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Agreement on TRIPS and Public Health

Introduction

As we have noted in Chapter 1, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was added to the body of multilateral rules in 1995 when the WTO was established. The inclusion of the Agreement on TRIPS in international trade rules had been a matter of some controversy from the time when initial proposals were made for the adoption of an instrument at the time the Uruguay Round was being launched. A number of countries, mainly the developed ones, considered that with the increasing technological content of products traded internationally, and in order to stimulate and facilitate international trade, it was necessary to develop rules on trade-related aspects of intellectual property rights, such as patents, trademarks, copyrights and industrial designs. They also considered the adoption of rules in this area was also necessary to bring under control the growing international trade in counterfeit goods (goods that are marketed using trademarks to which the seller has no right) and pirated goods (goods that infringe copyright and other rights).

This desire to include intellectual property rights in the Uruguay Round was not shared by developing countries. They contended that since intellectual property provides 'monopoly rights' to the holders of patents and other property rights within the full scope of trade law, including it would result in an anomalous and iniquitous situation, especially as the main objective of the existing multilateral trade framework was to create conditions that would enable producers to compete freely in world markets by removing tariffs and other barriers to trade.

The TRIPS Agreement that was nevertheless concluded in the Uruguay Round is intended as a complement to the international conventions developed over the years by the World Intellectual Property Organization (WIPO). The Agreement stipulates minimum terms of protection that countries must grant to the various categories of intellectual property. Its provisions have therefore to be applied in conjunction with those contained in the WIPO Conventions. For example, rules relating to patents have to be read with the relevant provision in the 1883 Paris Convention, the 1970 Patent Cooperation Treaty[1] and the 1977 Budapest Treaty covering patents for microorganisms.

One of the major concerns of developing countries in relation to TRIPS has always been the impact its rules can have on prices, particularly the prices of pharmaceutical products and the ability of the governments in developing countries to make drugs available to their peoples at affordable prices. The issue of prices for patented drugs created controversy in public debate soon after the adoption of the TRIPS Agreement due to the high prices charged by the pharmaceutical companies for new drugs they had developed and patented for the treatment of diseases such as HIV/AIDS. These prices were perceived by many as being very high and, in any event, were outside the financial reach of millions of people in the developing world.

Against this background, the Geneva project assisted delegations in examining how the TRIPS rules could be clarified and improved to ensure that people in the developing world, including the poor, could access drugs at prices they could afford. The various papers explaining the complex rules of the TRIPS Agreement and describing the modifications that could be made in them, particularly in the rules applicable to 'patents' were consolidated into a Working Paper on TRIPS, which was widely circulated by the Commonwealth Secretariat in October 2001 (Rege 2001). The main points are summarised below.

International Rules on Patents

Exclusive rights of holders

Patents give the owners of inventions exclusive property rights. Manufacturers wishing to use patented inventions must obtain licences or authorisations from the patent owners, who normally require them to pay royalties. The Agreement clarifies these exclusive rights of patent owners. In particular it states that where a patent applies to a product, third persons can only make, sell or import the product with the consent of the owner. Where the patent covers a process, third parties cannot use the process, nor sell or import products directly obtained from using the process, without the patent owners consent.

The exclusive rights to sell or import implies that the patent holder can prevent third parties from selling an imported product for which they hold the patent, at prices lower than the prices being charged in the markets where the patent was registered.

The Agreement recognises that in cases where the process used in the manufacture of a product has been patented it is difficult for the patent holder to gather evidence on how the identical product introduced in the market by a third party may have been produced; in civil proceedings, the burden of proof would be on said third party to establish that the product has been produced using a process that is different from the patented process. In particular, the Agreement states that where the process is patented, in the absence of proof to the contrary, it shall be deemed to have infringed the patent owner's rights for exclusive use if the product was identical and new, and

if there was a substantial likelihood that the new product would have been produced by the patent owner using the patented process.

Criteria to determine whether an invention is patentable

Not all inventions can be registered as patents. The laws of almost all countries require that before an invention can be registered it must conform to the following criteria:

- It must be new (novelty test);
- It must involve inventiveness (non-obviousness test);
- It must be capable of industrial applications (utility test).

Even after these criteria are met the patent office must be satisfied that the applicant has provided information relating to his/her invention as would enable any person well versed in the field to understand it and use it in future research and analysis. The requirement for public disclosure of information balances two objectives of governments in granting patents. By giving exclusive rights to patent holders the governments provide an incentive to persons engaged in scientific research and reward their inventive work. At the same time by requiring the inventors to make public disclosure of information on their invention when applying for patent, the governments seek to ensure that the inventions are used for the benefit of the community at large and for further technological research and development.

While the information contained in the 'disclosure' can be employed for further research and analysis by universities and other organisations or by even competing business firms, it cannot be used for commercial purposes before the expiry of the patent. It is however open to those actors wishing to use the information to apply for a secondary patent, using as a base the earlier patented invention. Pharmaceutical firms planning to produce generic versions of patented drugs rely on such information to conduct experiments for stabilisation of the generic version in order to get market approval from the drug control authorities in advance of the expiry date for the patent. This helps them in introducing the generic version in the market immediately after the expiry of the patent.

In the Uruguay Round developing countries attached great importance to the inclusion of the provisions relating to disclosure as they considered that such information could be useful to them in producing generic versions. Article 29 of the Agreement imposes an obligation on members to disclose in their patent applications, in 'sufficiently clear and complete form', such information as would enable a person skilled in the art 'to carry out the invention', and the best-known method for doing so.

In pursuance of these provisions, the Patent Office could require the applicants to disclose, against the setting of the present 'state of art' in the relevant field of technology; the essence of the invention, (including where relevant the chemical composition,

specifications, proportions, techniques and drawing) its essential novelty and the scope of the claim. The test the patent office would generally apply in determining the adequacy of disclosure, is to examine whether given the conditions prevailing in the country the information provided is sufficient 'to enable the local experts to reconstruct the invention through reengineering'.

Coverage of products

The TRIPS Agreement imposes an obligation on countries to grant patents for invention in all 'fields of technologies' and for both products and processes including those used in manufacturing.

Limitations applicable to exclusive rights

The exclusive rights of patent owners are however subject to three limitations. First, the exclusive right is territorial in that the patent holder can only claim it in countries where he/she has registered. Second, exclusive rights are exhausted after the patent holder sells the product to a wholesaler or trader, or gives a licence to another manufacturer to produce the patented product. The patent holder cannot then prevent the wholesaler, trader or manufacturer from selling it at prices lower than that being charged by makers with whom he/she has patent rights.

Third, the right is limited in time. In order to ensure that patent owners get a reasonable period of time to enjoy their exclusive rights and recover any research costs incurred, the TRIPS Agreement provides that the patent owner should have exclusive rights for a uniform period of 20 years from the date of the filing of the application for obtaining the patent. These provisions were perhaps the most controversial in the negotiations on the TRIPS Agreement. In the pre-Uruguay Round period legislation in a number of developing countries provided patentability exclusion for pharmaceutical products and processes. About 31 developing countries that had excluded pharmaceutical products from patentability and eight others had excluded the process used in the manufacture of such products from patentability. Most of the developing countries provided a period of protection of five to seven years for patented pharmaceutical products while in most of the developed countries the industry was able to obtain protection for a period of 15 to 20 years (Wattal 2001).

In the case of the developing countries these were conscious decisions that reflected the prevailing thinking about the adverse effects patent protection in sectors like pharmaceuticals and agricultural chemicals could have for their developmental and social policies. These countries also considered that they were under obligations to provide health-care facilities and to make available to their people drugs needed for the treatment of diseases prevailing in their territories either free of cost or at prices the poorer sections of the population could afford.

In countries where the pharmaceutical sector was excluded from patents, industries could produce patented products through re-engineering by using the information contained in the 'disclosure' made at the time of applying for the patent. In countries with shorter patent protection periods, substitutes copied from patented products were introduced in the domestic markets immediately after the expiry of the protection periods. As a result some of the developing countries such as Argentina, Brazil and India developed their own pharmaceutical industries, supplying low-priced generic versions of patented products to their people and even exporting some of these products to countries where the patent holders had not registered their patents. In most cases the governments adopted regulations and controls to maintain prices at reasonable levels.

Most of the developing countries were apprehensive that the removal of the flexibility to provide shorter patent periods would lead to price increases and thus compromise their ability to provide affordable drugs. But their pleas to retain the flexibility provision, at least for pharmaceuticals and agricultural chemicals, were completely ignored; it was decided that all countries should be required to provide a uniform protection period of 20 years. They were, however, given transitional periods of 5-to-10 years from 1995 when the Agreement became operational in which to modify their national laws and rules in line with the rules of the TRIPS Agreement. This transitional period has now expired. The least-developed countries have until 2016 to apply the provisions of the Agreement.

Proposals to Improve Patent Rules

Compulsory licence

The TRIPS Agreement leaves it open for a country to compel the patent holder to grant a licence to a domestic producer to manufacture and market the patented product in the country. A compulsory licence may be granted in the following (or similar) situations:

- A national emergency resulting from unreasonably high prices of pharmaceuticals or other essential products;
- Abuse of exclusive rights through refusal to activate the patent or insufficient activation;
- Protection of public health and nutrition;
- Promoting the public interest in sectors of vital importance for socio-economic development;
- Facilitating transfer of technology; and
- Anti-competitive behaviour.

However the TRIPS Agreement also places restrictions on the granting of such licences by laying down rules relating to their use and duration. These are as follows:

- Compulsory licences should be granted only after the failure of efforts by a private firm to obtain a licence from the patent holder to manufacture the product at reasonable commercial terms;
- They should be granted 'predominantly' for the supply of the domestic market;
- Remuneration that is considered adequate (taking into account the economic circumstances of the country granting the licence) must be paid to the patent holder; and
- The granting of a compulsory licence should not affect the patent holder's right to grant a licence on a voluntary basis to other firms or to commence production themselves.

However, for most of the low-income and least-developed countries and small economies the right of the governments to apply a compulsory licence is of no meaningful advantage as most of them do not have a pharmaceutical industry with enough skills and resources to produce a generic version of a patented product. It is those countries with well-established pharmaceutical industry that can take advantage of the provisions to produce generic versions under compulsory licences.

Proposals on exports under compulsory licence

As noted earlier the TRIPS Agreement provides that the production under compulsory licence should be undertaken 'predominantly' for the domestic market. The question was how should the term 'predominantly' be interpreted? Should it be interpreted to permit at least some exports? Some commentators held that the term should be interpreted broadly to allow exports of 50 per cent or more while others argued for a small percentage. However, such exports could take place only to countries where the patent holder has not registered the patent.

The working paper prepared under the Geneva project (Rege 2001) suggested that pharmaceutical firms producing under compulsory licences could export part of their products subject to the following conditions (and taking into consideration product and territorial limitations):

- The flexibility to export would be available only in respect of a limited number of pharmaceutical products manufactured under compulsory licences. The scope could be confined to those products designated as 'key pharmaceuticals' in the World Health Organization's model list of essential drugs.
- The countries to which export of such key pharmaceutical products may be allowed could be selected using the same criteria used for selection of countries

eligible for receiving pharmaceuticals under the WHO differential price system. One of the criteria for a country to participate in the system is that it must be eligible for loans granted by the World Bank International Development Association (usually applies to countries with a per capita income of less than US$885).

- The governments granting the compulsory licence must ensure that adequate 'remuneration' in the form of royalty is paid to the patent-holding company. One of the factors to consider in determining the level of remuneration should be whether or not the government granting the licence wishes to authorise exports. However, any such authorisation should be limited to exports for low-income countries listed under the WHO differential pricing system.

It was further suggested that where a pharmaceutical product is produced by an industry under compulsory licence in a country belonging to a regional economic grouping, it should be allowed to export such a product to other member countries. However this principle should apply only to those regional groupings in which all members are developing countries. Any such flexibility would provide an incentive to foreign pharmaceutical firms to establish production units in developing countries that have no manufacturing capacities, if the governments agree to give them a compulsory licence to produce the patented product. One issue foreign firms have in locating production facilities in developing countries is the small size of the domestic market, so wider access to regional markets would further encourage investments.

Affordable Medicines for Countries with no Manufacturing Capacities

The ideas and proposals contained in the working and other papers prepared under the project assisted the members of the Group in pressing for solutions to the problems faced by developing countries with no manufacturing capacities in providing medicines for the treatment of diseases prevailing in their territories.

The Declaration on TRIPS and Public Health, which was adopted in November 2001 during the launching of the Doha Round, affirmed that each WTO member country had a right to decide the grounds on which compulsory licences could be granted. But it also recognised that a large number of countries with no capacities for manufacturing pharmaceutical products could face difficulties in using compulsory licensing to provide the necessary medicines at reasonable prices. It called on the WTO Council on TRIPS to find 'an expeditious solution' to the problem.

Decision on access to medicines

The negotiations that took place in pursuance of this mandate resulted in the adoption of the Decision on Access to Medicines (30 August 2003). The Decision, which is

largely based on the proposals contained in the working paper (Rege 2001), creates a framework for 'production for export' of patented products under compulsory licence. For this purpose it divides the countries into two categories: countries with manufacturing capacities (referred to as 'exporting countries') and countries with no, or insufficient, manufacturing capacities (referred to as 'eligible importing countries').

All least-developed countries are treated as eligible importing countries. The developing countries, in order to be eligible as importing countries, have to meet the criteria laid down by the Decision to determine that they have at present no, or insufficient, capacity to manufacture the pharmaceutical products they wish to import.

The Decision authorises the governments of the exporting countries to grant a compulsory licence for production for exports to an eligible importing country or countries, subject to the following conditions:

- The production under the licence is limited to the amount required by the eligible importing member or members;
- The entire amount produced under each licence should be exported to the member countries;
- Products produced under the licences are be clearly distinguished through inter alia special packaging, and/or shaping of the products or colouring to ensure identification of the products in the event of diversion for sale in countries other than the eligible importing countries.

The Decision further imposes an obligation on the governments of exporting countries (and also exporting firms) and on the governments of the importing countries to notify the WTO. The basic purpose of these notification obligations is to ensure transparency in relation to production for export under compulsory licences and that there is no diversion of such exports to countries other than the importing countries.

The Decision incorporates the working paper proposal that a country with no manufacturing capacity that grants a compulsory licence to a foreign firm to produce a generic version of a patented product by establishing manufacturing plants in its territory could export such generic versions to other countries in the regional group to which it belongs. To encourage production on this basis the Decision calls on both exporting and importing countries to 'use the system' it has created for 'promoting transfer of technology for capacity building pharmaceutical products' in countries with no manufacturing capacities. It should be noted however, that the flexibility provided by the Decision is available only where:

- At least half of the current members of the regional grouping are LDCs;
- The member country to which products are exported shares the same health problem;

- The territorial nature of the patent right is respected by ensuring that where the 'original product' is under patent in a member country the generic version is exported only if a compulsory licence to import it has been issued by that country.

The Decision has subsequently been used to amend the provisions of Article 31 of the TRIPS Agreement.

Workshop on WTO Decision

After the adoption of the Decision a workshop was arranged in Geneva (12–14 October 2004) to assist developing countries in meeting challenges that may be encountered in its implementation. To encourage the widest possible participation of developing countries it was held in co-operation with the ACP Group and the Agency for International Trade Information and Co-operation (AITIC).

Discussions were based on case studies prepared by national experts on intellectual property regulations from nine Commonwealth developing countries (Barbados, Bangladesh, India, Jamaica, Kenya, Mauritius, South Africa, Tanzania and Uganda). The case studies focused on the steps that may have to be taken at national level to facilitate exports and imports of generic versions of patented pharmaceutical products produced under compulsory licences, granted in pursuance of the provisions of the Decisions. Following is a summary of the report on the workshop discussions (Rege and Kataric 2005):

Quality, safety and effectiveness of products

Most countries prohibit the marketing and sale of pharmaceutical products unless the products have been properly registered for sale in their domestic markets. Such registration is granted only after the health regulatory authorities have evaluated the product and found that it has been produced at sites meeting the recommendations and standards of good manufacturing practices, and that the product meets quality, safety and effectiveness standards.

For approval of drugs introduced in the market for the first time, the regulatory authorities require the manufacturer to submit information on the product – for instance chemical composition, packaging and labelling, and the results of tests undertaken on animals and of clinical studies undertaken on human beings to determine, inter alia, the maximum tolerated dose, the pharmacodynamic effects and the adverse effects, if any.

Regarding generic versions of products that are not already on the market, manufacturers are not required to undertake such clinical trials or tests on animals. They are only required to submit evidence confirming that the generic product is 'therapeutically

equivalent' to the innovative product and of the same quality, efficacy and safety level to be considered 'interchangeable' with the innovative product. For this purpose, the manufacturer is generally required to undertake studies to establish its stability and carry out clinical studies on a limited number of healthy patients in order to establish *in vivo* bio-equivalence of the generic version to the innovative drug.

For imported generic versions the practice in most developing countries is to grant registration and marketing authorisation for sale and use in the domestic market, on the basis of evidence presented by the importer that the product has already been authorised for marketing in the producing country.

For this purpose, most of these countries require the interested importer to obtain a certificate from health authorities in the producing countries, that the product has been granted authorisation for marketing in their territories, following the procedures of the WHO 'Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce'. The drug regulatory authorities in importing countries carry out detailed evaluations of the product and test data submitted by the manufacturer, before granting approval only in relation to products for which the manufacturer has not obtained marketing authorisation for sale in the country of production.

In this context it is important to note that while almost all countries producing pharmaceutical products require that both domestically produced and imported products must be approved for sale in the domestic market, not all require manufacturers to obtain such approval for products produced exclusively for export. Therefore the responsibility for undertaking evaluations of the generic versions of such products lies with the registration and regulatory authorities in the importing countries.

The WTO Decision on Access to Medicines requires that production should be undertaken only for exports to eligible importing countries that have notified the WTO of their requirements. In relation to such products, national legislations of most countries with production capacities do not presently require manufacturers to secure approval from the drug regulatory authorities in their countries, of the quality, efficacy and safety of the products that will be exported. However, the countries with no or insufficient manufacturing capacities, which would be importing these products, would not be able to carry out effective evaluations to establish that the products meet required standards, as the regulatory authorities do not have access to qualified and trained human resources and adequate well-functioning laboratory facilities. Some of them have not even been able to establish regulatory authorities.

Against this background the workshop proposed the following guidelines to ensure that the products produced and exported under compulsory licence meet the required quality, effectiveness and safety standards:

- Legislation and other regulations adopted should provide that the producing country would allow the export of products produced for export in accordance with the provisions of the Decision only after drug regulatory authorities have evaluated them and found to meet the quality and safety standards of the patented products.
- The country wishing to import such products could request the drug regulatory authorities of the producing and exporting country to make such an evaluation.
- The compulsory licence for exports should impose conditions stipulating that exports could be made only after being evaluated by the drug regulatory authorities and approved for sale.
- The exporting and importing countries may agree to rely on the WHO system for pre-qualification of pharmaceutical manufacturers and their products.

In this context the workshop noted that Canada, where previous patent legislation did not require manufacturers to obtain marketing approval for products produced solely for export, had amended its legislation to provide that generic versions produced for export to developing and least-developed countries must be approved by its drug regulatory authority before they are exported. The amendments further called on the authority to apply the same regulatory process to such products as is applied to products intended for sale in the Canadian market.

The workshop also discussed the feasibility and appropriateness of importing countries using the WHO system for pre-qualification of manufacturers and their products. The WHO representative informed the meeting that the evaluation of the quality of the medicines and of the manufacturing sites are made by the world's leading regulatory agencies, approved by the WHO Expert Committee on Specifications for Pharmaceutical Preparations. For this purpose the interested manufacturers are requested to provide comprehensive data on quality, safety and efficacy of their products, including the purity of all ingredients used in the manufacturing process. Furthermore, they are required to provide data on finished products, such as information about clinical trials conducted on healthy volunteers. If the evaluating authority finds the data satisfactory the products are sent to professional control testing laboratories, contracted by WHO in France, South Africa or Switzerland, for analytical verification of the quality. Simultaneously, an inspection team visits the manufacturing site to assess compliance with WHO Good Manufacturing Practices (GMPs) in the production of pharmaceutical products. If the products meet the specified requirements and the manufacturing site complies with the GMPs, both the products and the manufacturing site is included in the WHO list of pre-qualified manufacturers and products.

The list was originally intended for use by the United Nations procurement agencies but over time it has become a useful reference tool for non-governmental organisations and agencies as well as for countries in making bulk purchases of medicines. Therefore, it should be possible for any country importing pharmaceutical products in accordance with the provisions of the Decision, to require the exporting manufacturing firm to have its products and manufacturing site evaluated and approved under the WHO pre-qualification scheme. The estimated time for completion of the process is three months.

Another feature of the WHO system is that pre-qualified products are kept under continued surveillance and the firms are required to withdraw the products from the market if they no longer meet the required quality standards.

Steps to improve the effectiveness of regulatory systems

The meeting briefly discussed the steps that could be taken to assist developing countries in improving the effectiveness of their regulatory systems for registration and marketing approval, and post-market surveillance of products.

The workshop noted that an analysis of the information in case studies submitted by the participants suggested that in relation to quality developing countries encountered two sets of problems. First, in a number of medicines the contents of active ingredients were either too low or too high and a few failed to meet the required dissolution and stability standards. Second, in some of the countries there was a large quantity of counterfeit goods produced either locally, or brought into the country illegally.

WHO organises workshops and training of inspectors to assist developing countries in building up effective regulatory systems for granting of marketing approvals and for post-market surveillance of the products sold in the countries. The countries could also utilise the WHO manuals for drug regulatory authorities and background documentation on the system for pre-qualification of products and manufacturers, to build up their own systems for marketing approvals and for post-market surveillance. The WHO representative noted however that the main effort for building up a system of inspections and control must ultimately be made by the countries concerned if they wished to ensure that domestic and imported products meet the required quality standards.

Guidelines on the level of remuneration

The meeting discussed whether guidelines could be elaborated for future national laws with the purpose of facilitating the implementation of the specific provisions of the WTO Decision, on the remuneration issue. Each country should have the freedom to determine the appropriate level of remuneration to be paid, taking into account the provisions of the Decision. These provisions allow that the exporting

country, when granting a licence for production under a compulsory licence, shall decide the level of remuneration to be paid by the licensee to the patent-holder taking into account the 'economic value to the importing member of the use of the patent right that has been authorised'.

In this scenario it may be appropriate for the exporting country to seek information from the importing country on how the medicines would be supplied. For instance, would they be free, and if not, what price would be charged? Is the price comparable to that of the patented product in the country of origin? What are the prices of substitutes or other generic versions available in the country?

Some participants pointed to an emerging consensus on the capping of royalty payments in the range of 4–5 per cent. In this context, it was mentioned that the sliding scale for determining royalty payments adopted by Canada, using the United Nations 'Human Development Index' (UNHDI) system, could provide a useful basis for further examination of the criteria that could be used in determining the level of remuneration. Under this criterion the royalty payable by the patent holder to a firm producing for supply to the eligible country with the lowest standing on the UNHDI would be 0.2 per cent. Mathematically, the criterion cannot result in a royalty rate in excess of 4 per cent. This ceiling was considered to be consistent with the humanitarian and non-commercial considerations for which the WTO Decision on Access to medicines was adopted.

Development of regional trade and production

The Decision provides additional flexibility to developing countries belonging to regional economic groupings of which 'at least half of the current membership' is made up of 'countries presently on the United Nations list of least-developed countries'. The basic objective of this additional flexibility is to harness 'economies of scale' for the purpose of enhancing purchasing power for, and facilitate local production of, pharmaceutical products.

The Workshop discussed the development of regional trade and production in accordance with the above provisions. The main points discussed are summarised below:

General issues

A number of participants noted that by limiting the application of the rules on development of regional trade and production to member countries of regional economic groupings in which at least a half of the members are LDCs, the Decision prevented regional developing country groupings in regions other than Africa from taking advantage of this additional flexibility. Therefore, it would be necessary to review these provisions at an appropriate time to examine whether this additional flexibility could be extended to member countries of other regional economic groupings of developing countries.

Co-operation between countries: pooling import requirements

One co-operation possibility for member countries of the regional economic groupings is to 'pool' their import requirements of pharmaceutical products and issue joint tenders in order to benefit from discounts available on bulk purchases. One of the most successful systems in this respect, the OECS Procurement Services System (PSS), enabled Member States to obtain drugs at prices as low as 40 per cent of the price they might have been charged if each country had purchased drugs individually.

But even though procurement of pharmaceutical products on a pooled basis may result in price and other advantages for each individual country many countries were reluctant to take part as they wished to retain the right to make decisions themselves on the specific product to be imported (patented or generic), taking into account their price and quality.

Despite this general reluctance the meeting considered it would be desirable for countries belonging to eligible regional economic groupings to co-operate in purchasing pharmaceutical products produced under compulsory licences issued in accordance with the provisions of the Decision. Since the producing firms are not expected to sell such products in the domestic market or to export it to any other country than that indicated in the licence, the costs of production for manufacturing relatively small quantities, required by one or two importing countries, is likely to be high. In this situation, negotiating for price and other conditions on the basis of pooled requirements of countries in the region may result in lower prices, as the firm would be able to derive advantages of 'economies of scale' by being able to produce larger quantities.

Intra-regional trade in imported products

The meeting noted that some trade in pharmaceutical products (both in imported and domestically produced products) was taking place among member countries of regional economic groupings but the level of such trade was low compared to the total imports. One of the obstacles to developing trade arose from differences across countries in the regulations relating to manufacture, import, export and distribution of pharmaceutical and health products. The meeting noted the need, therefore, for collaboration among regional trading blocks to harmonise drug licensing and requirements relating to good manufacturing practices (GMP), enter into arrangements for mutual recognition of marketing approvals of drug inspections, and create free port facilities to act as a hub for re-exports to neighbouring countries. In addition, they would have to take steps to comply with the conditions of the Decision, which would have to include measures to ensure that products are re-exported only to member countries that 'share the health problem in question'.

Development of production to meet regional health needs

The workshop noted that development of a pharmaceutical industry requires not only the existence of a physical infrastructure (e.g. availability of electricity and clean water), but also availability of chemists, pharmacists and persons trained in related scientific fields as well as laboratory and other facilities to undertake research on production of both new and generic drugs. Participants exchanged views on the type of incentives that governments of countries wishing to establish a pharmaceutical industry could provide to encourage development of human resources and other required facilities, and those that the governments of countries with well-established pharmaceutical industries could provide to their firms, to encourage them to transfer technology and establish production capacity in countries with no or insufficient manufacturing capacities. They also discussed steps that would have to be taken to ensure 'resource sharing', 'industrial complementarity' and 'industrial co-operative activity' among the countries of regional economic groupings in developing the pharmaceutical industry.

Box 14 lists specific measures that the workshop participants suggested could be taken at national level for development of production on a regional basis.

Box 14: Measures for the development of production on a regional basis

A. Undertake background studies to:

- Take stock of the patent protection regimes in countries in the region;
- Make an inventory of the existing patents in these countries;
- Assess the needs of individual countries of the variety and volumes of patented and generic drugs.

B. Steps for development of production at national level

- Promote joint ventures on the basis of public–private partnerships aimed at limiting financial commitments and risks.
- Grant tax incentives on profits over a number of years.
- Waive custom tariffs on essential equipment and material.
- Make available purpose-built buildings for the commissioning of factories.
- Create awareness among entrepreneurs through industrial pharmaceutical forums, exhibitions and similar events.
- Limit control on the prices of selected classes of non-essential drugs.
- Adopt comprehensive preferential treatment clauses in legislations dealing with national procurement of goods for local manufacturers.
- Encourage foreign enterprises to delocalise parts of their services, e.g. accounting or invoicing, to a developed country.
- Carry out or assist companies in undertaking marketing studies in the region.
- Create regional directories of industries, particularly those supporting pharmaceutical industries.
- Create and maintain a database of regional manufacturers to avoid duplication.
- Determine a 'break even point' for the cost effective production of each drug.
- Exchange information on drug requirements of countries in the region, their sources of supply and impediments to sustained supply.
- Promote local pharmaceutical industries in regional trade fairs.
- Establish mechanisms to ensure complementarities throughout the chain of production and processes in drug manufacturing in the region to avoid duplication of efforts, investments and scarce resources.
- Encourage co-operation with countries, particularly developing countries that have developed a pharmaceutical industry, such as China, Egypt, India and Malaysia.

Note

1. An international patent law treaty that provides a unified procedure for filing patent applications to protect inventions in each of its contracting states.

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