Essential drugs in the new international economic environment

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Recent global developments in the regulation of trade and intellectual property rights threaten to hinder the access of populations in developing countries to essential drugs. The authors argue for state intervention in the health and pharmaceutical markets in order to guarantee equitable access to these products.

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Globalization and health

The term "globalization", as well as describing current world economic trends, prescribes a strategy of development based on the liberalization of markets and on the assumption that the free flow of trade, finance and information will produce the best possible outcome for economic development. However, as the Human Development Report for 1997 pointed out, "globalization has its winners and its losers. With the expansion of trade and foreign investment, developing countries have seen the gaps among themselves widen.... Poor countries often lose out because the rules of the game are biased against them, particularly those relating to international trade. The Uruguay Round hardly changed the picture" (*1*)

Globalization has serious implications for states, particularly for the role of the state in developing countries where the imperative to liberalize has led to reduced state involvement in the social sectors. The opening up of markets has, for instance, limited the possibilities for governments to subsidize health services for the poor. After a drastic privatization process, many states have become too weak to oppose powerful international groups (*2*). Structural adjustment programmes and globalization seem to weaken state influence, and current world trends clearly demand stronger states to preserve people's rights and maintain equity of access to the social sector, particularly to health services and drugs.

New international rules on drug patents

The Uruguay Round of negotiations on multilateral trade led to the creation of the World Trade Organization (WTO), which became operational in January 1995. Its purposes are to help the smooth flow of trade in a system based on mainly non-discriminatory rules, to settle trade disputes between governments, and to organize trade negotiations. It also supervises global trade agreements that were negotiated and approved during the Uruguay Round, which are essentially contracts binding all Member States to keep their trade policies within agreed limits.

Among these agreements, the Agreement on Trade-Related Intellectual Property Rights (TRIPS) links intellectual property and trade issues for the first time and provides a multilateral mechanism for settling disputes between states on intellectual property. This Agreement is the most comprehensive ever reached on intellectual property. It establishes minimum universal standards for almost all rights in this field (such as copyrights, patents, and trademarks) including patent protection for pharmaceutical products, which may have a significant impact on access to drugs in developing countries.

The purpose of intellectual property laws is to protect and reward inventors. Inventors who file patent applications in a particular state are asking that state to recognize their exclusive right to inventions within the state's territorial boundaries, and therefore to exclude others from the use of the inventions without the inventors' authorization and the payment of compensation (i.e. royalties). Because knowledge, unlike consumer goods, can be shared by any number of persons without being diminished, inventors are dependent on such legal protection against direct copying or use of the products or processes they have invented. The adoption of new international rules on the matter has been actively promoted by most industrialized countries in order to obtain worldwide protection for the innovations they generate.

The TRIPS Agreement provides minimum standards for the protection of intellectual property, and each Member State of WTO is required to incorporate these into its own laws before specified transitional periods have elapsed. Provisions in the TRIPS Agreement regarding patents, trademarks, health registration data and other items set the basic framework that virtually all countries are expected to follow, or they may be claimed before the WTO

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dispute settlement body. Some provisions of the TRIPS Agreement are controversial in the area of health care and pharmaceuticals, especially for developing countries.

Under the TRIPS Agreement, all WTO Member States have to make patent protection available for at least 20 years to any invention of a pharmaceutical product or process which fulfils the criteria of novelty, inventiveness and usefulness. This provision only applies to inventions for which a patent application was filed after 1 January 1995, and consequently is entirely prospective, excluding products "in the pipeline". (The protection of products in the pipeline would include patent protection for any patent applications made abroad prior to the date of the introduction of product patent protection in the patent law.) However, because some countries did not previously have any patent protection system for pharmaceuticals, the TRIPS Agreement allows them a 10-year transitional period in which to amend their patent legislation in compliance with the new rules. Countries that choose to delay the introduction of TRIPS-related patent laws and currently do not offer product patent protection therefore have to provide a mechanism to store patent applications for products invented after 1 January 1995. Such applications will remain unprocessed in a "mailbox" until the countries introduce new patent laws giving product patent protection. They are required to do this by 2005 at the latest.

In the past it was considered the right of each nation to determine such laws. Prior to the TRIPS Agreement, many developing countries did not make patent protection available for pharmaceuticals, in order to permit the manufacture of copies and generic equivalents of drugs at reduced prices. According to a study commissioned by UNIDO on pharmaceuticals, "the contrasts between industrialized and developing countries are sharpest in the case of patents. Almost all industrialized countries grant patents on both products and processes typically for a period of 20 years. The practice in developing countries is more varied. Only 45% of the countries studied grant product patents and these are usually valid for a shorter period of time than in industrialized countries. Patents on production processes are more common in developing countries, although, again, the period of validity is comparatively brief" (*3*). Such non-patent regulation for pharmaceuticals helped some developing countries to build an indigenous pharmaceutical industry based on imitative cheaper drugs. Some developed countries used to have the same kind of approach and thus managed to create powerful pharmaceutical industries.

If one looks at the global picture of intellectual property protection and economic development one finds that patent rights remain weak until countries reach a certain stage of economic development, when they are strengthened. This issue concerns the effect of intellectual property rights on the ability of firms in developing countries to climb the technological ladder. In the past, how did countries move from being technological followers to leaders? What role does imitation play in the early stages of development? How do countries move from imitation to innovation and so climb the ladder? In this context, what is the role of intellectual property rights?

During their industrial development, many industrialized countries had weak patent protection in vital sectors, such as pharmaceuticals, in order to strengthen their industrial and technological capabilities. It was only after they attained sufficient technological development in certain areas that they considered strengthening their patent laws. In fact, "the patent system has been an instrument of national economic policy for the industrialization and technological advancement of a country" (*4*). It seems fair that developing countries should have the same flexibility of intellectual property rules while they are improving their technological capacity.

According to another statement by UNIDO, "the TRIPS Agreement may have a severe impact, especially in the high technology sectors such as pharmaceuticals, working to the disadvantage of developing countries in two main respects: domestic manufacturers wishing to produce and commercialize products covered by patents will be forced into licensing agreements involving royalty payments to patent-holders; while research and development activities may be hindered since the TRIPS Agreement is likely to inhibit *reverse engineering*, the process by which research-based industry products are copied and adapted for developing country usage." (*5*)

Means of ensuring equitable access to essential drugs

Developing and least-developed countries have been granted a period of grace of 5, 10 or 11 years, depending on their level of development, in which to amend their intellectual property laws in accordance with the standards of the TRIPS Agreement. Some of them (such as Argentina, Brazil, Mexico and Thailand), have already modified their patent laws; others still have to do so. However, in implementing the TRIPS provisions at national level there are some options for ensuring that the poorest populations have access to essential drugs. Two types of provision in the TRIPS Agreement may be used to protect public health goals: exceptions to exclusive rights and compulsory licensing.

Exceptions to exclusive rights

Article 30 of the TRIPS Agreement allows Member States to include in their patent laws some limited exceptions to the exclusive rights of patent-holders. This means that countries can decide on some specific cases or situations where the use of a patent without the consent of the patent-holder would not constitute an infringement. The following examples can be found in several existing laws at national and global level.

It is important to provide for exceptions relating to research and experimentation on inven-

tions, for scientific and commercial purposes, so as to facilitate innovation based on the improvement of protected inventions (*6*).

Another type of exception relates to the price advantage of generic products. Some countries allow tests to establish the bioequivalency of generic products before patents expire, thus helping generic manufacturers to put their products on the market as soon as expiry occurs. The so-called US "Bolar exemption" contained in the 1984 Waxman-Hatch Act allows a generic manufacturer to reference an innovator's safety and efficacy data in its application, and to manufacture a small amount of the product before patent expiry to demonstrate bioavailability. In addition, generic companies in Canada can also stockpile their drugs for marketing six months before the innovator's patent expires. Moreover, an amendment to the Israeli patent law goes far beyond giving Israeli companies the right to carry out research and development in order to file for regulatory approval in countries with similar legislation (Canada, Hungary, and the USA), even during the life of the Israeli patent (which typically lasts a year longer than the USA patent). This amendment allows manufacturers of generic drugs to supply raw materials to generic companies abroad for the purpose of registering drugs with different health ministries. This kind of regulation makes it possible for generics to gain faster access to the market and therefore gives populations increased access to cheaper drugs. Such exceptions to the exclusive rights of patent-owners are very important, given that brand-name firms "evergreen" their products by continually adding patents for minor variations to the list of patents still in force, thus extending the period of protection. Additional patents may, for example, relate to coatings, manufacturing processes, delivery systems and crystalline forms.

Parallel imports, permissible under the principle of exhaustion of rights, may also be listed in patent law as an exception to exclusive rights. For example, if a patented product is sold in country A for US$ 100 and in country B for $80, the principle of exhaustion of rights allows any interested party in country A to import the product from country B without the consent of the patent's owner (*7*). This arises because once a product has been legally put on the market the rights of the patentee are exhausted, since he/she has already exercised his/her rights in the matter. Imports of such patented products by a party without the authorization of the title-holder are generally known as parallel imports. This issue is of particular importance for developing countries wishing to ensure access to products on a competitive basis and therefore at a lower price.

Compulsory licensing

Article 31 of the TRIPS Agreement allows "other use without authorization of the right-holder". This refers to use by governments or third parties authorized by governments and is known as compulsory licensing. The TRIPS Agreement establishes a number of conditions for granting licences by public authorities, notably the need for case-by-case evaluation and decision, which means that the patent law cannot indicate in advance the specific cases in which compulsory licenses will be granted. However, the law may provide a basis for granting such licences, for instance on the grounds of public health, abuse of patent rights or the refusal of a voluntary licence from the patent-holder. Such reasoning should be based on Articles 7 and 8 of the TRIPS Agreement, which provide for "the promotion of technological innovation and the transfer and dissemination of technology", as well as "measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development".

New trends in biotechnology

States should also be aware of another critical current trend: the move towards monopoly control over a wide range of plants, animals, microorganisms and even genes, including human genes. While the biotechnology industry is based in the North, 80% of the world's remaining biodiversity lies in the tropical and subtropical regions of the South. The new global trade rules give this industry easier access to critical bioresources. Yet it has been argued that the patenting of human life, genes and biochemical processes will artificially increase the price of delivering health care to people. The phenomenon of biopiracy of the biological resources of developing countries is increasing in importance: Western multinational firms are patenting a variety of indigenous plants and seeds that have been grown and used for centuries by farmers in these countries.

The TRIPS Agreement requires Member States to provide patent protection for micro-organisms and for "non-biological and microbiological processes", "on the doubtful premise", says UNCTAD, "that the patenting of microorganisms and microbiological processes does not entail the protection of life forms". However, "the lack of consensus concerning biological patents allows countries considerable leeway in fashioning their policy options... States may limit the availability of patents for biological inventions by insisting on strict standards of novelty, utility, non-obviousness, and disclosure... despite tendencies to honour broad claims in some developed countries" (*8*).

Conclusions

Ultimately, the TRIPS Agreement appears to request Member States to treat pharmaceuticals like any other technological products in so far as the granting of patent protection is concerned. But drugs are not ordinary consumer products (*9*): they save lives, and if patients want to be cured they have to buy them.

Moreover, it is often the prescriber rather than the consumer who decides which pharmaceuticals should be purchased.

Patents may well have stimulated the discovery of new cost-effective drugs, although it does not follow that these have been affordable to all people. However, research and development in the pharmaceutical industry are subject to market imperatives, and consequently new drugs that come on to the market do not always meet the most pressing therapeutic needs of the majority of the population. The patent system in the private sector should not be seen as the only source of finance for pharmaceutical research. WHO should also encourage other sources, such as the public sector, to finance research and development in pharmaceuticals and to provide incentives for innovation in vital fields, for instance that of tropical diseases. Therefore, is it not time to consider the idea of an "Action Programme on Essential Research"?

As we have stated elsewhere, "the differences between the health/drugs and other markets (informational imbalance, limited competition, externalities and non-profit objectives) justify government/state intervention in the health and pharmaceutical market" (*2*). It is essential that all involved in the health sector be aware of the stakes and issues and that they play a role in the continuing process.

The new international economic and social context is likely to have an important effect on the equitable access of populations to health and drugs, especially in developing countries. The new rules on intellectual property could increase these countries' dependence. Each country's strategy regarding globalization in the field of the production and distribution of drugs should be incorporated into a national pharmaceutical policy within national health policy (*10*). ■

Résumé

Les médicaments essentiels dans le nouvel environnement économique international

On utilise le terme de mondialisation pour décrire les tendances économiques mondiales et pour préconiser certaines politiques et mesures. La mondialisation, ce sont les tendances économiques observées dans le monde d'aujourd'hui (accords de l'OMC, marchés communs infrarégionaux) et une stratégie de développement fondée sur la libéralisation des marchés et sur l'hypothèse selon laquelle la libre circulation des produits, des capitaux et de l'information crée les conditions les plus favorables au développement économique.

Les négociations du cycle d'Uruguay sur les échanges multilatéraux ont abouti à la création d'une nouvelle organisation internationale, l'Organisation mondiale du Commerce (OMC), qui est entrée en activité en janvier 1995. Elle supervise les accords sur le commerce mondial négociés et approuvés pendant le cycle d'Uruguay. Il s'agit essentiellement de contrats aux termes desquels tous les Etats Membres sont tenus de veiller à ce que leur politique commerciale ne sorte pas du cadre convenu. L'un de ces accords, l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC), associe pour la première fois propriété intellectuelle et commerce. Cet Accord est le plus complet jamais conclu dans le domaine de la propriété intellectuelle. Il fixe des normes universelles minimales pour presque tous les droits de propriété intellectuelle (droits d'auteur et de reproduction, brevets, marques de fabrique...) et prévoit notamment la protection des produits pharmaceutiques par des brevets, ce qui peut avoir d'importantes répercussions sur l'accès aux médicaments dans les pays en développement.

Dans le secteur pharmaceutique, aux termes de l'Accord sur les ADPIC, tous les Etats Membres de l'OMC doivent accorder la protection par un brevet, pour une période minimum de 20 ans, à toute invention de produit ou de procédé pharmaceutique, à condition qu'elle soit nouvelle, utile et qu'elle implique une activité inventive. Jusqu'à présent, on estimait que chaque pays avait le droit de légiférer en la matière. Avant le cycle d'Uruguay, beaucoup de pays en développement n'accordaient pas la protection par un brevet pour les produits pharmaceutiques afin de permettre la fabrication à moindre coût de copies et de médicaments génériques. L'absence de brevets pour les produits pharmaceutiques a permis à certains pays en développement de se doter d'une industrie pharmaceutique reposant sur la fabrication d'imitations moins chères.

Le nouveau contexte économique et social international devrait avoir une incidence majeure sur l'équité d'accès des populations à la santé et aux médicaments, en particulier dans les pays en développement. Les nouvelles règles concernant la propriété intellectuelle pourraient rendre ces pays plus dépendants. Quand ils appliquent les dispositions de l'Accord ADPIC au niveau national, les pays en développement doivent savoir qu'il existe des solutions pour garantir l'accès aux médicaments essentiels aux populations les plus démunies, car certaines dispositions de l'Accord sont destinées à protéger les objectifs de santé publique. Chaque pays doit donc intégrer sa stratégie face à la mondialisation de la production et de la distribution des médicaments dans sa politique pharmaceutique nationale, l'un des éléments qui composent la politique de santé nationale.

Resumen

Los medicamentos esenciales en el nuevo panorama económico internacional

El término globalización se ha empleado para describir las tendencias económicas mundiales y para prescribir ciertas políticas y acciones. La globalización hace referencia a las tendencias económicas que existen actualmente en el mundo (acuerdos de la OMC, mercados comunes subregionales) y propugna una estrategia de desarrollo basada en la liberalización de los mercados y en el supuesto de que el libre desarrollo del comercio y la libre circulación de capitales y de información producirán los mejores resultados para el desarrollo económico.

La finalización de la Ronda Uruguay de negociaciones comerciales multilaterales condujo a la creación de una nueva organización internacional, la Organización Mundial del Comercio (OMC), que empezó a funcionar en enero de 1995. La OMC supervisa los acuerdos comerciales mundiales que se negociaron y aprobaron durante la Ronda Uruguay, que son esencialmente contratos que obligan a todos los Estados Miembros a mantener sus políticas comerciales dentro de los límites convenidos. Entre ellos, el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC) vincula por primera vez la propiedad intelectual y las cuestiones comerciales. Este Acuerdo es el más amplio jamás alcanzado en materia de propiedad intelectual. Establece unas normas mínimas universales para casi todos los derechos de propiedad intelectual (derechos de autor, patentes, marcas registradas, etc.) y en particular la protección de las patentes de las preparaciones farmacéuticas, que pueden tener unos efectos importantes en el acceso a los fármacos en los países en desarrollo.

En el sector farmacéutico, en virtud del Acuerdo ADPIC, todos los Estados Miembros de la OMC tienen que otorgar una protección de patentes durante un periodo mínimo de 20 años a todos los inventos de una preparación o proceso farmacéutico que cumpla los criterios de novedad, inventiva y utilidad. En el pasado se reconocía el derecho de toda nación a determinar esas leyes. Antes de la Ronda Uruguay muchos países en desarrollo no concedían la protección mediante patente a las preparaciones farmacéuticas, para permitir la fabricación de copias y equivalentes genéricos de los fármacos a un precio más bajo. Esa ausencia de reglamentación sobre patentes para las preparaciones farmacéuticas ayudó a algunos países en desarrollo a crear una industria farmacéutica autóctona basada en fármacos de imitación más económicos.

Es probable que el nuevo contexto económico y social internacional influya considerablemente en las posibilidades de acceso equitativo de las poblaciones a la salud y a los fármacos, en particular en los países en desarrollo. Las nuevas normas en materia de propiedad intelectual podrían agravar la dependencia de esos países. Al aplicar las disposiciones del ADPIC en el plano nacional, los países en desarrollo deberían saber que hay algunas opciones para garantizar el acceso de las poblaciones más pobres a los medicamentos esenciales, ya que pueden utilizarse algunas disposiciones del Acuerdo ADPIC para proteger las metas de salud pública. Así pues, la estrategia de cada país en lo que respecta a la globalización en la esfera de la producción y distribución de medicamentos debería incorporarse a su política farmacéutica nacional, que es un elemento de la política sanitaria nacional.

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