Chapter - V
THE DIRECT / INDIRECT CONTROLS OF WTO, GATT and WHO ON INDIAN PHARMA BUSINESS

In this chapter information is given about formation of GATT, key elements of GATT Agreement, formation of WTO, key factors of WTO Agreement, standards and non-tariff barriers of trade, tariff reduction and bindings, market access, domestic support, SPS measures, TRIPS, agricultural subsidies, and agreement on antidumping measures etc. After study of these factors the main objective of WTO to flourish globalised trade comes into focus.

5.1 Formation of GATT
In 1944, the international community, which was coming out of the shadow of second world war, was emphasizing on international co-operation for mutual prosperity and peace. In 1945, 23 members including India signed a protocol, which brought into existence GATT (General Agreement on Tariffs and Trade) on 1st January 1948, with the main objective of bringing order to international trade. By 1994, the GATT membership increased to 136 countries.

5.1.1 Key elements of GATT agreement
1. The Most Favoured Nations (MFN) Clause
2. Binding commitments
3. National Treatment
4. Removal of quantitative restrictions.
5. Transparencies

The MFN Rule provides that the country, which is offered most favourable treatment (like reduction in customs duty), should immediately give the same treatment to other member countries of GATT. Thus, there would be no discrimination among GATT members at the hands of one country.
The binding commitments stipulate that the members undertake commitments in which they state the maximum level of import duty or other charges or restrictions they will apply to the import of specific goods.

As regards national treatment the member country cannot discriminate between the national product and imported product once the imported product enters the boundaries of the country. Thus the national treatment principle means that the protection of domestic product should be given only through action at the frontier like levying customs duty etc. Once this protection has been offered and once the foreign goods enter the member country these goods come on par with domestic goods.

WTO expects removal of quantitative restrictions (QR) if not immediately at least in a progressive manner as per the schedule. According to WTO the QRs function as Non-Tariff Barriers and hence protection to domestic products be given through customs tariff.

As regards transparencies it has to be followed when the governmental agencies procure goods and services there should not be any discrimination between domestic goods/services on the one hand and the foreign goods/services on the other.

5.2 Formation of WTO

After over seven years of negotiations the Uruguay Round multilateral trade negotiations were concluded on December 15th, 1993 and were formally ratified in April 1994 at Marrakesh, Morocco. The WTO Agreement on Agriculture (AOA) was one of the many agreements, which were negotiated during the Uruguay Round.

The implementation of the Agreement on Agriculture started with effect from 1.1.1995. As per the provisions of the Agreement, the developed countries would complete their commitments of reduction of tariffs within six years, that
is, by the year 2000, whereas the commitments of the developing countries would be completed within ten years, that is, by the year 2004. The least developed countries are not required to make any reductions.

The products which are included within the purview of this agreement are what are normally considered as part of agriculture except that it excludes fishery and forestry products as well as rubber, jute, sisal, abaca and coir. The exact product coverage can be accessed in the legal text of the agreement.

5.3 Key factors of the WTO agreement
The WTO Agreement on Agriculture (AOA) contains provisions in three broad areas of agriculture and trade policy: market access, domestic support and export subsidies.

5.3.1 Market access
Market access refers to the ability of providers of foreign goods and services to sell in a given country. For the purposes of market access negotiations in the WTO context, tradeable items are subdivided into four groups: agricultural goods, textiles and clothing, industrial goods, and services.

This includes tariffication, tariff reduction and access to opportunities. Tariffication means that all non-tariff barriers such as quotas, variable levies, minimum import prices, discretionary licensing, state trading measures, voluntary restraint agreements etc. need to be abolished and converted into an equivalent tariff. Ordinary tariffs including those resulting from their tariffication are to be reduced by developed countries to an average of 36 percent with minimum rate of reduction of 15 percent for each tariff item over a six year period\textsuperscript{104}. Developing countries are required to reduce tariffs by 24 percent in ten years. Developing countries that were maintaining quantitative restrictions due to balance of payment problems were allowed to offer ceiling bindings instead of tariffication.
5.3.1. A. Main market access barriers

i. **Import tariffs and other price-based border measures:** Government policies usually targeted at restricting market access in a particular commodity and raising budget revenue. These measures include: import duties, tariff quotas, and other border duties, levies, and charges.

ii. **Non-tariff border measures:** Government policies that may restrict market access through non-price instruments. Such measures include: quantitative restrictions (import quotas, direct prohibitions, domestic content requirements, licensing); contingency measures (antidumping, countervailing, and safeguard measures); technical barriers to trade (TBT) (regulations, standards, testing and certification procedures); sanitary and phytosanitary measures (SPS) (food, animal and plant health and safety).

iii. **Domestic policy measures:** Government policies, which may restrict market access if not applied uniformly to domestic and imported goods and services. These are: tax, competition, credit, and investment policies; price controls; and fiscal incentives, in particular, trade-distorting export subsidies and domestic support.

Developing countries generally face higher barriers to their exports than industrial countries. However, underlying that general result, there are large variations in market access conditions depending on the type of product and the particular "exporter-importer combination."

5.3.1. B. Improving market access for developing country exports

The Doha development agenda contains important commitments but this initial effort needs to be sustained. Particular issues include:
1. The phasing out by all countries of tariff peaks (tariffs of 15 percent or higher) and escalation (tariffs rising with the degree of processing of imports) is critical to the development dimension of the current round of multilateral trade negotiations, and could best be achieved through formula approaches that ensure deep across-the-board reductions.

2. Disciplines on the application of trade remedy action should be strengthened through reviews of existing rules to deter their use as protectionist devices—and developing countries should receive more assistance to implement product and process standards.

3. Schemes that provide unrestricted market access for all least developed countries should be extended by all large trading nations (with liberal rules of origin) but set within a framework of multilateral liberalization.

Reform of market access in developing countries themselves would contribute as much to a development-oriented multilateral trading system as per OECD policies. Apart from domestic efficiency gains and a reduction in remaining anti-export biases, developing countries are increasingly large markets for each other.

5.3.1. C. Current and minimum access commitments

The underlying objective of tarrification was to impart transparency to the protection level granted in various countries and prepare ground for progressive liberalization of world agriculture trade. But actual ceiling bindings came at very high levels. For example new tariff rates applicable to temperate zone products range from 60 to 100 percent. For some tariff lines they stand as high as 300 to 350 percent. The issue has been further complicated with a number of countries imposing specific duty instead of ad-valorem duty. As the objective of liberalizing world agriculture trade through tarrification and tariff
reduction was not fully achieved, the provisions of current and minimum access commitments were brought in.

5.3.1.D. Tariff rate quotas – minimum access opportunity
Importing countries have made establishing tariff quotas for those imports which were allowed entry at lower duty rates to ensure continuity in the special dispensation. The higher tariff rates coming from tariffication are applicable to imports over and above the quota limits.

For those products whose trade was extremely restricted earlier because of impregnable national barriers, countries were required to give minimum access opportunity commitments. The commitment stipulates establishment of tariff quota equal to 3 percent of domestic consumption in 1986-88 (base period) and raising them to 5 percent by 2001 for developed countries and 2005 for developing countries. Lower rates, generally up to 32 percent of the tariffified rates, are applicable to imports up to quota limits. The higher rates from tariffification are to apply to the imports over quota limits.

5.3.1.E. Tariff reduction and binding
The tariff reduction for agricultural items are to be made in simple average. Besides, the tariffification process gives rise to so many specific duties for which ‘ad valorem equivalents’ were not available. And hence it is very difficult to quantify the net impact of tariff reduction on pharmaceutical bulk drugs derived from agricultural products.

As India was maintaining quantitative restrictions due to balance of payments reasons (which is a GATT consistent measure), it did not have to undertake any commitments in regard to market access. The only commitment India has undertaken is to bind its primary agricultural products at 100 percent; processed foods at 150 percent and edible oils at 300 percent. Of course, for some agricultural products like skimmed milk powder, maize, rice, spelt wheat, millets etc. which had been bound at zero or at low bound rates,
negotiations under Article XXVIII of GATT were successfully completed in December 1999, and the bound rates have been raised substantially.

5.3.2 Standards and non-tariff barriers to trade
Many developing countries are concerned that they are ill-prepared to meet increasingly complex and burdensome standards and regulations. Standards and regulations on products and production processes play an important role in facilitating trade by ensuring quality, safety and technical compatibility. However, there is often a risk that such regulations may be captured by special interests, particularly when regulatory processes are not transparent. Conditions might then be imposed that are tighter than needed to achieve the safety and health objectives in order to serve a protectionist purpose.

Technical barriers
Technical barriers have become a key concern regarding market access. Annual notifications of new technical barriers (including health and safety standards, and product standards) to GATT/WTO increased steadily from a dozen or two in the early 1980s to over 400 in 1999. Low- and middle-income countries reported that over the period from 1996–99 more than 50 percent of their potential exports of fresh and processed fish, meat, fruit and vegetables into the EU were “prevented” by their inability to comply with SPS requirements (OECD, 2001b). SPS and other technical requirements have been viewed by developing country trade officials as a greater constraint on their ability to export than tariffs and quantitative restrictions.

5.4.1 Special and differential treatment
These provisions are also available for developing country members. These include purchases for and sales from food security stocks at administered prices provided that the subsidy to producers is included in calculation of AMS. Developing countries are permitted untargeted subsidised food distribution to meet requirements of the urban and rural poor. Also excluded for developing countries are investment subsidies that are generally available
to agriculture and agricultural input subsidies generally available to low income and resource poor farmers in these countries.

India does not provide any product specific support other than market price support. During the reference period (1986-88), India had market price support programmes for 22 products, out of which 19 are included in our list of commitments filed under GATT.

Under the WTO exceptions, developing countries like India can extend export subsidies as long as the per capita income is less than $1000 per year (Rs. 4000 per month). Further, the share of the product in the world trade must be less than five percent. The per capita income of India is less than $500.

5.5 Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)

Globalisation in trade and investment through harmonisation of national laws, particularly dealing with intellectual property rights is one of the major impacts of GATT / WTO. The contribution of knowledge as a factor of production is being increasingly given central importance in economic development. The clashes between public need and private control will be the first challenge. The conflict between chemical intensive agriculture (despite declining productivity of inputs) and the non-chemical sustainable technological innovations generated by farmers as well as firms will pose a second challenge. The increasing trend towards larger areas under fewer varieties and the need for food security through diversified biological systems will be the third source of conflict. Production, protection, commercialisation and incorporation of intellectual property in formulation of national developmental strategies, will be crucial in defining the role India will play in world markets on the one hand and overcoming deprivation and hunger within the country on the other.
The strategy proposed is aimed at making Indian agriculture not only globally more competitive but also domestically more progressive by using knowledge as a strategic resource so that agriculture sustains livelihoods of millions of households dependent upon it in an environmentally sustainable manner. The major contention is that India should not view the challenges posed by WTO as if it will remain mainly as an importing country and that it has no substantive intellectual property to offer to the world market. There must be a registration system for encouraging protection of local land resources and incentive system must be generated for, in its conservation.

The provisions of TRIPs need to be strengthened to include,

♀ Registration system of grassroot innovations (unlike utility patent system). This registration system should be like product patent for ten years just as proposed in Australian Innovation patent system)
♀ Widespread patent search facility for educational and entrepreneurial networks and centres so that quality of research and education can be competitive.
♀ Just as a global registry has been proposed for wines under TRIPS, India must insist that similar global registry must exist for small innovations too. This will help link innovation, investment and enterprise each sector of which may be in different parts of the world.

The global trade regime has to deal with several related issues in regard to bio-safety such as ability of the importing country to assess the risks and deal with them, regulations for labeling of GMO products so that consumers can make informed choice, restrict GMOs which may pose hazard to the very viability of the food security, for example, through terminator gene technology, etc. Prior informed consent of farmers must be ensured while pursuing on farm trials on transgenic. The reciprocity in effective protection must exist that is those who access farmers varieties must disclose, acknowledge and undertake to provide reasonable share of their revenue with germplasm providers/conservators through appropriate institutions, and PVP / patent
claimant should unambiguously prove that the materials in which improvements have been made, had been obtained lawfully and rightfully.

The intellectual property rights deal with the reciprocity in rights and responsibilities of inventors and society at large. In lieu of the disclosure of the patented innovation or invention, the society agrees to recognise the right of inventor to exclude others not authorised, from commercial exploitation of the invention. It is a kind of social contract between society and the inventor. Society gains by getting access to the inventive process and product, which can be used by other inventors for making improvements as well as developing substantive new innovations. Inventor benefits by having incentive to invest himself/herself or assign it to some one else interested in commercial exploitation of the invention. The plants and animals were kept out of the purview of patents when the concept was developed initially. However, in the fifties, discussion started on finding out ways in which more plant varieties could be developed and breeders could be given incentives to innovate and disclose the improvements.

The sue generic system created, for protection of new varieties of plants by International Convention for Protection of New Varieties of Plants (UPOV) was a response to basically three factors (UPOV 1998),

a) Reluctance in fifties to the application of patent systems to agriculture and to the plant breeding in particular,

b) Realisation that a system was needed to protect plant varieties somehow to also safeguard the interests of the breeders. And

c) The conditions of patentability might not be appropriate for the plant varieties. Subsequently, the 1961 Act was modified in the 1978, which was further modified in 1991. After ratification of 1991 Act by more than six countries, it has come into force now.
While TRIPS (Trade-related Aspects of Intellectual Property Rights Agreement) does not explicitly state that sue generis system should be compatible with provisions of International Union of Plant Variety (IUPV), it is implied that such should be the case. Earlier, the option for the countries joining IUPV was to have their national laws compatible with IUPV 1978. However, after coming into force of IUPV 91, such an option does not exist for countries, which have not sent their Draft Bill to IUPV for reference. Although, this is a contentious issue, many countries including India have argued that providing "effective" plant variety protection through 'sue generis' system need to mean parity with IUPV 91. Increasing use of biotechnology in producing transgenic crop varieties and genetically modified organisms (GMOS) also requires development of bio-safety norms to regulate trade in such crops, animals and products. As much as sixty per cent of the marketed products in some commodities have biotechnological inputs in some of the developed countries. A significant part of it involves transgenic crops particularly in the USA.

The Indian government has not yet enacted either a sue generis system or a Plant Variety Act which is in conformity with WTO provisions. Our agriculture cannot be self-reliant, if the public sector agricultural research remains totally under the stranglehold of government. It should have autonomy and be much more accountable to various user groups. Such will continue to be the case till R & D institutions primarily rely on government for funds. It is obvious that public sector R&D has played a very crucial role in agricultural growth in the country. The tragedy is that even well off beneficiaries of this growth did not share any part of their economic gains with the R&D institutions. So much so that Central and State Seed Corporations never paid any revenue to the research institutes and universities. WTO implications will force agricultural R&D and trade sectors to become more efficient and competitive. Intellectual property rights protection for public and private sector scientists, as well as, institutions, is likely to contribute to this process.
5.6 India’s basic objectives in the ongoing negotiations

To protect its food and livelihood security concerns and to protect all domestic policy measures taken for poverty alleviation, rural development and rural employment.

The Indian proposals are based on the inputs received from wide-ranging consultations with various stakeholders and can be broadly classified into the following two categories:

I. Increasing the flexibility enjoyed by developing countries for providing domestic support to the agriculture sector under the special and differential provisions as also further strengthening of trade defense mechanisms with a view to ensuring the food security and to take care of livelihood concerns.

II. Demanding of substantial and meaningful reductions in tariffs including elimination of peak tariff and tariff escalation, substantial reductions in domestic support and elimination of export subsidies by the developed countries so as to get meaningful market access opportunities.

The proposal on market access co-sponsored by India along with other developing countries called upon the developed countries to reduce tariff peaks and eliminate tariff escalation; simplify the administration of tariff rate quotas making it more transparent and equitable for all trading partners; to address the provisions and procedures of the SPS Agreement which inhibit exports from developing countries, etc. The proposal also called for prohibition of dumping, elimination of all forms of export subsidies and demands substantial reduction in domestic support provided by developed countries.

The proposal on export credits for agricultural products, which is the other paper co-sponsored by India along with MERCOSUR and other countries, is designed to bring the work related to establishing rules and guidelines on export credits into the WTO, so that any rules/guidelines framed are fully
compatible with WTO rules and procedures. These proposals have been made with the objective of bringing agricultural export credits, export credit guarantees and export insurance programmes under specific multilateral discipline under WTO.

5.7 Responses to India's proposals submitted to the WTO
It was expected that some of our proposals on export subsidies may expand the scope of export subsidies rather than reduce it and that some criteria should be spelt out for the exemptions we have proposed on support measures for rural development and poverty alleviation. The paper on Market Access co-sponsored with other developing countries received support from a wide gamut of countries like EC, most of the Cairns group countries and US. However, US were not in favor of raising SPS issues in these negotiations.

The paper on export credits co-sponsored by India was supported by Japan, EC and members of the Cairns Group such as Guatemala, Thailand, Philippines, New Zealand, Canada and Columbia.

5.8 Implications of the WTO agreement on India
When implications for pharmaceutical sector is concerned this mainly affects many bulk drugs those are produced or derived from plants and animals.

Implications of the Agreement on Agriculture on India can be judged from the impact it will have on the following:

1. Whether the Agreement has opened up markets and facilitated exports of India's products.
2. Whether India would be able to continue with its domestic policy aimed at improving infrastructure and provision of inputs at subsidized prices for achieving increased agricultural production.
3. Whether imports of certain agricultural/food items in India will adversely affect it.
It is argued that because of increasing price of domestic agricultural commodities following improved export prospects for developing countries, farmers would get benefits, which in turn would encourage investment in the resource scarce agricultural sector. With the decrease in production subsidies as well as export subsidies in developed countries, international prices of agricultural commodities will rise and this will help in making India’s exports more competitive in the world market. Due to agro diversity, India has the potential to increase its agro exports in a substantial way. In the words of a social activist, “There will be growing pressure from the farmers to realize higher prices for their produce and to narrow the gap between the domestic and external prices. Both the patterns of production and price expectations will increasingly be influenced by the demands and trends in world markets.

On the one hand, the price incentive could be the best incentive and could give a strong boost to investment in agriculture as well as adoption of modern technologies and thereby, to the raising of agricultural production and productivity. On the other hand, the rise in domestic prices would put pressure on the public distribution system and accentuate the problem of food subsidy. Furthermore, freedom to export agricultural products without restrictions will also need shedding the long nurtured inhibition against their imports. The nature and character of State intervention and State support will have to undergo qualitative changes in order not only to realize the opportunities for exports, but also to cope with the implications of Indian agriculture coming into increasing alignment with the international market place”.

Regarding freedom to pursue our domestic policies, it is quite evident that in the short term India will not be affected by the WTO Agreement on Agriculture. The safeguards provided for developing countries give enough mileage to insulate India from any major impact of trade liberalization in agricultural commodities.
Within the provisions of the GATT Agreement, India has bound tariffs at high levels of 100 percent, 150 percent and 300 percent for primary products, processed products and edible oils respectively. Therefore, the QRs can be replaced with high import tariff in case, we want to restrict import of these commodities. In India, for the present, the minimum support price provided to commodities is less than the fixed external reference price determined under the Agreement. Therefore, the AMS is negative. Theoretically, therefore, we could increase the product specific support up to 10 percent.

5.8.1 Implications- long term
For a large majority of farmers in different parts of the country, the gains from the application of science and technology in agriculture are yet to be realized which would require infrastructural support, improved technologies and provision of inputs at reasonable cost. The Agreement recognized this and developing countries have been given the freedom to implement such policies under Article 6 relates to differential treatment, but any attempt in future to dilute provisions relating to differential treatment for developing countries could affect India adversely.

Regarding the impact of liberalization of trade in agriculture in the long term, Indian agriculture enjoys the advantage of cheap labour. Therefore, despite the lower productivity, a comparison with world prices of agricultural commodities would reveal that domestic prices in India are considerably less with the exceptions of a few commodities (notably oilseeds). Hence, imports to India would not be attractive in the case of rice, tea, sunflower oil and cotton. On the whole, large scale import of agricultural commodities as a result of trade liberalization is ruled out. Even the exports of those food grains which are cheaper in the domestic market, but are sensitive from the point of view of consumption by the economically weaker sections are not likely to rise to unacceptable levels because of high inland transportation cost and inadequate export infrastructure in India. Through proper tariffication, however, Indians will have to strike a balance between the competing interest
of 10 percent farmers who generate marketable surpluses and consumers belonging to the economically poor sections of the society.

The domestic support measures which are in conformity with the provisions of the Agreement may be the subject of countervailing duty auctions, but due restraint is to be exercised by members in initiating such investigations. Further, in so far as the support provided to individual products does not exceed that decided in the 1992 marketing year, these measures are exempt from other subsidy auction or nullification or impairment action. Export subsidies conforming to the Agreement on Agriculture are subject to countervailing duty actions, but here, also due restraint is to be exercised by members in initiating such investigations. The peace clause remains in effect for a period of nine years from 1995, that is, the entry into force of the WTO Agreement.

5.9.1 Proposals for tariff reduction formulae
- Linear reduction with DCs making two third cuts of developed countries
- Tariff peaks tackled by specifying that no rate should exceed three times the national average.
- Notion of 2/3 derives from previous rounds e.g. URAA had linear cut of 36 percent for developed countries and 24 percent for DCs.

5.9.2. Issues facing developing countries
Trade Liberalisation and Development
Trade liberalisation:
- Improves efficiency in the allocation of resources, increases welfare and can contribute to economic growth
- Can induce short-term negative adjustment costs

ii. Special and differential treatment
- Means lower tariff cuts and longer transition periods for DCs and LDCs
- Need a detailed elaboration of how to handle this
iii. Preference erosion

- Reductions in tariff rates in developed countries will lead to changes in preference margins which many DCs (especially LDCs) benefit from
- May require compensation e.g. Malawi (tobacco and sugar preferences)

iv. Tariff revenue

- Tariffs are an important source of revenue for many DCs
- (75% for Guinea, 28% for Cameroon, 20% for India)
- Revenue impact of tariff reductions depends on increased demand for imports
- Revenue losses would need to be replaced with non-trade taxes => long-term process that can be expensive to implement

5.10.1 India’s response to the ongoing proposals

The government of India has initiated Market Access Initiative (MAI) Scheme which is an Export Promotion Scheme envisaged to act as a catalyst to promote India’s exports on a sustained basis, during the Tenth Five Year Plan. The scheme is formulated on product-focus country approach to evolve specific strategy for specific market and specific product through market studies/survey. Assistance would be provided to Export Promotion Organizations/ Trade Promotion Organizations/ Exporters etc. for enhancement of export through accessing new markets or through increasing the share in the existing markets. Under the scheme the level of assistance for each eligible activities has been fixed.

The following activities are eligible for financial assistance under the scheme:

- To identify the priorities of research relevant to the department of commerce and to sponsor research studies consistent with the priorities;
WTO Studies for evolving WTO compatible strategy;
To support EPCs / Trade Promotion Organisations in undertaking market studies / survey for evolving proper strategies.
To support marketing projects abroad based on 'product-focus' country approach. Under marketing projects, the following activities are funded:
(a) Opening of showrooms
(b) Opening of warehouses
(c) Display in international departmental stores
(d) Publicity campaign and brand promotion
(e) Participation in trade fairs, etc., abroad
(f) Research and product development
(g) Reverse visits of the prominent buyers etc. from the project focus countries
   - Export potential survey of the states
   - Registration charges for product registration abroad for pharmaceuticals, bio-technology and agro-chemicals;
   - Testing, charges for engineering products abroad;
   - To support cottage and handicrafts units; and
   - To support recognized associations in industrial clusters for marketing abroad

5.11 The government's point of view
While the government along with foreign multinationals is keen to implement the agreement, it has faced resistance from local drug manufacturers and consumers.

The Indian Drug Manufacturers Association (IDMA) protested in 1994 “prices of drugs shall go up by 5 to 20 times as a consequence of accepting the TRIPS [Trade-Related Aspects of Intellectual Property Rights] proposals”
However, the government claimed, "once the crutches of weak patent law are removed, they can successfully negotiate with research-based international companies ... to boost export earnings, create more employment ... and benefit from the transfer of technology". The government had some reservations about the TRIPS Agreement. But it signed the deal, taking the view that the package of agreements in all areas of trade — the result of the 1986-94 Uruguay Round of negotiations — was on balance in India’s interests.

"The crux of the matter is that when the world is moving in one direction, it makes no sense for India to move in the opposite direction. At best, India can seek amelioration, which it has done successfully", said A.V. Ganesan, Indian commerce secretary, in 1993.

This is not happening overnight. As a developing country, India had a ten-year transitional period (until 2005) for giving full patent protection for pharmaceutical and agro-chemical products. It also had until 2000 to comply with other aspects of the TRIPS agreement. These provisions are designed to allow India and other developing countries time to adjust.

5.11.1 The fear drug prices to rise dramatically
In 1975, then Prime Minister Indira Gandhi, declared, "medical discoveries will be free of patents and there will be no profiteering from life and death". Some Indians fear that costs of medicines will rise as a result of royalty payments and increased prices for products manufactured under license. Local companies could face foreign competition. After India ratified the WTO agreements, the press accused the government of "selling out to rapacious multinationals" and "making Indian patients pay for the sell out".

However, recent evidence suggests that these gloomy predictions are largely unfounded. Firstly, as mentioned earlier, India has been granted breathing
space in the form of a ten year transitional period before it is obliged to enforce patent protection for drugs.

However, from 1995, developing countries that do not provide patent protection for pharmaceuticals and agricultural chemicals still have to do two things. They have to set up a mechanism (known informally as a “mailbox”) that allows inventions to be notified to the patent authorities — this is a way of establishing that the invention is “new”, an important criterion for granting a patent once the system for patent protection is eventually set up. And if the country allows the new drug to be marketed, the right has to be given exclusively for a period to the company that invented it.

The EU and US have filed two separate cases against India in the WTO on the grounds that it has not fulfilled these obligations under the TRIPS Agreement. Cases are pending — rulings have been made, and the disputes are in the stage when India is required to take action to conform to its commitments under the TRIPS Agreement.

One result of the transitional clause is that patent protection will have limited impact on the Indian drug industry until the year 2005. Even then, the impact will be limited as India is starting from a point of virtually zero patent protection in the sector.

One recent estimate suggests that only 15 percent of the Indian drug market will be covered by patents after 2005 and be subjected to price premiums as a result. The remaining 85 percent of the market will continue to be exposed to “the full impact of generic [i.e. non-brand name drugs] competition, to which patented products will themselves ultimately contribute when their patents expire”. Moreover, as the TRIPS Agreement does not allow for backdating, drugs already in the market will be exempt from patenting.