Report on the

Consultative meeting on TRIPS and public health

Amman, Jordan
8–11 December, 2003
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1. INTRODUCTION

Globalization has important bearings on public health in many different ways. Various agreements under World Trade Organization (WTO) represent important aspects of globalization, the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) being one of the most important. The linkages of the TRIPS agreement with access to medicines have been debated at different levels for the past nine years. Since the establishment of the WTO in 1995, this debate has become one the most important in the context of economic globalization and public health and is still continuing.

In a situation where one-third of the people in the world and more than half of the population in developing countries do not have reliable access to needed medicines, governments in developing countries are concerned with how a new and strong intellectual property rights regime would influence the situation. The issue has been raised regularly at the World Health Assembly (WHA) and fiercely debated in the WTO. It has been taken up in almost all important international forums, including the United Nations General Assembly and United Nations Commission on Human Rights. Lack of access to antiretroviral drugs, especially in sub-Saharan African countries, and international civil society and the media have all placed the issue high on the political agenda, both internationally as well as within many countries. As a direct result of all these efforts, a special resolution came out from the fourth WTO ministerial meeting in Doha in November 2001 entitled TRIPS and Public Health.

The World Health Organization (WHO) has been involved in this debate from the beginning. The World Health Assembly has issued many resolutions involving issues related with TRIPS and access to medicines, and WHO has produced a number of useful documents on the subject. It has sought to deepen the understanding about the TRIPS agreement and its linkages with public health and access to essential medicines through research, publications and training. WHO has also been helping countries to address the revisions of their patent laws and regulations, assisting countries in special and difficult situations with regard to access to important patented drugs and lately it has established an international network for the assessment of impact of TRIPS agreement on access situation in various countries in a standardized way; a number of country studies are taking place under this initiative.

A meeting on the TRIPS and public health situation in the countries of the WHO Eastern Mediterranean Region was organized by the WHO Regional Office for the Eastern Mediterranean (WHO/EMRO) in Amman, Jordan from 8 to 11 December 2003. Most of the countries in the Region are full members of the WTO, and some are in the process of taking up membership. The idea of the meeting was to review the current situation internationally, discuss the situation in both kinds of countries in the Region and underline areas where attention needs to be focused in this context.

Fourteen participants from 13 countries in the Region took part. Most of the participants were senior drug regulators. Seven temporary advisers from Egypt, Pakistan, Tunisia and United States of America attended, all of whom were academics and experts in this field. Representatives from important organizations such as the WTO and the International
Federation of Pharmaceutical Manufacturers Associations attended, as well as WHO staff from the Regional Office.

Dr Abdelaziz Saleh, Special Adviser on Medicines, WHO/EMRO, provided background by referring to various recent international meetings where concerns of developing countries in relation to economic globalization have been expressed including summit meeting of Group of 15, Group of 77 and recently the Group of the Organization of Islamic Conference (OIC), held in Putrajaya, Malaysia, from 16 to 18 October 2003. The Tenth Summit of the OIC, in its final communiqué, had emphasized the need to devise ways and means to minimize the adverse effects of globalization on the economies of the OIC countries and had called for an equitable share in the benefits of globalization for all countries. The conference called upon the developed countries for further liberalization of trade through increased access to their markets for the products and services produced in developing countries and it also called for speedy accession of all the developing countries to the World Trade Organization underlining that no political consideration should impede this process.

In Eastern Mediterranean Region, as of 4 April 2003, 10 countries are members of the WTO, 4 countries have observer status with the organization and are at various levels of accession, and 6 countries are non-members. Full members include Bahrain, Djibouti, Egypt, Jordan, Kuwait, Morocco, Pakistan, Qatar, Tunisia and United Arab Emirates. Observers or in-accession are Lebanon, Saudi Arabia, Sudan and Yemen. Non-members in the Region are Afghanistan, Islamic Republic of Iran, Iraq, Libyan Arab Jamahiriya, Somalia and Syrian Arab Republic.

The main objectives of the meeting were to determine what the national situation is in various countries with respect to TRIPS and public health, and how WHO/EMRO could best advise countries in the Region who are in accession or not yet applied for WTO membership.

The meeting was opened by Dr Mohamed Z. Khan, Acting WHO Representative in Jordan, who delivered a message from Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean. In his message, Dr Gezairy summed up the concerns listed in a number of WHO documents produced over the years on the subject of TRIPS and access to medicines, namely: that rigid intellectual property rights regulations would deny developing countries access to the outcome of new science and technology development; that rigid implementation of TRIPS would be associated with price increases and reduce access to essential medicines; that technology transfer currently faced many technical and financial obstacles; and that local drug industries would have greater difficulties in competing in the world drug market.

Dr Gezairy quoted from the explicit and strongly worded Doha Declaration on TRIPS and Public Health, which reaffirmed the supremacy of public health over commercial interests, and then referred to a recent resolution of WHO Regional Committee for the Eastern Mediterranean (EM/RC50/R.2) which clearly defined public health as the science and art of promoting, protecting and/or restoring the physical, mental and social well-being of the people through prophylactic, diagnostic, therapeutic and rehabilitative measures, applied to human beings and their environment. He provided figures about the WHO Essential Drug List
with reference to patented drugs included on it, but pointed out that the situation would not necessarily remain as such in future. The genome project was an example; if 10% of the genome represented targets for new drugs, the possibility existed for developing at least 3000 new molecular entities to combat disease. Through new technologies, 50 000 new drugs could be produced and screened by a laboratory in a week—more than a major pharmaceutical company could test in a year. These trends, in the wake of a new intellectual property regime, could seriously hamper people’s access to needed treatments. Dr Gezairy concluded by emphasizing the need for more concerted efforts in the Region to understand and respond effectively to these important challenges.

In an inaugural address, H.E. Mr Saeed Darwazeh, Minister of Health of Jordan, welcomed the participants and emphasized the importance of respecting intellectual property rights as one of the main incentives for inventions. He said that the intellectual property rights system aimed at promoting economic and social development. Jordan had taken progressive steps to build a national system that respected intellectual property rights. Jordan joined WTO in 1999 and had issued necessary national laws and legislation that ensured Jordan’s commitment to WTO’s agreements. Jordan had also signed a joint agreement with the European Union and the Free Trade Agreement with the United States of America. Jordan had been selected as the regional centre for the Arab Society of Intellectual Property Rights. The King Abdullah the Second Centre for intellectual property rights was the first centre of its kind in the Arab Region in the area of dispute settlement related to intellectual property rights.

It was expected that the meeting would focus on exchange of experience and analysis of the impact of TRIPS on public health, and would come up with practical recommendations as well as a regional strategy to promote and coordinate countries’ activities related to TRIPS and public health. The Minister closed by wishing the meeting full success.

Dr Maysa Khalil Al Saket (Jordan) was elected Chair and Dr Zafar Mirza (Pakistan) was appointed as Rapporteur. The programme and list of participants are included as Annexes 1 and 2. The full text of Dr Gezairy’s speech is attached as Annex 3. Resolutions of the WHO Regional Committee for the Eastern Mediterranean concerning the implications of WTO agreements on health are attached as Annexes 4 (1998) and 5 (2000).

This report provides the summary of all the presentations and discussions. It is not possible to reproduce all the presentations here, but care has been taken to include all the important points made during the meeting. A compact disc containing all the presentations and other meeting-related documents was distributed at the end of the meeting.
2. REGIONAL OVERVIEW ON WTO/GATT AGREEMENTS: IMPACT ON HEALTH

Dr Abdelaziz Saleh

The presentation started by tracing the evolution of GATT into WTO after the conclusion of the Uruguay Round. Right from the beginning it generated controversy in different parts of the world through conflicting reactions to various WTO agreements. Of special concern was the impact of these agreements on the health and nutrition sectors, including the impact on local drug industries, the cost of essential health services and the availability of essential requirements for good nutrition.

WTO agreements having direct implications on health sector include the following:

- Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)
- Agreement on Sanitary and Phytosanitary Measures
- Agreement on Technical Barriers to Trade
- General Agreement on Trade in Services (GATS)
- Uruguay Round Protocol-GATT 1994
- Agreement on Agriculture
- Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least Developed and Net Food-importing Developing Countries
- Agreement on Trade-Related Aspects of Investment Measures
- Agreement on Implementation of Article VI (Anti-Dumping)
- Agreement on Rules of Origin
- Agreement on Safeguards

The TRIPS agreement is perhaps the one that has attracted most of the attention in developing countries. There are voices today in developing countries which are saying “we gained nothing from TRIPS, and we only signed it because we were forced to”.

TRIPS contains some significant benefits for inventors and its obligations requires that product and process patents be available in all fields of technology. TRIPS specifies that patent owners must be given the right to prevent others from making, using, offering for sale, selling, or importing products covered by a product patent and from using a process claimed in a patent or using, offering for sale, selling, or importing at least the product obtained directly from use of the process. Of particular importance to patent owners are the restrictions that the TRIPS Agreement places on compulsory licensing.

The debate on TRIPS globally and in some of countries of the Region is characterized by controversy. On one side are the views of multinationals and multinational subsidiaries in developing countries and on the other side are the views of public and private national drug industries. On several occasions, views on the public health interest are also expressed.
Multinational views

- Rigid intellectual property rights will promote foreign investment and technology transfer;
- Rigid intellectual property rights will encourage national industry to invest in research and development (R&D);
- Strong intellectual property rights will be reflected in better quality;
- It is not expected that the implementation of TRIPS will have a serious impact on drug prices.

Views of the public and private national drug industries

- TRIPS implementation will not always attract foreign investment;
- Implementation of TRIPS will probably be accompanied by a large increases in prices;
- TRIPS has made it more difficult for developing countries to make use of compulsory licensing;
- The increase in cost of locally produced drugs will make it more difficult for local drugs industries to compete in the world drug market;

Views of those representing the public interest

- Multinationals exaggerate the cost of R&D;
- So-called new developments are not always real breakthroughs;
- Patent claims need more careful analysis;
- Rigid intellectual property rights and their abuse by multinationals will definitely deny developing countries and poor patients access to urgently needed scientific advances;
- The nature of the health sector necessitates a humanitarian approach;
- Rigid intellectual property rights and lack of ethical promotional practices will place a huge burden on poor patients and health care systems in developing countries.

There is a need for the establishment of national/regional committees including representatives from various sectors such as multinationals, public/private drug industry, professional associations, nongovernmental organizations, consumer associations, health economists, legal experts, politicians and public health leaders to develop appropriate national and regional plans to deal with TRIPS and its implementation.

Some details were also provided in the presentation on SPS; TBT; GATS; Uruguay Round Protocol-GATT 1994; Agreement on Agriculture; Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least Developed and Net Food-importing Developing Countries; Agreement on Trade-related Aspects of Investment Measures; Agreement on Implementation of Article VI (Anti-dumping); Agreement on Rules of Origin; and Agreement on Safeguards.

The next part of the presentation was about the WHO response to the WTO establishment and the new discussions and concerns it has raised. The participants were informed about various initiatives and publications produced at WHO headquarters as well as
at the regional levels. The WHO Task Force on Health Economics at headquarters published a document on WTO entitled *Health economics: WTO, what's in it for WHO?* The Director-General established a task force, the WHO Coordinating Group for WHO/WTO Cooperation. WTO staff were invited to the meeting of headquarters task force for briefing on WTO activities and discussion on ways of collaboration between the two organizations. A special adviser to DG was appointed as a result of a WHA resolution on WTO issues.

Various important publications produced on the TRIPS by WHO include *Globalization and access to drugs; Globalization, patents and drugs – an annotated bibliography* (two editions); *Implications of the Doha Declaration on TRIPS and Public Health; Cost-containment mechanisms for essential drugs, including antiretrovirals, in China; Network for monitoring the impact of globalization and TRIPS on access to medicines; Global comparative pharmaceutical expenditures; and Health reform and drug financing.*

In conclusion, what is needed is the development of institutions at national, regional and global levels for continuation of study, development of policies, strategies and plans of action, and to monitor the input of future development of WTO agreements. Such institutions should participate in any future negotiations to review WTO agreements or to develop new ones. Ad hoc committees and meetings are not enough. There is an urgent need for review of national legislation through establishment of national committees to meet country commitments to WTO agreements; national level studies, before countries make any commitment to GATS; in-depth studies for various articles of Antidumping and Safeguard Agreements; and special attention by developing countries to protect the national flora and medicinal plants from international exploitation.

*Intervention by Dr Mohamed Bahaa El-Din Fayez*

It is common knowledge that the vast majority of pharmaceutical chemicals currently in use in commerce are synthetic products. Another reality is that the small molecules from which such chemicals are synthesized are derived from fossil sources, the commoner forms of which are crude petroleum and natural gas. It is held in many quarters in the developed world and among authorities on the subject that such fossil resources will last for no longer than numbered decades to come, probably not exceeding 150–200 years.

Therefore, the world will have to face the challenge of acute shortages, perhaps a total absence of resources of starting materials for the synthesis of complex pharmaceutical chemicals, among many other organic chemical products. It is very likely that scientists will turn to the natural products residing in plants for the discovery and utilization of biologically active chemicals, or for transformation into basic or intermediate chemicals that can in turn be used in the making of useful pharmaceutical chemicals. The current view, substantiated by statistics, that one out of 100–150 selected plants can yield biologically useful products, is noteworthy. When compared with the much publicized ratio of 1:5000–10 000 in the synthetic chemicals field, the potential of the plant kingdom as a viable and inexhaustible resource becomes clearer.
2. GLOBALIZATION AND HEALTH

2.1 Impact of globalization on health: State responsibility

Dr Belgacem Sabri

Government’s role as a provider and protector of public health has long been established through various international covenants, such as the Alma-Ata Declaration on Primary Health Care (1978), WHO Constitution and national constitutions. Through ministries of health, governments develop health policies and legislation, manage health systems and services, mobilize financial resources and develop other kinds of resources for health services including human resources, provision of medical technology and supporting essential health research. Management of health systems includes coordination among various partners; supervision of the private and nongovernmental sectors; coordination of external support and management of external affairs (trade in health).

The interface of globalization with health has two sides. On one hand, it brings new opportunities for social and economic development, which in turn can enhance better access to health care; it increases health awareness and brings closer the modern diagnosis and treatment tools, i.e. tele-health. On the other hand, it also has negative effects, such as increasing poverty and unemployment. It contributes to environmental pollution and introduces unhealthy lifestyles (food, smoking, alcoholic beverages). In some ways it also weakens the role of governments in the protection of public health functions like standard-setting and protection of quality of health care. It also puts ministries of health in a weaker role when it comes to negotiations in relation with trade in health services.

Globalization is resulting in growing role of the private sector in health services provision which leads to cost escalation, e.g. in the case of pharmaceuticals, which in turn introduces or deepens inequity in health care. Because of better job opportunities in other countries, there is a drain of qualified professionals from developing countries, and a new generation of concerns has emerged with reference to bio-ethics.

In face of these challenges, there is a need for developing alternative approaches for health protection. First of all, the exceptions available in the WTO agreements to protect public health (e.g. rules of intellectual property rights, parallel importation) should be fully utilized. Secondly, advances in information technology should be harnessed for promoting health and setting better standards. Thirdly, the role of the governments should be strengthened in terms of their responsibilities for developing and updating health legislation.

There is need for improving negotiation skills of health professionals so that they can get better deals in health trade. In this scenario government should strive to secure equitable financing of health services. It should provide support to social and private health insurance initiatives and extend insurance coverage to informal sectors (small trades, farming, fishing, etc) through community-based insurance programmes.

It is important for governments to carry out studies in order to examine carefully the effects of globalization. They also need to work closely with a larger civil society.
2.2 Trade in health services in the Eastern Mediterranean Region: challenges and planned response

Dr Sameen Siddiqui

This presentation was based upon a WHO/IDRC regional consultation held in Beirut, Lebanon, 4–6 May 2003. The objectives of the consultation were to acquire an overview of globalization, trade and health, focusing on trade in health services; share experiences from within and outside the Region on trade in health services and review opportunities offered by GATS; assess country and regional situations in relation to trade in health services, and plan appropriate responses; outline strategic directions in areas of advocacy, capacity-building, support to research on trade in health services; and network to support health systems through WHO and IDRC collaborative efforts.

There are four main categories or modes of trade in services: cross-border supply of services: consumption abroad; commercial presence; and movement of natural persons. An example of cross-border supply of health services (Mode 1) is electronic delivery of health services: tele-health; tele-diagnostic, surveillance and consultation services; tele-pathology. The positive side of supply of such services is that it may improve the quality of diagnosis and treatment; however, on the negative side, it may affect equity in health if these services are supplied to a small segment of population only, e.g. urban affluent.

Movement of patients or students to another country (Mode 2) for health services or medical education may enable them to get better services but they may also at the same time negatively affect chances of the local health care system to improve.

Commercial presence (Mode 3) by way of establishment of hospitals, diagnostic centres, training facilities through foreign direct investment, cross-border mergers and acquisitions, joint ventures and alliances, may bring in foreign direct investment and decrease pressure on public health sector but at the same time it may also deepen the existing inequities in health and may cause a drain of qualified professionals from the public sector to the lucrative private health care sector.

Movement of health professionals (Mode 4) for jobs to other countries may bring prosperity to them and may bring in some foreign exchange but there is also a risk of permanent “brain drain”, loss of heavily subsidized medical education and implications for equity.

Eight countries in the Eastern Mediterranean Region have made commitments in one or more of the three categories: professional services (medical and dental services, veterinary services, and nurses, midwives); health-related and social services (hospital services, other human health service, social services and others); and health insurance services. Countries that have made commitments are Bahrain, Egypt, Kuwait, Morocco, Pakistan, Qatar, Tunisia and United Arab Emirates. Kuwait has made commitments in three categories, followed by Pakistan, Qatar and United Arab Emirates, which have committed in two categories each, and the remaining countries have made commitment in at least one of the category.
Key recommendations to ministries of health which came out of the May regional consultation on GATS and Public Health are to: develop units in the Ministry of Health to deal with issues of trade in health services and include concerned agencies and interest groups; undertake situation analysis, especially for countries in the process of accession to WTO; clarify trade/GATS terminology to public health professionals to better understand trade-related issues; strengthen policy, strategic planning, standard setting and regulation in health sector to better manage trade in health services; promote partnership between government, academic institutions and nongovernmental organizations to improve the knowledge related to trade in health services and develop priorities for research; and promote horizontal cooperation on trade and health with other countries of the Region.

Recommendations for WHO and IDRC were to: develop capacity to support countries in trade in health services through appointment of a full-time professional in EMRO; allocate resources under regional and country programmes for advocacy, capacity-building, and data collection and research on this; establish a regional forum on trade in health services to enhance awareness, capacity-building, research and advocacy activities; develop a handbook for health professionals on trade in health services, to serve the purpose of a ready reference; identify academic institutions from within and outside the Region for undertaking activities in trade in health services; undertake country case studies on trade in health services and its impact on performance of the health system; strengthen research activities related to trade in health services using academia and professional network in the Region; and analyse GATS and health from the perspective of ethics in addition to efficiency, equity, quality and access.

The key lessons from the experience to date, which was also reaffirmed by the participants of the consultation are that: the guiding principle underlying any dialogue on GATS and its public health implications should be to “protect public health interest”; challenges posed by GATS to public health should be tackled to minimize any adverse effect on the functioning of health services; opportunities provided by GATS should be harnessed to improve the access, equity, efficiency, and quality of health services. Countries do not have to put health on the table as the subjects for negotiation in accession; if they do, they should: be aware of the implications of GATS on efficiency, equity and quality of health services; assess the pros and cons of Market Access in health sector and clearly spell out the conditionalities; understand the implications of the WTO principles of “most favoured nation” status and “national treatment”, before opening the health sector.

The next steps after this consultation were: publication of report of the meeting (which has already been disseminated); exploratory studies initiated in four countries of the Region, Egypt, Oman, Pakistan and Tunisia; implementation of a two-year project developed with IDRC to advance the work on trade in health services in the Region, beginning January 2004 it would include workshop of research methodology in trade in health services; case studies in 10 countries of the Region; workshop on research to policy linkage. A full-time staff member for this work will be hired after the agreement from WHO headquarters.
3. ORGANIZATION’S VIEWPOINT

3.1 The Arab Company for Drug Industries and Medical Appliances
Dr Muwaffak J. Haddadin

TRIPS is more likely to cripple the pharmaceutical industry in developing and least developed countries. Despite of the promises of the TRIPS agreement, very little transfer of technology from developed countries has taken place. Intellectual property rights can do little to stimulate inventions in developing and least developed countries because of few resources for research facilities.

There has been an increase in patent applications since the introduction of the TRIPS agreement. More and more bilateral trade agreements are taking place which work against the interests of developing countries. Moreover, pharmaceutical multinational corporations are conducting little research on diseases of poor countries (malaria and tuberculosis,) unless diseases are common in rich countries (cardiovascular diseases).

What should developing and least developed countries should do to help themselves? They should invite technology transfer by offering incentives to intellectual property rights holders (e.g. tax exemptions); inject public funds into R&D although this a long range measure to bear fruit; and make use of the “Bolar”, or regulatory, exception, “government use”, compulsory licensing and parallel imports. Developing countries should review their patent laws to include maximum flexibilities available in the TRIPS agreement.

3.2 World Trade Organization: The TRIPS Agreement and public health—recent developments
Dr Hannu Wager

The Fourth Ministerial Conference of the World Trade Organization, which was held in Doha, Qatar, adopted a Declaration on the TRIPS agreement and public health (“the Declaration”). The purpose of the Declaration was to respond to the concerns that had been expressed about the possible implications of the TRIPS agreement for access to medicines.

It emphasizes that the TRIPS agreement does not and should not prevent countries from taking measures to protect public health and reaffirms the right of countries to use, to the full, the provisions of the TRIPS agreement which provide flexibility for this purpose. It signals acceptance by all WTO members that they would not seek to prevent other members from interpreting the agreement in a pro-public health way. It contains a number of important clarifications of some of the flexibilities contained in the TRIPS agreement, especially with respect to the freedom to determine the grounds upon which compulsory licences are granted and the right to permit parallel imports. This clarification on compulsory licences is, for example, a useful corrective to the view sometimes expressed implying that some form of emergency is a pre-condition for compulsory licensing under the TRIPS Agreement. The Declaration further makes it clear that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency (when a compulsory licence can be granted without a prior effort to obtain a voluntary licence) and...
that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent such circumstances.

While WTO members have clarified the flexibility in the TRIPS agreement and countries’ right to use it to the full, it should not be forgotten that it is not the TRIPS agreement but each country’s domestic law that has direct legal force in regard to acts relating to intellectual property on its territory. Thus, the Declaration does not obviate the need for each country to take steps at the national level to avail itself of this flexibility where necessary to secure the availability of medicines at affordable prices.

In regard to the least-developed country members of the WTO, the Declaration records an agreement of Ministers to accord them an extension of their transition period until the beginning of 2016 in regard to the protection and enforcement of patents and rights in undisclosed information with respect to pharmaceutical products. The TRIPS Council took the necessary action under Article 66.1 of the TRIPS agreement to give effect to this in June 2002 and, at the same time, recommended a parallel waiver for these countries from obligations under the “exclusive marketing rights” provisions of Article 70.9. The waiver was adopted by the General Council in July 2002.

It should also be noted that, while emphasizing the scope in the TRIPS agreement to take measures to promote access to medicines, the Declaration recognizes the importance of intellectual property protection for the development of new medicines and reaffirms the commitments of WTO members in the TRIPS agreement.

Problem of countries with insufficient manufacturing capacities in the pharmaceutical sector

An issue which arose in the work on the Declaration was that of the ability of countries with limited manufacturing capacities to make effective use of compulsory licensing. It is not in dispute that Members can issue compulsory licences for importation as well as for domestic production. However, there was concern about whether sources of supply from generic producers in other countries to meet the demand from countries who want to import under a compulsory licence would be available, given the requirement in Article 31(f) of the TRIPS agreement that, normally, any compulsory licences granted in potential supplying countries shall be “predominantly for the supply of the domestic market of the member” granting the compulsory licence. This constraint might be increasingly felt after 2005 when countries with important generic industries, such as India, come under an obligation to provide patent protection for pharmaceutical products. The Declaration recognized the problem in its paragraph 6 and instructed the Council for TRIPS to find an expeditious solution to it and to report on this before the end of 2002.

Intensive work in the Council for TRIPS in the second half of 2002 led to the Chairman of the Council presenting on 16 December 2002 a draft Decision on the subject representing his best assessment of how to achieve a balanced result taking all positions and concerns into account. Not all Members were ready to adopt the Decision at that time, either because they considered that it was too open-ended and open to abuse or that it was too burdensome in some respects. After further work, the Chairman’s proposal was finally adopted by the
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General Council on 30 August 2003, at which meeting a Chairman’s statement containing several key shared understandings of members was also put on record.

The Decision grants three distinct waivers from the obligations set out in subparagraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products, subject to certain conditions. The Decision covers any patented products, or products manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health, including active ingredients necessary for their manufacture and diagnostic kits needed for their use. The three waivers are as follows.

1) A waiver of the obligation of an exporting member under Article 31(f) of the TRIPS agreement to the extent necessary for the purposes of production and export of the needed pharmaceutical products to those countries that do not have sufficient capacity to manufacture them. This waiver is subject to certain conditions to ensure transparency in the operation of the system and that only countries with insufficient domestic capacity import under it, and to provide for safeguards against the diversion of products to markets for which they are not intended.

2) A waiver of the obligation under Article 31(h) of the TRIPS agreement on the importing country to provide adequate remuneration to the right holder in situations where remuneration in accordance with Article 31(h) is being paid in the exporting member for the same products. The purpose of this waiver is to avoid double remuneration of the patent owner for the same product consignment.

3) A waiver of the obligation under Article 31(f) of the TRIPS agreement on any developing or least-developed country that is party to a regional trade arrangement at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries. The purpose of this waiver is to enable such countries to better harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products.

The Chairman’s statement which was put on record at the time of the adoption of the Decision was designed to meet the concerns of those who feared that the Decision was too open-ended and might be abused in a way that would undermine the benefits of the patent system. For example, it recognizes that the system should be used in good faith to protect public health and not be an instrument to pursue industrial or commercial policy objectives; it addresses some concerns relating to the risk of diversion; and it sets out ways in which any differences arising from the implementation of the system can be settled expeditiously and adequately. The Decision also records that the 23 most advanced countries have agreed to opt-out of using the system as importers, to be joined, after their accession to the European Communities, by the 10 acceding countries. In addition, 11 other members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency.
The waivers provided for in the Decision will remain in force until an amendment to the TRIPS Agreement replacing its provisions takes effect. The TRIPS Council will initiate work by the end of 2003 on the preparation of this amendment, with a view to its adoption within six months. It is understood that the amendment will be based, where appropriate, on the Decision.

As mentioned earlier, reaching agreement on the Decision was far from easy, with some members having concerns that it might be too open-ended and opens to abuse and others that it might be too burdensome. Views in some industry and civil society circles were even more polarized. Notwithstanding these concerns, there is reason for confidence that the system strikes a balance that is both workable and provides the necessary safeguards. Certain notification and other requirements have to be complied with, but these are not unreasonable. Exporting countries should have no significant problems in meeting them. The system has been designed so as to keep to a minimum burdens on importing countries, especially least-developed ones, since they will generally be amongst those with more limited domestic administrative capacity. Where they have any difficulties, it will behove the international community, whether intergovernmental organizations, nongovernmental organizations or partner governments, to give them the necessary assistance. There is good reason to believe that this will be forthcoming.

It should not be forgotten that the system established by the Decision is only one small component of a much larger network of efforts required, both at the national and international levels, to address the grave public health problems afflicting many developing and least-developed countries and to facilitate their access to medicines. It is encouraging that the international community is increasingly seized with these problems, but further concerted action is required in the relevant forums, including to increase funding, develop social and health infrastructure and to increase R&D for neglected diseases that mainly afflict the developing world.

3.3 International Federation of Pharmaceutical Manufacturers’ Association

Dr Eric Hubert Noehrenberg

Debates about compulsory licensing and parallel trade, which are sometimes cited as measures to “protect” public health, are really debates about how to protect local industry and its interests. This is an industrial policy debate, not a public health debate.

Previous speakers had raised concerns about how the TRIPS agreement would affect local generic producers. Fully 95% of all drugs on the WHO Essential Drugs List are off-patent. Furthermore, many drugs are going off-patent in the next five years. Public health needs can well be met with off-patent and soon-to-be off-patent medicines. Furthermore, even when patented medicines may be needed to meet public health needs, breaking patents is not necessary, because experience has shown that partnerships have led to greatly expanded access to patented medicines.

The results of the research have shown a strong relationship between the strength of intellectual property rights and the level of foreign direct investment. Furthermore, stronger
intellectual property rights lead to more domestic innovation, which is also very important. Indeed, it has been seen that strong intellectual property rights have led to more domestic innovation and technology transfer to encourage such innovation. Stronger intellectual property rights also give incentives for local innovators to stay in their countries, instead of going abroad to do their work.

Experience has shown that parallel trade always moves products from a low-price market to a high-price market. A particularly dangerous aspect of parallel trade is that it cuts at the very basis of the expanded access programmes.

On the industrial policy side, the local industries in the Region would also not welcome parallel trade. Indian and Chinese producers have more capacity and are generally cheaper than producers in the Region itself. Thus, if allowed in through parallel trade, they are likely to take away the markets of the local producers in the Region. It has already been seen in Africa that some local generic producers have been driven out of business by imported generics from India and other countries.

With regard to compulsory licensing, this action would certainly drive away foreign investors. IFPMA believes that the decision reached by the WTO General Council in August 2003 on the issue of compulsory licenses for countries with insufficient or no capacity in the pharmaceutical sector is a good example of how states can work together to solve a perceived problem.

In conclusion, far from hurting public health, TRIPS promotes it, including in developing countries. It facilitates local innovation in health care, foreign direct investment, and the introduction of new products and new technologies into developing country markets.

3.4 Civil society contributions

Dr Zafar Mirza

The first ever meeting which took place on the debate about TRIPS and access to medicines was held in October 1996 in Bielefeld, Germany and brought together WHO, WTO, consumer organizations from both developed and developing countries and many independent researchers and activists. Since this meeting, civil society has taken over the subject with its deep concern about the difficulties the “new agreement” by the name of TRIPS will pose to access to medicines in poor countries. International civil society has played a major role in pushing this issue on the political agenda of the international level as well as in many countries. The Doha Declaration on the TRIPS Agreement and Public Health is the latest manifestation of the importance this issue has assumed.

It is now clear that pharmaceutical corporations along with the software and motion picture industries were the main forces behind the inclusion of the intellectual property rights agreement in WTO although intellectual property rights, to begin with, do not belong to trade. Developing countries raised this issue during the Uruguay Round but eventually accepted the agreement. Soon the concerns about stronger and prolonged patent protection conditions and terms gave rise to concerns about the impact of these on prices of medicines and on
development of local pharmaceutical industry in developing countries with a net result of negative implications on access to medicines, especially for the poor in developing countries. WHO estimates that in lower income countries up to 50% of the people do not have access to medicines. These concerns were readily picked up by civil society organizations, and soon the campaign became a “flash-point of globalization”. There is no doubt of the importance of intellectual property rights and their link with research and development and the need for R&D in the area of pharmaceuticals, especially for diseases prevalent and emerging in developing countries. However, it is also important that countries should make decisions about introducing the level of intellectual property protection in accordance with the level of social and industrial development; interestingly, this is the lesson from the history of intellectual property protection in industrialized countries. The issue of R&D is complex. There has been a great deal of controversy about the level of high prices of patent medicines and the money spent by pharmaceutical corporations on R&D. From the point of view of developing countries this becomes interesting, as research by Médecins sans frontières has shown that R&D is actually very negligibly undertaken by pharmaceutical corporations for diseases prevalent in developing countries. Because of this continued neglect on the part of the multinational companies that Médecins sans frontières has now launched a major international initiative called the Drugs for Neglected Diseases (DND) initiative. Pharmaceutical multinational companies do not pay attention R&D in developing countries simply they don’t see big money as compared to rich consumers in developed countries. However, they insist on strong intellectual property protection through TRIPS in these countries in order to secure present but more importantly future markets.

Civil society organizations have been involved in these debates in a very active through research, advocacy and mobilization. Médecins sans frontières, Health Action International, Act-up, Oxfam, Action-Aid are just a few. These and other organizations use public health perspective in these debates and have successfully raising the issues at health assemblies, WTO ministerial conferences and at country level. In Brazil, India, Mexico, Pakistan and South Africa, and in many other countries, civil society organizations have played a major role in raising issues, making technical contributions and ensuring that public health considerations are not compromised at the time of patent law reviews. The HIV/AIDS situation and lack of access for poor patients to antiretroviral drugs has been at the forefront of this work, but definitely not limited to it.

The struggle is on and challenges are still there; however, civil society organizations have become important actors in these debates and are increasingly difficult to ignore.

4. ANALYSIS OF TRIPS AGREEMENT

4.1 TRIPS agreement: a global view

Dr Heinz Klug

Various important sources of international obligations related to intellectual property rights and access to medicines need to be understood. In historical context, obligations started with the State practice and varied from State to State. Conflicts were adjudged as thought fit
in the opinions of courts. These practices became the sources of international law which remained customary in nature for a long time. The Vienna Convention on the Law of Treaties became an international reference for development and interpretation of international law. The principles of the United Nations Universal Declaration of Human Rights (1948) also provide an important backdrop against which intellectual property rights and access to medicines issues should be appreciated. More specifically, international health law and regulations overseen by WHO, the Constitution of WHO especially Articles 19, 21, 22 and 23 and more recently WHO’s Revised Drug Strategy, all provide a sound background for entering the TRIPS and access to medicines debate. Public health advocacy with reference to WTO and the TRIPS agreement is, and should be, embedded and informed by this legitimate background.

There are various approaches for establishing a relationship between domestic law and international obligations. In one approach, signing an international treaty enables it to be self-executing; in another approach, legislative action is required to be taken at the domestic level to incorporate the treaty. A monist approach is about automatic incorporation and a dualist approach is where legal incorporation is required. Some countries today have a mixed system, for example, in the United States treaties become self-executing at the same time the Senate ratification process occurs.

The World Intellectual Property Organization (WIPO) is the UN organization to promote intellectual property rights, but this role has been undermined by the establishment of WTO in 1995. WIPO did not have a jurisdictional role and only dealt with promoting intellectual property rights and providing technical assistance to UN members for bringing in place a better intellectual property rights regime to promote R&D. WTO, in contrast, has jurisdictional authority as well through its dispute settlement system.

Relevant international case law has accumulated over the years and now serves as an important source of interpretation. A 1997 panel decision in the India Mailbox case is an important example: “Article 3.2 of the dispute settlement understanding directs panels to clarify provisions... ‘in accordance with customary rules of interpretation of public international law’... embodied in the text of the 1969 Vienna Convention on the Law of Treaties...Article 31(1) of the Vienna Convention states that ‘treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its objects and purpose’.” Good faith requires the protection of legitimate expectations derived from the protection of intellectual property rights provided for in the agreement.

In the Japan Alcoholic Beverages Case of 1996, the Appellate Body wrote that TRIPS is a part of the WTO system and Article XVI (1) of the WTO Agreement provided that the WTO shall be guided by the jurisprudence established under GATT 1947 unless there is a contrary provision.

It is also important to understand the origins of intellectual property protection, trade negotiations and TRIPS. Prior to the TRIPS agreement, nations were sovereign in deciding about the kind of intellectual property rights regime depending upon the level of their level of
industrial development. Then came the Paris Convention, which did not set any minimum standards or definition of subject matter of patent or trademarks but it did introduce the notions of National Treatment (NT) and Most Favoured Nation (MFN) in the international trade arena. The Berne Convention set a minimum level of protection for Copyright Protection. It is also interesting to note that the initial concern of the GATT (1947) was only to restrict illicit trafficking in counterfeit trademarked goods (Article IX). Gradually an understanding developed among industrialized countries that the absence of international protections “could and did have a direct distorting impact on trade”. This understanding and concern got on the negotiation table during the Uruguay Round, where the subject of intellectual property was taken up in 1986. The initial debate was about the mandate of jurisdiction on intellectual property issues between WIPO and WTO. A powerful private sector from industrialized countries played a key role in the background in these negotiations. The United States, through its Office of the Trade Representative (USTR), was most active. The United States also has Law s301 through which it can take unilateral action against those countries which do not respect intellectual property rights; through this law the United States exerts a lot of bilateral pressure on less powerful countries.

The TRIPS agreement has introduced more extensive protection (Article 1[1]) of intellectual property by setting the minimum standards. Minimum substantive protections relevant to pharmaceuticals have been set at least for 20 years (Article 33) and for both process and product patents. These protections must be available “without discrimination” based on place of invention, field of technology, imported or locally produced (Article 27[1]). Countries are required to incorporate these standards in their intellectual property laws. The agreement describes the subject matter, provides for enforcement guarantees (Article 28) but also provides for judicial review through Article 32. Basic principles also include National Treatment (Article 3), Dispute Settlement Mechanisms (Article 4), Most Favoured Nation (Article 5) although exceptions to NT and MFN are also provided. TRIPS has reversed the burden of proof in civil proceedings with respect to infringement of a process patent. It also provides for protection of confidential data, within internal limitations (Article 39[3]).

Obligations of industrialized countries include: broader WTO trade-offs for poor countries; pursuance of objectives of trade and development; technology transfer (Article 7); and technical and financial co-operation (Article 67) with developing countries.

Principles of interpretation in terms of defining the boundaries of TRIPS agreement generally include: balance of rights and obligations (Article 7) and good faith negotiations. In an interesting case (India Mailbox, 1997), the WTO Appellate Body rejected the suggestion that “only India can assess whether Indian law is consistent with India’s obligations under the WTO agreement”. This case is important for future adjudication for interpretation of national laws for being consistent with WTO.

In another important case, Canada Generics (WTO Panel, 3/2000) Canada argued that Article 1(1) provided it with “substantial discretion in determining the scope of exceptions to patent rights” for the purpose and objectives of Art 30, 7 and 8.1. In contrast, the United
States argued in another case (WTO Panel, 6/2000) on the same Article 1 (1) that it emphasizes flexibility.

In terms of limitations, Article 30 is important for providing exceptions, e.g. “Bolar exception”; health emergencies etc. Likewise Article 27 (3) provide for exclusions from patentability for diagnostic, therapeutic and surgical methods; and plants and animals except micro-organisms. Article 8 and 27.2 provide internal limitations within TRIPS for “measures to protect public health”. Article 31 is for compulsory licensing and Article 6 is about exhaustion of intellectual property rights (parallel imports).

Apart from WTO/TRIPS bilateral agreements, s301 of the United States Trade Act, and in general TRIPS-plus, call for too much intellectual property protection and constitute “barriers to legitimate trade”.

TRIPS flexibilities are important to be clearly understood, incorporated in national laws and implemented when required. At the same time it is also important to appreciate the limits on flexibilities, i.e. rules cannot be “stretched beyond reasonable good faith interpretation”.

WTO members have legitimate expectations from the TRIPS agreement and these have been more explicitly reaffirmed in the Doha Declaration on TRIPS and Public Health. The Declaration clearly established the basic principles of interpretation of the TRIPS agreement, especially for using the flexibilities.

Do demands for TRIPS-plus provisions in bilateral and regional negotiations reflect a failure to perform in good faith? This question is now troubling developing countries and is a source of erosion of their confidence in the system.

4.2 Some issues of relevance to the TRIPS agreement and public health

Dr Mohamed Baha El Din Fayez

Significance of general provisions and basic principles

A critically important duty, in the study and enforcement of the TRIPS agreement, is to explore the significance of the provisions contained in its Part I: General Provisions and Basic Principles. It is fair to say that the obligations expressed therein are, to a notable extent, balanced by the opportunities they pose. Because of their broad nature and location in the agreement horizontally ahead of all other parts, these provisions must be seen as applicable in all eight areas of intellectual property and in all fields of technology, including pharmaceutical technology.

Standards of intellectual property rights

Minimum standards set by the TRIPS are like a floor without having a ceiling, and thereby can be the object of persuasions (even pressures) that can go to any extent above the Agreement standards. In the pharmaceutical field, several types of higher-standard claims are
known to have been expressed by developed country multinational corporations, and have come to be referred to as TRIPS-plus standards.

*Seeing opportunities in the proclaimed objectives and principles*

It is a painful reality that the agreement, which is enforceable equally in all countries regardless of their levels of technological development, is laden with new and burdensome obligations that challenge the capacities and capabilities of developing countries. Because the explicit pronouncements of the agreement address *par excellence* the Members’ obligations, the opportunities need to be extracted by reading the implicit in these pronouncements. In this context and for this purpose, the TRIPS objectives and governing principles (Articles 7 and 8, respectively) must be examined and indeed utilized for their content of favourably development-impacting provisions. Of paramount importance is the highlighting of public health and nutrition the protection of which, by express law and regulatory provisions and the requisite administrative measures, is a duty of governments in parallel with the protection of intellectual property rights as per the agreement provisions. Each provision of the agreement should in fact be read in the light of the agreement’s objectives and principles.

According to the Paris Convention (Article 5A), failure to work or insufficient working is an abuse of the rights enjoyed by a patent owner that can be counteracted by the issuance of a compulsory license. That ethics behind the working of the patent is that the society that grants the patent and enforces its protection, for the benefit of the title-holder on exclusive basis, deserves also to benefit from the field application of the invention.

*Term of protection for pharmaceutical inventions*

Doubtlessly, the extension of the term of patent protection to at least 20 years is chief among the higher standards heralded by the TRIPS agreement. The cost to be borne as a result by the developing countries is perhaps more pronounced in the field of pharmaceuticals than in any other field of technology. The painful implications for countries that do not innovate or manufacture, but rather depend on the importation of pharmaceuticals, are compounded on account of the fact that the protection now extends to the pharmaceutical products themselves—whereas the protection was formerly limited to the production process. Thus any attempt to make the same product by an alternative, even better, process, i.e. by ‘inventing around’ will no longer be available.

The pressure created by the extended protections period will be further accentuated by yielding to the persistent demands of patent owners who, particularly in the pharmaceutical field, seek to achieve TRIPS-plus standards by further expanding the effective life of the patent. It is not uncommon that such requests may be accompanied by political pressures that may involve some positive and/or some negative incentives. It is wished in the present context to emphasize the role of the national R&D establishment in creating a viable complementarity between the contributions of foreign supplies of pharmaceutical products and those of local firm.
Practical significance of the disclosure provision

In the entire course of the technological development experienced in the industrial societies, the protection of inventions and innovations has been one of two supporting pillars of critical importance. The other pillar has been the inventor’s obligation to work, i.e. implement his invention in the field of production in the country that provides patent protection. The patent provides an invaluable opportunity for the society to learn from the knowledge contained in the patent disclosure. Such knowledge should, in a healthy situation, inspire R&D workers in their pursuits of catch-up and competition with each other and with the patent title-holders themselves.

Disclosure of the invention, thus, is a cardinal feature of the patent system, where two levels of operation are applicable: a) the patent applicant must “disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art” (TRIPS Article 29.1); and b) the applicant may be required “to indicate the best mode for carrying out the invention known to the inventor”. It is definitely a sovereign right of the country to ensure that, by law, the applicant for a patent must fully be in compliance with these requirements. It is useful, even necessary to note in the present context that the language of the TRIPS agreement is explicit in obligating the disclosure at level a), while leaving the matter as an option at level b), above. It is a fact of everyday life that, historically and until today, the disclosure of inventions has been a crucially important instrument for the advancement of technology and manufacturing industry.

Possible benefits of permissible exceptions in the pharmaceutical field

The inclusion of some exceptions in the TRIPS agreement is generally taken to represent one of the most important internal balances that alleviate somewhat the pressures resulting from the exclusive rights of the right holder. The basic premise in the patents field, for example, is that the inventor’s rights, although well recognized and respected, are not boundless or absolute. They are, just like rights in civil life, subject to limitations in terms of duration, scope and effect. The balance is achieved through a number of TRIPS provisions that address the question of exceptions directly or indirectly. These are found in Article 7 and 8 (on objectives and principles, respectively); Article 6 (on the exhaustion of intellectual property rights); Article 28.1 (on parallel importation); Article 30, which straightforwardly addresses the matter of exceptions to the intellectual property rights conferred by a patent; Article 31 (on compulsory licenses); and Article 40 (on the control of anti-competitive practices in contractual licenses). The exceptions are allowed only if they are provided for in the national law and meet the broad conditions as stipulated in TRIPS Article 30.

Obligations and duties associated with grant of compulsory licenses

It must be stated at the outset that the grant of a license to use the subject matter of a patent without the authorization of the patent owner—commonly referred to as compulsory licensing—is the most important and also the most controversial among all exceptions to the exclusive rights conferred by the patent. For this reason, it is surprising that the instrumentality of compulsory licensing has hardly been used in developing countries
(perhaps with the exception of India), while it was well recognized and used in the developed world. Compulsory licensing should be recognized and made use of, at least in the pharmaceutical field, as a corrective measure and a critical balancing element in the national legislations of developing countries that functions, in the least, to deter the excesses and abuses of intellectual property rights by patent owners. It is a reality of life that many developing and least-developed countries have insufficient or no manufacturing capacities in the pharmaceutical field. The Doha Declaration on the TRIPS Agreement and Public Health (November 2001, Paragraph 6) recognized the fact that these countries “could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”

**Protection of undisclosed information in the pharmaceutical field**

The protection of undisclosed information, commonly known as trade and industrial secrets, is a new area of intellectual property rights that the TRIPS agreement introduced and required all Member countries to include in their respective legislation. Because of its newness, at least to most developing countries, the protection of undisclosed information and the related enforcement measures need to be considered in the light of the specific TRIPS provisions (Article 39) and the fields of trade and industry affected by the protection. The pharmaceutical sector is one of these fields, not only at the level of commercial transactions but, more importantly, at the level of manufacturing processes.

**The question of exclusive marketing rights for pharmaceutical products**

The award of exclusive marketing rights is another special feature of the transitional arrangements that precede the full application of the TRIPS agreement provisions. Therefore, exclusive marketing rights will be known and exercised only in those countries, which decide to delay the application of the agreement beyond 1995. The use of exclusive marketing rights, and all the rights and obligations attached thereto, is limited to invention subject matter in the fields of pharmaceutical (and agricultural) chemical products. For their application and regulation, special provisions need to be introduced in the national laws of the countries affected that conform to the stipulations of the TRIPS Article 70.9. It must be remembered, for practical reasons, that the instrumentality of exclusive marketing rights is a device that enables innovators in the pharmaceutical field to enjoy protection of their invented products for a limited length of time (not exceeding 5 years) during the transitional period without the need for a real or valid patent. Such protection has the effect of excluding third parties from the marketing of the pharmaceutical product in question. Exclusive marketing rights, therefore, are obtainable on a case-by-case basis and relate to specific individual products.

The following are general remarks concerning the actual, as well as potential, implications of the award of exclusive marketing rights. 1) The likelihood exists that a pharmaceutical) product is granted exclusive marketing rights for 5 years which expire before a decision is taken on its eligibility for protection under a patent. It is also not unlikely that when a decision is taken, the pharmaceutical product invention—after having enjoyed 5 years of exclusive marketing rights—will be denied protection because or its failure to meet the criteria of patentability. 2) The effects of exclusive marketing rights deserve careful consideration, since the agreement does not provide clear indication about their nature and
scope. The right of total exclusion is sometimes challenged, where the argument holds that the exclusive marketing rights holder can only collect royalties from third parties but not exclude them from commercial activity. 3) There is also a view that the exclusive marketing rights holder cannot prevent third parties from making the product in question, but only for export purposes. 4) It is conceded, in all readings, that a third party that uses the invention subject matter during the transitional period will not be allowed to do so after a patent is granted. 5) In situations of abuse by the exclusive marketing rights holder of a dominant market position or of actions that adversely affect health needs, resort may be made to measures for limiting exclusivity to contain the resulting damage. These may include compulsory-licensing type of measures or even the revocation of the exclusive marketing rights altogether, in case of serious abuse. 6) It should be remembered that the award of exclusive marketing rights for a pharmaceutical product hinges upon the decision of the local health authorities.

Review of the more important pressures posed by the agreement in actual application

Developing countries will do themselves a service if they consult with each other and cooperate in building a position that calls for introducing a limited number of reasonable modifications or amendments that alleviate somewhat the existing pressures in all fields of technology, and particularly in the pharmaceutical field. These pressures are: prolongation of the term of patent protection to at least 20 years; extension of patent protection to all fields of technology, including drugs and foods without any discrimination; placing no restrictions (or a ceiling) on the more extensive protection of intellectual property rights than is required in the agreement; patentability of pharmaceutical processes and products alike; claiming the patentability of uses, in addition to products and processes in the pharmaceutical field; requiring that a broad range of commercial activities be included in the exclusive rights of the patent owner; narrowing the scope of application of the exhaustion exception, and hence the right of parallel importation; requiring the mere importation of pharmaceuticals to be considered as sufficient for the working of the patented invention; narrowing to a minimum the forms of patent use for scientific and research purposes; the practices of broad-blocking and defensive patenting; extension of the exclusive rights to include the products resulting from a patent-protected process; reversal of the burden of proof in process patents, and the threat of strategic litigation; pressuring developing countries to reduce (sometimes to eliminate) the transitional period; enforcement of all the agreement provisions equally after the date of application; not making the disclosure of the best mode for carrying out the invention an obligation; no differentiation in all allowed exceptions between patented pharmaceutical products even when critically needed, and other product categories; restricting the use of compulsory license-produced pharmaceuticals. in the manner that prevents their export to needy markets even where health crises exist; not giving priority to the use of pharmaceutical patented inventions among the grounds for the granting of compulsory licenses, even in situations of public health crises; non-differentiation between countries (on the basis of manufacturing capacities) and technological capabilities as to their ability to make use of the exception of compulsory licensing, particularly in the pharmaceutical field; and lastly; giving no regard to the possible absence in some countries of adequate pharmaceutical quality control when granting exclusive marketing rights.
5. TRIPS AND ACCESS TO MEDICINES

5.1 TRIPS and access to medicines for all

*Dr Abdelaziz Saleh*

The presentation discussed briefly the concept of medicine security within the overall concept of health and human security. Reference was also made to Para 4, Doha Declaration on TRIPS and Public Health, where the concept of Medicine for All was emphasized:

We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provision in the TRIPS Agreement, which provide flexibility for this purpose.

The development of WHO Model list of Essential Drugs over the past 20 years was discussed briefly. There is need to carry on a forecasting study on the possible contents and changes in the Essential List of Drugs during the coming 20 years. Such a study should take into consideration ongoing technological developments in drug design and therapy. Special attention should be given to unaffordable medicine prices. More in-depth studies should be carried out on the real cost of drug research and development as well as drug pricing policy. Developing countries should be supported to use all possible cost containment strategies to ensure access to medicine for all. It is important to develop a sustainable system for drug financing through an appropriate social health insurance system.

5.2 TRIPS and drug access: local industry perspective

*Dr Adnan Badwan*

The WTO era should be appreciated on both political and economic lines. From a political angle, it must be understood that in the current unipolar world, policies are almost dictated across the board. This era is also characterized by new and political definitions of terrorism and international legitimacy; national feelings are fading and geography is no longer a defining element. Social rest or unrest is to be closely watched in the wake of these characteristics of the era. In economic terms, the world is moving towards fewer tariffs, i.e. fewer obstacles to trade. Quality is being given primary importance, and in this discussion there is no concept of nationality. Trends towards enlarging the business organization are on the rise, as seen in the growing number of mergers and acquisitions. In the name of more competition actually more unfair competition, unfair competition is escalating. Global dispute forums are also being made available; however, WTO is an organization influenced by political parties even in the presence of dispute resolving mechanism.

To understand the world pharmaceutical industry and its structure and profit margins, it is useful to divide the pharmaceutical business in to originators (multinationals), international generics and regional brand generics. At the same time, it is important to look at the existing
distribution networks. Net profits of multinationals are anything above 50%, those of regional brand generics are around 30% and international generics hover around 10%.

A comparison was made of the distribution of personnel in an American versus Jordanian generic pharmaceutical company. In the American company, more people worked on the side of production and packaging, and quality and regulatory affairs. In the Jordanian company, relatively more human resources were engaged in R&D, marketing and sales, administration and finance, warehouse and storing, and maintenance.

Multinational companies now seem to want a total monopoly. They also want control over all the marketing steps ranging from patented drugs, generic versions and all the distribution channels. Against this backdrop, the future of local industry in developing countries is either to group into larger organizations or stay small, with gradual erosion of profit margins.

Various deliberate strategies and techniques are used by the multinational companies to keep hold on patents and to extend the patent protection term of their products. First of all, admittedly they spend more on R&D in order to develop new drugs on which they can keep patent hold. For example, in 2002 pharmaceutical manufacturers spent an estimated US$ 32 billion on R&D, a 77% increase from 2001 and more than triple from 1999. Strategies used by the multinational companies to extend the life of their patented products include composition patents; new use patents; process patents; and environment-friendly composition patents.

Submitting a new patent application by changing the composition of the existing patented drug may end up in extension of patent term of the “same” product. For example, Biaxin is a patented product of Abbott containing clarithromycin with sales in 2002 soaring to US$ 1.10 billion. The product patent of this drug is due to expire in May 2005 but Abbott has already introduced Boaxin XL as a drug with a “new composition” and has applied for its patent and is in the process of switching patients from Biaxin to Biaxin XL.

Submitting a new use patent application is another strategy used by the companies to extend their patent terms. In a recent example, Astrazeneca obtained an extension for its blockbuster product Prilosec (omeprazole) already having sales of US$ 5.68 in 2001. In May 2001 it was approved as a first proton pump inhibitor for children as treatment of esophageal reflux in patients aged one month to 16 years. The patent extension was granted for 6 months. Even half a year extension in this case means closer to US$ 3 billion sales, using 2001 as a criterion.

Extension in patent protection is also sought through submitting a new process patent application with a claim that the new process yields a better product. Example of such extensions includes Neurontin (gabapentin) of Pfizer. Its method-of-use patent was granted on 12 May 1978 but was extended through a Waxman-Hatch extension until 16 January 2000 and then it was again extended until 16 July of the same year on the basis-of-use patent.
New patent applications are also submitted on the basis of new products being more environment-friendly. An example is the Ventolin inhaler (albuterol HFA), which was approved prior to January 1982, but the patent was extended protection until 4 December 2012 because the manufacturer submitted a new application for extension on the basis that the new product is free of CFC (chlorofluorocarbon), and uses HFA–134 as a propellant (1112 tetra fluorocarbon), which is environment-friendly.

In conclusion, the regional brand generics need to explore new strategies, e.g. to group into a loose partnership in the area and develop project by project agreements; to join into a larger organization by exchange of shares in each company; to join into coalitions where capital investment in research is valued; and to cooperate with multinationals by producing new molecules with local trade names to overcome the problem of parallel imports.

5.3 The Doha Declaration and public health: global view

Dr Heinz Klug

Status and origins of the Doha Declaration

The Doha Declaration represents a significant victory for developing countries in the arena of multilateral trade negotiations. It is a result of an initiative by developing countries, represents an important political statement and also has significant legal implications, particularly for the interpretation of the TRIPS agreement.

As for its legal status, the Doha Declaration is an international agreement which gives rise to legally binding international obligations. It is not merely a political statement. In the Nuclear Tests Case (Australia/France) the International Court of Justice held that declarations, even when made by individual states, give rise to legal obligations. This is especially so in a multilateral context where the declaration is the outcome of a negotiation among states. In the context of WTO, as a product of the Doha Ministerial meeting, the Doha Declaration is in effect a “decision” of the Members under Art IV(1) and is consistent, being a product of consensus, with Articles IX(1) and (2) of the WTO Agreement. This characterization is strengthened by the decision of the General Council of 30 August 2003 (pre-Cancun Agreement) which is explicitly framed as a decision made in terms of Paragraph 2 of Article IV of the WTO Agreement i.e. the General Council conducting the function of a Ministerial Conference in the interval between meetings. This latter decision, made explicitly in response to a request contained in Paragraph 6 of the Doha Declaration, leaves no doubt as to the legal status and effect of the Doha Declaration.

At the minimum the Doha Declaration, in elaborating on the relationship between TRIPS and public health, is clarifying the meaning of Article 8 of the TRIPS agreement, i.e. that there are cases in which private interests in intellectual property rights are subordinate to more compelling public interests (Paragraphs 1 and 4); and that patent protection should not be used as a means of merely extracting high rates of return on pharmaceutical investments, rather than as a means to encourage the development of new medicines (Paragraph 3). While the Doha Declaration reaffirms the members commitment to the TRIPS Agreement it is important to recognize that it is also a response to dramatically changed circumstances—the
The origins of the Doha Declaration may be found in a number of developments in the period which followed the initial adoption of the TRIPS agreement.

- The legal challenge brought by the major pharmaceutical companies against the 1997 amendment in South African Medicines Act, which they claimed violated the TRIPS Agreement.

- Adoption of the Revised Drug Strategy, by the World Health Assembly urging WHO Member States “to ensure that public health interests are paramount in pharmaceutical and health policies, [and] to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs” (WHA 52.19, 1999).

- The HIV/AIDS pandemic in Africa, which has led to increasing NGO activism directed at the American political process, including: demonstrations at campaign meetings; the introduction of a bill (HR2700) calling for access to drugs in Africa, followed by changes in U.S. policy leading to President Clinton’s speech at the WTO Ministerial in Seattle on 2 December 1999 promising not to take action against African countries.

- Anthrax attacks in the United States, which led the American administration to threaten to use compulsory licensing to obtain the antibiotic Ciprofloxacin, leading Bayer to offer its patented drug to the Government of the United States at a much reduced cost.

- Finally, the developing countries, including the Africa Group, with support from various nongovernmental organizations, such as MSF and others, began to raise their concerns in the TRIPS Council.

**Overview of the Doha Declaration**

While the Doha Declaration acknowledges the threats posed by particular diseases, such as HIV/AIDS, tuberculosis, malaria and other epidemics (Paragraph 1), the Declaration is not limited to these or any other diseases; rather, the Declaration affirms that TRIPS “does not and should not” prevent states from taking public health measures (Paragraph 4). It also implies that pressures to impede the use of available flexibilities are contrary to the spirit and purpose of TRIPS (Paragraph 4), raising the question of whether pressures to adopt TRIPS-plus measures or understandings in bilateral negotiations are violations of the TRIPS agreement.

The Declaration takes a balanced approach to rights and obligations-by reaffirming member’s commitment to TRIPS while simultaneously recognizing the effect of TRIPS on pharmaceutical prices and hence the legitimacy of efforts to increase access by reducing prices. It takes a number of specific steps to clarify existing flexibilities and implement these goals, including: reaffirming the right of members to adopt an international principle of
exhaustion of rights with respect to parallel importation under Article 6 of TRIPS (Paragraph 5.a); and reaffirming the right of members to grant compulsory licenses and to determine the grounds upon which such licenses are granted (Paragraph 5.b).

- By clarifying that each member has a right to determine what constitutes a national emergency or other circumstance of extreme urgency, the Declaration effectively shifts the burden to a complainant who argues that there is a violation of the TRIPS agreement to prove that such circumstance does not exist (Paragraph 5c).

- The Declaration allows the extension of the transition period for least developing countries to 2016 (Paragraph 7), but it is important to note that this is largely symbolic because most have already adopted patent protection of pharmaceuticals.

- The problem of capacity to use compulsory licensing was sent to the TRIPS Council for resolution (Paragraph 6).

*The implementation of Doha Declaration*

While the Doha Declaration was hailed as a victory for developing countries, the expected benefits have been very slow to materialize, and the debate over the Declaration began before the ink was dry.

The first challenge was to the scope of the Doha Declaration. While developing countries argued that the Declaration was designed to allow states to address all public health issues, the developed countries argued that it was really designed to address three major epidemics, HIV/AIDS, tuberculosis and malaria and any others of similar magnitude.

The second challenge took the form of questioning whether patents had any effect on the problem of access to essential drugs. Here it was pointed out that there are various African countries in which the relevant drugs are not patented yet they are still not available at an affordable price. This argument failed to address the issue of supply as many of the countries in which no patents had been taken out were also countries with no capacity to produce generics.

The third challenge took the form of a medical concern, that patients in developing countries, it was argued, would not have the ability to follow the burdensome drug regime required in the case of HIV/AIDS and therefore there was a threat of drug resistance developing, as has been the case with tuberculosis.

Finally, it was argued that the Doha Declaration had little to do with health concerns and it was really just a means for some developing countries to continue to pursue an export-oriented program to develop their own competitive pharmaceutical industries, at least in the area of generics or “pirated” medicines.

The effect of these various claims—all of which were countered in the public debate—was to draw out the Paragraph 6 negotiations over the need to address the question of
countries which had insufficient or no manufacturing capacity in the pharmaceutical area, since Article 31(f) of TRIPS limited the use of compulsory licensing to the production of products which would be primarily used in the domestic market of the member employing compulsory licensing. This delay has not only affected those countries without capacity. It soon became clear that generic producers would not make the required investments in circumstances where either there was insufficient security over the period they would be able to operate or more importantly it was not financially-viable to produce primarily for small domestic markets at an affordable price. It would only be a viable proposition if the generic producers could export into larger or regional markets in developing countries enabling the costs of production to be reduced to the point where the medicines could be sold at an affordable price. Many participants in the debate argued countries should merely use their rights under the general exceptions clause of TRIPS (Art. 30) to address their public health needs, however apart from Brazil’s threats to use compulsory licenses as a negotiating stance, there is little evidence that countries felt free to exercise these rights either prior to or after Doha.

The decision of the General Council of 30 August 2003

This decision is also called as a pre-Cancun agreement. With the pressure of another Ministerial summit looming and eight months beyond the time initially set in the Doha Declaration, the General Council of the WTO reached a decision on the implementation of paragraph 6. Welcoming the decision, the WTO Director-General Supachai Panitchpakdi stated that this “historic agreement... [allowed] poorer countries to make full use of the flexibilities in the WTO’s intellectual property rules in order to deal with the diseases that ravage their people”. The structure of the Decision is to adopt a system of “waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products.” These obligations concern the conditions under which a member may issue compulsory licenses. The waiver only applies to “eligible importing Members”, including any LDC and any other member who has made a notification to the Council for TRIPS of their intention to use the system as an importer (Paragraph 1 (b) and to the obligations of an “exporting Member under Article 31(f) of TRIPS.

The compulsory license issued by the exporting member must also meet a number of conditions including: limitation of the amount that may be manufactured, all of which must be exported to the relevant importing member; products produced must be clearly identified through specific labelling or marking, special packaging, colouring/shaping of the products themselves, provided that it is feasible and does not have a significant impact on price (2.b.ii).

Detailed notification requirements include: adequate remuneration pursuant to Article 31 (h) of the TRIPS Agreement must be paid to, taking into account the economic value to the
importing member of the use that has be authorized in the exporting member. It does provide that there is no double compensation, i.e. in both exporting and importing members; there is a commitment from importing countries to make reasonable measures within their means, proportionate to the administrative capacities and to the risk of trade diversion to prevent re-exportation.

The Decision provides for economies of scale by allowing the export of products produced through this system to countries within a regional trade agreement so long as at least half the members of the regional agreement are presently on the UN list of LDCs (Paragraph 6.1). The decision also promotes the transfer of pharmaceutical technology (Paragraph 7). Brazil has just committed itself to aid Mozambique in building a US$40 million pharmaceutical plant to produce antiretrovirals. And finally, the decision provides for annual reviews by the TRIPS Council (Paragraph 8) and the termination of the waiver system after amendments are made to TRIPS (Paragraph 11).

**Doha and beyond**

Despite the pre-Cancun decision there remain many areas of contention and possible dispute, particularly with respect to the interpretation of the conditions imposed in the Decision. In addition to conditions, the Decision imposes both bureaucratic and substantive obstacles to the use of this mechanism. The greatest impact seems to be the response of the brand-name industry which is now granting licenses to enable generic production in countries such as South Africa. The global pharmaceutical market and continuing TRIPS-plus negotiations including the inclusion of provisions preventing governments from using their bargaining power to negotiate for cheaper prices (see United States–Australia Free Trade negotiations).

The questions of innovation, R&D and diseases effecting developing countries remains unresolved, as does the broader question of the relationship between TRIPS and the future of generic pharmaceutical production.
5.4 Doha Declaration and public health: national view

Dr Mohamed A Eldawy

Balance et al (1992) have classified countries according to their level of pharmaceutical development into five categories:

1. Countries with sophisticated pharmaceutical industry and research base.
2. Countries with innovative capabilities.
3. Countries with reproductive capabilities: active ingredients and finished products.
4. Countries with reproductive capabilities-finished products from imported ingredients only.
5. Countries with no pharmaceutical capability.

The Doha Declaration has special significance for the fifth category.

It is important to understand the structure, function and scale of the pharmaceutical business to fully appreciate the Doha Declaration and its effects. Only 10% of global health research (private and public combined) is devoted to diseases that account for 90% of the world’s disease burden. Globally, of the 1393 new drugs approved for sale between 1975 and 1999, only 16 (a little over 1%) targeted tropical diseases and tuberculosis, which between them account for 11.4% of the global disease burden. The majority of these were developed outside the research laboratories of big pharmaceutical companies. Patent filings by all the developing countries together in 2002 were 4.7%. The remaining 95.3% were filed by industrialized countries.

Each party highlights aspects of the Doha Declaration on TRIPS and Public Health that most suit its particular agenda. The transnational corporations represented by IFPMA issued a statement indicating agreement with the Declaration that “intellectual property protection is vital to trade access and innovation”. WHO welcomed the ministers’ conclusion “that the TRIPs agreement can and should be interpreted in a manner supportive of WTO members’ right to protect public health and in particular promote access to medicines for all”. A joint statement by several major nongovernmental organizations including MSF, Oxfam and Health Action International indicated that they “would have liked to see stronger wordings” and that “now it is up to governments to use these powers to bring down the cost of medicines and increase access to life-saving treatments”.

Soon after, Doha Declaration backtracking was started by developed countries on the promises and commitments made in the Declaration on one pretext or another. The backtracking actually started undermining the flexibilities already provided in the TRIPS agreement.

Effective use of compulsory licensing by countries not having manufacturing capacity emerged as a big debate. Then came the idea of “list of diseases”. The European Union, United States of America, Japan and Canada came up with the list of 22 diseases. The Director-General of the World Health Organization, Dr Gro Harlem Brundtland insisted on 14 January 2003 that one should be careful about excluding some diseases from the scope of the
Doha Declaration on TRIPS and Public Health, and not limit the scope (for compulsory licensing and imports) to a few very prominent ones like HIV/AIDS, tuberculosis or malaria. The United States of America came up with an offer of moratorium on disputes. The Chairman of the TRIPS Council came up with a “Statement of Understanding” on 16 December 2002 the text which said that: “Secondly, delegations have made it clear that they see the system that we are establishing under Paragraph 6 of that Declaration as being essentially designed to address national emergencies or other circumstances of extreme urgency.

After many failed attempts and meetings came the decision of the TRIPS Council on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, on 30 August 2003 (WT/L/540). This decision comprised 11 elaborately worded Articles, 9 footnotes and an annex, and is supplemented with a GC Chairperson’s statement, to which “Best practices” guidelines are attached. This agreement was received with relief by most stakeholders, though some still remained concerned, sceptically waiting for outcomes of the test of time to validate its applicability in real life. In this connection, certain relevant case studies including Canada’s C54 patent bill, the United States’s HR2427 bill regarding importation, and Egypt’s and India’s EMR and PTD litigations will be brought to discussion. The extent to which bilateral and regional free trade agreements such as FTAA are compatible with the spirit of the Doha Declaration and WT/L/540 will be brought to discussion as well.

6. TRIPS AND ACCESS TO MEDICINES: COUNTRY SITUATIONS

6.1 Egypt

*Dr Soad Abdel Shafy Tawfik Ahmed*

- In formulating or amending national laws and regulations, necessary measures were taken to protect public health and care exercised that such measures are consistent with the provisions of the TRIPS agreement.
- Egyptian Law No. 82 of 2002 concerning the protection of intellectual property rights includes 4 books. The first book includes section 1, covering patents, and section 3, which handles undisclosed information.
- Patent Article 10, paragraph 2, “patent shall confer on its owner exclusive rights where the subject matter of a patent is product or process”, cancelled the Law No. 132 from 1949 which was protecting the process of manufacturing of pharmaceutical products with the patency period 10 to 15 years. In Law 82, Article 9 in book 1, section 1, “the duration of protection is 20 years from the date on which the application for a patent was filed in the scientific research academy.”
- Chapter 3, undisclosed information: the most important articles are 55, 56, 57, 58 and 59.
• Some problems have emerged in the field of drug manufacture and access to medicine, namely:

  – Some multinational companies cancelled the license issued to public sector companies to manufacture some drugs. This problem was overcome by manufacturing the generic product.

  – Litigation issues remain between generic manufacturers and innovators.

  – Some drugs with a very high price are not available for most Egyptian patients, e.g. Mebthera, 500 (Roche).

• For the development of drug manufacturing in Egypt, it is essential that:

  – Many research centres, universities and R&D departments of drug factories cooperate together to develop some drugs and discover new ones (especially through genetic engineering).

  – Old factories are renewed, developed and extended and new factories are built with high technology. Currently, the number of factories in Egypt is 68. All of these factories are working on the international principles of GMP.

  – New centres for research in herbal medicines need to be established to identify and extract active ingredients. Many factories exist for production of biotech products (in bulk) with high grade technology.

6.2 Islamic Republic of Iran

Dr Mohammad Hossein Nicknam

The Islamic Republic of Iran is not yet a member of WTO. However an application for membership was submitted in 1996. The application was attended to for the first time in 2001, i.e. 5 years after submission. The Libyan Arab Jamahiriya and Syrian Arab Republic are other examples in this regard. From 2001 to 2003, the issue was raised 12 times in the General Council of WTO, but each time a decision was postponed to a later meeting. The issue was last raised on 15 May 2003 in the General Council by two countries, but again it was postponed to the next meeting.

By presidential order, a national body responsible for TRIPS has been formed in the Ministry of Commerce in the Trade Representative Office, which is headed by the Minister of Commerce. The responsibility of this office is to follow up the process of joining WTO. Apart from this, a body has been created in Ministry of Health and Medical Education for TRIPS and public health, with participation by the Director-General of International Affairs and Representatives of Ministry of Commerce, Ministry of Foreign Affairs, Food and Drugs Under-Secretary, Public Health and Curative Under-Secretary and a representative of Legal Department.
In order to align internal rules and regulations with TRIPS, a documents organization (working under the judiciary system) formed a committee consisting of lawyers, judges and university professors to change and amend the current laws, bring them into conformity with TRIPS, prepare the bills and submit them to the parliament.

The existing rules on intellectual property in the country include a set of laws concerning signs and inventions registration and copyright law and its related internal rules. The Islamic Republic of Iran ratified the Paris Convention in 1958 and its amendment in 1997, and the Madrid Protocol was recently ratified by the parliament. There is also a law for protecting writers and compilers (1969) and another for protecting computer software (2000).

As part of preparations to join the WTO, four studies have been carried out with reference to pharmaceutical industry: acquaintance with WTO; review of the pharmaceutical industries in the Islamic Republic of Iran; review of the status of some other countries’ pharmaceutical industries; and a comparative study of Iranian pharmaceutical industries.

6.3 Jordan

Dr Maysa Khalil Al Saket


Apart from being a member of the WTO, Jordan is also a signatory to the European Union association agreement; Free Trade Agreement with the United States of America; and European Free Trade Association (EFTA).

According to the current laws Jordan provides patent protection for 20 years. Along with that, a supplemental protection certificate for 5 years is also available. Protection for new indication is available for 3 years as part of the FTA (Article 4.22); data protection is available for 5 years. Jordan is committed to acceding to the patent cooperation treaty by 2005. As a retrospective commitment, Jordan committed itself to apply the foregoing rights to drug applications pending at the Ministry of Health during accession to WTO in 1999.

There are no studies on implications of intellectual property rights protection on public health and on prices of drugs. An explanatory document regarding intellectual property and data protection is needed.

Implications for the pharmaceutical industry include access to new markets in developed countries like the United States of America, European Union countries and others which would increase the drug exportation. It also opens up the possibilities for co-marketing, co-production under licensing, upgrading of capabilities, specialization and investing in research and development.
6.4 Lebanon

Ms Souheir Nadde

The pharmaceutical situation in Lebanon is characterized by 92% imports with local manufacturers maintaining the remaining 8% of the market share. 28% of traders cover about 90% of the import market and play a key role as a link between Lebanon and the international pharmaceuticals market. American and European research manufacturing companies control 71% of the Lebanese market. The size of the Lebanese pharmaceutical market is estimated at approximately US$ 300 million. Local manufacturers are also exporting their products which slightly exceeded US$ 4 million in 1999, though this figure also includes drug re-exportation activities.

Lebanese demand is quality-driven but is increasingly becoming price sensitive, as the economy is in recession and the government is making efforts to reduce the health bill. The government also wants to encourage consumers to move from branded to generic drugs.

Lebanon is not yet a member of the WTO but it is actively engaged in the accession process which includes submission of required documents, developments of laws at home and ongoing process of bilateral negotiations especially with the European Union, Australia, Japan and the United States of America. Lebanon is a signatory of many relevant international conventions and treaties. The “1924 Law”, which was amended in 1946, deals with regulations and systems of commercial, industrial, literary, artistic and musical property in Lebanon. The Copyright Law (Law No. 75/99) was issued in April 1999. The law concerning directly with patents was introduced in August 2000. This patent law, also known as Law No. 240, apart from patents also deals with protection of plant variety, layout designs of integrated circuits, and undisclosed information. The Ministry of Economy and Trade and the Ministry of Health are the responsible national bodies in this connection.

The Patent Law 2000, according to an assessment conducted by the WIPO in 2002, is in complete conformity with the TRIPS Agreement. The law eliminates the exception to patent protection for pharmaceutical products which was there prior to this law. This law has a 20-year term of protection; provides for compulsory licensing; and protects undisclosed information. Compulsory licensing is allowed in cases where the patent holder fails to work after 3 years from the date of the decision granting the patent or in case of insufficient working. Compulsory licenses can be provided to protect public health and food security to secure the public interest in the fields that have vital importance for economic, social and technological development and where the national defence so requires.

While pipeline protection is not part of the GATT/TRIPS provisions, the United States, European Union and EFTA states are asking for such protection. Unauthorized copies of innovative pharmaceutical products are not allowed to be registered in Lebanon. The registration process of medicines is being made efficient and the Ministry of Public Health is taking strict actions to regulate parallel importation of medicines.

To tackle the challenges in the wake of WTO/TRIPS and public health, regional coordination with regard to current and future WTO negotiations is very important. Special
regional committees are needed for development of common positions against narrowing the scope of the Doha Declaration on TRIPS and Public Health; to push developed countries for an effective implementation of the provisions of the Decision of the General Council of 30 August 2003 concerning the implementation of the Doha Declaration on TRIPS and Public Health; to urge these countries for an effective implementation of the Transfer of Technology clauses of the TRIPS Agreement in particular Article 7 and Article 66.2.; for exchanging information in order to improve intellectual property rights enforcement; for exchanging expertise in order to improve systems related to administering TRIPS and Public Health; for conducting joint studies to highlight the problems and propose effective solutions; and for ensuring the implementation and enforcement of recommendations that arise from meetings and seminars like this.

6.5 Oman

Dr Batool Jaffer Suleiman

Oman has a dominant state health care system with medicines available free of charge to all Omanis. The government has a central procurement system with some international tendering. Generics are preferred over brands in the government procurement system.

Just before becoming a WTO member in November 2000, Oman introduced a patent law in September 2000. The patent system is still evolving under the auspices of the new law and the situation is not very clear at the moment. There is a lack of expertise in this area.

6.6 Pakistan

Mr Muhammad Arshad Khan

The pharmaceutical manufacturing industry in Pakistan is well developed. It caters for 80% of the local market and has the capacity to meet all the domestic requirements, except for special high-tech products like those originating from biotechnology. Total manufacturing units are 347, including 30 units of multinational companies. Market values are estimated as follows:

- Prescription market: Rs. 53 billion (US$ 0.9 billion)
- Trade discounts: Rs. 7 billion
- Institutional business: Rs. 7 billion
- Total (approximate): Rs. 67 billion (US$ 1.2 billion)

The top 20 corporations include 4 national companies. The multinational corporations have a market share of about 53% (by value) and the national manufacturers about 47%. During the past 15 years, there has been a shifting of about 15% market share from the multinational corporations to the national manufacturers. Multinationals are known to have around half a dozen patented drugs in the market. However, the performance of the national industry in R&D has been simply ‘nil’ with no patent holding. Unfortunately the multinational corporations also do not have any research and development activity in Pakistan, except for improvement and development of their formulations. No basic research is carried out. In the face of global challenges, national manufacturers are just realizing the need for investment in
research and development. The national manufacturers are under pressure from multinational corporations in the courts on intellectual property rights laws.

Patent laws are administered by the Ministry of Industries. Some institutions offer short courses on WTO/TRIPS. Originally Pakistan had a Patents and Designs Act of 1911, which provided for process patent only. However, in order to have its intellectual property rights laws in line with TRIPS, the Patent Ordinance 2000 was promulgated, repealing the 1911 Act. The new ordinance included little or no input from the Ministry of Health and the private sector due to administrative reasons and little expertise vis-à-vis TRIPS at that time.

The national pharmaceutical industry objected, and negative feedback was also received from the nongovernmental organizations. At the initiative of the Federal Ministry of Health, an exercise was carried out by the Ministry of Industries and the said ordinance was amended in 2002 on the following principles.

- Removal of TRIPS plus provisions, such as second use of a product
- Utilization of flexibilities available under the TRIPS Agreement, like compulsory licensing, parallel imports, etc. This is a task yet to be accomplished in its true spirit.

Rules to administer the patent law were also drafted recently. The pharmaceutical sector is administered by the Drugs Act 1976. No provision of this Act has been found inconsistent with the TRIPS. The product registration application under the Drugs Act 1976 has a column for information on patent, if any. Many applicants prefer to maintain silence on this matter at the time of making an application; however, they invoke their rights later. The European Union and United States have been objecting to the requirement under the rules for printing of generic name with equal prominence of trade name, with the argument that it undermines the brand name. However, the Ministry of Health did not accept this position, for public health reasons, including the professional requirements of prescribers and pharmacists.

Pakistan supports patents for pharmaceuticals as a way to revive national research and development activities. However, for that purpose the patent laws should not be very strong and take care of the level of local industrial development and capabilities. The prices of patented drugs should be negotiated.

6.7 Saudi Arabia

Dr Ibrahim Al Showaier

Saudi Arabia is still not a member of WTO, but because of the religion and culture of Saudi Arabia intellectual property rights are being protected. National laws go back to the year 1409 H (25 years). A new law has been prepared in conformity with TRIPS which is in the final stage of issuance.

The national body is the Permanent Committee on Intellectual Property, which has representatives from the Ministry of Interior, Ministry of Foreign Affairs, Ministry of Commerce and Industry, Ministry of Information, Ministry of Finance, Ministry of Petroleum,
Ministry of Justice, Board of Grievances, and King Abdulaziz City for Science and Technology.

There are also some nongovernmental organizations and intellectual property rights committees in the chambers of commerce. In relation to the pharmaceutical industries, there are 12 factories producing generic, brand and second brand (under license from international companies) and also radio pharmaceuticals. The market value of pharmaceuticals is more than US$ 1 billion.

The main feature of national intellectual property law is copyright law and trademark law, including geographical indication. A proposed law for patenting industrial designs, layout designs of semiconductors and plant varieties is in the final stages of legislative process.

6.8 Sudan
Dr Mustafa Salih Mustafa

In 1994, Sudan submitted a request to join the WTO as a member. This was followed by formation of a higher committee under the First Deputy President, and a comprehensive report on trade-related aspects was submitted to the WTO in 1998.

In November 2000, the council of ministers decided to form a general secretariat for WTO affairs. Main objectives of the secretariat are to study the effect of the WTO agreements and to suggest suitable means and measures. The general secretariat for WTO affairs is headed by the Minister of Foreign Trade, and there are 25 members representing related sectors including health and 5 departments (services, property rights, pricing, investment and financial and administrative affairs) represented on the secretariat. Various sectoral committees have been formed, including a health committee. The main objectives of the health committee are to decide on which health sections to be open for accession, prepare the documents needed for accession and revise health-related laws.

The health committee formed two sub-committees in 2001 to study the effect of TRIPS on drugs supply and manufacturing in Sudan; the effect of the agreements on “Application of Sanitary and phytosanitary measures-SPS” and “Technical Barriers to trade-TBT”. A report was prepared on TRIPS and TBT and sent to the secretariat. There are about 18 health-related laws in Sudan, and none of these have been revised as yet.

6.9 Syrian Arab Republic
Dr Rajwa Jbeily

At present, good effort are being made to establish a national body responsible for TRIPS in order to coordinate between concerned ministries, including the Ministry of Economy and External Commerce, Ministry of Agriculture, Ministry of Health, and Government Planning Board. The law on intellectual property rights is being updated.

There is a sizable pharmaceutical industry in the Syrian Arab Republic, with 47 pharmaceutical factories. There are 3879 authorized pharmaceutical products in the country,
factories producing traditional drugs. 50 pharmaceutical factories are working under license from multinational corporations. Drugs are exported to 35 countries.

High quality standards are maintained. All pharmaceutical products (locally produced) meet international pharmacopoeia requirements. All national factories are certified by ISO 9001 and ISO14001 and working according to current international good manufacturing practice (GMP). The Ministry of Health applies and monitors a very strong drug quality assurance system for the whole drug supply chain, i.e. registration, importing and production, storage, prescription and dispensing.

The national drug quality assurance laboratory is certified by ISO 9001, ISO 14001 and regularly participates in an international proficiency testing programme. A project has been started between the Ministry of Agriculture and Ministry of Environment with assistance of UNDP in order to protect national flora and national traditions.

6.10 Tunisia

Dr Amro Toumi

Tunisia has a per capita GNP of US$ 2000, average life expectancy of 73 years and infant mortality rate of 22 per 1000 live births. Health is considered a priority and 5.6% of GNP is spent on health annually.

Currently there are 29 pharmaceutical units in the country, an increase from only 3 in 1987. Tunisia is a signatory of many relevant international conventions and has a patent law. According to this law, Tunisia provides 20-year patent protection without possibility of extension. Bolar exception has been introduced. It permits the swiftest introduction of generics by accomplishing the whole set of necessary tests during the protection period. Voluntary and compulsory licenses are defined by national legislation and mailbox provision has been put in place.

6.11 United Arab Emirates

Dr Easa Al Mansoori

The United Arab Emirates is a member of the WTO and has amended its intellectual property rights laws to fulfil its TRIPS responsibilities. Federal Law No 4 from 1983 provides for licensing of pharmacists and assistants; licensing of pharmacies, stores and factories; and licensing and pricing of medicines. The law is implemented by the Drug Control Department and does not cover intellectual property rights.

In 1992, three specific laws were introduced: Federal Law 37, 40 and 44, for trademarks, intellectual property and industrial property. These laws came five years before entry into WTO. They did not cover manufacturing methods and are not concordant with WTO requirements.

Ministerial Resolution no. 404 was introduced in 2000, by virtue of which registration of any medicine or pharmaceutical which does not have a patent is prohibited. Essential drugs
are excluded from intellectual property protection and data exclusivity and confidentiality of
the registration file is recognized and protected. However, a few problems remained even
after Resolution 404, e.g. specificity of patent and exclusivity.

In 2002, a long-awaited Federal Law No. 17 came on intellectual property rights which
is in concordance with the national WTO/TRIPS responsibilities. This law describes the legal
framework for intellectual property rights in the United Arab Emirates. For drugs, it will be
applicable from 1 January 2005. At present, patented pharmaceuticals are protected by the
TRIPS Article 65/4.

The government also issued Circular no. 34/2003 which provides practical guidelines on
the way the intellectual property rights law will be interpreted. It defines which patents are
accepted, explains market exclusivity and describes limitations on when and how a
manufacturer can apply to register a generic medicine.

According the law and regulations the applicant must state clearly the market of origin.
The innovator product in the United Arab Emirates must be the same as the innovator
product in the market of origin. Exclusive national market authorization will be given to innovator
medicines if there is current patent protection in the market of origin. At the time of
application, the marketing authorization holder of the innovative product will have to provide
details of the patent protection for the product in the market of origin. These patents must be
under registration with the Patent Directorate at the Ministry of Finance and Industry. It is
also provided that protection will stop if the patent is rejected by the national Patent
Directorate or rejected by the courts in the market of origin. Post-patent market exclusivity,
provided in some markets does not apply to the United Arab Emirates market.

An application to market a generic drug in the United Arab Emirates will be accepted 12
months before the expiry of the national protection of the innovator. The generic drug
applicant must state in the application the name of the innovator product. An application to
register a generic drug must not contain any data relating to the innovator which is protected
under Article 39 of the TRIPS agreement. The marketing approval will not take effect until
the patent protection of the innovator has expired.

6.12 Yemen

*Dr Yahia Yahia Al-Babily*

Yemen, with a population of about 20 million, depends on the import of drugs for both
the public or private sectors. The first national pharmaceutical plant started during the early
1980s. At present, there are five pharmaceutical plants depending on imported raw materials.
The Ministry of Public Health and Population controls the registration of pharmaceutical
products, the import of pharmaceutical products and raw materials and the prices for the
locally produced and imported pharmaceutical products.

Membership of the WTO is in process. At present, Yemen is attending WTO meetings
as an observer and expects a long period of accession. A national body at the Ministry of
Industry and Commerce was established to follow up all issues regarding the accession. The
national body also formulated sub-committees for each international agreement (TRIPS, GATS, TBT and SPS, etc.) including members from different ministries and the private sector. The expected time for accession is between 5 to 7 years. There is a law on intellectual property rights. More expertise is needed with reference to accession, intellectual property rights and protection of public health from other countries in the Region.

7. SPECIAL TOPICS

7.1 TRIPS and other agreements and their understanding

WHO/EMRO in one of its regional consultations technical papers identified 11 WTO agreements that may have a direct or indirect impact on health sectors. TRIPS has always been the focus of most discussions. However, other agreement may also affect the pharmaceutical sector, particularly the local drug industry and access to essential medicines. These agreements particularly include the Agreement on Technical Barriers to Trade (TBT), Agreement on Implementation of Article VI (Anti-Dumping) and Agreement on Safeguards.

The Agreement on Technical Barriers to Trade seeks to ensure that technical regulations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. However, it recognizes that countries have the right to establish protection, at levels they consider appropriate, for example for human, animal or plant life or health or the environment, and should not be prevented from taking measures necessary to ensure that those levels of protection are met. The agreement therefore encourages countries to use international standards where these are appropriate, but it does not require them to change their levels of protection as a result of standardization. This article refers to appropriate international standards-setting bodies. It is therefore important to take the initiative, so that WHO is recognized as the international standard-setting body in issues related to health.

The Agreement on Implementation of Article VI (Anti-Dumping) of GATT provides for the right of contracting parties to apply anti-dumping measures, i.e. measures against imports of a product at an export price below its “normal value” (usually the price of the product in the domestic market of the exporting country) if such dumped imports cause injury to a domestic industry in the territory of the importing contracting party.

The Agreement on Safeguards allows WTO members to take a “safeguard” action to protect a specific domestic industry from an unforeseen increase of imports of any product which is causing, or which is likely to cause, serious injury to the industry.

In the event of critical circumstances, a provisional safeguard measure may be imposed based upon a preliminary determination of serious injury. The duration of such a provisional measure would not exceed 200 days.

These agreements require detailed studies and should be appropriately reflected in the national legislation to ensure the legal framework for protection of local drug industries.
7.2 Institutional response at country level

Ultimately, it is the country level where capacity needs to be developed for effective engagement with the WTO. The meeting repeatedly underscored the importance of this aspect. Many speakers not only emphasized the point but also provided national examples.

To maximize the advantages in terms of enhancing exports and benefiting from technology transfer and ultimately economic growth and to minimize the negative impacts on local industry and employment and income situations (even in the short to medium term), it is important that a national evidence base is developed for appropriate policy responses. There is neither a shortcut nor a substitute to this national preparation. Interministerial and intersectoral collaboration is the key to this process. With Ministries of Commerce acting as the fulcrum, other relevant ministries should be closely consulted on an ongoing basis. Many countries have created special arms within the ministries of commerce and trade and/or industries to deal with WTO issues.

The other very important institutional arrangement required is to undertake policy research. This, at present, is a weak area in the Region. For this however, the ministries have to move out and build collaborations with the private sector, especially private and independent economic policy research institutes. Close collaboration with major export sectors in the country should take care of resources required for such work, which can benefit all parties. Lastly, regional cooperation between countries for enhancing national institutional capacities is very important.

An example of how a country is dealing with these challenges at country level was provided by Pakistan. The Ministry of Commerce has established a WTO Wing under the leadership of a senior and expert bureaucrat. The Wing has created committees with wider participation from all sectors of society on almost each one of the WTO agreements and each committee has developed its own prioritized work agenda for research and analysis. This work is now picking up. Apart from this institutional arrangement at the government level, federal chambers of commerce and industry have created an arrangement whereby they not only undertake their own analysis but also work closely with the government. There are also important civil society initiatives, e.g. Sustainable Agriculture Action Network, Pakistan Center for Trade and Sustainable Development and WTO Watch Group. All these initiatives work to monitor government’s engagement with the WTO from the perspective of civil societies and provide them with analysis and critique. In this way, institutional foundations are being created in the country.

Special reference must be made about the capacities of ministries of health in this regard. Ministries of health are generally weak on trade issues in the Region, and there is an acute need to invest in human resource development which is a pre-condition for developing institutions. At present, generally, it is the ministry of commerce in a country which makes all sorts of decisions. From a health point of view, it will only change when the Ministry of Health would be able to contribute in these discussions in a meaningful way. Here the role of WHO becomes critical.
7.3 TRIPS-plus approach

TRIPS-plus means more than the minimum standards of patent protection enshrined in the TRIPS agreement. It is important to understand that though there is no bar on having standards higher than those set in the TRIPS agreement, developing countries need not to go beyond these. On the contrary, the approach should be to not only just follow the minimum standards but also to exploit fully the flexibilities wherever they are found in the agreement and to interpret the clauses in the best national interest, which means not to go above the bottom-line standards. Needless to say, there can be no objection on the countries if they do not go above the minimum standards according to the international laws. Dispute settlement mechanisms would not even entertain any such complaints.

However, in real-life situations the unequal bilateral relations between the more powerful and less powerful countries can be used by the later countries to ask for more patent protection than set-out in the TRIPS agreement. This has happened in many countries especially in their relations with the United States of America. At the behest of the pharmaceutical corporations, the Government of the United States wants as much prolongation as possible in the patent term of the medicines. The United States closely maintains a “watch-list” of countries which, according to the United States interpretation, do not comply “fully” with their TRIPS commitments.

In some countries the difference of opinion and interpretation on various points between the Office of the United States Trade Representative and the national authorities in developing countries has caused difficulties in bilateral relations, and in some cases the disputes have ended in the courts of law. South Africa is a case in point.

The participants of the consultation discussed such situations and problems, and were of the view that TRIPS-plus approach should not be imposed and that countries should be defending their policy decisions on the basis of their international commitments rather than what other countries want them to do. In this connection, however, it was also felt that the governments in developing countries should also be doing their necessary homework and that they should develop capacity to technically defend themselves in such cases where their decisions are either not considered as TRIPS compliant or where more is demanded from them. This defence is crucial for protecting the local pharmaceutical industry and for protecting the access of the people to the needed medicines.

The most common measures demanded by industrialized countries from developing countries which fall in the category of TRIPS-plus are:

- Persuasion to relinquish the transitional period altogether or to substantially reduce its duration.

- Persuasion to institute (in the national legislation) protection periods of longer-than-20-years duration or to be willing to grant, at least on a case-by-case basis, limited extensions (usually 1–5 years) beyond the minimum of 20 years specifically for pharmaceutical products.
• Persuasion to grant selectively a retroactive protection for pharmaceutical inventions that have been granted protection, or were subject to patent applications, in their countries of origin before the entry into force of the WTO Agreement and the TRIPS Agreement (i.e. 1 January 1995). This level of TRIPS-plus term extension (also known as pipeline protection) has not found acceptance in many countries since it has no direct support in the Agreement provisions.

• Persuasion to accept ‘ever greening’ practices which aim at giving longer, even renewed life to the patent/s protecting the invention subject matter. These practices include the protection of other inventions that comprise: a) an improved process for making the same pharmaceutical product; b) a new and more efficient process for the same purpose; c) a novel pharmaceutical formulation or dosage form that incorporates the same product; or d) another ‘use’ of the product in the treatment of a health problem not previously specified in the earlier patent/s. The protection of any one of these inventions may be claimed by a separate patent application. The result may be a succession of patents, each one with a full term of 20 years, that follow each other in a line.

7.4 Accession process

Currently there are four countries in the Region which are at various levels of the accession process, namely Lebanon, Saudi Arabia, Sudan and Yemen. Six countries are non-members, including the Islamic Republic of Iran, which first applied for membership the very next year after the establishment of WTO, i.e. 1996. The first time the application was attended was in 2001, five years after submission. Between 2001 and 2003 the issue was raised 12 times in the General Council but every time it was postponed to the next meeting. The situation is almost the same with the Libyan Arab Jamahiriya and Syrian Arab Republic.

The meeting discussed in detail the difficulties faced by the countries in acceding to the WTO. It was noted with regret that political considerations rather than technical reasons are becoming obstacles in the way of a few countries like the Islamic Republic of Iran. In this connection, the final communiqué coming from the recently held Islamic Organization Conference in Malaysia was quoted which has called for speedy accession of the developing countries to the WTO underlining that no political consideration should impede this process.

An important point was made during the meeting that there must be more cooperation between the countries in the region in terms of accession process. Countries who have been through the exercise share their experiences with those still in the process and in this case WHO should also pay a role, when it comes to health related issues. Lebanon shared its experience in terms of procedures, documentation and negotiations. Documentation of Lebanon’s experience might be a good resource for other countries which are in the accession process and for those considering beginning the process.

7.5 Importance of regional trade agreements

According to economic theory, trade is all about comparative advantages. Theoretically the concept of comparative advantage can work most efficiently and optimally between
trading partners that are geographically close to each other, as opposed to intercontinental trade. The best case scenario is when the trading partners are neighbours and the second best scenario is when the trading partners are neighbours of the neighbours, and so on. This has long been recognized by many countries, hence the existence of hundreds of bilateral and regional trade treaties.

WTO promotes free trade through multilateralism, though it also recognizes regional trade agreements. There is an interesting situation whereby more trade under regional arrangements undermines the role of the WTO and on the other hand multilateral trade under the auspices of WTO goes against the spirit of regional trade agreements. Not surprisingly, WTO regards regional trade agreements as the second-best choice after multilateral trade agreements.

Interestingly, the same developed countries who vehemently promote multilateral trade through WTO are also the champions of the most important regional trade agreements, e.g. NAFTA. The United States of America also has a highest number of bilateral free trade agreements with other countries.

Many developing countries are also increasingly realizing the importance of regional trade and hence they are, and rightly so, revitalizing the existing regional economic associations and trade agreements and are also engaged in formulating new regional trade blocks through regional trade agreements. The latest is the South Asian Free Trade Agreement (SAFTA). There is a need for more neighbouring developing countries coming together and forging regional trade arrangements. Trade can also promote peace between countries and help improve international relations.

7.6 Implications of TRIPS on medical devices and technology market

Dr Adham R. Ismail

Since TRIPS covers broad areas of new technologies, there are areas of health technology other than pharmaceuticals which are also being influenced by the new intellectual property rights regime. Very important among these is medical equipment.

The global medical devices market comprises firms dealing with medical equipment (surgical, dental, etc.) and medical supplies (furniture, instruments, consumables, prosthetics, reagents, etc.). This total market is US $169 billion, of which the United States, European Union and Japan enjoy the highest shares, with 71.8%, 39.4% and 24.8% of market shares, respectively, according to 2000 figures. The market is expected to grow steadily by 7% over the next few years.

The trends in the market for medical devices are rising because of host of factors. There is an increase in demand due to ageing of old equipment in developed countries. In developing countries there is a growing demand because of widening markets and focus on disease specific requirements (e.g. AIDS, hepatitis and cancer). One reason is also increase in home health care in some developed countries and focus on new advances in medical technologies including tissue engineering, nanotechnology, robotics, etc. Of course there is
more public awareness about awareness of medical technologies, now than before, through
greater exchange of information via websites, multilateral exchanges and some international
harmonization initiatives.

There is a need for harmonization of regulatory control of medical devices with clear
objectives to enhance public health, promote technological innovation; facilitate international
trade, and reduce the proliferation of unharmonized regulatory requirements and practices. To
achieve these objectives there would be greater reliance on manufacturer quality systems
/design controls, internal testing, process verification and validation, manufacturing control
and third-party certification) and there would be wider application of international standards
in quality systems, risk management, labelling, electrical safety, electromagnetic compatibility
and product-related specifications. By implication it would mean that one standard
specification would be applied for devices placed in national or international markets (FDA
has two standards for medical devices) and there would be greater exchange and usage of
vigilance information. On these lines, Freeman has suggested a global regulatory model in

A study was conducted by International Trade Center in 1999 aimed at assessing the
impact of TRIPS on technology products and equipment. The study represented a mere
ensemble of views and opinions collected from business and public-sector representatives
through direct interviews with senior executives and officials from different countries. Two
kinds of concerns were raised in the study: the increase the cost of technology acquisition, and
reverse engineering and development of applications.

There are issues related with legality of reverse engineering. Reverse engineering is a
multistage process aimed at utilizing capital resources in an efficient and productive way. It
involves developing a set of functional specifications for a product, system or piece of
equipment, based on an analysis of existing product, system or piece of equipment. Frequently,
engineers use reverse engineering to obtain quick solutions to design and
maintenance problems of medical equipment. Generally, reverse engineering is an accepted
and lawful practice in industry (applied in drug industry). However, because it involves
gathering data and copying, it can violate the intellectual property rights of others. TRIPS
does not restrict usage for experimentation, private and non-commercial use, or use on a non-
commercial scale. It is only illegal to make, use or sell patented items without permission
hence items to be reverse engineered should be pre-screened. The reverse engineering process
may require disassembly of items to discover inner workings and features. To avoid liability,
engineers should ensure that the items have been lawfully procured and that no expressed or
implied duty of “confidence” exists that may be breached in the reverse engineering process.

Despite scrutiny by governments, counterfeiting of medical devices has grown in recent
years. In an incident that occurred with an international organization in 1999, more than 2000
kits containing stethoscopes and sphygmomanometers were counterfeited (packaging,
instructions, all devices, and European standards marks) during transport from one Asian
country to a European one. Counterfeiting leads to losses in revenues and reputation of
trademark companies. The counterfeit business is profitable since it has very low risk of
caught, very low risk of severe punishment if caught, and very high reward in terms of profit with low overhead. Strict regulations are needed in this case.

The TRIPS agreement can be of great benefit and significance to medical devices manufacturers and exporters society, as in the case of counterfeiting, and can be a hurdle in providing an appropriate health care medical service at a reasonable price, as in the case of reverse engineering. The agreement, in its present shape, can affect to a great extent the quality and cost of health care service provided to developing countries’ populations. It is felt that such an agreement has to be further discussed to include many special cases, statutory controls and limitations before applying it to the medical technology field.

7.7 Issues related with undisclosed information

It is common knowledge that a patent protecting a pharmaceutical chemical process discloses only the essential information (with minimal detail) which characterize the process and establish its uniqueness. All other information of practical value at the manufacturing level remains a securely guarded industrial secret. These include: a) the fine details of the conditions (temperature, pressure, pH, catalysis, etc.) of the chemical process steps which lead in each step to maximal yields while using minimal quantities and least expensive input materials under the most logical handling methods and the safest operation conditions; and b) the nature and specifications of the requisite capital equipment used in the unit processes and unit operations.

The importance in developing countries of undisclosed information, including in the pharmaceutical sector, will undoubtedly increase with the increased openness of the economy and the further deepening of the manufacturing operations. Also with the increased participation of the local research and development establishment in the formulation of industrial know-how, there will be an increased keenness to protect the new, hard-earned knowledge of commercial value.

According to the new world regime for the protection of undisclosed information (TRIPS Article 39), the infringement of such information occurs when other parties disclose, acquire or use the information without the consent of the rightful owner in a manner contrary to honest commercial practices. It is considered a criminal offence. By contrast, it is to be concluded that the disclosure, acquisition or use of the undisclosed information by other parties will not be an infringement if it is established that no acts contrary to honest commercial practices were involved.

The TRIPS Agreement (in Article 39.3) attaches special importance to the protection of undisclosed information, comprising confidential tests or other data, that are submitted to the appropriate health authorities in order to obtain an approval for marketing. The products to be marketed are pharmaceutical or agricultural chemical products, which utilize new chemical entities, and the origination of the submitted information involves a considerable effort. Because of this background and the cost and effort involved, it becomes an obligation of the receiving authority to protect such information against unfair commercial use.
Another obligation of the health authority that receives the undisclosed test or other data is to protect such data against disclosure, except where necessary to protect the public. The latter exception has been interpreted by some authors as a license for the health authority to use the data in testing similar pharmaceutical products submitted by other manufacturers for marketing approval. This matter seems to be controversial and remains to be settled.

8. RECOMMENDATIONS

Regional plan

1. A regional network should be established on TRIPS and public health, initially coordinated by WHO in order to:
   - promote knowledge and up-to-date information on TRIPS and public health;
   - exchange experience and studies on TRIPS and public health;
   - establish a regional database of experts and documents, reports and various resources on TRIPS and public health and make it available on the internet;
   - publish news bulletins and questions and answers on TRIPS and public health.

2. Human resource development is the key to undertaking TRIPS and access to medicines work effectively at the national level. Efforts should be made to build capacity of the officials in ministries of health and commerce through organizing training courses and through providing opportunities for participating in relevant training programmes.

3. Research studies should be supported at regional and national levels on TRIPS, new innovations and public health.

4. Countries should be supported in strengthening national health systems, capacity building on various aspects (present and future) relevant to TRIPS and public health. WHO and Member States should work closely to implement Regional Committee resolutions EM/RC45/R.10 (Annex 3) and EM/RC47/R.7 (Annex 4)

5. Relevant documents should be made available in national languages. The translation and publication of relevant documents on TRIPS and public health should be supported.

6. WHO/EMRO should work closely with national and Regional nongovernmental organizations and civil society to protect public health interest and promote public awareness during the full implementation of the TRIPS agreement.

TRIPS and access to Medicine for All

7. A comprehensive analysis should be conducted of essential drug list development and future direction in light of new biotechnological developments.
8. Research and development should be encouraged in biotechnology and drug development.

9. Information systems and market intelligence systems should be established on analysis of drugs and raw materials, drug prices and cost of drug development.

10. National systems and national drug policy should be strengthened for access to drugs and vaccines for all within the appropriate national system for financing the health services.

11. Countries should be supported in developing appropriate mechanisms for cost containment, access to medicine and fair financing for medicines.

Regional programme on TRIPS and biomedical devices

12. WHO should develop guidelines for regulation of biomedical devices in terms of aspects such as quality, safety in usage, specifications, reliability and validation of claims.

13. WHO should include a questionnaire in the report to evaluate country situations with regard to status of patency and licensing of medical devices.

14. WHO should continue its regional meetings, activities and workshops to further elevate the standards needed to develop the guidelines regarding the provision of harmonized and standardized medical devices. Emphasis should be placed on building biomedical technology in the Region as requested by directors of health technologies in their annual gatherings.

15. Countries should adopt WHO guidelines for procurement and regulation of medical devices.

16. Countries should initiate the development of a collaborative programme with WHO on essential biomedical devices.
Annex 1

PROGRAMME

Monday, 8 December 2003

8:30–9:00 Registration
9:00–10:30 Opening Ceremony
Regional Director’s Address
H.E. the Minister of Health’s Address
Objectives of the meeting
10:30–11:00 Election of officers and introduction of participants
11:00–12:00 Regional overview, Dr Abdel Aziz Saleh
WHO/HQ activities, Dr German Velasquez
12:00–14:00 Organizational overview(WTO-ACDIMA-AUPAM-IFPMA-WIPO-IOMS)
14:00–17:00 WTO agreement and public health
Impact of globalization on health: state responsibility, Dr Belgacem Sabri
GATS and public health, Dr Sameen Siddiqui

Tuesday, 9 December 2003

8:30–10:00 Analytical analysis of TRIPS agreement
Global view, Dr Heinz Klug
National view, Dr Mohamed Bahaa El Din Fayez
Some issues of relevance to the TRIPS agreement and public health
10:00–11:30 Discussion
11:00–12:30 Doha Declaration and public health
Global view, Dr Heinz Klug
National view, Dr Mohamed Al Dawi
12:30–16:00 Country presentation
16:00–17:00 General discussion on support country in accession and ongoing negotiation

Wednesday, 10 December 2003

8:30–11:00 National intellectual property rights legislation
Pakistan, Dr Zafar Mirza
Tunisia, Dr Amor Toumi
TRIPS and biomedical devices and technology, Dr Adham Ismail

11:00–12:00  TRIPS and drug access, Dr Adnan Badwan
Regional overview, Dr Zafar Mirza

12:00–14:00  General discussion on TRIPS and drug access

14:00–15:00  TRIPS and access to medicine for all, Dr Abdel Aziz Saleh

15:00–17:00  General discussion on regional plan on TRIPS and public health

Thursday, 11 December 2003

8:30–11:00  On going and future WTO negotiations on TRIPS
Group discussions on national and regional plan on TRIPS and public health

11:00–12:00  Presentation of regional plan

12:00–13:00  Conclusion and recommendations
Closing session
Annex 2

LIST OF PARTICIPANTS

BAHRAIN
Mr Bader Hamad Hamad
Drug Pricing Specialist
Pharmacy and Drug Control Directorate
Ministry of Health
Manama

EGYPT
Dr Soad Abdel Shafy Tawfik
Inspector, Ministry of Health and Population
Cairo

ISLAMIC REPUBLIC OF IRAN
Dr Mohammad Hossein Nicknam
Director General for International Affairs
Advisor to the Minister of Health and Medical Education
Ministry of Health and Medical Education
Teheran
e-mail: nicknam_m@yahoo.com

JORDAN
Dr Ghassan Ayoub Al Fakhouri
Assistant General Secretary for Planning and Development
Ministry of Health
Amman
e-mail: ghass@dr.com

Dr Maisa Khalil Al Saket
Director for Drugs Directorate
Jordan Food and Drug Administration
Amman
e-mail: drugdirect@index.com.jo

Dr Riyad Okour
Director, Health Economic Directorate
Ministry of Health
Amman
e-mail: akourrr53@yahoo.com
LEBANON
Ms Souheir Nadee
Legal Trade Coordinator
Ministry of Economy and Trade
Beirut
e-mail: snadde@economy.gov.lb

MOROCCO
Mr El Bachir Claine
Chief of the Unit of Economic Studies Services
Medicine and Pharmacy Division
Ministry of Health
Rabat

OMAN
Dr Batool Jaffer Suleiman
Director of Rational Drug Use
Ministry of Health
Muscat
e-mail: rdumoh@omantel.net.om

PAKISTAN
Mr Muhammad Arshad Khan
Deputy Director General Hea
Federal Ministry of Health
Islamabad
e-mail: khanmarshad@hotmail.com

SAUDI ARABIA
Dr Ibrahim AlShowaier
Director General of Medical and Pharmaceutical Licenses
Ministry of Health
Riyadh
e-mail: i_alshowaier@yahoo.com

SUDAN
Dr Mustafa Salih Mustafa
Director of Health Planning
Federal Ministry of Health
Khartoum
e-mail: ms_mustafa2000@yahoo.com
SYRIAN ARAB REPUBLIC
Ms Rajwa Jbeily
Director of Drug Quality Assurance
Ministry of Health
Damascus

Dr Ghazal Faris
National Trainer, Center of Health System Management
Ministry of Health
Damascus
e-mail: gazal_f@scs-net.org

UNITED ARAB EMIRATES
Dr Easa Ahmed Al-Mansoori
Director of Drug Control Department
Ministry of Health
Abu Dhabi
e-mail: essaj@moh.gov.ae

YEMEN
Dr Yahia Yahia Al-Babily
Deputy Minister for Pharmaceuticals and Medical Supply
Ministry of Public Health and Population
Sana’a
e-mail: yahia_babily@hotmail.com

TEMPORARY ADVISERS

Dr Mohamed A. Eldawy
Emeritus Professor and Founding Dean
Faculty of Pharmacy
Tanta University
Tanta
EGYPT
e-mail: eldawymo@thewayout.net

Dr Mohamed Baha El Din Fayez
Professor Emeritus
National Research Centre
Cairo
EGYPT
e-mail: mfayez@mcit.gov.eg
Dr Mahmoud Abdel Maksoud  
Chairman, EMROPHARM Forum  
Cairo  
EGYPT  
e-mail: maksoud@pharmwebegypt.com

Dr Adnan Badwan  
Director General  
The Jordanian Pharmaceutical Manufacturing Company  
Naor  
JORDAN  
e-mail: jmpo@go.com

Dr Zafar Mirza  
Executive Coordinator  
The Network for Consumer Protection  
Islamabad  
PAKISTAN  
e-mail: zafarhenetwork.org.pk

Dr Amro Toumi  
Director of Pharmacy and Drug Administration  
Ministry of Health  
Tunis  
TUNISIA  
e-mail: amor.toumi@rns.tn

Professor Heinz Klug  
Professor, University of Wisconsin Law School  
Madison, Wisconsin  
UNITED STATES OF AMERICA  
e-mail: klug@wisc.edu

OTHER ORGANIZATIONS

Arab Company for Drug Industries and Medical Appliances (ACDIMA)  
Dr Muwaffak Haddadin  
Director General  
Amman  
e-mail: acdima@go.com.jo

Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances (AUPAM)  
Dr Adnan Kilani  
Representative  
Amman
International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
Dr Eric Hubert Noehrenberg
Director, International Trade and Market Issues
Geneva
e-mail: e.noehrenberg@ifpma.org

World Trade Organization
Mr Hannu Antero Wager
Counsellor, Intellectual Property Division
Geneva
e-mail: hannu.wager@wto.org

WHO SECRETARIAT
Dr Abdel Aziz Saleh, Special Adviser to the Regional Director for Medicines, WHO/EMRO
Dr Mohamed Z. Khan, Acting WHO Representative, Jordan
Dr Belgacem Sabri, Director, Health Systems and Services Development, WHO/EMRO
Dr Hossein Salehi, Regional Adviser, Health Economics/Legislations and Ethics, WHO/EMRO
Dr Sameen Siddiqui, Regional Adviser, Health Policy and Planning, WHO/EMRO
Dr Mohamed Binshahna, Short Term Professional, Essential Drugs and Biologicals, WHO/EMRO
Dr Nabila Metwalli, Regional Adviser, Blood Safety, Laboratory and Imaging, WHO/EMRO
Dr Adham Rashad Ismail, Short Term Consultant, Biomedical Engineer, WHO/EMRO
Mr Mohamed Helmy Hamada, Intern, WHO Regional Office for the Eastern Mediterranean
Mr Hossam Younes, Technical Assistant, Help Desk Administrator, WHO/EMRO
Ms Engy Hamdy, Senior Secretary, WHO/EMRO
Ms Hoda Omera, Senior Secretary, WHO/EMRO
MESSAGE FROM THE REGIONAL DIRECTOR

Your Excellencies, Distinguished Guests, Ladies and Gentlemen,

It gives me great pleasure to welcome you all to this beautiful country of Jordan on this important occasion. I would like first of all to thank His Excellency Engineer Saeed Darwazeh, Minister of Health, for graciously accepting to host this Consultative Meeting on TRIPS and Public Health here in Jordan. We are all honoured to be here and grateful for the generous hospitality that His Excellency and members of his team have extended to us.

Following the conclusion of the Uruguay Round of Negotiation in 1994, and the establishment of the World Trade Organization (WTO) in 1995, several studies were carried out on the impact of WTO agreements on the health sector. WHO headquarters in Geneva and the Regional Offices have published several of these documents. The World Health Assembly and Regional Committees have passed several resolutions on TRIPS and public health. The main concerns expressed in these documents include the following:

1. that rigid intellectual property right regulations will deny developing countries’ access to the outcome of new science and technology development;

2. that rigid implementation of TRIPS will be associated with price increases and reduce access to essential medicines;

3. that technology transfer currently faces a lot of technical and financial obstacles; and

4. that local drug industries will have greater difficulties in competing in the world drug market.

The Doha Declaration on the TRIPS Agreement and Public Health made a clear statement in paragraph 4: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”

It was therefore important to emphasize the scope of public health. The WHO Regional Committee for the Eastern Mediterranean, at its 50th session held in Cairo in October of this year, passed resolution EM/RC50/R.2 which defines the scope of public health as follows: The science and art of promoting, protecting and/or restoring the physical, mental and social well-being of the people through prophylactic, diagnostic, therapeutic and rehabilitative measures, applied to human beings and their environment.

The declaration also emphasized the WHO concept of “access to medicines for all”. “We therefore need to define the scope of medicines referred to in this context. Analysis of the
WHO model lists of essential drugs showed that between the third list in 1983 and the latest (thirteenth) list of 2003, 162 new drugs were added to the list (113 to the main list and 49 to the complementary list), and 33 new formulations were added to the already listed drugs. In the meantime, 41 drugs were deleted from the list (28 from the main list and 13 from the complementary list), and 12 formulations were deleted (10 from the main list and 2 from the complementary list). Furthermore, 9 formulations were replaced by new ones and 6 drugs were moved from the main list to the complementary list, while 9 drugs were moved from the complementary list to the main list.

Concerning the patency status of added drugs, the 2003 list includes 18 drugs that are still protected by patency; 12 of them are antiviral drugs, 2 are anti-malarial, 2 anti-infective, and 2 anti-cancer.

This analysis may give the false impression that strict application of TRIPS may not have serious impact on the availability of essential drugs. However, the other dimension that we should consider is the outcome of recent advances in biotechnology, particularly as a result of the completion of the human genome project. We are witnessing breakthrough discoveries that will result in production of biotechnology derived medicines and interventions capable of diagnosis, prevention, control and treatment of serious diseases.

The human genome, according to Barry Bloom and Dang Duc Trach in a recent BMJ report, offers unprecedented opportunities to all countries for understanding mechanisms of disease and developing new drugs and vaccines. All the drugs in the world act on only 479 known molecular targets. If only 10% of the genome represents targets for new drugs, the possibility exists for developing at least 3000 new molecular entities to combat disease. Through new technologies, 50 000 new drugs can be produced and screened by a laboratory in a week—more than a major pharmaceutical company could test in a year.

Ladies and Gentlemen,

At the regional level, more efforts should be made to achieve self-sufficiency in the production of essential vaccines and medicines. Our initiative to strengthen regional cooperation and technology transfer between Islamic Republic of Iran, Pakistan and Indonesia has had some success and we expect other countries to join this initiative.

One possible way to ensure medicine for all is the establishment of a global fund managed by WHO that could negotiate and buy the patent rights of new drugs for developing countries. The fund would take into consideration the reasonable cost of new innovations and the share of developing countries in the global market, which is usually less than 10%. The fund could also cover the cost of contracting research studies on new drugs for diseases of developing countries that may not attract the interest of multinational drug companies, and provide funds for capacity-building in developing countries in areas of new technology, including genomics and proteomics research.
Ladies and Gentlemen,

Within this framework, this consultative meeting on TRIPS and Public Health has the following objectives:

- review countries’ situations with respect to TRIPS implementation;
- exchange countries’ experience with TRIPS flexibilities; and
- develop a regional strategy on TRIPS and public health.

We need to move forward from discussions to action, at both regional and national levels.

Ladies and Gentlemen,

In the Eastern Mediterranean Region countries hold a range of statuses in relation to WTO as follows:

1. Member States that are not yet members of WTO.
2. Member States that are members of WTO and have formulated national intellectual property rights law, and are preparing for full TRIPS and other WTO agreement implementation.
3. Member States that are members but have not yet taken action for TRIPS or other WTO agreement implementation.
4. Member States that have observer status and are in accession.

As of 5 April 2003, the total WTO membership is 146 countries, of which 12 are from the Eastern Mediterranean Region of WHO. In addition, four countries of the Region have applied to join WTO and have initiated accession negotiations.

The health sector in Member States who have applied for membership should contribute to the negotiation of accession in order to protect the public health interest, and should conduct studies on the possible impact of joining WTO on access to essential drugs, the local drug industry and trade in health services.

I look forward to the outcome of this meeting and wish you a pleasant stay in this beautiful city of Amman.
RESOLUTION EM/RC45/R.10  GATT AGREEMENT—ITS IMPACT ON HEALTH

The Regional Committee,

Having discussed the technical paper on the GATT Agreement and its impact on health\(^1\) Noting the concern expressed in recent summit meetings of developing and non-aligned countries and the Regional Committee for the Eastern Mediterranean of the possible impact of globalization and World Trade Organization agreements on the socioeconomic sectors in developing countries;

Noting the efforts of some Member States to make the best use of the transition period to prepare the national system for the full implementation of World Trade Organization agreements;

Appreciating the efforts made by WHO to publish information on the impact of WTO agreements on the health sector;

1. **URGES** Member States to:
   
   1.1 Ensure that ministries of health are represented on national committees entrusted with the task of studying the negative impact of World Trade Organization agreements on the health sector;
   
   1.2 Conduct studies to coordinate response to World Trade Organization health-related agreements in cooperation with the Regional Office.

2. **REQUESTS** the Director-General to:

   2.1 Continue, and expand upon, the ongoing studies on the impact of World Trade Organization agreements on the health sector, inviting contributions from Member States, and widely distribute the outcome of the studies;
   
   2.2 Continue to promote WHO’s role as the international agency responsible for setting standards in the health field;
   
   2.3 Make constructive efforts with bodies and institutions concerned in order that they might take into account the social and health aspects of the impact of the World Trade Organization agreements;

3. **REQUESTS** the Regional Director to support the Ministries of Health in their efforts to address the negative impact of World Trade Organization agreements on the health sector, and act for the development of a regional plan for addressing this impact.
RESOLUTION EM/RC47/R.7 THE IMPLICATIONS OF GATT AND WTO AGREEMENTS ON HEALTH IN GENERAL

The Regional Committee,

Having discussed the technical paper on the implications of GATT and WTO Agreements on health in general

Recalling the Regional Committee Resolution EM/RC45/R.10 on the same subject and the call for further studies at national, regional and global levels on the possible impact of WTO Agreements on the health sector;

Noting the efforts made by Member States to develop appropriate studies to protect the public health interests during the implementation of WTO Agreements;

Appreciating the efforts made by the Regional Office to carry out studies and provide technical support to Member States and present position papers on health and trade at international conferences;

Expressing serious concern about the potential negative impact of WTO Agreements on the health sector;

Emphasizing health as a basic human right and that implementation of WTO Agreements should not hinder universal and equitable access to essential health services and technological development;

Emphasizing strongly the necessity to balance the rights of the patient and those of the patent holder;

1. URGES Member States to:

1.1 Take the necessary measures to translate the relevant articles in the WTO Agreements relating to technology transfer and socioeconomic development in developing countries into practical plans of serious cooperation;

1.2 Ensure that representatives of the health sector participate in meetings and negotiations dealing with the implementation and revision of WTO Agreements;

1.3 Establish national bodies in which all relevant sectors are represented to study the impact of WTO Agreements on the various sectors, particularly the health sector, and to prepare necessary studies and contributions to future negotiations;
1.4 Take urgent measures to revise national legislation to meet country commitments to WTO Agreements, taking into consideration national interests and protecting national resources, particularly national flora.

2. REQUESTS the Regional Director to support Member States in their efforts to formulate appropriate strategies in response to WTO Agreements.

3. REQUESTS the Director-General to:

3.1 Strengthen active collaboration with Member States and ensure a proactive role for WHO in protecting the interests of the health sector and in presenting the views of Member States, particularly those of developing countries, in future WTO meetings and negotiations;

3.2 Continue WHO’s efforts to negotiate preferential prices for new essential drugs and technologies;

3.3 Seek the representation of WHO in the Ministerial Council of the World Trade Organization.