of submission of information to the regulatory authorities before the expiry of term of patent {Section 107A (a)}.
- For acquisition of patent right by Government {Section 102}.
- To enable use of patent for research, experiment and education purpose {Section 47(3)}.
- To enable use of invention for the purposes of Government {Section 100}.
- For revocation of patent for non-working in India.
- For revocation of patent in public interest {Section 66}.

Following paragraphs illustrate the relevant changes that occurred due to enactment of the Patents (Amendment) Act, 2005, including that over the Patents (Amendment) Ordinance, 2004.

### *Patentability criteria*

- Definition of “inventive step” in the Principal Act<sup>1</sup> has been made more clearer and definition of “new invention” has been added vide the Amendment Act of 2005. The Amendment Act of 2005 has also introduced the definition of “pharmaceutical substance,” which would mean any new entity involving one or more inventive step. None of these were attempted in the Ordinance of 2004.
- Furthermore, the Amendment Act of 2005 also made a change with respect to “what are not inventions” as provided under the Principal Act {S.3}. There has been changes in S.3(d) vide the Amendment Act of 2005, according to which the following are not inventions, and hence not patentable:
  - Mere discovery of a known substance, which does not result in the enhancement of the known efficacy of that substance.
  - Mere discovery of any new property or new use for a known substance.
  - Mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant
  - Salts, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substances shall be considered to be the same substances, unless they differ significantly in properties with regard to efficacy

While the Amendment Act of 2005 tried to broaden the base of inventions that are not patentable, hence narrowing down the patentability criteria, the Ordinance tended to open the gate for the patentability of new use of a known substance, by substituting “new use” with “*mere* new use” as a non-patentable invention.

### *Current Production of Generics of the Mailbox Applications*

With introduction of a Proviso in Section 11 A of the Principal Act, through the Amendment Act of 2005, the Act as it stands now allows the continuation of the production of generic drugs for which patent applications have been moved under the Mailbox provision and to which patents could be granted under the Act. After the a patent has been granted for the Mailbox applications, the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1.1.2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceeding shall be instituted against such enterprises.

The Ordinance did not provide for continued current production of the generic versions of the Mailbox applications.

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<sup>1</sup> The Patents Act, 1970 as it stood before the Patents (Amendment) Act, 2005.

### *Parallel Imports*

Both the Ordinance and the Amendment Act of 2005 introduced changes in the Principal Act, which will allow parallel imports. Earlier the permission of Patentee was required for importing any product, now it can be imported from “any person duly authorised under the law to produce and sell or distribute the product”, which would include person not necessarily the patentee. By not putting any geographical restriction, India has thus followed the principle of “international exhaustion of IPRs”.

### *Pre- & Post-grant Opposition*

The Patents (Amendment) Act, 2005 restored the pre-grant opposition provisions, which was diluted significantly vide the Ordinance.

### *Compulsory Licensing*

The Amendment Act of 2005 clarified that the “reasonable period,” for the purpose of applicant making efforts to obtain a license from the patentee, shall be construed as a period not ordinarily exceeding six 6 months. This was not made clear in the Ordinance.

The Amendment Act of 2005 has also introduced a new section (Sec.92A) to enforce Para 6 of the Doha Declaration on TRIPS & Public Health. The Ordinance had also introduced such a section, but it required the importing country (with insufficient or no manufacturing capacity in the pharmaceutical sector) also to issue a Compulsory License, as a condition for manufacture in and export from India. The Amendment Act of 2005 has removed this proviso, by giving option to the importing country of “notification or otherwise” for allowing importation of pharmaceutical products from India.

### Future Imperatives

In the above-backdrop, the future challenges before the Indian Government are:

- *Implementation of safeguards* available in the Patent Act. Some of the questions in this regard that would require further discussion and debate are: How to achieve the requisite amount of inter-ministerial and inter-agency coordination? Is there a need for a Watch Dog to monitor prices and make recommendations to relevant government agencies?
- Developing a suitable mechanism for *monitoring and control of the prices of the patented drugs*. Is the present Drug Price Control Regime effective in dealing with the changed scenario or would it require overhauling? Should we downsize the present price control regime or we need to strengthen it?
- *Engendering fair competition* in the pharmaceutical market, as there could be lesser competition due to introduction of product patent regime, which in turn may enhance the probability of “abuse of dominance”. More so, the pharmaceutical sector globally is notorious for anti-competitive practices, like cartels (e.g. vitamin cartel), harsher conditions in licensing agreements etc. Can the competition law of India deal with such anti-competitive practices? If yes, how to implement it for optimal output. Is there proper statutory and institutional

synergy between patent regime and competition regime? Is there a need to enhance the synergy? Propagation of rational prescription practices (read prescription of generic drugs) by medical doctors will also lead to better competition in the market. Furthermore, competition to the allopathic system of medicine can also come from other recognized systems of medicines, such as Homeopathy, Ayurveda, Unani etc. How to enhance such competition?

- Developing newer strategies for *prevention of diseases* and focusing more on prevention of disease rather than on their cure. Among other things, propagation of healthy life style, including Yoga (lifestyle-based diseases are on rise) can prevent occurring of diseases. Irrational use of drugs, which at times leads to drug resistance, may also be discouraged through a proper strategy.

# Technical Session I

Chairperson: Dr. K. Satyanarayan, Chief, IPR Unit, Indian Council of Medical Research

## **Manufacture of ‘Quality’ generic drugs – options available with the Indian Pharmaceutical sector and its preparedness to deal with the changed scenario**

**Shri Gajanan Wakankar, Executive Director, Indian Drug Manufacturers’ Association (IDMA)**

Founded in 1961, IDMA is the oldest association of indigenous drug manufacturers in the organized quality oriented sector. It has both Bulk Drug producers as well as Formulators as members. There are over 650 members of IDMA spread over the length and breadth of India. IDMA members handle almost 70-75% of the domestic drugs market.

The growth of domestic drug sector in India basically took place because of policy changes, such as enactment of the Patents Law in 1970, which remain one of the boldest steps taken by our government. Growth of this **Rs.40000 crore** industry is attributed to this. In an atmosphere of strong market competition, drug prices came down. With the TRIPS regime (Product Patent regime) in force from 1-1-2005, the rules of the game have now changed. We have now gone back to pre-1970 situation, as far as pharmaceutical sector is concerned. As the law now favours product patents i.e. monopolies, and since the patent holders are mostly MNCs, if sufficient care is not taken, both our domestic industry as well as consumers (patients) will be very adversely affected as happened in Italy, South Africa, Spain, Brazil etc.

The cost-effective medicines played an important role in bringing down health concerns, which can be inferred from the statistics given below.

	<u>1960</u>	<u>2002</u>
Life Expectancy (yrs.)	41	61
Birth rate (per 1000)	41.7	25.8
Death Rate (per 1000)	23	8.4
Infant Mortality (per 1000)	146	66 (2001)
Decadal growth rate		21.3

As far as the quality of drugs is concerned, there is a legal base to it under the Drugs and Cosmetics Act, 1940. The Scheduled 2 of the DCA requires standards of identity, purity, and strength to be in accordance with the Indian Pharmacopoeia or in absence it the official pharmacopoeia of any other country, as prescribed by the MOH&FW. Apart from the standards, the drugs manufacturers are required to follow the Good Manufacturing Practices (GMP) and Good Laboratory Practices. For export purposes, a manufacturing firm must also obtain WHO-GMP certification. This also requires following of International Committee on Harmonisation (ICH) Guidelines and bio-equivalence certification. Off late, more and more importing countries are further insisting on Current GMP (cGMP), which may be stricter than WHO-GMP.

What matters at this hour is price and quality. We do not have a robust social security system in India (medical insurance has just started) and number of people below poverty line is significant, hence prices of medicine will have to be low. Here supportive law and policy from the government is required. For example, apart from the patents law, recent measures such as MRP based Excise Duty with Low Abatement and a high Excise Duty of 16% on Pharmaceutical products has affected the SSI adversely. These are some factors, which affect the price, apart from patents.

Reflecting on fears and hopes in the post-TRIPS era, Shri Wakankar, said that the main fear is that the domestic sector may loose out to MNCs. At Doha also this was one of the major fears. Litigations will also grow. Also the mergers & acquisition by MNCs will increase which may also crowd out the small & medium enterprises. For instance, in Italy, there has been almost complete erosion of domestic pharmaceutical industry after it introduced product patents in 1970. Similar phenomenon occurred in Japan, Brazil and South Africa. Rise in prices of critical patented medicines is the most crucial fear. In addition, the export market of the Indian drug manufacturers, which is very good at the moment, may also shrink.

The hopes from the WTO/TRIPS era are:

- Because of cost-efficiency advantage and good entrepreneurship the Indian drug sector may adjust to the changed scenario. Some Indian companies may improve to the international standard, but we still doubt that overall Indian generic industry will be affected adversely.
- Domestic market has come down from 15% to 7-8%; R&D, however, is going up.
- Opportunities are there, such as outsourcing of R&D, outsourcing of manufacturing, outsourcing of clinical research and trials etc., but the government policies have to be supportive to the Indian companies.
- The growth of generic industry has certainly benefited some firms, but the growth is not evenly spread out across the entire industry. Particularly, the SMEs are extremely vulnerable to M&As, hence may be wiped out.

According to IDMA, there are serious shortcomings in the Indian Patents Act as amended up to date. This will lead to, among other things, rise in litigations and threat of litigations. For instance, under pre-grant opposition provisions, there is no Board and there is no provision of appeal. Also compulsory license provisions are extremely lengthy

and cumbersome. All these are going to increase litigations, putting MNCs at advantageous position.

One of the major shortcomings in the Patents (Amendment) Act, 2005 is that it has qualified many of the provisions. These qualifications nullify the advantage that it intends to give to the generic drug manufacturers. For each definition there are words like “reasonable” and “significant”. It is very likely that there will be litigations on issues such as “what are reasonable or significant”. Who will decide “significant investment” etc.

As far as spurious drugs, there is common insinuation that drugs manufactured by smaller firms are not good, and may likely to be sub-standard, spurious etc. There are three categories of drugs, viz., misbranded, adulterated and spurious under Indian law that are liable to be face penalties. There are different penal schemes for each of the three. The drug manufacturers under IDMA, which are SMEs, are victim of the said insinuation. This affects their reputation and goodwill in the market, which in turn results in revenue losses.

Many a times it happens that the firms that produce spurious drugs, put the name of reputed companies on their labels. For e.g. two or three years ago, Nigeria gave India a list of drugs imported from Indian manufacturers that according to them were of sub-standards. There were 3-4 names from the IDMA member companies. On enquiry conducted by the IDMA it was found that such drugs were never exported to Nigeria. This is the type of thing that is happening with the SMEs drug producers.

The IDMA completely supports government’s stand on spurious drugs and believes that the existence of spurious drugs in the market is a serious matter and should be dealt with all the seriousness it deserves. The IDMA supports strengthening of CDSCO but would like to retain State Government’s powers for more local initiative. Drug Regulatory bodies set up in States should be improved. It also supports all other measures to check spurious drugs, such as good laboratory practices, establishment of more laboratories, consumer awareness etc. Demanding cash memos by consumers for medicines is an important step that could help in tracing the spurious drug manufactures.

Export is a very strong point for the Indian generic manufacturers, which at present is more than rupees three billion. Almost 85-90% of exports are done by the domestic companies, as the subsidiaries of MNCs in India are precluded from exporting drugs by their own parent companies. Emphasizing exports has been one of the policy goals of the government. As the export of generic drugs is the advantage for India, therefore all those things that would promote such export should be incorporated in law as well as policy. Government’s help would be required in product registration, advertising, brand development in foreign countries, which are very expensive. Government’s help would also be required in defensive litigation in foreign countries against MNCs – patent and brand holders. This exercise is very expensive.

The following concluding remarks were made by Shri Wakanker:

- The R&D in a country, which is very important, depends on many things – only one of them being the Patent Law. Government (public) funding and Public-Private joint funding strongly recommended for R&D. Even in US 30% of R&D is public funded.
- CSIR and other national research institutes should extend supportive preference to Indian Generic Industry in R&D matters.
- Patent Office fees should be reduced by 50% for SMEs as in the US.
- Spurious Drugs menace must be curbed.
- Regulatory costs be reduced and procedures simplified to maintain generic industry's competitiveness.
- A very strong patent law which protects the interest of the Patent Holders who are invariably MNCs, is detrimental to the interests of a developing country. A balanced law is preferable
- Avoidance of protracted litigation from MNCs requires a balanced Patent Law which means it should be both pro-people as well as pro-generic industry.
- Bring in all flexibilities available under TRIPS. Remove all 'qualifying' phrases from our Patent Law.
- Monopolies created by patents tend to increase prices of drugs which being essential, have an inelastic demand.
- This adversely affects 'Right to Health' and 'Access to Medicine'.
- To offset this loss of welfare, the generic industry should be encouraged and strengthened through price control on patented drugs and other measures. This will lead to low prices and good access to medicines for our population, which has no social security or insurance.
- Being competition driven, the Generic drug industry should be exempted from routine price controls resulting in uneconomic price fixation. This will encourage cost effectiveness and capacity expansion.
- As against generic drugs, being monopolies, prices of patented drugs should be tightly controlled in public interest as in Canada, Japan etc. TRIPS or WTO do not affect Price Control Policy of Members.
- In the post TRIPS or the WTO era, there will be adjustments. Success will depend upon both supportive laws and policies of the Government and continued pursuit of cost efficiency that the Indian drug manufacturers have today.

## Para 6 of Doha Declaration and India's response

**Shri Narendra B. Zaveri, Advocate, Mumbai**

The gravity, magnitude & the urgency of the problem can be understood by the following quotation from an US Statute: *"HIV/AIDS will soon become the worst epidemic of infectious disease in recorded history, eclipsing both the bubonic plague of the 1300's and the influenza epidemic of 1918-1919, which killed more than 20,000,000 people worldwide"*. *"More than 34,300,000 people in today are living with HIV/AIDS, 95 percent living in the developing world."* Therefore, it is clear that the patent issue is not a trade issue but is an issue of life & death – it is an Human Rights Issue of the present and coming generations.

WTO/TRIPS is an international treaty and is subject to UN Charter and Human Rights treaties, in same way as any law in India is subject to the Constitution of India, particularly Fundamental Rights. The same is true for international treaties, and TRIPS Agreement is no exception. There are judgements by the UN Human Rights Commission, which establish primacy of public health over trade rules. Even Vienna Convention on Treaties says that in the cases of conflict between two treaties, the treaty that is more important would prevail over the other treaty. The Doha Declaration on TRIPS & Public Health also confirms this.

Most part of the problem is man made. For instance, AZT – drug formulation for the treatment of HIV/AIDS – imported and marketed by MNC patentee was priced at US\$10,000 per patient. There were no generic companies in developing countries and LDCs to compete with the AZT. Not even 1% of HIV/AIDS victims in developing countries could afford the price of treatment. Things changed substantially when Cipla, an Indian drug company, began manufacturing generic version of AZT and priced it at US\$300 per patient. This was possible because India did not have product patent provision in its law. The key question is: would it be possible under a product patent regime?

The Doha Declaration accepts the gravity, magnitude & urgency of the health problem and asserts primacy of public health over commercial interests, as well as recognises Members' rights in this regard. It further urges all nations to take all measures necessary, including the grant Compulsory License, to provide healthcare to their people, treating TRIPS as a flexible international instrument.

There is an imbalance, however. Out of 140 odd WTO Member, hardly 8 to 10 have the capacity to carry on R&D and full-fledged production of pharmaceuticals. India is one of the countries, which has shown capability to produce quality drugs at the cost-effective price. Deeply concerned with the fact that access to medicines would be denied to people in developing & LDCs, the WTO Ministerial Conference at Doha recognises that *"WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement,"* and instructs the TRIPS Council to find an expeditious solution to this

problem. The General Council of the WTO adopted a Decision on August 30, 2003 in this regard. **“The August 30 Decision is unworkable, and India should oppose that,”** observed Shri Zaveri.

The first fear for Indian generic drug exporters to the LDCs and developing countries is from the pending 9000 applications in the Mailbox, most of which are with respect to pharmaceuticals and agro-chemicals, with the intention of “ever-greening” of existing patents. In the recent past only 300 new drugs have been approved by the USFDA. That means most applications are with the intention of “ever-greening”, which in turn may affect the “generic basket” of HIV/AIDS drugs. If that is affected then India may not be able to export cost-effective AIDS drugs. However, Shri Zaveri opined that unlike the Ordinance, the Patents (Amendment) Act, 2005 has made an attempt to address the threats pertaining to ever-greening of patents. These, according to him, are steps in the right direction. These provisions must be enforced in a correct manner. He, however, felt that there are lots of “ifs and buts” in definitions, which should have been avoided. The objective should be clear i.e. **only genuine inventions should be patented and others should be weeded out.**

The second fear is with respect to compulsory license (CL). Using CL as an instrument is accepted under TRIPS, even for commercial purpose. This is permitted not only for the purpose of Para 6 of the Doha Declaration but also for the domestic purpose. India should take maximum advantage from it. Under the earlier regime of process patent, this may not have been an issue at all, but under the product patent regime this is a concern. The CL system should statutorily be very clear, and also the long-term policy objective should be clear. In an uncertain law/policy environment with respect to CL, we may not be able to see investment by generic drug producers, who would also have to carry out research on process of such drug manufacture and for obtaining market approval. The TRIPS only requires that the CL applicant approach the patent holder with reasonable terms and s/he has to respond within reasonable time; failing which s/he loses her/his rights to object to the grant of CL. Then “why do the Indian law allow for opposition by patent holders,” he questioned. Before a generic manufacture invests in preparatory steps, s/he should be reasonably clear on the grant of CL.

CL is absolutely necessary. Price control, which is only a stopgap arrangement, may not always be an answer. One would need to have competition in the market for prices to come down. In the US, there are at least 25 Bills pending in the Congress and all of them emphasises the Federal Trade Commission (FTC) finding that big pharmaceutical companies adopt lots of malpractices to delay the competition at the cost of consumers. All the pending Bills provide only one solution that to control the prices the best way is to introduce the generic versions of drugs as soon as possible. Therefore to achieve this end, the **CL provisions should be realistic, clear, workable and self-operating.** This should also be kept in mind that the generic manufacturers would also require economy of scale and hence just for export (under Para 6) purpose they may not ask for CL, s/he must have a substantial domestic market to realise economies of scale and hence an incentive to invest.

Shri Zaveri welcomed changes in Section 90 by redrafting Clauses (vii) and (viii). This clarifies that CL granted for pre-dominant purpose of supply in Indian market, the licensee may export the patented product, similar facility of export is also permitted when licence granted to remedy anti-competitive practice. This, to him, will allow stock piling in anticipation of exports orders under CL. However, he opined that in both these provisions the clause “if needed” should be deleted as it dilutes the whole thing and would create doubts and disputes.

He further emphasised that we should not accept any “data protection” or “data exclusivity”. This was not there all these years, and there is no reason why should it be now. It is part of public duty that the Drug Controller is performing and hence there is no need to be secretive about it. Also there are no IPRs, by way of copyright or otherwise, recognised on these data. More so, **TRIPS does not require “data exclusivity” or “data protection”**.

A new section, Section 92A, has been introduced in the Indian Patents Act to implement Para 6 of the Doha Declaration. This is a good beginning but needs further improvements. It is certainly better than the August 30 Decision of WTO General Council, which provides eligibility of importing and exporting countries. Also the August 30 Decision restricts pharmaceutical products to that of HIV/AIDS and other endemics, while the Indian law does not insist for these drugs only. There is no requirement of CL if there is no patent protection in the importing country; this is a good change made over the Ordinance.

However, no guidelines have been provided under the Indian Act for terms & conditions to be prescribed for compulsory licenses. The royalty is to be fixed by the Patents Controller. This is most crucial factor. We have to be very careful in leaving the rule-making power to the Controller or the Department of Industry Policy and Promotion. If the corresponding amendments in Rules of the amendments done in 1999, 2002 and 2004/05 are looked into, there is a marked tendency of Rules favouring the MNCs. For examples, **while “public interest” has been so widely interpreted by the Supreme Court in number of cases, the Rules go about restricting “public interest” to say that it shall mean only national emergency or extreme urgency.**

He proposed that the guidelines for terms & conditions should:

- provide for repeat supplies for the same product to the same party under the same CL;
- prescribe reasonable royalty as not exceeding 2% of net ex-factory value;
- avoid any other restrictive conditions – particularly those prescribed by August 30 Decision.

One of the crucial questions is “what should be the royalty”. If MNCs themselves are not bothered for a major chunk (up to 99%) of consumers and if another company wants to cater to the left over section by providing a minimum royalty (say 2%) to a MNC, it should make sufficient business sense for such MNC. In other words, large part of the market goes unserved by the MNCs by their own conduct, so if they want any income

from that source then it is quite reasonable to say that 2% royalty is sufficient. Canada has recently come out with a law that specifies limits on royalty for each country according to its standing. For India it is 1.4 or 1.6% royalty that would be chargeable to Canadian party, while that for many other countries is 4 to 6%.

Similarly, there are problems with the corresponding Rule for Section 92A (i.e. Rule 96) publication to invite opposition as per Sec. 87(2) (which allows for opposition by the patentee and also by any person interested). If the timeframe given under the Rule is followed the grant of CL will be delayed at least by one year. Furthermore, there is no appeal provided for the applicant for CL. The decision of the Controller would be final. None of these provisions are required either by the Section 92A of the Patents Act or by the Article 31 of TRIPS.

In conclusion, Shri Zaveri made the following suggestions:

- Provide simpler & faster procedure for CL under Section 92A.
- Restrictive conditions of the August 30 Decision should not be accepted.
- Reasonable royalty to be fixed (not exceeding 2%).
- To avoid restrictions by way of “data protection” or “data exclusivity” in Drug Rules.
- Not to agree to any amendments of PCT or harmonization efforts through PLT/SPLT.
- Not to extend any TRIPS plus patent protection under Free Trade or Regional Agreements.
- LDCs exempted from TRIPS Patent provisions must not give up or compromise

## **Discussions**

Chairman Shri Satyanarayna, speaking in his personal capacity, pointed that both the speakers represents IDMA, directly or indirectly, hence opinions of both the speakers could be clouded in favour of generic industry. It is unfortunate that the debates on the current patents issues are industry driven – on the one hand, many commentators feel that that the US policy is driven by PHARMA, on the other hand, in India the local industry voices for more and more generics. The debate is more on how the industry to be promoted than how public health to be protected.

Prof. Ray, consultant VHAI while endorsing the chairman’s remarks that public (patients) are being overlooked, complemented the effort that MOHFW has undertaken in setting up the WTO Cell. He suggested that the WTO Cell should look at TRIPS not in isolation as just one international agreement. TRIPS is a part of larger framework of the WTO, or rather globalisation. Talking about DPCO, he said that under the present philosophy of globalisation the emphasis is on removing quantitative restriction and reducing the list of products under price control progressively.

Professor Ray further commented upon the recent movement towards harmonisation of quality/standards, which has not been debated at all in India. One of the stated objectives of the US Pharmacopoeia is to be the leader in determining, devising and designing pharmacopoeia guidelines (quality guidelines) for the entire world. If we see the international efforts towards harmonisation, this is indeed a step forward towards a kind of global quality norm. How is this global quality norm driven? If we look at the composition of the US Pharmacopoeia, one can see that it is largely guided by the industry lobby, which include drug manufacturers, pharmacists etc. In UK, however, the health fraternity does have a voice in developing the national pharmacopoeia.

On the question of price rise, there is apprehension that prices of patented drugs will rise, but what happens to the prices of the existing drugs. The generic market will now be very competitive and will have higher degree of competition, which will lead to further lowering of prices. The economic dynamics of medical practice in India must be kept in view, where there is a nexus between the industry and medical practitioners. VHAI has done some work on this issue and it has been found that persuasions by medical representatives play a very important role. Aggressive promotions do determine the prescription of drugs by the practitioners. In the eventual run large companies will possibly dominate and weed out the smaller once and prices can actually go up.

Mr. Anand Grover, AMTC/Lawyers Collective, observed that even in the earlier regime – process patent regime – the access to drugs by the HIV+ people were miserably low. India has the cheapest ARV drugs in the world and the government has a roll out programme to reach 1 lakh patients by 2005, today only 4000 people are getting it. He emphasised that both MNCs and domestic generic producers are really not concerned with patients, for them business interest prevails. Ranbaxy is exporting 80% of its drugs in generic market of the US, even though there may be shortage in the domestic market.

On price control, he was not clear as to how the prices of patented drugs can be controlled under DPCO, when it only takes into account landed cost, while working of the patent does not require manufacturing cost. According to a FTC report, the actual cost of R&D in pharmaceutical products in the US is only 16% of the overall sales turnover. If that is the case, more resources are going in marketing; this phenomenon is seen in India also. Therefore actual costs are very low. There is a group in Baroda, which is manufacturing low cost drugs, where prices of drugs are one tenth of the cost of the corresponding generic drugs. The real cost, hence, is not known. **In addition to the nexus between the industry and practitioners, there is also a nexus between chemists, which affect drugs prices.**

As far as the Patents Act is concerned, Mr. Grover showed serious reservations over the recent amendments and whether it is going to achieve its objectives. “As it is the accessibility of medicines is low, it is going to go down further,” he opined.

Mr. Grover raised the matter of recent Government **notification with respect to the “Mailbox” applications, which says that all the application put into the mailbox before a particular date are “deemed” to be published. How one can invoke pre-**

**grant opposition, when one does not know what are the contents of such applications?**

Mr. Grover also raised the matter of EMR granted to Novartis for its cancer drug Gleevec, which is priced at Rs.1,20,000 for a dose of one month. The Government had powers under Chapter IVA of the Patents Act for control of prices (not for issuing a compulsory license). Nothing has been done under the Chapter, which has now been deleted by the Amendment Act of 2005. Now how one is going to control the prices – it cannot be controlled under the Patents Act nor can it be controlled under the DPCO nor even a compulsory license can be issued. As a result around 25,000 cancer patients are not able to access the drugs, which they were able to do till last year when generic versions of such drugs were available at a much lower price.

Mr. Charna, OPPI, voiced his concerns in respect of fear being raised about price rise of the patented drugs, before a product patent has actually been granted. He particularly objected to Mr. Wakankar's views/stand with respect to possible rise in prices of generic and patented drugs.

Mr. Charna also talked about the Mailbox applications, and was surprised to see people talking about the number of such application for new drugs pending in the Mailbox. The statistics, to him, is very clear. The number of New Chemical Entity (NCE) being invented is going down every year, which has come down to 19 at present. Even if we assume that inventions of NCEs are 35 every year, which means in the last 10 years (1995-2005) there would be about 350 NCEs and say all of them are in the Mailbox. Ridiculing on the data that most people in general are using, which will mean that for every NCE there would be at least 30 applications on salts, polymorphs etc. This does not appear to be a plausible scenario.

He expressed serious concern about the present strategy of MNC bashing adopted by many people who are opposing the product patent system, and in doing so these people rely on their own assumptions.

On the issue of Gleevec, Mr. Charna informed the participant about his meeting with the Managing Director of Novartis a couple of days back. The Managing Director had said to him that Novartis' records are open for the public and the government to see. Novartis has supplied Gleevec worth of Rs.325 crore free to the cancer patients in India who are earning less than Rs.3.25 lakh per annum. The real sell of Gleevec is only worth Rs.5 crore. Still he finds people bashing up Novartis, saying, "We do not want charity".

Responding to remarks, Mr. Wakankar made the following remarks:

- Mr. Grover said that we cannot control the prices of Gleevec, while according to an IDMA study it is possible to do so. But there are some limitations on imported patented drugs. DPCO is not a very suitable mechanism in the present scenario, rather this mechanism is not as evolved as it has been in certain other countries like Canada.

- The ratio of patented drugs against generic drugs will go up in future, particularly because of the adoption of biotechnology route.
- Prices of second substitute (there can be substitute, although it is very difficult in the present prescription practices) may also rise. General price rise may not happen because of product patent regime *per se*. It may happen due to other measures, whether or not due to WTO obligations. For example closing down of the small-scale industry is going to affect the prices of drugs. Small-scale industry is in real danger.

Ms. Leena Menghaney, AMTC, New Delhi opined that this Workshop should have been organised before the Patents (Amendment) Act, 2005 was passed. She further stressed that **there are very crucial issues such as compulsory licenses, royalty, drug price monitoring etc. where active participation of the MOHFW is required.** For example, for the grant of compulsory license MOHFW is much more equipped than the Commerce Ministry to deal with such issues. Similarly, on royalty MOHFW should have some guidelines and should be involved. She hoped that MOHFW would take up these matters more actively in future.

Mr. Gurdeep Singh, Director, Department of Chemicals and Petrochemicals, was requested to make comments on the queries raised on price control. He said that the Department deal with very limited issue i.e. with respect to the issue of drug availability and prices. Concurring with Mr. Wakanker, he said that there are limitations under DPCO in the changed scenario. He was of the view that **a new mechanism is needed. The DCP is working on it at present and is also taking into account the Canadian model of drug price control.**

Mr. Singh was not happy with the DIPP's lack of transparency in the whole process of the recent amendments in the patents law. Many things were done without proper consultation with the Ministry of Chemicals & Fertilisers and Ministry of Health & Family Welfare. However, he opined that the two Ministries should take their own action on the issues that are under their domain, without waiting for amendments in the patents law. **All the things need not be done through the patents law. There can be numerous other mechanisms, which can be devised and adopted to deal with public health concerns.**

Mr. Bipul Chatterjee, CUTS, Jaipur, asked the panellist that how many essential (WHO prescribed) life saving drugs are patented in India. With respect to the Para 6 of Doha Declaration, he said that it is very limited in terms of its scope and applicability. This paragraph is not about public health; it is for a limited number of medicines. If we are concerned about public health, the scope of Para 6 needs to be expanded. Mr. Chatterjee wanted to know from Mr. Zaveri that "how the scope and applicability of Para 6 could be increased" in order make it more reflective of the public health concerns in the developing countries.

Mr. Chatterjee further made a remark that many public health issues, such as price rise, availability etc. are not only relevant from IPR-aspect. **There are numerous anti-**

**competitive practices adopted by drug manufacturers, retailers and medical practitioners that can cause public health concerns. According to him, an effective competition law and policy can take care of many such public health concerns.**

Mr. Zaveri concurred with Mr. Chatterjee and said that viewing price rise and non-availability of drugs as attributes of anti-competitive practice is the correct way to approach the whole problem. He also pointed out that Article 31(k) of TRIPS allows compulsory licenses to deal with any anti-competitive practice. He further talked about a case in South Africa, which is an example of how competition law was used to check prices of an HIV/AIDS drugs – AZT – that are under patent. Consumers in South Africa approached the Competition Commission on three grounds, viz., (a) non-availability, (b) excessive pricing, and (c) licenses not given on reasonable terms. The Competition Commission took the cognisance of the matter and sent notice to the MNCs concerned. When the company did not turn up, the Commission threatened to move to the Competition Tribunal and take up the matter on behalf of the State. The moment that issue was raised, the MNCs came around and voluntary licenses were given on 5% royalty (earlier they were asking for 30%). The MNC also allowed the export of the drugs made under such license. One more thing that came out from this case is that the patentees also have rivalry amongst themselves. In a combination drugs, because of rivalry between the patentee of one drug and the patentee of another drugs, the combination was not available to the public. The out of court settlement in this case also lead the patentees to use such drugs as a part of combination drugs. The time taken between the complaint being made to the Competition Commissioner and the settlement reached was two years.

Mr. Zaveri further said about the applications in the Mailbox. Upon enquiry, he was told on the first account that there were 5000 such applications; subsequently he was told that it is around 7000. Now it is being said that the number is 8900 odd, 3% of which are by foreigners. Concurring with Mr. Charna that only 18-19 NCEs are coming up each year, he himself was curious to know why such a large numbers of applications have been filed. He felt that most of such applications would be claims reached through known methods or made out of known salts etc. and hence predictable by the person skilled in the science or person knowledgeable on the subject. If that is so, then it does not satisfy the test of inventiveness as it is obvious, and hence it is not patentable. So it can be said that not more than 200 drugs, which are NCEs, are patentable. The other drugs for which applications have been filed are not patentable. If it is a new drug, it has to go to the DCG(I) for obtaining market approval. He opined that **whatever criteria are given under Section 3(d) of the Patents Act is perfectly TRIPS-compliant and we should go ahead with it.**

Mr. Charna informed the participants that **the Indian companies are patenting polymorphs etc. of known substances in Brazil, while the same has been kept as non-patentable subject matter in India.**

Mr. Vijay Kumar Sahu, RIS, wanted to know about the license of rights and Bolar provision. Mr. Zaveri responded that the license of rights is permissible under Article

31(b) of TRIPS. License of rights can be asked by anybody and if s/he satisfies the criteria s/he can obtain this irrespective of any other ground available or not. As far as Indian law is concerned, Section 83 spells out the grounds need to be taken care of. However, while TRIPS leaves this matter open-ended, our law provides for big enquiry, which may take up to five years, if appeal is preferred. The benefits bestowed by the Act are being taken away by the Rules. Bolar provision enables a generic manufacturer to manufacture and stockpile drugs during the patent period for obtaining market approvals. This is provided under the Indian law.

Mr. Ujjwal Kumar, National Consultant, MOHFW said that there is a significant improvement in the new Amendment Act over the Ordinance of 2004 and that there are now enough safeguards in the law. He asked Mr. Wakanker that given the safeguards under the law, shouldn't we be focusing on their implementation, and if yes, then how we should go about it?

Mr. Kumar further observed that under the WTO regime, Members are obliged not to discriminate between foreign companies and domestic companies. He sought clarification from Mr. Wakanker as to why he has been distinguishing between the two in his presentation.

Mr. Wakankar agreed with Mr. Kumar that there are safeguards under the Act, however, all the safeguards has not been included under the law and should be included. He further suggested that the Rules that would be amended to correspond with the amendments made in the Act, should not undo/mitigate the safeguards that has been achieved under the Act. Secondly, the manual for examiners is also very important because this is where all those 9000 applications would be processed. If care is not taken then we might find patents being granted on the claims that are non-patentable as discussed earlier by Mr. Zaveri. As far as non-discrimination between foreign and domestic companies, Mr. Wakankar said that he is looking from the Indian point of view. He said that whether it is Indian company or a MNC, if they are doing wrong under the law it should be dealt alike. IDMA does not support any wrongdoer, whether Indian or MNC.

Mr. Grover showed **concern about the inclusion of “economic significance” in the amendment of “inventive step”**. **This is actually not an intellectual property criterion, but it is there in some statute like that of the US. He wondered as to how the Patent Controller is going to decide on this.** The Patent Controller to decide whether the claimed invention has economic significance, *prima facie* looks impossible.

Dr. N.S. Dharamshatru, Project Director, National AIDS Control Organisation, stressed that HIV/AIDS is a big issue in India because there are 5.1 million HIV+ people are estimated in the country at present. NACO is planning rapid extension of the AIDS programme under which 1.88 Lakh people will be covered on free ART services throughout the country in the next 4-5 years. These patients will have to take medicines lifelong, as HIV/AIDS is not like other diseases. What about the HIV/AIDS patients who are having TB and other diseases on whom the present available drugs are not suited? At present NACO is using the cheapest available combinations, for many patients these

drugs may not suit. To alter the drugs, NACO has to spend on very expensive drugs. Cost of travelling may also be added to the cost of the medicines. At present NACO is offering HIV/AIDS drugs in the medical colleges. At the most NACO can reach to the district hospitals. If we want that the medicines to reach in rural areas, compulsory license may need to be granted for costly generic medicines as well as new-patented medicines that will come. Because newer drugs will come for HIV/AIDS and that may not be available in India. More so, second line ARV drugs, even though it is generic, they are still costly in India.

Chairperson Shri Satyanarayan made the following remarks on the R&D issue:

- More than 53% of money is put in by the pharmaceutical industry as R&D support to bio-medical research focussed towards new drug development, according to the Global Health Forum statistics. The industry would want and should get return out of their investments. One would have to pay for the development of new drugs. How much we need to pay, however, could be an issue that could be discussed.
- There have been several studies to show that most of the so-called new innovations are based on academic research done by scientists. The US puts in about US\$ 29 billion in the medical research. The entire budget for India for R&D is US\$ 2.5 billion. This is where the industry's responsibility comes into picture – how much knowledge is derived from public-funded research.
- Industry as whole in India should now get into innovation in big way. It cannot survive on copying. It has to create new molecules.
- The saying that “Indians are good individually, but cannot work together” is coming true in the whole debate of TRIPS and Public Health. In order to address the public health concerns much beyond TRIPS and HIV/AIDS, various ministries such as Health Ministry, Commerce Ministry, Ministry of Chemicals and Fertilisers will have to work in a synergy amongst themselves as well as with industry, NGOs, and inter-governmental organisations like WHO, UNCTAD and WTO. All should put their heads together for effective solutions to the discussed problems.

## Technical Session II

Chairperson: Dr. Abdul Sattar Yusuf, Director, Sustainable Development & Healthy Environment (SDE), WHO Regional Office for South-East Asia

### **How far the TRIPS-Flexibilities are being addressed in the Patent (Amendment) Act, 2005?**

**Mr. B. K. Keayla, Centre for Study of Global Trade System and Development, New Delhi**

At the outset Mr. Keayla observed that **the Patent (Amendment) Act, 2005 has certainly shown improvement over the Ordinance from public health perspective, but still there are scopes for improvements. If these crucial amendments had been carried out, public interest could have been served better and there would have been balance between rights and obligations in the patent system.**

Mr. Keayla briefly talked about the TRIPS Agreement and Doha Declaration on TRIPS & Public Health. The Preamble of the TRIPS Agreement recognises the underlying public policy objectives of national systems for the protection of intellectual property. The underlying policy constitutes the constitutional obligations, health policies etc. Article 7 of TRIPS Agreement talks about IPRs “conducive to social welfare” and “a balance of rights and obligations”, reiterating the importance of welfare society. Article 8 says that in amending patent law members may adopt measures necessary to protect public health and nutrition as well as promote public interest in sectors of vital importance.

Doha Declaration does not dilute the TRIPS Agreement as such, but it helps in implementation process. It clarifies that the TRIPS may be interpreted and implemented in a manner supportive of Members’ right to protect public health and to promote access to medicines. The Doha Declaration also affirms right to grant and freedom to determine grounds of compulsory license. All possibilities have to be explored and have to be incorporated while amending the patents law. “Unfortunately this has not happened here in India,” Mr. Keayla said.

In the given background, the following points were emphasised in his presentation:

- Scope of patentability
- Role of domestic enterprises in the patented product
- Export of patented product

## 1. Scope of patentability (Definitions, exclusion of patentability and patentable subject matter)

Following are the main problematic areas:

- The definitions of “invention” in S. 2(j) of the Patents Act and “pharmaceutical substances” in S. 2(ta) are both broad in nature and should have been narrower.
- An important exclusion from patentability that should have taken place is microorganisms. In addition, the position about non-biological and microbiological processes is not clear. Because these are a part of mandated review of the TRIPS provision {Article 27.3(b)}.
- The formulation of the explanation given under S.3(d) of the amended Act may pose interpretative problems in future.
- All the above expands the scope of patentable subject matter.
- Instead of omitting S.5 of the Principal Act, the same should have been reformulated to define narrowly the scope of patentability.

There are important studies that recommends the need to address the above-said issues. The Report of the UK Commission on Intellectual Property Rights, 2002, points out that the WTO members are free to define invention, as no such definition is provided under the TRIPS agreement. The recommendation for the developing countries is to be careful about the scope of patentability. It is clearly indicated that the subject matter of patent should be as limited in extent as possible and the ability of patentee to prohibit other from building around or designing around the patented product should be restricted.

There is one recent US FTC Report that expresses worry about the volume of patent applications that are filed in the USPTO. According to the Report there are around 3 lakh applications filed annually in the US. China is also witnessing large number of patent applications being filed. In China, in the last 5 years there were around 10,69,000 patent applications. It is to be kept in mind that 3000 patent examiners in the US hardly get time to examine patents and are not able to do justice, because questionable patents have been granted. In India there are only 225 sanctioned posts, although it is not clear how many posts have been filled, as competent people are not readily available due to newness of the issues.

The 2002 Report of the US National Institute of Healthcare Management, Research and Education Foundation says that wide range of inventions, are incremental modifications on which patents have been taken. They have clearly mentioned that only molecules should be patentable and patents on incremental invention should be discouraged. According to the Report this is the main reason for the large number of applications that are being filed and this is what that discourages the generic companies.

In India, the Mashelkar Committee Report recommended that in the pharmaceutical sector, only New Chemical Entity or New Medical Entity should be patented. Therefore it should be clearly indicated that only new molecules are patentable.

Keeping this in mind, Mr. Keayla proposed that the **definition of invention should be “invention means basic novel product or process involving an inventive step”**. The idea is that only invention coming out of *basic research* should be patentable. Modification here or there should not be a patentable matter. Therefore so far pharmaceuticals are concern, only *basic molecules* should be patentable.

So far exclusions to the patentability criteria are concerned, the TRIPS provisions regarding microorganisms etc. are under mandated review. Review is not complete yet. Not only the EU is seriously concerned about it, the entire African countries have submitted a joint memorandum before the WTO. Unfortunately, India has gone forward and has provided that microorganisms etc. are patentable. Mr. Keayla proposed that this particular provision of the Patents Act should not be implemented at this stage, and the same should be withheld for future date till this matter gets settled in the WTO.

There is no definition of microorganism provided under the law. Microorganisms are genetically modified, which makes a case for its patent although they perform only activities. The question is whether genetically modified microorganisms need to be patented or only its *activities* qualify for patents. In his opinion, it is the latter. In that case, **only process patent need to be given to genetically modified microorganisms.**

**So far the Sec 3(d) explanation is concerned, if the intention is that salt, derivatives etc. are not to be patentable then this explanation is creating a problem.** This means that if there is a patent on a molecule then these are going to be treated as same substance, which in turn qualifies salts etc. as possible subject matters of patents. If the intention is to exclude them, then in his opinion, the explanation should have clearly excluded them from getting patented. Instead of phrase “considered to be the same substance” in the explanation of Sec. 3(d), the proper wordings should have been “are excluded from patentability”. The present formulation of the explanation would certainly create problems.

**Section 5 of the Patents Act should not have been omitted, but should have been reformulated as: “patent shall be available for basic invention, including pharmaceutical substances as defined in Section 2, whether product or process, in all field of technology provided they are new, involve an inventive step, industry application and it excludes all inventions which are mentioned in Section 3”.**

## 2. Role of domestic enterprises in patented product

Out of 8-9 possibilities, that have been listed in the paper written supplied by Mr. Keayla, **Article 31(b) of TRIPS is the most important provision that has been left out in the Indian Patents Act** and which have been incorporated by many countries including, UK, Germany, France, Argentina, Brazil. This provision is also important from the export angle.

According to Section 84 of the Patents Act, if the patent holder is abusing its patent rights then there is a case for compulsory license. This arises from Article 5 of the Paris

Convention. Here one of the conditions of the CL is that the enterprise has to first approach the patent holder. Will the patent holder ever entertain when the enterprise says to him that he is abusing his patent rights? The abusing aspect has to be clarified to the Controller for obtaining the CL.

Article 70.3 of TRIPS means that for the mailbox products that have fallen in public domain, there is no need of providing protection. But we are providing such protection under the Act, although we have allowed those who are producing to continue production. Even after the claim has fallen in the public domain, the generic manufacturers are being penalised and asked to pay royalty.

Extreme urgency has not been defined. Extreme urgency could be health or environmental emergencies.

Pre-grant opposition, although, has been restored, but it is not appealable. This is problematic.

### 3. Export of patented product

Unless compulsory license provision related to Article 31(b) of TRIPS is there in the Indian Patent Act, export will never take place. Companies has to be producing for at least 3-4 years under the new technology to get their production stabilised in order to meet the domestic as well as export demands.

## **Anti-competitive practices in Patent Licensing Arrangements and the scope of competition law/policy in dealing with them**

**Mr. Anand Grover, Affordable Medicine & Treatment Campaign, Mumbai**

At the outset Mr. Grover commended the MOHFW in bringing all stakeholders together to discuss this important subject matter. He however would have liked the presence of the Ministry of Commerce in the meeting.

The relationship between the patent law and competition law is very important. In theory, patent protection spurs on innovation and make new technology for the consumer and competition law spurs on competition for competitive products at competitive prices. Both are to be for the welfare of the consumer and the public. If we accept the patent law and competition law, then a right balance has to be struck between the two to achieve the goal of serving the overall interest of the public and the consumer. If there is imbalance then it is fatal to the rights of consumers and hence may go against public interest.

Unfortunately there is no competition law is in place today in India, in the sense that it not operative at present. Now that the full-fledged patent system is becoming operational, in absence of a balance with an effective competition law, we may face great problems.

In other countries, such as in US the anti-trust law is extensively used for CL. It regulates the anti-competitive practices that companies resort to. Even though the US is much more conscious of linkage between anti-trust law and patent law, still the FTC report of 2002 talks about the lack of synergy between the US anti-trust law and patent law. In our system, therefore, it is even worst. Therefore in India, this is an area where we need to first understand the linkage between the two laws and there should be linkages between the Ministries and the Departments concerned. The FTC Report has recommended that there should be an ongoing organic process of linkages and the both must relate to each other. The same philosophy is being followed by the European Union.

TRIPS Agreement recognises the adverse impacts of anti-competitive practices. Article 40(1) of TRIPS says, “Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology”. One objective under Article 7 of TRIPS is the dissemination and transfer of technology. Therefore, within the TRIPS Agreement (which is an IPR agreement) there is an understanding that IPR regime itself may restrict competition, while competition *pre se* is accepted.

Furthermore, the Article 40(2) of TRIPS says, “Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market”. Thus TRIPS allows Member states to prevent anti-competitive licensing practices & conditions through a domestic legislation.

Therefore we can have a competition law, which allows for scrutiny of licences where there are anti-competitive clauses. Within the competition law, there can be a provision, which will take care of abuse of patents, apart from CL provisions that are within the patent regime.

In addition, under Article 31 of TRIPS, we do not have to resolve to all the procedures of the CL under the Patents Act, if a judicial or administrative body determines that there exists an anti-competitive practice. This is recognised under the TRIPS system itself; therefore, we should take advantage of it.

Sections 2, 3 and 25 of the Patents Act are the filter to get rid of the abusive/frivolous patents. This filter has to be strong. But once patent is granted, then there can be abuse of patents, which can be anti-competitive. In patent regime such abuses are taken care of by CL, among other things. Therefore, CL can be a tool to deal with anti-competitive practices by patent holders. In India CL can be granted under three grounds, viz., reasonable requirement not being met; products are not available at affordable prices; and non-working of the patents. Working of the patents is to protect public health. When we invoke the provisions of the CL, the general principles that are set down in Section 83 of the Act, become very important, which include making patented product available at reasonable prices. Therefore prices are key thing in the Patent Act.

Now coming to the competition law of India, it deals with three categories of prohibition or regulation – anti-competitive agreements, abuse of dominance and M&As. Anti-competitive agreements are agreements that have appreciable adverse effect on competition. Prohibition of “abuse of dominant position” is very important in the present context. The “dominant position”, which has been vaguely described in the Indian competition law as if an enterprise operates independently of market forces and affects competitors, consumers and relevant market. This dominant position if it is abused will invite actions under the competition law. When it is an “abuse”? “Abuse” has been described as **unfair discriminatory practices including pricing**, practices denying market access etc. Therefore there is an inroad for pricing. It is not, however, like the South African Law, which is very precise. Under SA law, if it is an **excessive pricing** then there is a ground for competition authority to pass an order. So there is a ground for changing our competition law accordingly, which is not yet in force. The new Competition Act, which is not yet force, would replace the existing MRTP Act when it will enter into force.

Therefore, there is a clear linkage between the patent law and competition law. Patent means monopoly implying no competition. In practice, therefore patent protection on drugs can lead to abuse of dominant position by drug companies that adversely affect consumer (patients) welfare. The abuse could *inter alia* be excessive pricing or refusal to issue voluntary license on reasonable terms. There has been an actual case in South Africa (which was earlier referred to by Mr. Zaveri) that illustrates both the abuses clearly.

In the South African case, two companies GlaxoSmithKline and Boehringer were producing a number of ARV drugs for HIV/AIDS. The prices were four times that of the estimated actual value prices in SA and also as compared to the WHO generic price for the same drugs. Further, these pharmaceutical companies also defeated voluntary and compulsory license negotiation under SA patent law by demanding 25% royalty on sales as compared to the international rate of 4-5%. The “Treatment Action Campaign” of South Africa approached the Competition Commission of South Africa.

In 2003 Competition Commission admitted complaint based on their duty to protect consumer interest, under Section 8 of SA Competition Act (excessive price bearing no relation to the economic value of the good) leading to exclusion and anti-competition. The procedure in SA is that the Competition Commission can issue a notice, saying that this is order that it is going to propose. The proposed order of the Competition Commission was that the practices of the pharmaceutical companies have violated the Competition Act, as there has been excessive pricing and exclusionary acts that have anti-competitive effect. The Commission recommended that compulsory licenses should be issues to market generic versions of the patented ARV drugs in return for the payment of reasonable royalty, which is to be decided by the Competition Tribunal. Ultimately the companies agreed.

According to Mr. Grover, unlike that in the South Africa, in India there is no synergy at all in the patent law and competition law. He further observed that in absence of an efficient CL mechanism and an effective drug price control mechanism, competition law becomes very crucial to address consumer (patients) welfare. He made the following recommendations:

- Excessive pricing and anti-competitive practices resulting from the new patent regime should be addressed in the competition law.
- Crucial legislative synergy between patent & competition law be established.
- Whosoever decides what is a anti-competitive practice and monitors excessive pricing should notify it to the Competition Commission.
- Sec 3 to 6 of the Competition Act need to be reviewed keeping in mind anti-competitive practices arising out of abuse of dominant position by patent owner.
- Grant of compulsory license on certain grounds should also be within the powers of Competition Commission.

## WHO perspective on TRIPS & Public Health

**Dr. K Weerasuriya, Regional Adviser, Essential Drugs & Medicines Policy, Department of Health Systems Development, WHO Regional Office for South-East Asia**

WHO position on the WTO/TRIPS can be described in one statement made very early on in 2000 by the former Director General of WHO that “**medicines should be available on the basis of need rather than the ability to pay**”. This is the critical statement on which WHO activities are framed. WHO do not think of medicines being a barrier to achieving health. Therefore if we apply this statement on the Gleevec issue, the drug Ematini (generic name for gleevec) should be available to patient simply because they have cancer, not because its financial affordability.

The statement of former DG of WHO can mean an ideal situation, which may tend to ignore incentives to research, manufacture and commerce that comes with medicines. The question is how to implement this, while achieving a balance between trade and health.

It has been said that the TRIPS Agreement comes under what is called as “**constructive ambiguity**”. On the one end, there can be very strong industrial perspective (i.e. protecting the industry and therefore seeing that the industry is extremely profitable), on the other hand, the TRIPS Agreement can be interpreted in terms of health becoming more important (i.e. the industry are going to serve health and make reasonable profit but not given ultimate freedom to do whatever it wants). So countries have to make a reasonable choice between these two ends.

A question has often been asked – **does health follow wealth or does wealth follow health**. That means if we make country rich or its people rich enough, then will they become healthy; or is it the other way i.e. if we make the people healthy then will they become more productive and therefore there will be wealth. The WHO strongly believes that wealth will follow health; that we need an investment in health before wealth will come about. This is why the WHO’s Macro-economics Commission has advocated to the governments that there must be a minimum expenditure on the basic packages in health, and the return on that will give the governments good health of its people, which in turn will yield more wealth.

The other aspect that the WHO has looked at is **whether the IPR system does help in producing medicines that are relevant to public health**. New Chemical Entities or new drugs come out from intensive research, which is a cost intensive activity. Pharmaceutical companies spend enormous amounts on research. Society has, therefore, decided to protect the pharmaceutical companies’ investment and allows them to generate profits so that they will produce new drugs. The issue then is: Although the society has allowed the companies to make these profits to produce new drugs, have these drugs served ultimately the needs of the society? In some ways yes, there have been drugs for high blood pressure, diabetes and other conditions which are common and which are public

health problems. On the other hand there are conditions/diseases for which there are no new drugs, and which affects millions of people and are inevitably fatal. Malaria, TB, sleeping sickness are some of the many examples of such neglected diseases, which are mostly relevant to the developing world.

As the global community have we developed drugs for diseases like Malaria, which are common in developing countries? The answer is a big NO. **The big question is whether the particular model that we are using – of allowing the pharmaceutical companies, the private sector, to decide on the priority of research – is an efficient way for dealing with diseases of the global community. The answer is Yes and No. Yes, for diseases like hypertension and diabetes, but No for diseases like Malaria and TB.** Furthermore, whether this particular IPR model is serving the needs of the global community. These are the questions that WHO has raised and are seeking answers. For the last one year there has been a WHO Commission on Intellectual Property, Innovation and Public Health, which is looking at this issues.

In this backdrop, Dr. Weerasuriya tried to look at the post-2005/post-TRIPS scenario. He observed, **“If ever there was a crystal ball, this is the one. It is very difficult to actually foresee what is going to happen in the future”**. There can be examples that can support positions on either side of the TRIPS & Public Health debate.

He cited the example of Japan, which brought product patent on pharmaceutical patents in 1976 and after that the Japanese industry continued and have benefited from such patent system. And hence, it is said, India can do it too. However, there are great differences. The Japanese industry had a very strong domestic pharmaceutical market, which supported it. Japanese industry, in general, does not depend on an international market to make its profits. In the mid-1990s, Japan was the country that spent the most amounts (US\$ 400) per person per year on drugs. Therefore the pharmaceutical sector was very profitable within its own country. Is it possible to translate the Japanese experience to India in 2005, where a maximum of say US\$ 10 is spent per person per year on drugs?

On the other hand, generic drugs virtually treat 90% of conditions/diseases that are at present prevalent in India. And the generic drugs are available at such a low cost that even if India spends a very small amount (say US\$ 7) on drugs per person per year, most of the public health concerns would get wiped away.

Therefore one can be very optimistic and say that in the case the drug prices rise due to product patent regime, the prescribers (medical practitioners) will certainly use the more affordable drugs. May be in that sense the new patent regime would be good, because the doctors in that case be prescribing essential drugs that are much more affordable. However, those who know the pharmaceutical market may laugh at this optimism, because **medicines are not a perfect market**. In fact, they are not anywhere close to a perfect market. One who decides does not pay, and one who pays does not decide. Someone has added the third dimension that the one who decides is paid, which means extensive promotion and buying more of the prescribers. Therefore, despite affordable

essential medicines being available, as in the past, we will continue to see the market drive prescribers (not unwillingly) towards the more expensive drugs. This may result in a situation where patients may not have drugs at all.

## Discussions

Mr. Bipul Chatterjee, CUTS, Jaipur, said that one essential point that has come out of the meeting is that these issues are very complex, particularly the complexity of linkage between the competition law and patent law. Therefore, we have to have several experts in the Competition Commission of India (CCI) to deal with these issues. Unfortunately, if we look at the composition of CCI, there are retired bureaucrats in them. We need to have more experts in it. Secondly, from the WHO presentation the developmental angle (in form of public health) in the IPR context has been highlighted. Brazil has taken initiative in introducing the Development Agenda in WIPO. He suggested that India should back this initiative. He opined that the group IBSA (India, Brazil and South Africa) should press this matter further at the WIPO.

Mr. Sunil Nandraj, WHO-India office, said that access to drugs in India is less than 15% despite India being the 4<sup>th</sup> largest producer of drugs, and this was in the pre-TRIPS era. So it is mandatory that we see the access to drugs issue more in availability terms. Secondly, viewing the prescription practices of doctors and promotional practices of drug companies that are prevalent in India, drug prices might rise because this, rather than due to new patent regime. Therefore capacity to regulate the prescribers assumes much importance.

Mr. Gurdeep Singh commented on the state of EMR that had been granted. There is a section that provide for the continuity of EMR granted, but the section that provided for CL on EMRs has been removed. On the appealability of pre-grant opposition, he said that if we go by Rules, the decision on the pre-grant opposition would be given simultaneously with the decision on the patent application. If the person gets the patent then post-grant opposition comes into play. Therefore, if we go by the present Rules, then possibly there is no appeal.

Mr. Anand Grover, responding to the appointment of experts in the CCI, said that “experts with judicial training” is ideal. If there are only experts decision might not be taken following basic principles of justice. He further stressed that the authority should be such so that it is able to deal with pharmaceutical industry, which very strong. We need an independent commission, like the National Human Rights Commission. Unfortunately, the CCI is not independent as under Competition Act government can intervene by issuing *directions* to the Commission.

He further noted that the US is no more relying on the WTO/TRIPS system. It is relying more and more on bilateral and regional trade agreements. On the contrary, India is not using such approach. In the Indo-Thai Free Trade Agreement or the proposed SAARC trade arrangement we are not taking into account the IPRs. We can take advantage of

regional free-trade agreements and get more and more countries to introduce a more development-friendly IPR system. These agreements may also look at targeting research into common diseases.

In his opinion, the idea behind holding this workshop after patent amendments is doing a post examination, which is needed. All the suggestions made therein can be constructively used.

Mr. Keayla on the issue of appealability of the pre-grant opposition said that earlier the entire section 25 was appealable. But now because of the amendment of Section 117A only sub-section (4) of section 25 is appealable, which deals with post-grant opposition.

Speaking on the EMR issue, Mr. Keayla observed that if the intention of S.3(d) is that if the derivatives of the salt etc. are not patentable, then EMR granted earlier to Gleevec was wrong. It was granted because of the faulty EMR norms. The original molecule of Gleevec was patented in 1992 in Switzerland and this derivative is not patentable now. Therefore, EMR granted should be cancelled.

On the appealability of the pre-grant opposition decision, Mr. Wakanker said, that in addition to pre-grant opposition not being appealable, there is also no Opposition Board for this purpose. The Patent Controller will decide a pre-grant opposition application and if it finds it untenable, it will grant patent. After that the unsatisfied opposition applicant would have to move another application under post-grant provisions, which will be decided by the Opposition Board. However, the Board may chose not to entertain the application saying that the grounds raised therein have already been decided and there is no appeal for it.

Dr. Weerasuriya asked a question from the audience. The US-PHARMA has said that the annual loss in sales/profits due to the Indian pharmaceutical industry is US\$ 1.4 billion. Although this amount is very large and any organisation will try to recover it, but considering the global pharmaceutical market of US\$400 billion, the amount is not even 1% (it is 0.35% to be precise). His question is: why do they bother for such a miniscule market share that is being taken away? Is this because that at this moment this may be unimportant and they are looking for it in future thinking that India, China and other developing countries will grow and become a major part of the pharmaceutical market.

Mr. Zaveri commenting upon the Dr. Weerasuriya's question said that this figure features in a FTC report referring to losses actually incurred in the year 2003-04. The report speaks of protectable patents not being protected. That means the drugs, which are in the market today as generic drugs, they are going to claim patents on them. This speaks about the 9000 applications pending in the mailbox. He also pointed out that in that particular FTC Report (2003) a list is given of the protectable molecules for active ingredients. The list includes talc, zinc, aspirin etc. which has been there for ages. So, it is the permutations and combinations of these drugs which must have been claimed for patent protection through the mailbox applications.

Mr. Bipul Chatterjee quoting the price of Gleevec (Rs.1,20,000), wanted to know the profit margin on the said amount.

Mr. Anand Grover said that there has been lots of studies done in the US, which tries to estimate how much it costs for a blockbuster molecules to come in the market. The studies show that 9 out of 10 permutations and combinations fail and only one becomes a blockbuster. How much is the total cost? and how much is the profits out of that? The first study that was done was actually an industry study (PHARMA-sponsored study), which puts the figure at US\$ 800 million. Another study done by Ralph Nader pointed out the earlier study did not take into account tax credit given to such R&D. Ralph Nader put a figure of around US\$100 million for bringing a blockbuster drugs into market. Yet another study done by James Love put the figure at US\$ 50 million.

As far as Gleevec is concerned, it got huge tax credit and fast-track approval, so it may not have incurred cost of even US\$ 100 million. But the annual turnover from it in the last one year was US\$ 1 billion.

In the US the consumer groups had tried to find out what is the cost, they never got the actual cost from the industry. They have never revealed the cost. In fact, the US Supreme Court had blocked questioning and enquiry in this regard. So if anybody thinks that s/he can actually get the cost, is mistaken. What we know that pharmaceutical industry is the most profit making industry – the annual profits of the pharmaceuticals is about 2-3 times more than any other industry.

Mr. Grover further mentioned that it is not the pharmaceutical industry that is pumping money in R&D of drugs. Majority of the money is coming from the US Federal Government. It is the marketing, on which they spend money. The AZT, the first HIV/AIDS drug, was not invented by pharmaceutical industry, but obtained huge gains from its marketing. It is very well documented that R&D costs for around 90% of the blockbuster drugs are not coming from the pharmaceutical sector.

Dr. Weerasuriya, concurring with Mr. Grover on the funding of drug R&D, clarified that the basic research for a drug, generally comes out from the funding from the US Federal Government. For example in the Gleevec, “the pathway of what happens” (i.e. (why Gleevec works in cancer?) was worked out by the US government money, which is very expensive. Novartis found the chemical that went and blocked the pathway. The pharmaceutical companies (whether MNCs or Indian) are very good in using the invented chemicals and making it a drug that can be given to human being. They are bad at basic research.

He further informed that in 80s and 90s the WHO developed some nice compounds for tropical diseases, but they went nowhere. This is because there was no expertise with them to translate these chemical compounds to actual drugs. This expertise was neither with the governments nor with the basic research laboratories, but was with the pharmaceutical companies.

Mr. Venkateshwaran, Director, Department of Consumer Affairs, quoting Mr. Grover that one cannot find actual cost of drugs from the companies, mentioned about a story by NDTV, a news channel, that in the recent times a medicine that just cost around Rs.2 was being sold at Rs.26 to 28. There were several such medicines in the list that had very high trade margins. He asked the speakers whether the consumers would be better off or worse off because of the amendments in the Patents Act.

Mr. Keayla replied that if the scope of patentability were not taken care of, the consumers would be worse off. He hoped that the Technical Committee, which is considering the scope of patentability, would recommend further narrowing down of such scope.

Mr. Grover said that nothing is going to happen now (the prices are not going to *shoot* up), because of the new patent regime. But slowly and slowly the thing are going to get worse, like that in Pakistan. By that time we might feel helpless. That is why further changes in the Patents Act are needed.

## **Panel Discussion**

# **The Way Forward**

Chairperson: Dr. Abdul Sattar Yusuf, WHO-SEARO

### **Mr. Z. H. Charna, Director, Organisation of Pharmaceutical Producers of India**

Mr. Charna spoke on the topic “Effect of the new patent regime on the prices of the medicines”. He began talking about several myths that are being propounded by the anti-patent lobby, most of which are contexture and are not supported by facts. A myth is propagated that after introduction of product patent regime in compliance with TRIPS, the prices of medicines will accelerate and medicines will become unaffordable for the common people.

This fear is due to lack of understanding of how the transition to a product patent regime works and how pharmaceutical prices are determined. It should be noted that patents cannot be granted retrospectively and are granted to only new discoveries. The transition provision of TRIPS allows the grant of product patents in developing countries like India on new discoveries made only after 1<sup>st</sup> January 1995. Since patents of over 95% of drugs manufactured in India have expired and there are no patented drugs in the WHO List of Essential Drugs, these drugs will continue to be available at the current prices. Also the National Pharmaceutical Pricing Authority (NPPA) has the power to control prices of even de-controlled drugs, if found to be excessive.

It should also be noted that it takes around 10-15 years for a new drugs to be granted a registration by the drug authorities of any country, only after which marketing permission is given. This registration period comes out of the overall life of the patent on the medicine, which is 20 years from the date of application. A discoverer, thus, enjoys at best only 5-10 years of exclusive marketing to recover the cost of R&D. The number of new drugs registered worldwide each year is only 25 to 35.

What this essentially means are:

- (a) Within the transition period allowed for India – 1995 to 2004 – not more than a handful of new drugs would actually qualify for any form of exclusivity.
- (b) Even after India commences granting patent, by the time patented product will become a significant proportion of the drugs available locally, it will be another 10-15 years i.e. 2015-20.
- (c) It is not correct to believe that the MNCs have only one price for a product everywhere in the world, and as such the prices charged in India would be exorbitant. There are several examples to show that even when the product is unique, it is introduced in India at a price significant lower than that in western countries. Most international manufacturers will base their pricing strategy in countries like India on “affordability criteria”.

Therefore, Mr. Charna suggested that we should wait for the patent regime to take hold properly and only then we should decide whether MNCs behave responsibly in India or not.

There is empirical evidence, a study conducted by the National Economic Research Association, Washington in 1998 and one study done by Dr. Heinz Redwood entitled “New Horizons in India” in 1994, show that prices do not rise after introduction of IPR regimes.

A study of prices of six therapeutic categories (anti-ulcerants, anti-depressants, calcium antagonists, non-narcotic analgesics, broad spectrum penicillin and ACE inhibitors) in nine countries (South Korea, Mexico, Hungary, Taiwan, Brazil, Argentina, Egypt, Jordan and Turkey) demonstrates that strengthening IPR does not have a measurable impact on real or nominal prices of existing drugs. Globally only 25 to 35 new drugs enter the market every year and only a few of them are commercial successes. At the same time, each year patents expire for earlier products. On an average therefore, there will not be more than 15 to 20 patented products in the market at a given time. Newer products being more effective ultimately lead to lower per day cost of therapy to the patients. Beyond all these, in India the drug prices are administered by the government.

The difficulties, which developing countries have in providing access to vital medicines to their populations clearly suggest that there is no single factor that constitutes a barrier to improved healthcare. As far as association between the patent status and price level is concerned, it is to be noted that while patents do have an effect on prices, this effect is not in general relevant to the healthcare problems of the underdeveloped world for the following reasons:

- a. There are very few patented products needed for the improvement of developing country healthcare status. All the products on the WHO List of Essential Drugs are off patent.
- b. Where patented products are important (e.g. for HIV/AIDS), manufacturers are actually seeking to offer special prices which have regard to economic and social realities. Pharmaceutical companies have individually been offering substantially reduced prices on medicines and vaccines to developing countries for many years.
- c. Patented medicines are not *per se* a cause for healthcare problems or of limited access. Indeed many examples show that absence of patents does not automatically create affordable price levels. Even off-patent drugs supplied by generic manufacturers are unaffordable or in short supply.
- d. The cost of the drugs itself is in any case minimal compared to the entire cost of effectively distributing, administering and monitoring its use.
- e. The main causes of limited access to medicine is undoubtedly poverty, the under funding of healthcare systems, and the lack of developed medical infrastructure in many of the countries concerned.

Therefore to attack IPRs vested in patents or to presume that there must necessarily be excessive prices is patently wrong, and give rise to policy ideas which, if implemented,

would quite simply fail to achieve the intended objective, shared by all, of better health in developing countries.

Although patented medicines are not prominently important in the global issue of improving access to health, patents are essential as they provide incentive to research-based pharmaceutical companies to invest in the development of new and better treatments, including for diseases prevalent in the developing world.

He summed up by recapitulating the reasons for prices of drugs not going up because of the introduction of new patent regime, as following:

1. Globally 25-35 drugs enter the market each year. Only few of them succeed commercially.
2. At any point of time only 5-7% of drugs in the world market are under patent protection. The rest, 93-95% market is of generics.
3. For any new patented medicine, there are a minimum of 6-10 generic equivalents available.
4. The price difference of the two itself acts as control on patented drugs.
5. In India, most patients pay out of their pockets. Their limited purchasing power will also act as a check on prices.
6. One cannot compare prices of patented medicines in US & UK with those in India. In those countries, the consumers mostly do not pay. The insurance companies pay. India's per-capita income is also far less.
7. Drugs (Price Control) Order, 1995 is very effective in India. There is a 3-tier control. Government can fix prices of even uncontrolled medicines under para 10(b) of DPCO 1995.
8. The provision of Compulsory Licensing and Parallel Imports in the amended Patents Act will also help common man, by keeping prices at a realistic level.
9. Drugs patented before 1<sup>st</sup> January 1995 will not be patentable and will continue to be available as generics.
10. All drugs in the WHO List of Essential Drugs are off patent.
11. The 400 odd drugs listed in our own Health Ministry's List of Essential Medicines are also off patent.
12. Indian copiers of molecules in the mail box will continue to manufacture and market them till patents are granted to the inventor, after three or four years that too prospectively. After that they will have to only pay a reasonable royalty and continue to market these drugs.

For the reasons stated above, it is therefore, patently wrong to say that prices of medicines will increase under the new patent regime.

## **Shri Ashwini Kumar, Drug Controller General of India, MOHFW**

As the focus is on the way forward, two things are necessary to note – first, access to medicines (which is a public health issue) and the second, is growth of Indian pharmaceutical, which is essential to achieve the first.

The recent patent amendments have attracted diverse views. On the one hand, people consider it as an act of genocide, on the other, there are people who consider that it is an opportunity which can be exploited and can prove to be a boon to Indian pharmaceutical sector. He concurred with Dr. Veerasuriya's views that "it is like a crystal ball and is unclear how the new patent regime will affect in future". He, however, opined that if at all there would be an impact, it is not likely to be felt before 2009.

Quoting from an article in the Chronicle Pharmabiz, Shri Kumar pointed out the changing views of the IDMA with respect to the patent amendments. From the views such as "it will put Life-Saving Drugs out of reach" and "...grand design of the developed world and multinationals to kill local industries..." ultimately to "Patents law is favourably amended". If it has been favourably amended, he was bewildered to hear so many concerns that were raised during the earlier sessions of the present Workshop.

Continuing on the presence of diverse views and reflections on the new patent regime, Shri Kumar further quoted one leading drug manufacturer saying that the "it will lead to MNCs monopoly", while our Commerce Minister saying that "the prices of medicines will not rise due to new patent regime". One journalist analysed that "the new regime will put our healthcare system in total disarray". These all, to him, add to the uncertainty of picture to come.

Coming to the access to medicines aspect, he said that there are three important issues to be kept in mind. The government views health as a lifetime concern, and hence access to medicines is the critical component of the success of any healthcare delivery system. Such access will depend upon "affordability", "availability" and the "kind of healthcare coverage of the country". So we have to see whether the post-TRIPS regime is going to affect the national healthcare system or there are already certain infirmities in that system, which need to be corrected. According to him, we need to approach from both the sides in the post-2005 era.

There are apparent positive and negative effects sides on the Indian drugs and pharmaceutical due to TRIPS. The positive side is that it will provide some incentives to innovation and that may lead to better drugs in future. The negative side is that because of the monopoly that is provided by the society vide the patents law to the innovator, there may be adverse impact on the prices of new drugs. There has to be balance between the two, because when we talk about public health, we need both.

Representing the Regulatory, Shri Kumar's concern is more with respect to the growth of Indian pharmaceutical sector. In order to move forward in the post-TRIPS era, we have to first see: how the Indian pharmaceutical sector has evolved over the years; what kind of

strength it has gained; and can we take off further through various enabling government policies to strengthen Indian industry.

From being import dependent after independence till 1970, the Indian industry in the 2001-05 period has been able to create a niche for itself in innovative research and has made huge investments in drug research (including new drug development research). The Indian research-based drug industry has geared itself to the realities of new patent regime.

Furthermore, the regulatory system/policy in the last four-five years has undergone tremendous change. India has now in place the best of Good Manufacturing Practices requirements, Good Laboratories Practices requirements and Good Clinical Practices requirements. We also have in place norms for pre-clinical and clinical data. We have now exhaustive norms for registration of all imported drugs. In sum, lot of corrections have been made in the regulatory system and we have benchmarked ourselves more or less with the international standards. The industry is also geared to meet those standards. Another important change that has been witnessed in the last four years is the growth of the biotechnology sector in India. Biotechnology sector, in the government's view, is going to be *the* sector of the future in the drug industry.

According to the DCG(I), these developments in the last few years have not only set a favourable environment for take off in the post-TRIPS era, but has also led to the Indian Pharmaceutical Industry being recognised globally for:

- its process development competencies;
- its economies of scale, low cost high quality manufacturing;
- the drug research potential, which gets reflected in increasing outsourcing in every area of drug manufacture; and
- the increased international exposure, which has lead the Indian industry to enable them to tackle the post-TRIPS concerns.

Shri Kumar highlighted the changing disease profile in the country, which in turn will change the demands scenario of drugs. Although India still has the largest utilisation (albeit decreasing tendency) of anti-infective drugs (around 18%; which is hardly 2% in the developed countries), there is increasing trend in the life-style disease (such as heart diseases, chronic geriatric and psychiatric diseases). There is a “double burden” of diseases on India. Therefore, in future the demands for medicines to cater the increasing life-style diseases would certainly be on a higher side. According to him, there is tremendous potential in the Indian pharmaceutical industry to meet the changing demands of the local population.

Following are the competitive advantage that the India enjoys:

- Quality Producers (many approved by US-FDA)
- Competitive cost base (Plant/Development/Labour costs)
- Scientific talents
- Educated and English speaking work force
- Managerial/technical competence

- Excellent record of improved cost-beneficial chemical synthesis for various drug molecules
- Wide variety of “Bulk Actives”
- Rich Biodiversity
- Presence of National Laboratories
- Regulatory norms in place
- Increasing presence in biotech therapeutics (in the 2001, globally the share of biotech-pharmaceuticals was 20% of the total pharmaceuticals; it has been projected that by the year 2025 it will increase to 70%)

In this context, Shri Kumar informed that the Indian Government already has a Vision 2010 Statement for the people of India. The statement is to build a Healthy India by 2010 by:

- Achieving world class quality and create world class manufacturing facilities, backed by contemporary regulatory work;
- Achieving the highest market-share of production in the Global Generic Pharmaceutical Market (more specifically, by 2010 to reach a size of 16% of global volume and a turn-over of US\$ 15 billion with export of US\$ 8 billion);
- Creating for India a strong brand image as the ‘least cost-highest quality’ supplier of pharmaceuticals to anyone, anywhere, anytime.
- Becoming a preferred global destination for clinical research, custom synthesis and genomic research, including bio-informatics.

The whole idea is to create a Brand India i.e. to be known as assured source of good quality generic drugs at the most competitive prices.

Shri Kumar further shared the following data that shows the increasing expenditure in the R&D especially in the private sector, although it is nowhere as compared to that of the developed countries. He opined that there is a need to increase such investments in India.

- Current pharmaceutical R&D expenditure in India of Rs.320 crore is 2% of sales against an all industry average of 0.3%. However, this 2% is the highest compared to other sectors in India, which is a good sign.
- R&D spending by the MNCs in the US and Europe is more than 15% and that by Japanese companies is 9-10%;
- Mid-Sized European companies is 7-8%; and
- International Generic companies is 6 %

Summing up the way forward, Shri Kumar made the following observations:

- The likely impact because of the new patent regime would not be felt before 2009.
- Pricing of patented drugs is a complex issue. Here it would be important to distinguish between the drugs for the mass use and those that are niche products. There may be a drug for which there could be only 5000 patients in whole of India. How to negotiate the price of that drug keeping in mind that the one who makes that drug available has to recover the costs. According to him, the

government would have to develop some kind of model where, on the one hand, there can be some negotiations, on the other, it may have to subsidise the prices of such drugs.

- There is a vast local market for existing drugs, which will keep the domestic generic manufactures alive. It is not likely that such manufacturers would be wiped away due to the adoption of the new patent regime.
- There is a kind of dichotomy in India. It is the fourth largest producer of the low-cost drugs in the world, but at the same time the per capita consumption is one of the lowest in the world. This, however, is going to change as India's healthcare system develops, as economy develops, which would lead to a huge demand for drugs within the country.
- The shifting disease pattern will entail more demands of the drugs for life-style diseases and geriatric care drugs.
- We might also see the introduction of tradition plant-based medicines in the mainstream. This area has been neglected, may be because no patents are available for plant-based traditional medicines. The Government of India has a project "Golden Triangle Project", in which the CSIR, ICMR and the Health Ministry (Department of AYUSH) are supposed to work together and make investments in partnership with the Indian industry. The idea is that some of the molecules, out of our own plants that has been traditionally used, can be obtained through "reverse pharmacology" and that can be introduced in the mainstream. This opportunity is available to India and it will bring more respect for Indian traditional medicines.
- There will be an increase in the filing of patents, most of which would be frivolous, however. If there are frivolous applications, we may not worry as long as patents are not granted on them. The number of patent application *per se* might not be a concern. The government cannot stop anybody in filing an application.
- There is an increase in government support for drug research, for which there is already a Drug Development Fund and funds for drug research etc. There are very visible initiatives and policy interventions taken by the government to ensure that our strength in the pharmaceutical sector and drug research sector continues unabated (and not get adversely impacted) in the post-TRIPS era. This is all because we continue to move towards in making the "Brand India" a success.

**Mr. Gurdeep Singh, Director, Department of Chemicals and Petrochemicals,  
Ministry of Chemicals & Fertiliser, Government of India**

As the DCP deals *inter alia* with prices of medicines, he decided to speak on the issues related with National Pharmaceutical Pricing Authority (NPPA). He began with commenting on Mr. Charna's observation that NPPA has power under DPCO to bring even un-controlled drugs under control. He concurred with the observation that the Government has that power. The issue, according to him however, is how effectively the Government has been able to implement it. There is not only absence of a clear-cut mechanism for its implementation, there is also lack of resources, lack of information, lack of data and lack of support that come as hurdles. Furthermore, there is lack of interaction between NGOs and NPPA, which is mainly due to lack of awareness about NPPA amongst the NGOs and about NGOs in NPPA. Therefore **the existing system of the pricing of drugs, which also has authority to control even un-controlled drugs, does not has much back up.**

Furthermore, the NPPA relies only on ORG data, which has its own limitations. ORG data does not cover institutional sales and it is basically industry-focussed. NPPA or DCP has mechanism, unlike the Department of Consumer Affairs, to obtain some consumer-related data through various consumer activist groups. According to Mr. Singh, **the NPPA under DPCO is not effective even for those categories of drugs, which are under price control.**

Mr. Singh did not concur to Mr. Charna's observation that "it is not correct to believe that the MNCs have only one price for a product everywhere in the world, and as such the prices charged in India would be exorbitant". He mentioned about his interaction with a representative of Novartis, to whom he asked why instead supplying free Gleevec to patients, Novartis is not reducing its price in India and sell it to everybody. The Novartis representative said that if they reduce price in India, the drugs would be smuggled to some other country in the neighbourhood. Therefore, they maintain the same price throughout the world. Mr. Singh, however, was not convinced with the argument.

According to him, an effective mechanism is needed in place of the existing price control system, which has not achieved the results that were expected. He suggested having a multi-pronged strategy – one cannot have only price control, one can't have only subsidy, one cannot have only health insurance. **For the purpose of developing a new mechanism a multi-stakeholder consultation is required, including enhanced communications with NGOs and civil society.** He was not happy with present status of communications between the stakeholders, including communication within the government between different departments and agencies.

Mr. Singh informed about the constitution of a committee in the DCP under Joint Secretary, with two specific issues to be looked upon viz., (a) how much should the span of price control be increased; and (b) how to deal with the issue of "trade margin". Later on, due to intervention by the Prime Minister Office the DPC constituted a Task Force, which is headed by a Principal Advisor of Planning Commission. This Task Force has to

look upon options other than price control to keep the prices of medicines at a reasonable level. The issues such as negotiation of prices, health insurance, subsidy or other things can come up before the Task Force. He felt that the report of the Task Force would definitely be of much use for making decisions in future.

**Mr. Sunil Nandraj, National Programme Officer, WHO India Office**

The issue of “access to drugs” in the context of patents is one of the key technical issues that WHO is providing support and technical assistance to many countries, including India. The WHO will continue to provide support to the GOI to establish a focal point, including the establishment of the WTO Cell in the Ministry of Health. The WTO Cell was established in July 2004 for precise reason that the Ministry of Health was not playing more than active role on the TRIPS and Public Health issues. The Cell was set up with a view to provide relevant information to the Ministry to take the issue forward.

The WTO Cell, which at present constitutes two National Consultants, is also looking at the issues of GATS, Standards (WTO Agreements on SPS and TBT) and competition policy from the public health perspective. There are several studies that are going to be commissioned on these issues. For the purpose of awareness generation and advocacy various workshops would be organised by the Cell on the concerned issues, which will provide platform to various stakeholders to exchange their views. Prior to this Workshop, WTO Cell had organised a national workshop on Accreditation of Health Service Providers in the GATS framework. The WTO Cell would also be responsible for documentation and dissemination of relevant information. In the WHO-SEARO region, for the first time this kind of Cell is established within a health ministry. He commended the whole exercise as a good beginning.

He also emphasised that capacity building on complex trade rules and its impact on public health would be supported by the WHO. Monitoring of drug prices etc. may also get WHO support. He opined that the mechanism to monitor of the prices of patented drugs should have a multi-stakeholder approach, rather than the typical inspector-approach.

He also stressed the need of information dissemination in India, where few have all the information while a vast majority are often in want of information. A kind of web-based Clearing House that would contain all the relevant information in form of studies, presentations etc would be a good idea. There is lots of information available with NGOs and civil society groups as well as with the government that should to be used. To him, the WHO will be more than happy to support a mechanism of the kind of a Clearing House for the purpose of information dissemination.

He further informed that the WHO is not only looking at the access to drugs issue from IPR perspective, but is also looking it from a much broader perspective such as that related to financing, rational use of drugs, support to the DCG(I) in terms of strengthening regulatory capacity, providing relevant information and issues related to the governance of health system. WHO is looking at the access to drugs issue in a comprehensive way.

Summing up the session, **Dr. Abdul Sattar** observed, that there is still no true indication of the impact of the new patent regime on the access of drugs in India. He also appreciated GOI/DCG(I)'s vision of promoting Brand India and took cognisance of concerns raised by Mr. Singh on the existing price control regime. He also commended the WHO-India effort in setting up the WTO Cell at the MOHFW.

He reiterated the WHO's effort in providing support to understand and assess impacts of globalisation, in general, and trade agreements like TRIPS, GATS and SPS & TBT, in particular. This exercise is done in order to balance the right and obligations in the trade negotiations taking into account public health concerns. He hoped that in future there would be better team effort by national negotiators and that public health dimension gets built into the national negotiating strategy.

WHO looks at this issue within the context of Health & Environment globalisation. Although the trade agreements are the major facets, globalisation process goes beyond WTO. Globalisation is multi-dimensional and multi-sectoral concept and in order to bring coherency in the globalisation and hence take optimum advantage, we need to have synergy amongst all the sectors working together at the country level. Ministry of Health is just one dimension, facilitates treating illness of people. But causes of all health problems lies in other sectors, for instance, industry (environment pollution), agriculture (chemical poisoning), water supply (diarrhoea) etc. When we are looking at WTO, we are looking for trade and hence looking for money. But money does not bring health, unless we look at it cogently and establish the right linkages. For all this we need to adopt a strategy.

## **Discussion**

Mr. Wakanker wanted to know in the context of biotech-pharmaceutical having a major share of the global market by 2025, how much would be the impact of patents, as all these would be patented ones.

Shri Ashwini Kumar responded that major molecules coming out of biotechnology are going to be off-patents in another 4-5 years. And this is one of the major threats that the MNCs face.

Mr. Anand Grover wanted Mr. Charna to respond on the issue "how would the OPPI-members/MNCs react/behave if there were opportunities for voluntary license".

Mr. Charna responded that first the Patents Act provisions need to be explored and only then the question of voluntary license would come. Why we would price our products beyond affordable limits? Why can't we price our products at a lower side and earn in volumes.

Mr. Anand Grover suggested to Mr. Gurdeep Singh that the involvement of civil society institutions in the whole issue has to be encouraged by the government. He suggested that

the consultative process should be decentralised, rather than holding consultations only in Delhi or Bombay. Although it is the prerogative of the government to formulate laws and policies, but if proper consultation is held at least an informed decision would be the result and also civil society groups would be satisfied being heard, even if their views may not get reflected in such laws/policies.

Mr. Gurdeep Singh agreed with Mr. Grover that there is a need for more communication with civil society. He assured that he would invite civil society groups to reflect their views before the Task Force.

Mr. Keayla informed the participants on the international pricing of patented drugs and TRIPS linkage. In early 80s, the US President Advisory Council looked into the drug pricing aspect and said that internationally they are not able to realise the same price everywhere. Therefore they agreed that there should be a model that should be applied in every country. That is why the TRIPS Agreement is there, so that in future the MNCs can follow a uniform price all over the world on their patented products.

The pricing issue even in the competitive environment, such as that in India, is very important. How India's competitive environment has contributed in controlling the prices of drugs can be understood by example of Renredim a drug by Glaxo, which is priced in India at Rs.6 a pack. The same drug is priced per pack at Rs.74 in Pakistan and Rs.178 in Indonesia, which are also poor countries. The same drug is priced at Rs.864 in the US. Although the competitive environment in India has given us the lowest prices in the world, this may not continue because the compulsory license provisions in our new patent regime is still very weak. Prior to 1970, when product patent was taken off in the pharmaceutical sector, the prices of antibiotics in India were one of the highest in the world. Furthermore, the DPCO today is not that strong, as it used to be in 1979, when it was created.

Mr. Keayla opined that the Indian industry is very strong and is capable of developing good technologies and they must concentrate on that. However, Mr. Kealya was not optimistic about Indian industry's potential for basic research. According to him, the investments may go waste, if they are in basic research. The Indian industry cannot match pace with the MNCs, who will come first with the inventions and would get patents, with obvious consequences.

Mr. Nagendra Iyer, Consultant, NACO, said that the Revenue Department has given custom duty exemption authority to the Ministry of Health and Family Welfare. Can, in the same way, the Ministry of Health be empowered to decide on the prices of drugs as well as to decide whether the same drugs are life saving drugs instead of Commerce Ministry deciding it?

He further noted that even the generic drugs are sold at higher prices across the retail counters than the prices on which it is procured at the national level. The situation may get worse when it would be a patented drug; say for example the second or third generation HIV/AIDS drugs. Mr. Iyer on behalf of NACO sought the help from the

participants (stakeholders) as to what mechanism should be there – should we go for price control or should we negotiate prices while giving marketing approval or any other mechanism needs to evolve.

Mr. Zaveri informed the house that **in the US there are at least 25 Bills pending, and all of them aims at enhancing competition in the drug market by removing hurdles in the manufacture and sale of respective generic version.** He quoted from one of them: “Prescription drug cost are increasing at an alarming rate and are a major worry for American families and senior citizens. Enhancing competition between generic drug manufacturers and brand-name drug manufacturers can significantly reduce the cost of drug price for American families. The Federal Drug Commission has discovered that there are increasing opportunities for drug companies owning patents on brand-name drugs and generic drug companies to enter into private financial deals in manner that could restrain trade and greatly reduce competition and increase prescription drug cost. The use of generic pharmaceutical for brand name pharmaceutical could save on the purchase of pharmaceuticals between US\$ 8 to 10 billion each year...”

He further informed that many US senior citizens have to travel to Canada to purchase the same drugs at a price one-fourth of the US price.

He questioned Mr. Charna (basing his question on the facts given by the later that only 25-35 new drugs are discovered each year) whether OPPI will facilitate pulling out patent applications from the Indian Patent Controller so that the number of application is significantly reduced.

## Summing Up & Vote of Thanks

Mr. Ujjwal Kumar presented the **vote of thanks** by thanking all the participants and the speakers for engendering discussions amongst the highly diversified stakeholders. He said that a clue could be taken from the fact that even there was low number of participants in the Workshop, the degree of participation was very high and contentious. The clue is that even if there are two competitors in the pharmaceutical market, and if there is a price competition between them, we may not require the Government to intervene, because such market will take care of many concerns. He requested the pharmaceutical industry to be a fair player in the market.

Mr. Kumar further said that the expectation from the Workshop was that there would be some convergence of views on the agenda items. But still a significant degree of divergence exists. He, however, said that the whole proceeding has been recorded and important points would be culled out from that.

Mr. Kumar once again thanked all the participants and resource persons, and the staffs of the MOHFW as well as the WHO in helping to organise this workshop.

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**National Workshop**

**Patent and Public Health: Addressing the Future  
Imperatives of Health Security in the Post-TRIPS Era**

**Monday, 11<sup>th</sup> April 2005  
Casuarina Hall, India Habitat Centre, New Delhi**

**(Organised by the Ministry of Health and Family Welfare, Government of India in  
collaboration with the WHO India Country Office)**

**Agenda**

**0930 hrs – 1000 hrs Registration**

**1000 hrs – 1030 hrs Inaugural Session**

1000 hrs – 1005 hrs Welcome address by Shri B. P. Sharma, Joint Secretary,  
Department of Health, Ministry of Health & Family Welfare

1005 hrs – 1020 hrs Inaugural Address by Shri P. Hota, Secretary, Department of  
Health, Ministry of Health & Family Welfare

1020 hrs – 1030 hrs Address by Dr. S. J. Habayeb, WHO Representative to India

1030 hrs – 1035 hrs Vote of thanks by Shri Rajesh Bhushan, Director (IH), Department  
of Health, Ministry of Health & Family Welfare

**1035 hrs – 1100 hrs Introductory Session**

*An overview of recent law/policy developments on patents &  
public health*

WTO Cell, Ministry of Health & Family Welfare

**1100 hrs – 1130 hrs Tea Break**

**1130 hrs – 1300 hrs Technical Session I**

1130 hrs – 1145 hrs *Manufacture of 'quality' generic drugs – options available with Indian pharmaceutical sector and the preparedness of the Indian pharmaceutical industry to deal with the changed scenario*

- Shri Gajanan Wakankar, Executive Director, Indian Drug Manufacturers Association, Mumbai

1145 hrs – 1200 hrs *Para 6 of Doha Declaration and India's response*

- Shri Narendra B. Zaveri, Advocate, Mumbai

1200 hrs – 1300 hrs Open Discussion

**1300 hrs – 1400 hrs Lunch Break**

**1400 hrs – 1530 hrs Technical Session II**

1400 hrs – 1415 hrs *How far the TRIPS-Flexibilities are being addressed in the Patent (Amendment) Act, 2005?*

- Shri B. K. Keayla, Centre for Study of Global Trade System and Development, New Delhi

1415 hrs – 1430 hrs *Anti-competitive practices in Patent Licensing Arrangements and the scope of competition law/policy in dealing with them*

- Shri Anand Grover, AMTC, Mumbai

1430 hrs – 1445 hrs *WHO perspective on Patents and Public Health*

- Dr. Weerasuriya, Regional Adviser, EDM, WHO-SEARO

1445 hrs - 1530 hrs Open Discussion

**1530 hrs – 1600 hrs Tea Break**

**1600 hrs – 1730 hrs Concluding Session - The Way Forward**

1600 hrs – 1645 hrs *Post-TRIPS scenario and Access to Medicines: the way forward for India*

- Shri Z.H. Charna, Director, Organisation of Pharmaceutical Producers of India
- Shri Ashwini Kumar, Drug Controller General of India, New Delhi
- Shri Gurdeep Singh, Director, Department of Chemicals and Petrochemicals, New Delhi
- Shri Sunil Nandraj, WRI Office

1645 hrs – 1715 hrs Open discussions

1715 hrs – 1730 hrs *Valedictory & vote of thanks*

## **List of Participants**

1. Mr. D.K. Shringi, Drug Controller, Rajasthan
2. Dr. Nalini Abraham, Health Advisor, Plan India Country Office, New Delhi
3. Mr. Mahesh Mishra, DFID India, New Delhi
4. Mr. Z. H. Charna, Director, OPPI, New Delhi
5. Mr. N. B. Zaveri, Advocate, Mumbai
6. Dr. Vijay Garg, Deputy Director, Department of Health, Haryana
7. Mr. B. K. Keayla, Centre for Study of Global Trade System & Development
8. Mr. Bijon Mishra, VOICE, New Delhi
9. Dr. K. Satyanarayan, Chief, IPRs Unit, ICMR, New Delhi
10. Professor Amit Ray, JNU & VHAI, New Delhi
11. Mr. Alok Mukhopadhyay, Chief Executive, VHAI, New Delhi
12. Mr. Gajanan Wakankar, Executive Director, IDMA
13. Mr. Adhikari Singh, Somakar Jyot, New Delhi
14. Mr. Bijay Kumar Sahu, RIS, New Delhi
15. Ms. Leena Menghaney, Advocacy Officer, Lawyers Collective HIV/AIDS Unit,  
New Delhi
16. Mr. Anand Grover, Advocate, Lawyers Collective, Mumbai
17. Ms. Sharmila Roychowdhury, Lex Orbis, New Delhi
18. Mr. Rajeev Kumar, Lex Orbis, New Delhi
19. Mr. Bipul Chatterjee, Director, CUTS-CITEE, Jaipur
20. Ms. Sanchita Chatterjee, Trade Policy Division, British High Commission, New  
Delhi
21. Mr. Vinod C.B., Project Consultant, Support for Good Governance, New Delhi
22. Mr. Trilok Narayana, JNU, New Delhi
23. Mr. Akash Taneja, NIPO, New Delhi
24. Mr. H. Kumar, CSN, Alwar
25. Mr. P. Venkateshan, Director, Department of Consumer Affairs, New Delhi

26. Mr. Gurdeep Singh, Director, Department of Chemicals & Petrochemicals, New Delhi
27. Dr. Abdul Sattar Yusuf, WHO-SEARO
28. Dr. Than Sein, WHO-SEARO
29. Ms. Karin Timmermans, WHO-SEARO, New Delhi
30. Dr. Salim J. Habayeb, WHO Representative to India, New Delhi
31. Mr. Sunil Nandraj, NPO, WHO India Office, New Delhi
32. Dr. D.C.S. Reddy, NPO (HIV/AIDS), WHO India Office, New Delhi
33. Dr. N. S. Dharamshatru, NACO, New Delhi
34. Mr. C. Nagendra, NACO, New Delhi
35. Mr. P. Hota, Secretary, MOHFW, New Delhi
36. Mr. B.P. Sharma, Joint Secretary, MOHFW, New Delhi
37. Shri Ashwini Kumar, DCG(I), MOHFW, New Delhi
38. Mr. Rajesh Bhushan, Director (IH), MOHFW, New Delhi
39. Mr. Mohan Kumar, Under Secretary (IH), MOHFW, New Delhi
40. Mr. S.K. Mohapatra, MOHFW, New Delhi
41. Mr. Prabhat Kumar, MOHFW, New Delhi
42. Dr. Shaktivel, Economist, National Commission on Macroeconomics & Health, MOHFW, New Delhi
43. Ms. Anagha Khot, National Consultant, MOHFW, New Delhi
44. Mr. Rajendra Mehrotra, National Consultant, MOHFW, New Delhi
45. Mr. Ujjwal Kumar, National Consultant, MOHFW, New Delhi