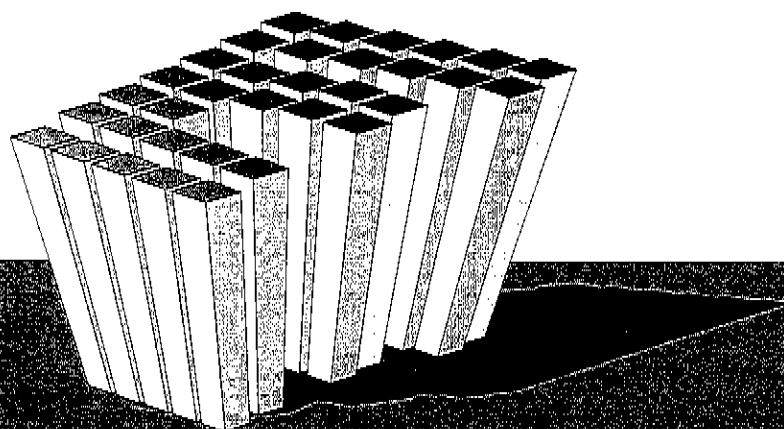


HEALTH

ECONOMICS

WTO: WHAT'S IN IT FOR WHO?



WHO TASK FORCE ON HEALTH ECONOMICS

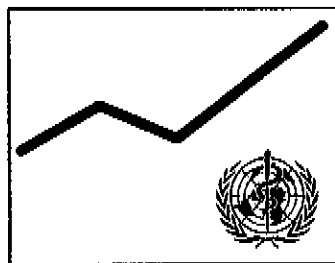
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HEALTH ECONOMICS

WTO: WHAT'S IN IT FOR WHO?

Colette M. KINNON
WHO Task Force on Health Economics



**WHO TASK FORCE ON
HEALTH ECONOMICS**

October 1995

Documents of the WHO Task Force on Health Economics

- A bibliography of WHO literature.
WHO/TFHE/93.1. e-mail access: hecon1@who.ch (English)
hecon1f@who.ch (French)
- A guide to selected WHO literature.
WHO/TFHE/94.1. e-mail access: hecon2@who.ch (English)
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- Une démarche participative de réduction des coûts hospitaliers. Hospices cantonaux vaudois (Suisse).
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the 1990s, the number of people in the UK who are aged 65 and over has increased from 10.5 million to 13.5 million (15.5% of the population).

There are a number of reasons why the number of people aged 65 and over has increased. One of the main reasons is that people are living longer. The life expectancy at birth in the UK is now 77 years for men and 81 years for women. This is a significant increase from the 1950s, when life expectancy at birth was 71 years for men and 75 years for women.

Another reason why the number of people aged 65 and over has increased is that people are having children later in life. This means that there are more people aged 65 and over who have children who are still alive.

There are a number of other reasons why the number of people aged 65 and over has increased. These include the fact that people are getting married later in life, and the fact that people are having children who are still alive.

The increase in the number of people aged 65 and over has a number of implications for society. One of the main implications is that there is a need for more social care services for older people.

Another implication is that there is a need for more housing for older people. This is because many older people live in unsuitable housing, and there is a need for more housing that is designed for older people.

There are a number of other implications of the increase in the number of people aged 65 and over. These include the fact that there is a need for more health care services for older people, and the fact that there is a need for more financial support for older people.

The increase in the number of people aged 65 and over is a significant demographic change in the UK. It is important to understand the reasons why this change is occurring, and the implications of this change for society.

There are a number of ways in which society can respond to the increase in the number of people aged 65 and over. One way is to provide more social care services for older people.

Another way is to provide more housing for older people. This can be done by building more housing that is designed for older people, and by providing more financial support for older people who are unable to afford suitable housing.

There are a number of other ways in which society can respond to the increase in the number of people aged 65 and over. These include providing more health care services for older people, and providing more financial support for older people.

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FOREWORD

Building upon activities already undertaken in the area of health economics, the Director-General created in November 1993 the Task Force on Health Economics in order to enhance WHO's support to Member States.¹ Its goal is to further the use of health economics in the formulation and implementation of health policies, giving priority to countries in greatest need.

The Task Force aims not only to strengthen the technical content of WHO programmes so that they can better adapt the tools of health economics to country needs, but also to foster cooperation among development agencies in applying health economics at country level.

A series of documents in English and French is being produced to help meet the information needs of both those involved in the organization, planning and financing of the health sector and health professionals whose expertise may lie in other areas. The documents currently available, distributed free of charge, are listed on page ii.

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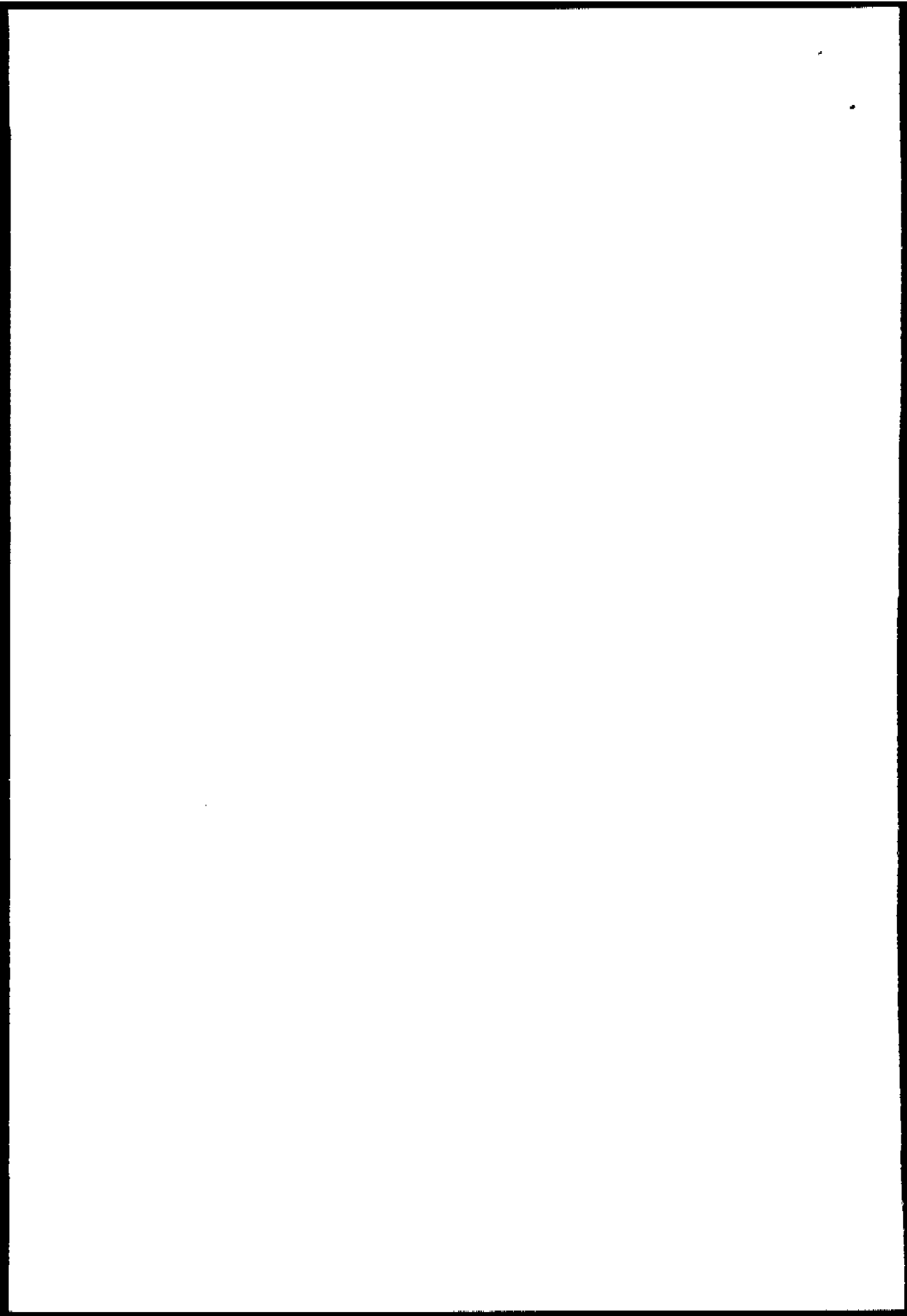
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¹ Members of the Task Force: O.A. Adams, F.S. Antezana (Chairman), M. Jancloes (Co-Chairman), G. Carrin (Secretary), S. Bertozzi, A.L. Creese, D.B. Evans, K. Janovsky, J.M. Kasonde, C.M. Kinnon, E. Lambo, P. Lowry, J.H. Perrot, B. Sabri, C. Sakellarides, Than Sein, L. Tillfors, G. Velasquez, C. Vieira, A.E. Wasunna.



SUMMARY

The Uruguay Round of multilateral trade negotiations concluded in 1994 with the agreement establishing the World Trade Organization and a number of others intended to boost international trade. Some of these clearly have implications for the health sector. Within the context of WHO's own public health work, this paper reviews both their potential impact and the efforts made to protect and develop health in an environment of expanding trade.

The continued lowering of tariff barriers is expected to lead, in the developing countries, to rising exports of goods, based chiefly on natural resources. Increased national income derived from trade liberalization should provide opportunities for improving public health standards, especially those related to healthy working and living conditions. WHO is striving, in cooperation with other organizations, to build up occupational health services, especially in the economic sectors involved, and to protect environmental health, notably through risk assessment and better pollution monitoring and control.

Of more direct relevance, the Agreement on Technical Barriers to Trade is designed specifically to encourage application to traded goods of internationally agreed standards, including WHO's quality standards for pharmaceutical, biological and food products. In this case, protecting health also contributes to easing trade. Further, the Agreement on the Application of Sanitary and Phytosanitary Measures sets out to harmonize national measures to protect human, animal and plant life or health, stipulating application of the food safety standards drawn up by the joint FAO/WHO Codex Alimentarius Commission. By virtue of the General Agreement on Trade in Services, Members may, as some have, open up their domestic market to foreign suppliers of hospital and medical services. The Agreement on Trade-Related Aspects of Intellectual Property extends, for the first time, patent protection to pharmaceuticals, raising concerns about the continued accessibility in developing countries of adequate drug supplies at reasonable cost.

Only participation of the health sector in framing national development policies can ensure that additional resources derived from increased trade are channelled to health and used in the most cost-effective way. For WHO, involvement in an area that has so far received little attention - that of links between trade policy and health development - would provide **opportunities** to bring health concerns to the forefront of current political debate, reaffirm its **commitment** to achieving improved health status and greater equity in health, and set out a range of **options** for action.

The first part of the document discusses the importance of maintaining accurate records of all transactions. It emphasizes that every entry, no matter how small, should be recorded to ensure the integrity of the financial data. This includes not only sales and purchases but also expenses and income. The document provides a detailed list of items that should be tracked, such as inventory levels, accounts payable, and accounts receivable. It also outlines the procedures for recording these transactions, including the use of double-entry bookkeeping to ensure that the books balance.

The second part of the document focuses on the analysis of the financial data. It explains how to calculate key financial ratios and metrics, such as the gross profit margin, operating profit margin, and return on investment. These metrics are used to evaluate the company's performance and identify areas for improvement. The document also discusses the importance of comparing the company's performance to industry benchmarks and providing a clear explanation of any variances.

The final part of the document covers the preparation of financial statements. It provides a step-by-step guide to creating the income statement, balance sheet, and cash flow statement. It also discusses the importance of auditing the financial statements to ensure their accuracy and reliability. The document concludes with a summary of the key findings and recommendations for the future.



INTRODUCTION

The Uruguay Round of multilateral trade negotiations concluded in April 1994 with the signing of the Final Act. Does this event have a particular significance for WHO? Is the evolution of international trade likely to affect public health?

These are questions to which WHO - in view of its responsibility to provide information and counsel to Members States in the field of health - started to provide answers as soon as the Final Act was signed. The Director-General immediately advised ministries of health of likely effects on food standards and food safety of the Agreement on Technical Barriers to Trade and the Agreement on Sanitary and Phytosanitary Measures.² In June 1994 eminent personalities forming WHO's Task Force on Health in Development examined in their first meeting some of the consequences of the new trade agreements on health in developing countries, identifying certain areas where effects may be adverse.³ The following month a number of WHO technical staff met for a brainstorming session on implications of the agreements for WHO's work. It concluded that the Organization, as advocate for the health sector, could enter into partnerships with other international organizations to help ensure that health was taken into account when trade policies were framed,⁴ without prejudice, naturally, to WTO's role of legal and institutional foundation of the multilateral trading system.

Public health personnel may not always be provided with adequate information on an area that is not directly related to their work. With this in mind, the following pages review the several agreements within the Final Act that have implications for WHO's work, outlining their purpose, main provisions and obligations, with particular reference to developing countries. In each case, information is given on the WHO activity involved, pinpointing what is already being done to protect health and, in some cases, how public health work can facilitate trade relations. The paper starts with a brief account of the functions and structure of the new World Trade Organization and a short background to the negotiations, and concludes with some policy considerations. Although subjects are not covered exhaustively, it should provide a useful basis for those who represent the view of the health sector within a broader economic context.⁵

² Note C.L.8.1994, 26 April 1994

³ Health in development: prospects for the 21st century. Geneva, World Health Organization, 1994. Unpublished document WHO/DGH/94.5.

⁴ Implications of GATT for WHO's international health work. Notes for the record, 8 August 1994.

⁵ For a comprehensive analysis of the results of the trade negotiations, see UNCTAD, *The outcome of the Uruguay Round: an initial assessment*.

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The final part of the document covers the preparation of financial statements. It provides a step-by-step guide to creating the income statement, balance sheet, and cash flow statement. It also discusses the importance of auditing the financial statements to ensure their accuracy and reliability. The document concludes by emphasizing the role of financial reporting in decision-making and the overall success of the business.



1 A NEW PARTNER IN THE INTERNATIONAL COMMUNITY

The most tangible achievement of the Uruguay Round of multilateral trade negotiations has been the establishment of a new organization designed specifically for the conduct of trade relations. For the Final Act that concluded the Round is made up of the Agreement Establishing the World Trade Organization (WTO), which constitutes an umbrella for a number of trade agreements issuing from the negotiations (see next section).

In fact, a charter creating an international trade organization had originally been agreed at the United Nations Conference on Trade and Employment (Havana, 1948), but had not been ratified by a majority of signatories. For this reason the General Agreement on Tariffs and Trade (GATT) - the multilateral treaty governing international trade - had been administered by a secretariat with relatively limited legal and practical authority.

The new Organization, which came into operation on 1 January 1995 and replaces the GATT administrative structure, is the legal and institutional foundation of the multilateral trading system.⁶ Based in Geneva, WTO provides the principal contractual obligations determining how governments frame and implement domestic trade legislation and regulations. And it is the platform on which trade relations among countries evolve through collective debate, negotiation and adjudication.⁷

WTO's mandate

The essential functions of WTO are:

- administering and implementing the multilateral and plurilateral trade agreements which together make up WTO;
- acting as a forum for multilateral trade negotiations;
- seeking to resolve trade disputes;
- overseeing national trade policies; and
- cooperating with other international institutions involved in global economic policy-making.

Agreement Establishing the World Trade Organization, Articles II and III

Most Members of WTO were contracting parties to GATT which concluded their market access negotiations and signed the Final Act of the Uruguay Round. Others had participated in the round of negotiations and became Members after concluding domestic ratification procedures. Other States may accede to WTO on agreed terms and upon approval by a two-thirds majority of Members. WTO currently has 109 Members,⁸ a large number of which are developing or "transition" countries.

⁶ GATT continues to exist as the basic treaty governing international trade in the form of GATT 1994. See sections 2 and 3.

⁷ For an explanation of WTO and its functioning, see *Trading into the future: WTO, the World Trade Organization*.

⁸ as at 13 September 1995.



WTO is headed by a Ministerial Conference, which meets at least every two years and can decide on all matters under any of the multilateral trade agreements. Between meetings, day-to-day operations, notably dispute settlement procedures - streamlined under the new Agreement - and trade policy review, are overseen chiefly by the General Council, together with a number of subsidiary entities. All Members of WTO belong to these bodies, in which decisions are generally reached by consensus; when this is not possible, decisions are taken by a majority vote, on the basis of 'one member, one vote'.

One of the foremost standing committees of GATT had been the Committee on Trade and Development. A corresponding WTO Committee on Trade and Development, reporting to the General Council, has been set up to review participation of developing country Members - especially the least-developed among them - in the multilateral trading system and cooperation with them to expand their trade and investment opportunities.⁹ It serves as a focal point for development work in WTO and for links with development-related activities in other international organizations. Further, the WTO Secretariat has the responsibility to provide technical support to developing countries and those in transition, in particular through cooperation on such matters as accession negotiations, implementation of WTO commitments, or effective participation in multilateral negotiations.¹⁰

With a potential new partner among the multilateral agencies, WHO welcomes the opportunity to set out certain public health aspects related to international trade, so that they may be taken into account both in implementation of several of the new agreements and in future negotiations.

⁹ WTO and other intergovernmental organizations. Preparatory Committee for the World Trade Organization, 1994.

¹⁰ Trading into the future: WTO. the World Trade Organization.



2 TRADE NEGOTIATIONS EXPAND INTO NEW AREAS

International trade is organized under a set of principles contained in the GATT - originally adopted in 1947. The purpose of the Agreement, among other objectives, is to promote trade with a view to raising standards of living and to ensuring a growing volume of real income. The Agreement codifies a number of trade practices and lists schedules of tariffs on many traded goods.

The contracting parties to GATT met periodically in a round of negotiations to reduce tariff barriers or other obstacles to trade. Revised schedules of concessions and new agreements stemming from each round updated or expanded the original agreement.

Until the 1970s, GATT negotiations had centred on the lowering of tariff barriers; the last two rounds also tackled the question of nontariff barriers (such constraints on trade as import quotas and licensing systems, technical regulations, or "buy-national" provisions). Launched in 1986, the Uruguay Round broadened the scope of earlier negotiations in such areas as textiles and clothing, agricultural produce or government procurement, and introduced new items, such as trade in services and more stringent rules for the protection of intellectual property.

The Round concluded in 1994 with the signature of the Final Act. Probably one of its more significant outcomes in the long term is to have brought a range of measures, previously viewed as falling within the scope of domestic policy, under multilateral discipline and linked to the rights and obligations governing international trade and market access.¹¹

The Final Act is made up of the agreement establishing WTO, which constitutes an umbrella for all other agreements, understandings, ministerial decisions and so forth contained in the Act. There are thirteen multilateral agreements governing the conduct of international trade in goods, including GATT 1994 - the amended and updated version of GATT 1947 - and a series of understandings on the interpretation of certain GATT articles, together with a multilateral agreement on trade in services, and another on trade-related aspects of intellectual property (see chart below). The "package" also includes a number of ministerial decisions and declarations.

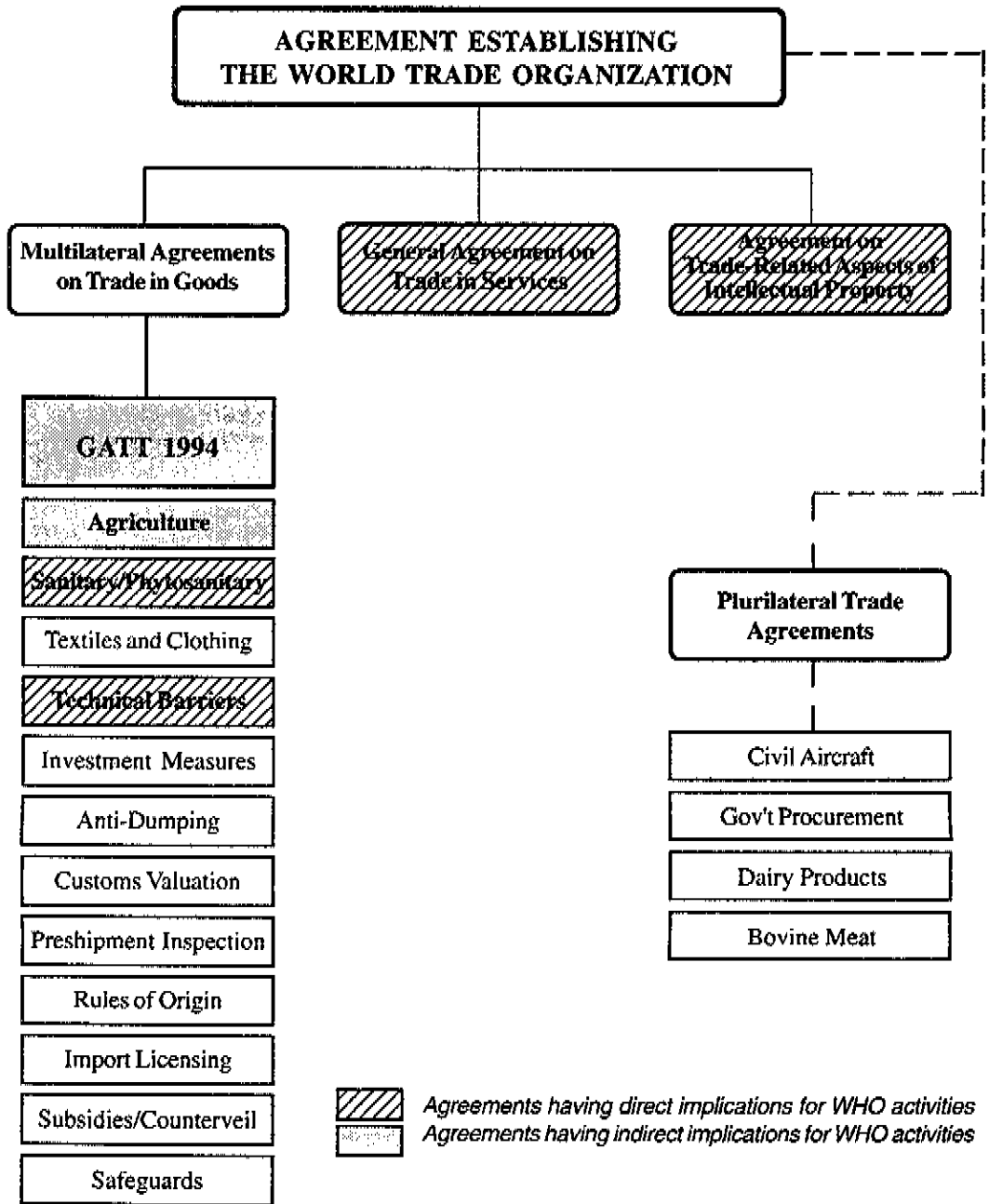
The set of agreements forms a single legal instrument which must be accepted in its entirety. That is to say, by accepting the WTO agreement, governments agree to be bound by the rules and obligations of all its multilateral trade agreements. This establishes roughly the same set of obligations for all WTO Members, and links such rights and obligations to trade concessions. As the Multilateral Trade Agreements together cover a broader area than GATT 1994 alone, WTO supplants the existing GATT legal system for trade relations.¹² WTO came into effect on 1 January 1995.

¹¹ See SESRTIC and ICDT, *The Uruguay Round of Trade Negotiations: a preliminary assessment*.

¹² See *The results of the Uruguay Round of multilateral trade negotiations*. GATT, 1994.



AGREEMENTS COMPRISING THE FINAL ACT OF THE URUGUAY ROUND



Source: Adapted from "The results of the Uruguay Round of Multilateral Trade Negotiations. Market access for goods and services: overview of the results". GATT Secretariat, November 1994



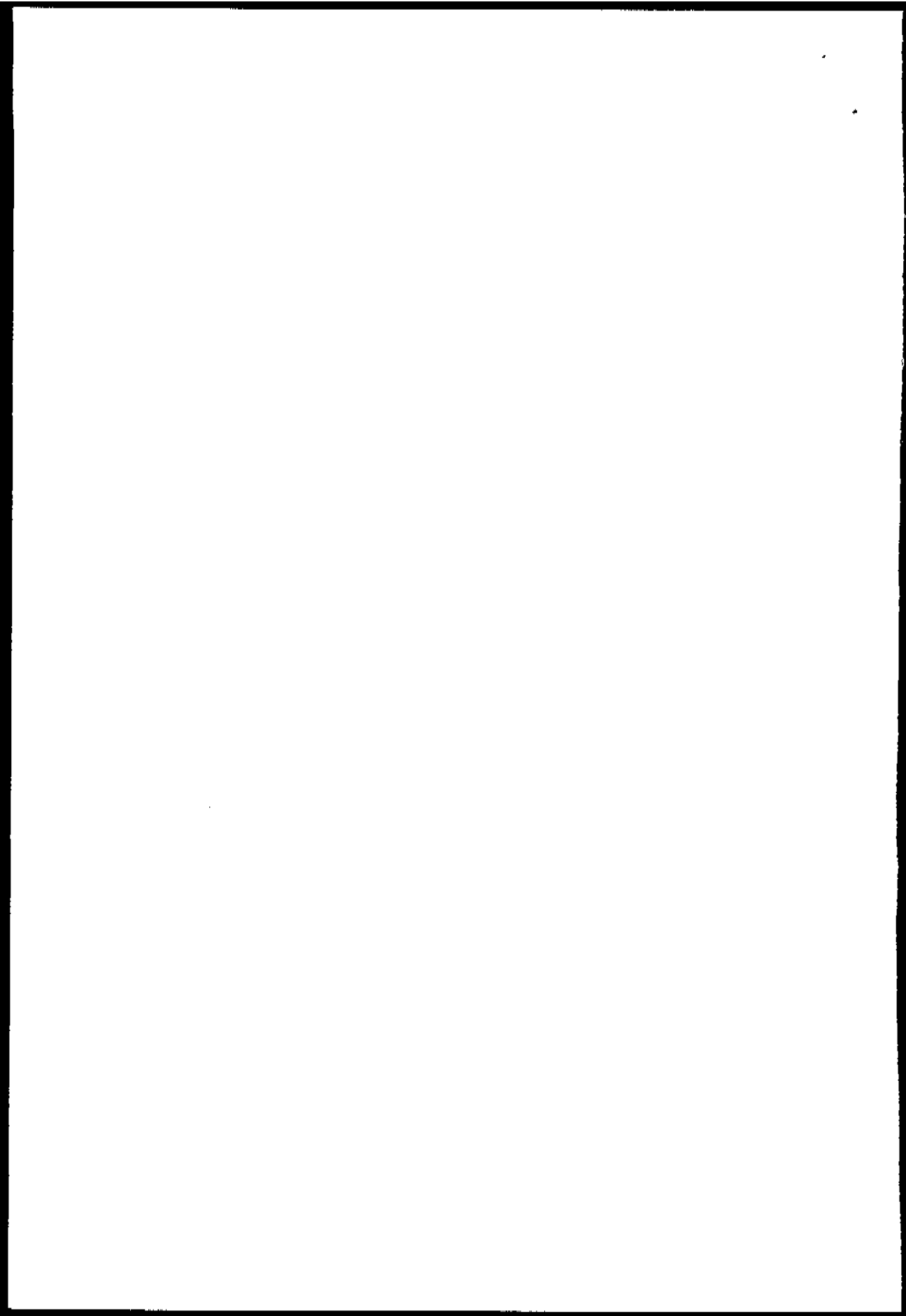
The preamble of the WTO agreement restates the purpose of the original GATT, and introduces several new concepts. Trade growth should allow for the optimal use of resources in accordance with the objective of sustainable development - seeking to protect and preserve the environment - while efforts should be made to ensure that developing countries, especially the least developed, obtain a share in such growth commensurate with their needs.

In fact, a feature of the Uruguay Round was the active participation of nearly 90 developing countries in negotiations, reflecting a desire to be part of the process of globalization of the international economy and to bolster an international system of enforceable trade rules.¹³ As a result, the individual agreements generally provide for favourable treatment for developing countries, and a Decision on Measures in Favour of Least-Developed Countries recognizes their participation in the world trading system and need for continued preferential access to markets. The Decision allows them flexibility to undertake commitments and grant concessions to the extent consistent with their individual development, financial and trade needs, or their administrative and institutional capabilities. The signatories also agree to grant least-developed countries "substantially increased" technical assistance to develop and diversify their production and export bases.¹⁴

Over a third of the multilateral agreements are likely to affect WHO activities either indirectly or directly. In the first case, further trade liberalization resulting from GATT 1994 should produce income gains, part of which could be channelled to protecting **workers' health** and **environmental health**; the provisions of the Agreement on Agriculture might, in the short term, have repercussions on **food security**. In the second case, the Agreement on Technical Barriers to Trade is intended to encourage setting of **international quality standards** for traded products, a responsibility of WHO in certain areas. The Agreement on the Application of Sanitary and Phytosanitary Measures refers specifically to the use of standards, guidelines and recommendations drawn up, among others, by the WHO/FAO Codex Alimentarius Commission with regard to **food safety**. As a result of the General Agreement on Trade in Services, Members may, as some have, open up their domestic market to foreign suppliers of hospital and medical services, with implications for **national and district health systems**. The Agreement on Trade-Related Aspects of Intellectual Property Rights strengthens patent protection for inventions in all fields of technology, including **pharmaceuticals**. The following sections review these agreements in the light of WHO's public health work.

¹³ *World economic and social survey 1995*.

¹⁴ For a summary of the special and differential treatment accorded to developing countries, see *World economic and social survey 1995*, Table VII.1..





3 GATT 1994 - THE CORE AGREEMENT

GATT is the cornerstone of relations in the trade of goods, a set of multilaterally agreed rules governing the commercial relations of the contracting parties. Along with a schedule of negotiated tariff concessions, GATT 1947 had set out several trade-policy principles. These are, essentially, the "most-favoured nation" principle;¹⁵ nondiscrimination between domestically produced goods and imported products and among imports from different foreign suppliers; and use preferably of customs tariffs to restrict trade. These principles apply to all agreements under the WTO umbrella.

Of particular interest to WHO among GATT provisions is Article XX.1(b). This article allows contracting parties to adopt or to enforce measures "necessary to protect human, animal or plant life or health", in so far as they neither unjustifiably discriminate between countries where the same conditions prevail, nor act as a disguised restriction to trade. In other words, countries may, for that purpose, impose more stringent requirements on imported products than they require of domestic goods.¹⁶

Use of Article XX.1(b) to defend a national tobacco control programme

In a recent trade dispute, WHO was called upon to present evidence to a GATT dispute settlement panel. At the beginning of 1990, Thailand had refused to lift its restrictions on imports of foreign cigarettes as requested by the United States, invoking, together with another exclusion concerning agriculture, GATT Article XX.1(b). WHO provided information on the potential damage to Thailand's successful tobacco control programme of the opening of the domestic cigarette market. The panel agreed with WHO experts that smoking constituted a serious risk to human health, but recommended that Thailand, while abolishing restrictions on cigarette imports, should apply pricing and taxation regulations equally to both domestic and foreign brands.

WHO programme on tobacco or health: implementation of resolutions WHA42.19 and WHA43.15. Geneva, WHO, 1991. Unpublished document A44/9

GATT 1994 consists of the provisions of GATT 1947, as rectified or amended after previous negotiating rounds; legal instruments that entered into force under GATT 1947; the Understandings reached in the Uruguay Round on interpretation of several articles of GATT; and the Marrakesh Protocol containing the schedules of concessions as negotiated during the Uruguay Round.

¹⁵ Under this principle, any advantage related to customs duties and charges granted on any product originating in or destined for any other country is automatically extended to the like product originating in or destined for all other contracting parties.

¹⁶ Understanding the World Trade Organization, GATT Secretariat, 1994



Improved market access

Increased access to markets was one of the critical areas of negotiations during the Uruguay Round. Negotiations aimed at reducing tariff and nontariff barriers in agricultural and nonagricultural goods. On average, industrialized countries have reduced by 37% their tariffs on imports from developing countries.¹⁷ Further, the largest trading partners - Canada, the European Union, Japan and the United States - agreed to eliminate completely their tariffs on certain products, some of which are of interest to developing countries, such as steel, pulp and paper, and pharmaceuticals. Tariff reductions, however, were lower, and tariff levels, higher, on labour-intensive manufactures (for example, textiles and clothing, leather goods) and certain processed primary products (such as fish products).¹⁸

Improved access to markets, coupled with gains in trade efficiency, is expected substantially to increase world trade, to the benefit of all partners, including developing countries. As a group, the latter currently account for a quarter of world merchandise exports.¹⁹ In 2005 - when market access commitments should be fully implemented - the volume of merchandise exports from developing countries (excluding China and Taiwan, Province of China) is expected to rise by between 13% and 37%²⁰. The annual increase in income in developing countries and transition economies due to liberalization of trade in goods is estimated to amount to up to US\$116 thousand million in 2005.²¹ This growth in income will provide an opportunity to improve living conditions throughout developing countries, provided that the additional wealth is fairly distributed.

Developing countries are expected to expand production and exports of agricultural goods and labour-intensive manufactures. Textiles and clothing constitute the principal category of exports of developing countries, followed by machinery, metals and mineral products, chemicals, and natural resource-based commodities, including wood, pulp and paper, leather and rubber, and fish and fish products (but excluding petroleum).²² Some of these products are precisely those subject to less favourable tariff conditions.

Least-developed countries generally export a more limited range of goods, chiefly agricultural products, natural resource-based commodities, and textiles and clothing. These primary-producing developing countries, many in Africa, stand to gain less from

¹⁷ The WTO and the developing countries. *WTO Focus*, No. 1.

¹⁸ See *World Economic and Social Survey 1996*, Table VII.2.

¹⁹ *Idem*.

²⁰ The results of the Uruguay Round of Multilateral Trade Negotiations. GATT Secretariat, 1994.

²¹ WTO internal document.

²² An analysis of the proposed Uruguay Round agreement, with particular emphasis on aspects of interest to developing economies. GATT Secretariat, 1993. Chart 1.



increased market access. In industrialized countries, tariffs are already low on most tropical foods, and primary products in general face low demand elasticity.^{23,24} Nevertheless, trade liberalization should help them to diversify their exports, thus reducing their dependence on primary commodities.

Stronger growth derived from increased trade should benefit the health status of the individual and the community in developing countries. Increased employment opportunities and higher wages means that people can afford better food and health care for themselves and their families. Additional government resources stemming from export earnings can be used to improve not only public health services, but also other health determinants such as education, sanitation and housing, a reason for the health sector to participate actively in framing national development policy (see section 9). In turn, better health status enhances the quality of labour and raises productivity.

Trade liberalization, *per se*, is linked neither to better or worse public health conditions. Indirectly, it should provide opportunities for improving public health standards. It should be easier, for example, to introduce more stringent health standards in new exporting activities, where the cost structure can more easily accommodate additional expenses on health objectives. Income gains deriving from increased trade should provide means for strengthening health regulatory systems. Indeed, if that were not the case, health authorities may be faced with a difficult task, considering that possible increased production in such sectors as agriculture, mining, manufacturing, or processing industries could have repercussions in two areas under their responsibility: occupational health and environmental health.

Protecting workers' health ...

An outcome of rising national income should be an improvement in a country's administrative capacity to ensure that health and safety standards are respected in the work place.²⁵ For disease and illness stemming from the work environment and conditions, along with sometimes fatal work-related accidents are not uncommon in developing - or industrialized - countries. A notable health hazard for agricultural workers, for example, is the increased use of pesticides, in particular in large-scale farming for international and domestic markets that requires intensive pest control. Industrial workers, particularly miners, often to suffer from respiratory diseases or from illness resulting from exposure to common industrial materials and chemicals. In manufacturing industries and assembly plants, health problems may include chemical poisoning, eye and respiratory diseases, and fatigue from intense, monotonous work and long hours.²⁶

²³ I.e., growth in demand is lower than growth in incomes.

²⁴ *World economic and social survey 1994*.

²⁵ *World Bank Development Report 1995: workers in an integrating world*.

²⁶ Cooper Weil et al., *The impact of development policies on health*.



WHO's concern is to cooperate with countries in building up workers' health programmes and infrastructure for occupational health services, through information, training, research, and monitoring, among other activities. The global strategy on occupational health for all, drawn up through the global network of WHO collaborating centres, provides a framework for countries both to formulate policy and to develop health services within a national and international context.

The Organization has for many years given special attention to the production sectors which are now likely to be stepped up through trade liberalization, in particular agriculture and mining.²⁷ Together with UNEP it has assessed the scope and severity of exposure to pesticides used in agriculture and their effect on health.²⁸ Together with ILO it has promoted better conditions of life, work and health for miners through the establishment of international labour standards and medical reporting systems.²⁹ It has also recommended limits for occupational exposure to pesticides, mineral dusts, heavy metals, solvents, vegetable dusts and respiratory irritants; assessed carcinogenic risks in the wood, leather and rubber industries; and provides authoritative advice for workers handling industrial chemicals.

Within the International Programme on Chemical Safety (IPCS), WHO, in collaboration with ILO and UNEP, aims to safeguard health and the environment from the adverse effects of potentially toxic chemicals, whether industrial or agricultural. The Programme issues Health and Safety Guides for decision-makers, managers, trade union officials or others involved in safe use of chemicals and avoidance of health hazards. It also produces jointly with the Commission of the European Communities a series of International chemical safety cards for workers, providing evaluated information useful in any work place, and conducts training courses in the safe use of pesticides.

Part of the broader issue of working conditions, the use of child labour persists in a number of developing countries, even though it is usually prohibited by legislation. WHO has examined the special health risks of children at work in order to raise awareness of their vulnerability to occupational risks and to help combat the practice.³⁰ Within the international community the question is being raised of whether trade sanctions should be imposed on countries that fail to meet a minimum set of labour standards (see box below).³¹

²⁷ See, for example, resolution WHA33.31 (1980).

²⁸ WHO/UNEP, *Public health impact of pesticides used in agriculture*. Geneva, World Health Organization, 1990.

²⁹ Resolution WHA24.27 (1971).

³⁰ *Children at work: special health risks. Report of a WHO Study Group*. Geneva, World Health Organization, 1987. Technical Report Series No.756.

³¹ For a discussion of labour - including occupational health - standards and international trade, see *World Development Report 1995: workers in an integrating world*, Chapter 11.



Should working conditions and international trade be linked?

Although the subject was not included in the Uruguay Round of negotiations, some countries are pressing for WTO to examine how working conditions and workers' rights should affect trade rules, leading eventually to agreement on a "social clause". This, more so than other trade issues, has tended to polarize industrialized and developing countries. Some of the former feel that developing countries might be engaging in "social dumping": their low wages and poor working conditions, and use of child labour, enable them to undercut prices and compete unfairly. Developing countries consider this to be a pretext for raising protectionist trade barriers.

WHO would be able to contribute useful information on aspects of occupational health. Recent material produced has covered, for example, the special health risks of working children³² and occupational health for working women³³. Resolution WHA40.28 (1987), recognizing that certain groups of workers, particularly in agriculture, mining, and smaller industries, were underserved by health services, urged Member States to identify health problems in these sectors and to extend their health care coverage.

The Economist, April 9th-15th, 1994; World Economic and Social Survey 1994.

In view of this focus on labour standards and on recognition of social protection, WHO is well placed to provide information and advice on such aspects as minimum health and safety standards in the work place, workers' right to health care, or provisions for health insurance, leading possibly to the formulation of a code of ethics of professional practice for health and safety.³⁴

... and environmental health

Environmental concerns had not been neglected in GATT; the original version already contained, as an exclusion under Article XX, measures necessary to conserve exhaustible natural resources. The WTO agreement further recognizes in its preamble the need both to protect and preserve the environment and to enhance the means for doing so.³⁵ Further, the Uruguay Round Ministerial Decision on Trade and Environment, noting that there need be no policy contradiction between upholding a multilateral trading system and acting for protection of the environment, decided that a Committee on Trade and Environment should be established with the aim of making international trade and environmental policies mutually supportive.³⁶

³² *Children at work: special health risks.*

³³ Report of the Expert Committee on Occupational Health for Working Women. Geneva, WHO, 1986. Unpublished document WHO/OCH/86.1.

³⁴ See Implications of GATT for WHO's international health work.

³⁵ For a discussion of environmental aspects of WTO agreements, see Schultz J. The GATT/WTO Committee on Trade and the Environment - toward environmental reform.

³⁶ For a detailed discussion on the interactions between trade and the environment, see Anderson K and Blackhurst R. *The greening of world trade issues.* New York. Harvester Wheatsheaf, 1992.



Developing countries may have limited experience of production and regulation in areas involving processing if they had previously concentrated on supplying raw materials or on simple manufacturing, and possibly less experience with pollution control technology and application of environmental safeguards and standards to industrial emissions and waste disposal. Greater use of agrochemicals, heavy metal wastes from mines, or toxic effluent from such industries as paper and pulp, chemical and dye, or leather processing, for example, carry risk for environmental health in the form of water, land, air or food contamination, as may the concentration of manufacturing activities in certain zones.³⁷ The concern also exists that some countries may tolerate lax domestic environmental standards in order to gain a competitive advantage for their exports or to attract investment - so-called "eco-dumping".³⁸

Nevertheless, the stringency and scope of environmental health and safety regulations are improving in developing countries; it is rather the administrative capacity to enforce them that remains weak.³⁹ Innovative approaches may be required to channel part of the revenue generated by export industries not only to upgrading existing plants or improving pollution control, but also to ensuring that regulations are respected when installations are set up, such as industrial parks, storage or transport facilities, and infrastructure in general.

National efforts may also be backed up by transnational corporations which introduce in their production plants in developing countries environmental health protection measures similar to those applied in home-country factories. For example, the Industry Council for Development - a nongovernmental organization in official relations with WHO - constitutes a group of such companies which supports drinking-water and food-safety programmes.

For its part, WHO pays special attention to protection of environment health in the development process. Consistent with UNCED's appeal in Agenda 21 for countries to design national plans for environmentally sound and sustainable development, WHO encourages the health sector to participate in related activities. Its own work includes assessment of environmental health risks, monitoring and control of air and water quality, setting and updating of guidelines and standards for air- and drinking-water quality and for environmental pollutants, and management of environmental health information, which is widely disseminated through computerized information systems. In cooperation with UNEP, UNESCO and WMO, it assesses the likely impact on environmental health of new agricultural or industrial development projects, in particular possible water pollution, and provides guidance on measures to prevent or mitigate adverse effects. It also cooperates with national and municipal authorities to improve monitoring and control of air and water pollution in urban areas by drawing up inventories of pollution sources and emissions, and provides support for protection of drinking-water resources.

³⁷ *Our planet, our health;* and Cooper Weil et al., *The impact of development policies on health.*

³⁸ UNCTAD, *op. cit.* Annex 2, Trade and environment.

³⁹ Cooper Weil et al., *op. cit.*



To further the environmentally sound management of toxic chemicals, WHO, through IPCS, scientifically assesses the hazards and risks arising from exposure to chemicals or environmental pollutants. Results are disseminated in the series *Environmental Health Criteria* to enable authorities to establish policies for the safe use of chemicals. The Programme not only promotes public campaigns for safe chemical use, but also works to prevent and control poisoning with the help of the IPCS INTOX Package. An interactive software system, it provides information on toxic risks and health response to toxic exposures, and facilitates the collection and analysis of data concerning human exposure to chemicals.

In view of the potentially greater risk of chemical disasters arising from increased industrial production and transport of dangerous goods, particularly in developing countries, the Programme also works on the medical aspects of preventing, preparing for, responding to and following up chemical accidents. Further guidance is provided, in collaboration with UNEP and OECD, on measures to prevent and mitigate the health impact of such accidents.

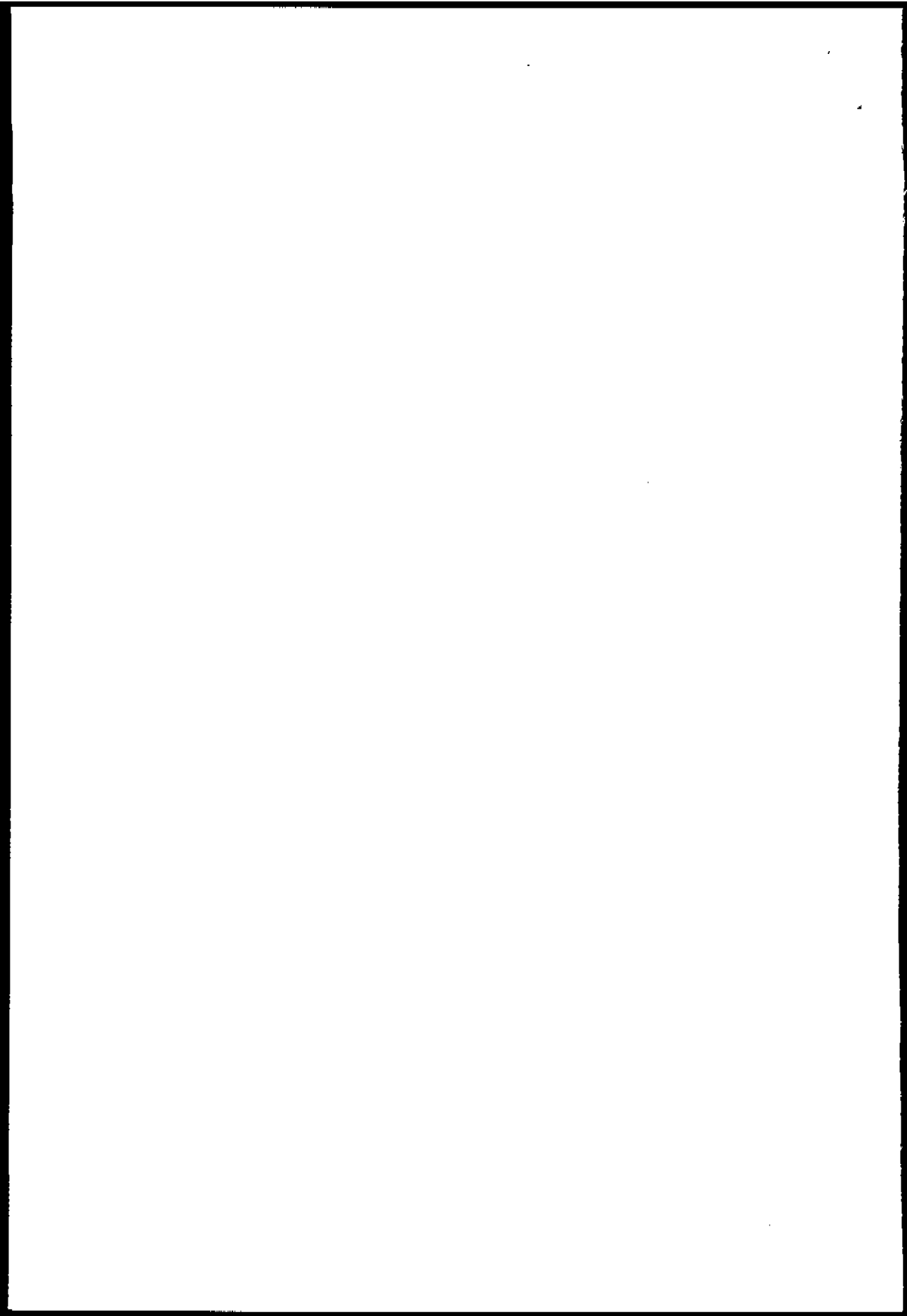
WHO is also responsible for coordinating a global food contamination monitoring and assessment programme in which over 60 countries participate. The aim is not only to protect public health, but also to promote confidence in the purity of foodstuffs through the exchange of information on food contamination. Aside from technical cooperation in setting up national monitoring, the programme provides periodic global assessments of the nature, extent and trends of food contamination. In this way it contributes to encouraging international trade, particularly important for many food-exporting developing countries.

WHO's knowledge and experience of the broad field of environmental health would constitute a useful resource for the WTO Committee on Trade and Environment, whose main task it is to identify the relationship between trade measures and environmental measures, in order to promote sustainable development.⁴⁰ For example, the preliminary agenda of the Committee includes measures to regulate the export of goods whose sale is prohibited on domestic markets - such as pesticides and toxins, expired pharmaceutical products, or contaminated food - yet which frequently arrive in developing countries.⁴¹ In view of the public health implications of such trade, this is an area of concern for WHO.

Since the question of environmental standards (and possibly labour standards) will probably be included in future trade negotiations, WHO would also have a contribution to make when consideration is given to those matters.

⁴⁰ Trading into the future: WTO, the World Trade Organization.

⁴¹ Schultz J. *op. cit.*





4 HOW WILL FOOD SUPPLIES FARE?

Negotiations in the Uruguay Round on the agricultural sector, of broader scope than in previous rounds, resulted in the Agreement on Agriculture. Essentially, in order to achieve a fairer trading environment for foodstuffs, Members agree to reduce tariff barriers to agricultural imports, subsidies for agricultural exports, and quantities of subsidized exports, bearing in mind the effects that agricultural reform could have on food security, and on the least developed and the net food-importing developing countries. The Agreement is expected to lead to a more even distribution of agricultural production throughout the world economy.

It was recognized during negotiations that trade liberalization might affect availability of supplies of basic foodstuffs from external sources on reasonable terms, and cause difficulties in financing normal levels of commercial imports of basic food stuffs. Members therefore agreed upon mechanisms to offset possible adverse effects on availability of food and to ensure that food aid is maintained at a level sufficient to meet the needs of developing countries.⁴²

In fact, an initial outcome of the Agreement is likely to be a moderate and gradual rise in world food prices as a result of a reduction in export subsidies production and an increase in world food demand as agricultural markets are gradually liberalized. Generally speaking, net food-exporting countries will gain from higher prices, in particular those exporting temperate farm products, whereas net food-importing countries are likely to suffer a terms-of-trade loss.⁴³ The latter include many countries in Africa and Asia, major importers of dairy products and wheat. In the longer term, however, domestic production levels in developing countries, including the least-developed and the net food-importing countries, are expected to increase, if changes in world market prices are allowed to feed through to domestic producers.⁴⁴

As an immediate outcome of the Agreement, food security could be affected in two ways: promotion of export crops might have an impact on the national food supply,⁴⁵ and the reduction in subsidies might lead to a reduction in surpluses available for food aid, affecting in particular the least developed countries that depend heavily on food aid. Both are of relevance to household consumption and nutrition.

Food aid, aside from providing emergency food supplies, aims at promoting sustainable human and economic development of the 1.4 thousand million food-insecure people

⁴² Decision on Measures concerning the Possible Negative Effects of the Reform Programme on Least-developed and Net Food-importing Developing Countries.

⁴³ World Economic and Social Survey 1995.

⁴⁴ An analysis of the proposed Uruguay Round agreement. GATT Secretariat.

⁴⁵ - although recent research discerns a positive link between expansion in cash crop production and staple-food production. Cooper Weil et al., *op. cit.*



living in extreme poverty.⁴⁶ It is used for specific development projects through a variety of mechanisms such as school feeding schemes, food rations in exchange for work in rural or agricultural projects, or as an incentive to attend training courses.

Getting food to the poorest people

In 1993 the World Food Programme - the food aid arm of the United Nations system - provided food to nearly 50 million people throughout the developing world. A significant number to be reached by a single body, it still represents only 5% of the total population in need.

Food assistance programmes include such mechanisms as food distribution systems, particularly for the poor and unemployable, and income transfer schemes. These involve targeted food subsidies, food stamps and feeding programmes for vulnerable groups (mostly mothers and young children, school children and very poor employable people).

WHO internal document, July 1995

As health and medical adviser to the World Food Programme, WHO aims at ensuring that food-aid recipients derive long-term health benefits from development projects in all sectors, and that food aid is integrated in national development plans and programmes.

In principle, trade liberalization need not conflict with food security goals, the protection of global food stocks, or food aid. New incentives for agricultural production should in time reduce the dependency of net-food importing developing countries on food aid. Reductions in trade restrictions and subsidies are expected to have a limited impact on world food supply, demand and prices. In the end, these are more likely to be affected by technological change, which will continue to boost food production, and rising commercial demand in developing countries as income increases.⁴⁷

⁴⁶ Proposed programme budget for the financial period 1996-1997. Geneva, World Health Organization, 1995. Unpublished document PB/96-97

⁴⁷ Global food aid resources. Rome, WFP Committee on Food Aid Policies and Programmes, Thirty-fifth Session. Unpublished document CFA: 35/P/5, limited distribution.



5 STANDARD-SETTING: SAFEGUARDING HEALTH, FACILITATING TRADE

The area of standard-setting is of particular interest for WHO, which constitutionally has the function of developing, establishing and promoting international standards within its field of competence.

In 1980 a number of GATT contracting parties had agreed to disciplines on standards in the production of internationally traded goods, by virtue of the Agreement on Technical Barriers to Trade negotiated during the Tokyo Round. That Agreement was intended to encourage the formulation of international standards and certification schemes while ensuring that national standards did not create unnecessary obstacles to international trade.

Similarly, the 1994 Agreement, recognizing the contribution of international standards, technical regulations and conformity assessment systems to facilitating trade, is designed to encourage their development and to ensure that national standards that are not based on international ones do not hinder trade unnecessarily. The Agreement covers, among other items, packaging, marking and labelling requirements and conformity assessment procedures.

All Members of WTO are encouraged to apply internationally agreed standards as a basis for their technical regulations and to take part in the work of the standard-setting body concerned. National criteria based on these standards will not constitute a discriminatory barrier to imports. Technical regulations drawn up by countries in the absence of international standards may not be more trade-restrictive than necessary to fulfil such objectives as protection of human, animal or plant health or safety, or the environment. A Member adopting a technical regulation that might significantly affect the trade of others - for instance, that is considerably stricter than the international standard - must give notice, and could be requested to provide justification for it.

Special provisions are made for developing countries. They may adopt technical regulations or standards aimed at preserving indigenous technology and production methods, and are not expected to base them on international standards if these are inappropriate to their development, financial or trade needs. If faced with difficulties, they may also request time-limited exceptions from their obligations. Members will try to ensure that, where possible, international standard-setting bodies prepare norms for products of special interest to developing countries. They will also provide support to these countries for setting up their own standards agencies and for participating in the work of the international bodies.

WHO is responsible for setting standards for **pharmaceutical, biological** and similar products, and for **food**; they are designed to provide the basis for national legislation and are of particular value to countries that cannot afford to mount their own standard-setting agencies.

With respect to pharmaceuticals and biologicals, WHO aims to support and complement the work of national drug regulatory authorities to ensure recognized standards of quality, efficacy and safety.



Quality assurance for pharmaceutical products ...

WHO's standards for pharmaceuticals are contained in *The international pharmacopoeia*. This is one of the main compendia that provide quality specifications for the preparation of pharmaceutical substances, essentially those contained in the WHO Model List of Essential Drugs (see also section 8). The specifications are intended to serve as references for establishment of national requirements, and are drawn up by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, with the needs of developing countries in mind. They have legal status only if they are introduced into appropriate national legislation.⁴⁸

An initial survey on the use of *The international pharmacopoeia* conducted in 1993 and 1994 among 75 countries (nearly 90% developing countries or economies in transition) indicated that 95% of respondents resorted to the standards described, either for consultation when drawing up national standards or for adoption directly as a basic requirement.⁴⁹ Pharmaceutical standards are widely used for the quality control of locally manufactured products for the domestic market or for export, and of imported products, in conjunction with good manufacturing practices.

The requirements of good manufacturing practices such as those drawn up by WHO, should be met when preparing pharmaceutical substances and dosage forms for human use, as described in *The international pharmacopoeia*. Such practices are based on the principle that quality has to be built into the product and that the major responsibility belongs to the manufacturer.⁵⁰

WHO materials used for trade purposes: manufacturing guidelines ...

Application of standards not only provides assurance of quality but also facilitates trade in other ways. For example, the partners in the Mercosur (the recently established common market between Argentina, Brazil, Paraguay and Uruguay) decided that they would apply WHO's requirements for good manufacturing practices before the end of 1994. This kind of harmonization in the pharmaceutical industry is intended to help ensure fair competition and avoid distortions in the free-trade area.

Correa C and Czar de Zalduendo S, El Mercosur y los medicamentos. Buenos Aires, 1995. Unpublished document.

⁴⁸ See *The international pharmacopoeia*. Geneva, World Health Organization, 1994, Vol.4, Preface.

⁴⁹ Progress report and replies to the questionnaire on the future of *The international pharmacopoeia*. Geneva, WHO, 1994, Internal document QAS/EC/SPP/94.5.

⁵⁰ Resolution WHA20.34. The latest version of Good Manufacturing Practices for Pharmaceutical Products are contained in *WHO Expert Committee on Specifications for Pharmaceutical Preparations: Thirty-second report*. Geneva, World Health Organization, 1992. WHO Technical Report Series N° 823.



For countries importing pharmaceuticals, the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce provides a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assurance that the manufacturer has been found to comply with WHO standards of good manufacturing practices. Adopted in 1975⁵¹, the Scheme was extended in 1988 to cover certain veterinary and starting materials and the provision of approved product information. At present, 139 countries have agreed to participate in the Scheme.

Certificates are usually requested at the time of product registration or, in the absence of a registration system, when a product is first imported, and particularly when the manufacturer is unknown. With increasing production of pharmaceuticals in developing countries, and more trade between them, it is likely that they will also wish to issue, as well as to receive, certificates.⁵² The weakness of the Scheme, however, is that it is based on self-evaluation of the competence of the authority that issues certificates. It is thus left to the importing country to decide upon which authorities to trust.⁵³

In short, increased emphasis on the use of international standards and codes should encourage the application of good manufacturing practices and strengthening of regulatory controls, leading to an overall improvement of the quality of pharmaceutical products.⁵⁴

... and nonproprietary names

For over forty years WHO has assured international standardization of nomenclature for pharmaceutical substances through its programme on the selection of international nonproprietary, or generic, names. More than 6500 such names have been published, and are used by countries for regulatory, pharmacopoeial, labelling and other purposes.⁵⁵

Within the framework of GATT 1994, a number of mostly OECD countries agreed to eliminate customs, and all other, duties and charges on imports of certain pharmaceutical products from any origin, such as all pharmaceutical active ingredients bearing a WHO international nonproprietary name. Additional products include those used for the production and manufacture of finished pharmaceuticals.

This agreement should provide an opportunity for some of the developing countries that export pharmaceuticals - largely generic products - to widen their markets.

WHO internal document, September 1995

⁵¹ Resolution WHA28.65.

⁵² See Wehrli A. Certification of pharmaceutical products.

⁵³ Wehrli A. WHO internal document, 1995

⁵⁴ Wehrli A. Certification of pharmaceutical products.

⁵⁵ Latest list: *International nonproprietary names (INN) for pharmaceutical substances. Cumulative list No.8.* Geneva, World Health Organization, 1992.



... and for biologicals

Work on international biological standardization was taken over by WHO from the Health Organization of the League of Nations in 1947, when the first Expert Committee on Biological Standardization was held. WHO's responsibility is to establish primary international standards against which others can be calibrated world wide. WHO also produces guidelines and requirements for the production and control of biological medicines. Its Expert Committee serves as the international focal point for discussing requirements, evaluating candidate preparations and establishing international standards for the activity and identity of biological products. As a result of its work, along with that of WHO's International Laboratories for Biological Standardization, both biological standards and reference reagents are now universally used.^{56,57}

Unlike other pharmaceuticals, which are produced and controlled using reproducible chemical and physical techniques, manufacture of such biologicals as live vaccines, blood products, therapeutics, recombinant DNA products, and genetically modified organisms, involves processes and materials which display inherent variability. Hence the need for strict adherence to the good manufacturing and in-process control practices, which WHO has prepared with those difficulties in mind.⁵⁸

The revised Agreement should not hinder international commerce of biologicals, even sensitive items such as live vaccines or blood products, provided that there is no infringement of one of the basic principles of international trade: nondiscrimination between sources of supply (see section 3).

It is expected that by 1995 all countries will have adopted standards for the potency and safety of biologicals and will be applying them routinely. Developing countries such as China, Cuba, Egypt, India or Mexico produce the vaccines required by WHO's Expanded Programme on Immunization (EPI) for their domestic markets, and some export their surplus (see also section 8). Assuring the quality of vaccines, however, can pose problems for a number of these manufacturers, mostly public institutes.⁵⁹ In this respect, WHO provides support to ensure that vaccines produced or imported meet its safety and potency requirements. It is paying particular attention to regional scope when setting new biological standards, whose adoption and application should be furthered by the revised Agreement on Technical Barriers to Trade.

⁵⁶ See *WHO Expert Committee on Biological Standardization: forty-fourth report*. Geneva, World Health Organization, 1994. Technical Report Series N° 848.

⁵⁷ Assessing the quality of biological substances used in medicine is difficult as they cannot be evaluated by conventional analytical measures. They are calibrated by comparing, in a biological assay, a substance's activity with that of a standard with a defined activity or potency.

⁵⁸ Good Manufacturing Practices for Biological Products, in: *WHO Expert Committee on Biological Standardization: forty-second report*. Geneva, World Health Organization, 1992. Technical Report Series N° 822, Annex 1.

⁵⁹ Guérin N, Kaddar M, de Champeaux A. *Le marché du vaccin et l'avenir des programmes de vaccination en Afrique*.



Wholesome food: from raw to processed

WHO has actively participated in the formulation of international food standards since 1962 when the Joint FAO/WHO Food Standards Programme was established.⁶⁰ The specific purpose of the Programme is to draw up internationally agreed standards in order to facilitate trade in food while safeguarding consumers' health. With world trade in food⁶¹ amounting to some US\$250 thousand million,⁶² there are strong economic reasons for countries to ensure that their food exports meet those standards.

The Programme is implemented by the Codex Alimentarius Commission, an intergovernmental body open to all Member States of WHO and FAO. Its membership, which has been steadily rising, currently stands at over 150. The Commission sets out in objective terms the required qualities of all the principal foods - whether processed, semi-processed or raw - for international trade, in order to ensure at least the minimal level of quality. Members are invited to embody the standards, published in the *Codex alimentarius*, into their national legislation. The participation of leading scientists and national food safety experts in their preparation helps to make them nationally acceptable, although some countries encounter difficulties in adopting them.⁶³

As food processing calls for special attention to wholesomeness of raw materials and to hygienic processing, the Commission recommends to governments guidelines on good manufacturing practices. It has also drawn up a code of ethics for international trade in food, covering such aspects as food hygiene, labelling, infant food, or nutritional value. The increasing use of Codex standards and codes of practice in trade contracts indicates that they are an authoritative reference source for the purposes of trading and of consumer protection.⁶⁴

Codex standards and trade dispute settlements

The Codex standards long served as a reference for GATT with respect to technical barriers to trade and played an important role in procedures to settle food-related trade disputes, functions which will continue under WTO. In assessing complaints about misuse of food safety standards as trade barriers, a dispute resolution panel examines whether a country has, without scientific basis, exceeded an international food standard in an attempt to discriminate against foreign suppliers, rather than to safeguard public health. If national standards are comparable to Codex standards, a panel would assume that they are not trade discriminatory.

Relation between the Codex Alimentarius Commission and the General Agreement on Tariffs and Trade. Geneva, World Health Organization, 1993. Document A46/25, Annex

⁶⁰ Resolution WHA16.42 (1963).

⁶¹ Commodities that are considered edible and contain nutrients. FAO definition.

⁶² in 1993. *FAO trade yearbook and FAO fisheries yearbook*. Rome, Food and Agricultural Organization of the United Nations, 1994.

⁶³ See The Codex Alimentarius Commission. WHO, 1987.

⁶⁴ *Idem*.



Codex standards and codes are particularly useful for developing countries, which in 1992 accounted for 27.5% of exports of food, live animals, beverages and tobacco (excluding oils and fats).⁶⁵ Food commodities are often their initial, and possibly principal, export, and adding value through processing is a source of increased revenue and employment. Application of standards, for exporters, helps to ensure quality and avoid possible rejection of shipments, with consequent loss of foreign exchange. For importers, which may not yet have strong food control mechanisms, it should counteract attempts to offload poor quality or unsafe food.⁶⁶ For producers in general, it raises the quality of goods for the domestic markets.

The revised Agreement should strengthen the function of Codex standards, guidelines and recommendations as a yardstick for national requirements and should encourage countries to use them more effectively.⁶⁷ It is worth noting that it should have no effect on implementation of the International Code of Marketing of Breast-milk Substitutes, which is a marketing, not a trade, code. None the less, WHO will remain vigilant to the possibility that restrictions on advertising of breast-milk substitutes may be interpreted in some jurisdictions as restrictions on trade.⁶⁸

WHO has recently been accorded observer status at WTO's Committee on Technical Barriers to Trade, which Members may consult on any matter relating to operation of the Agreement or to furtherance of its objectives.

⁶⁵ *International trade statistics yearbook 1993*. New York, United Nations, 1995.

⁶⁶ *Introducing Codex alimentarius*.

⁶⁷ *Relation between the Codex Alimentarius Commission and the General Agreement on Tariffs and Trade*. WHO, 1993.

⁶⁸ *Implications of GATT for WHO's international health work*.



6 FOOD PRODUCTION: SAFETY FIRST

With regard to the work of the Codex Alimentarius Commission on **food safety**, a number of implications stem from the Agreement on the Application of Sanitary and Phytosanitary Measures.

This Agreement derived from the Uruguay Round negotiations on trade in agriculture which covered, among other areas, sanitary and phytosanitary measures. Its purpose is to establish a multilateral framework of rules to guide the development and application of such measures in order to minimize their negative effects on trade, and to encourage the use of harmonized measures based on international standards, guidelines and recommendations. It covers all legislation, regulations, requirements and procedures applied by Member States to protect human and animal life or health from risks arising from additives, contaminants, toxins and disease-causing organisms in foods, beverages, and feed; to protect human life or health from the risk of diseases carried by animals; and to protect animal or plant life or health from risks arising from the entry or spread of pests, diseases or disease-causing organisms.

With the reduction of other barriers to trade, it is possible that sanitary and phytosanitary measures might be used for protectionist purposes. Thus the provisions of the Agreement are more specific than those negotiated for the Agreement on Technical Barriers to Trade,⁶⁹ and elaborate, among others, on the provisions of GATT article XX.1(b) (see section 3).

Members have the right to take the sanitary and phytosanitary measures they deem appropriate to protect human, animal or plant life or health, but must ensure that they are not more trade restrictive than necessary to meet their health objective, are based on scientific principles, and are not maintained without sufficient scientific evidence. They will continue to determine their own level of protection, based on a risk assessment that takes account of available evidence and relevant processing and testing methods. The procedures used and decisions taken by a country in assessing health risk have to be made available to others upon request.

In the preparation and application of sanitary or phytosanitary measures, account will be taken of the special needs of developing countries, in particular, the least-developed ones. Where the appropriate level of sanitary or phytosanitary protection allows for the phased introduction of new measures, such Members would have a longer period in which to apply them to their products, so as to maintain their export opportunities. For developing countries, the Agreement can be a useful tool to challenge unjustified barriers to their food exports, and to assist them in resisting political pressures to accept unsafe food and feed imports.

⁶⁹ See Relation between the Codex Alimentarius Commission and the General Agreement on Tariffs and Trade.



In order to harmonize national sanitary and phytosanitary measures, Members should take as a reference international standards, guidelines or recommendations. In the case of **food safety**, the Agreement expressly stipulates that these reference standards will be those established by the **Codex Alimentarius Commission** relating to **food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice.**

Should a Member choose to apply a national standard stricter than the corresponding international one, it would need adequate supporting scientific evidence in the case of a trade dispute. It may be asked to demonstrate that the international standard would not result in the level of health protection it considered appropriate.⁷⁰

Members are committed to playing a full part in the work of the Codex Alimentarius Commission. This participation is important to ensure that future Codex texts are consistent with the health and safety requirements of the different Members and supportive of their food export industry. However, the role that such standards will play in international trade may make the formulation of new Codex standards more difficult, and subject to political pressure. Existing standards will be subject to greater scrutiny, so must be up-to-date and irreproachable. In particular, more transparency and public participation is being demanded in the Codex process.⁷¹

In order to ensure that its texts fulfil their new function, the Codex Alimentarius Commission is taking action in the various fields referred to in the Agreement.⁷² The Joint FAO/WHO Expert Committee on Food Additives - whose recommendations, derived from risk assessment, provide a sound scientific basis for the work of the Commission - has reviewed most of the 250-some Codex food standards containing provisions for the use of certain **food additives**.⁷³ So far, standards for food additives have been drawn up for individual types of food. In order to cover the large number of processed foods available, the Commission is now developing a horizontal approach so that food additive standards can be applied across foods or food categories.

The maximum limits for **pesticide residues**, which cover a wide range of chemical compounds in many food commodities, will be revised to take account of reliable information on dietary intake, patterns of use and levels of pesticides, and of levels of pesticide in food at the time of consumption. Methods of **analysis and sampling** are evolving towards identification and monitoring of critical control points in food production and processing, and away from end-product testing. This approach is encouraged by the Commission as the most cost-effective way to assure food safety. The Commission also recommends to governments codes of **hygienic practice** covering premises, equipment and handling procedures for a wide variety of foods.

⁷⁰ See Understanding the World Trade Organization. GATT Secretariat, 1994.

⁷¹ See Relation between the Codex Alimentarius and the General Agreement on Tariffs and Trade.

⁷² The following paragraphs draw from The GATT Uruguay Round of multilateral trade negotiations. WHO, 1994.

⁷³ See, for example, the Forty-fourth report of the Expert Committee: *Evaluation of certain food additives and contaminants*. In press.



The heightened role of Codex standards has, however, highlighted some sensitive questions. The procedures followed to determine the health risks of **veterinary drug residues** are particularly rigorous, and the Commission has recommended maximum residue limits.⁷⁴ None the less, the use of certain animal drugs is a delicate matter that may cause trade disputes in which health and safety concerns are likely to be advanced. Settlement would take into account risk assessment techniques developed by international organizations, relevant processing and testing methods, and available evidence. In the case of **contaminants** - principally heavy metals - in food, maximum levels were established some time ago. However, defining the lowest limit compatible with the availability of food in the case of such contaminants as aflatoxin requires the assessment of risk and benefit on which it has been difficult to reach an international consensus.

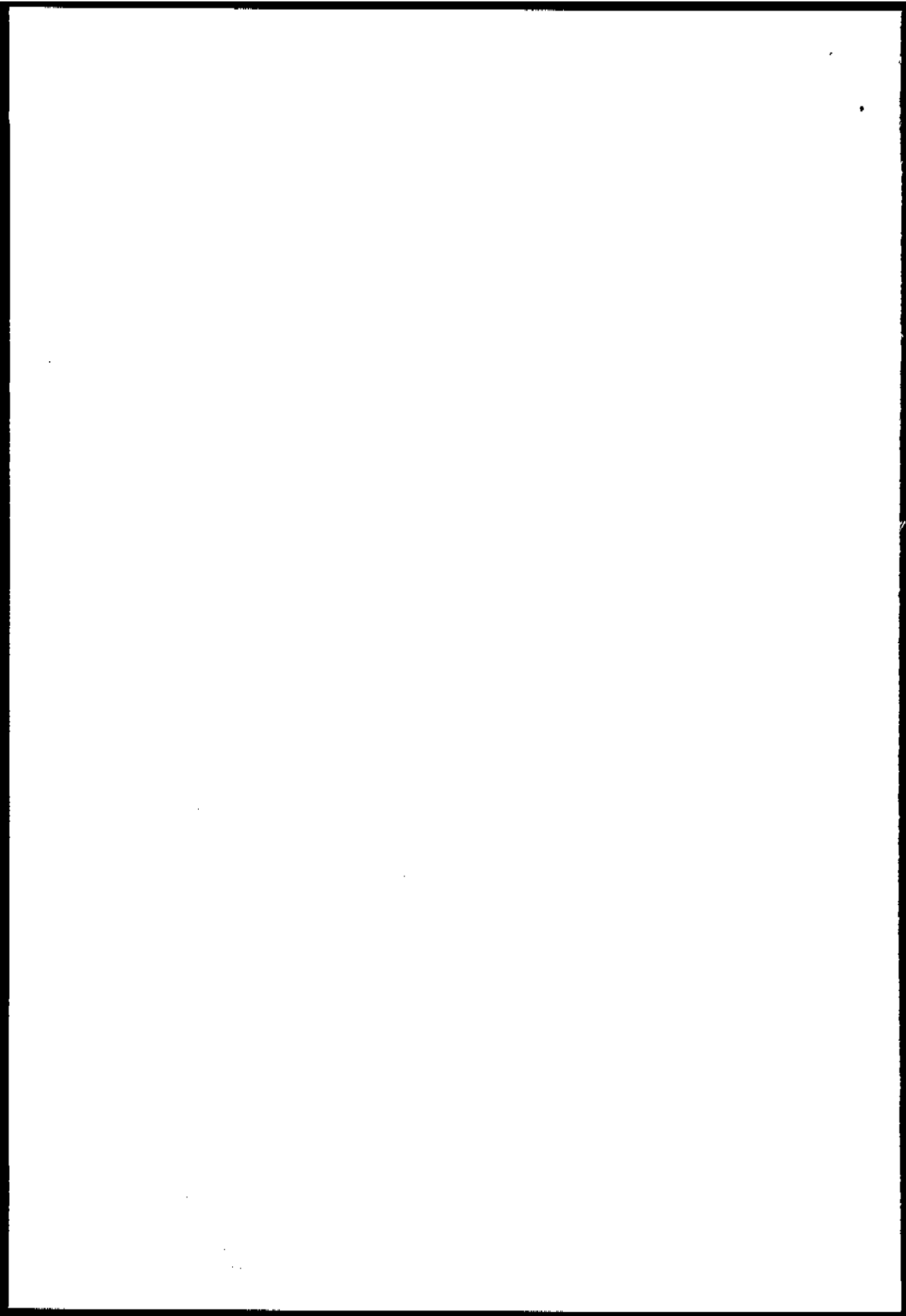
In order to benefit from new possibilities through trade liberalization, developing countries will need to demonstrate that their products meet Codex requirements. The development of agricultural export industries may be hampered by the absence of food control infrastructure that would assure the safety of exported food products. Under the Agreement, Members agree to provide, either bilaterally or through the appropriate international organization, technical assistance in the areas of processing technologies, research and infrastructure, including the establishment of national regulatory bodies, so that developing countries can achieve the appropriate level of protection in their export markets.

In the light of the Agreement, WHO will gear its work along two main lines. It will continue to play its part in setting food safety standards, while helping to build up health sector participation in the work of the Codex Commission.⁷⁵ In particular, it can make a tangible contribution to countries' efforts to meet Codex standards, guidelines and recommendation by cooperating in establishment of national food control infrastructure, including inspection facilities and laboratories for food analysis. Further, in a case of dispute concerning a national health standard stricter than the international one, WHO would be well placed to evaluate the scientific evidence required as justification.

WHO has recently been accorded observer status at WTO's Committee on Sanitary and Phytosanitary Measures, which provides a forum for discussion and monitors the process of international harmonization of standards.

⁷⁴ *Evaluation of certain veterinary drug residues in food: Forty-third report of the of the Expert Committee.* Geneva, World Health Organization, 1995. WHO Technical Report Series No. 855.

⁷⁵ Recommendations of the WHO Executive Board's subgroup for the review and evaluation of specific programmes: food and nutrition. Geneva, WHO, 1995. Unpublished document EB95/Working Paper N°1.





7 OPENING UP HEALTH SERVICES MARKETS

An innovation of the Uruguay Round was the introduction of negotiations to liberalize trade in services, a sector which accounts for a growing share of the national product in both industrialized and developing countries. The outcome was the General Agreement on Trade in Services (GATS), which lays the basis for further rounds of negotiations. A two-part document, it provides a framework for regulating such trade according to a set of principles similar to those of GATT - notably, most-favoured nation treatment and nondiscrimination between sources of supply - and contains schedules of Members' specific commitments related to services.

Services are defined in the Agreement according to the way in which they are supplied:

- across a border (telemedicine services, for example)
- through consumption abroad (for instance, a patient travelling to another country for treatment)
- through commercial presence, i.e. establishment of a foreign enterprise in a country (such as a health maintenance organization)
- through the presence of people who are service suppliers (foreign health professionals, for example).

These definitions are considerably broader than the cross-border supply of services alone. The framework of principles, however, applies only to those services for which a Member has agreed to open its domestic market. In other words, it covers what countries have themselves placed on offer to foreign service suppliers. A national schedule indicates the service sectors and activities to which a Member will apply market access and national treatment obligations. It contains two kinds of commitment: "horizontal", that apply to all sectors included in the schedule, and specific, that apply to a specified sector. Members are entitled to place limitations on their commitments, provided that these are clearly indicated. In other words, they are not obliged to lift all barriers to trade in services, but must specify those they intend to maintain; these limitations are spelled out in the schedules.

With regard to the movement of people supplying services under the Agreement, an annex stipulates that provisions apply only to those who are service suppliers or employed by a service supplier in accordance with the terms of a specific commitment. They do not apply to people seeking access to a foreign labour market.

For developing countries, initially reluctant for services to be included in negotiations, the main objective was to ensure that priority was given to development, and that national laws and regulations would remain supreme.⁷⁶ In effect, the Agreement, to which they could accede by making commitments in a minimum of one service sector, recognizes the right of Members to regulate the supply of services to meet national

⁷⁶UNCTAD, *op. cit.*



policy objectives. Members will help developing countries to benefit from the growth of trade in services by liberalizing market access in sectors of export interest to them and by improving the efficiency of their domestic services through access to technology (on a commercial basis). In both cases priority is given to least developed countries.

National policy objectives and the level of development of individual Members will be respected as the process of liberalization continues. Developing countries may open fewer sectors and liberalize fewer types of transactions, progressively extending market access in line with their development situation.

Of particular interest to the health sector is the provision in the Agreement which excludes services supplied in "the exercise of governmental authority", understood as provided neither on a commercial basis nor in competition with other service suppliers. This is reflected in the comparatively few commitments made in the health sector, where services are often provided essentially by government and where competitive or commercial provision is not widespread. In all, some 27% of Members (industrial and developing in equal numbers) made commitments to open up hospital services to foreign suppliers, and 35% (also roughly even among the two groups) did so for medical and dental services. Some 19%, mostly industrialized countries, scheduled the services of health personnel other than physicians.⁷⁷

Of the 21 developing countries involved, most place no limitation on foreign consumption of hospital or medical service. They often make no commitment on cross-border supply of services, usually because it is not technically feasible; and occasionally place a foreign-equity ceiling on commercial presence. It is clear that the most sensitive category is the presence of persons supplying services, which is usually subject to the horizontal limitations applying to all sectors. For example, they must be specialists

China sets its conditions for foreign suppliers of medical services

China makes no commitments on the cross-border supply of medical and dental services, which is likely to be technically unfeasible. Nor does it make any commitment on its nationals consuming such services abroad. Foreign-owned hospitals or clinics (i.e. foreign-capital enterprises) are not permitted, but foreigners may establish equity or contractual joint venture hospitals or clinics with Chinese partners. The number is limited in line with China's needs. However, these establishments have to assume sole responsibility for the relevant foreign exchange balance of payments and for their profits and losses. Most of the medical staff must be Chinese nationals.

Foreign doctors with more than five years' experience may provide medical services for up to one year in China, provided they have a contract with a Chinese medical institution.

Legal instruments embodying the results of the Uruguay Round of Multilateral Trade Negotiations done at Marrakesh on 15 April 1994. Annex 1b: General Agreement on Trade in Services

⁷⁷ Based on The results of the Uruguay Round of multilateral trade negotiations. GATT, 1994



and senior staff, must already belong to a service-supplying enterprise, must train local counterparts, or must belong to the national medical association.⁷⁸

The extent to which governments might wish to open their health sector to foreign service suppliers is a policy choice. They might be reluctant to take this step without prior experience either of national private provision of health services or - and perhaps more important - of managing contracts for those services. Where the private sector is already involved, the question would be whether to take this option a step further and permit foreign private sector involvement, a decision likely to be taken in the context of a country's development strategy as a whole.

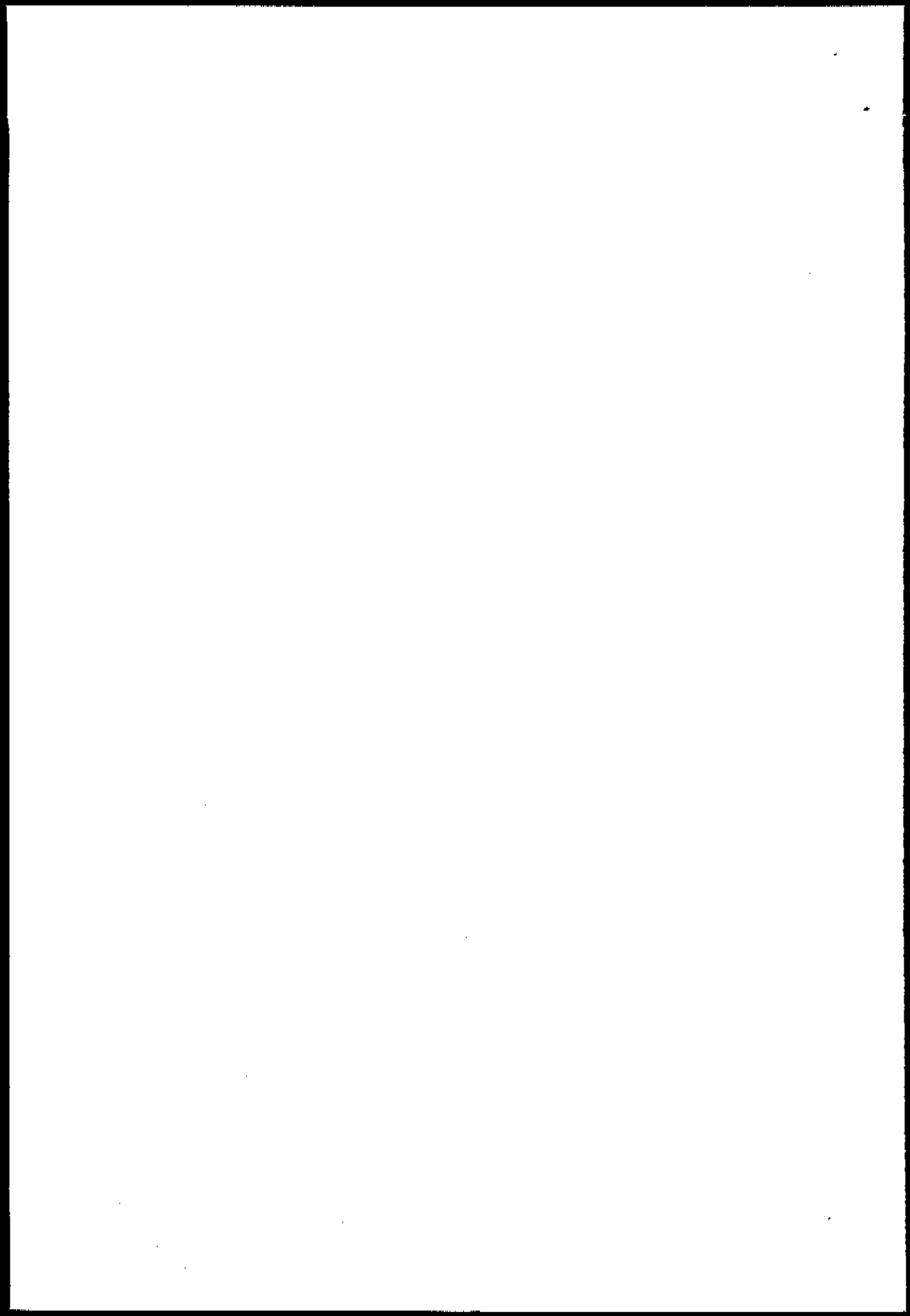
To face this potentially radical change, ministries of health in developing countries need strong analytical and managerial capability. As part of its support to the organization of health systems based on primary health care, WHO provides governments with updated information on ways to manage change. It advises them on such aspects as the appropriate mix of public and private involvement in health services, encouraging them to share their experience in managing that mix, and the maintenance of effective links between central authorities, district health systems and local communities. It develops the methods and instruments needed to analyse policy options and to plan and manage physical resources.

Effective regulatory capacity is essential if policies that encourage private sector participation are to be successful, *a fortiori* if that participation is foreign. WHO emphasizes country-specific cooperation in order to build up the ability of ministries of health to frame policy, to regulate the provision of health services, and to harmonize private sector activities with the objectives of the national health system.

None the less, access to new private services might not be possible for everyone; and the needs of those left underserved would require special attention. Thus WHO is working to improve planning and management at district level, and is analysing the impact of decentralization policies on equitable access to care. It encourages, in particular, the participation of communities in the operation of local services.

The effect of the new Agreement on the health sector is limited at present, although a trend towards foreign private sector participation in national health services might develop in the future. For WHO, the foremost objective is to ensure that change makes health systems more equitable and accessible to all the population.

⁷⁸Legal instruments embodying the results of the Uruguay Round of Multilateral Trade Negotiations done at Marrakesh on 15 April 1994. Annex 1b: General Agreement on Trade in Services.





8 EXTENDING PATENT PROTECTION

Intellectual property rights have long been protected by several specific conventions. Since the establishment of the World Intellectual Property Organization in 1967 they have been administered by a single body, which also worked on harmonizing national legislation. However, rights could not always be strictly enforced. Infringements of protection and growing trade in counterfeit goods induced several industrialized countries - the major holders of intellectual property rights - to introduce in GATT negotiations rules for provision of protection, to be applied in all countries.⁷⁹ By bringing protection of intellectual property into trade, enforcement could be carried out on a broader basis: countries would have the right to retaliate against infringement in one sector by action in another.⁸⁰ In fact, a number of developing countries had already started to strengthen protection of intellectual property rights in order to attract foreign direct investment and to promote the transfer and dissemination of technology.⁸¹

Essentially, the Agreement on the Trade-Related Aspects of Intellectual Property Rights - building on existing international conventions - establishes minimum standards and enforcement measures for the protection of, among other, patents, copyrights, trademarks⁸² and industrial design - which are to be incorporated into national legislation by all Members. Patents will be available for any new, innovative and industrially applicable invention, **whether product or process, in all fields of technology**, and without discrimination as to place of invention, field of technology or origin of the product (locally produced or imported). Patents will be protected for 20 years from the date of application; protection of existing patents will be extended accordingly. However, there is no obligation to recognize rights retroactively, or to restore protection to subject matter which has fallen into the public domain.

The Agreement allows certain exclusions to patentability, in particular for the purposes of protecting human, animal or plant life or health or to avoid serious environmental damage. Members may also exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals (e.g. heart bypass methods), plants and animals, and biological processes for the production of plants and animals (e.g. naturally produced livestock). They may not, however, deny a patent for micro-organisms or for nonbiological and microbiological processes for the production of plants and animals.

While setting out a considerable number of conditions, the Agreement also provides for use of a patent without the authorization of the holder. Although not specified

⁷⁹ Evans P, Walsh J, *The EIU guide to the new Gatt*.

⁸⁰ Suspension of concessions, however, should be restricted to the sector in dispute. Cross-retaliation is allowed only as last resort. *World Economic and Social Survey 1995*.

⁸¹ Evans P, Walsh J, *op. cit.*

⁸² The provisions of the Agreement on trademarks are unlikely to effect WHO's work on international nonproprietary names for pharmaceutical products. They refer essentially to the working of a trademark: a registration may be cancelled after three years of non-use.



in the text, this can be understood as the granting of a compulsory license.⁸³ This may be done in the case of a national emergency or for public noncommercial use. A compulsory license could also be granted to protect public health and nutrition, or for other reasons of public interest, or to correct anticompetitive practices.

A series of penalties are set out for the infringement of rights. Usually, it will be for a complainant to prove infringement of a patent. In the case of a process patent, though, the burden of proof is reversed when certain conditions are fulfilled that establish the likelihood that a protected patent has been used. In other words, it is for the defendant to prove that the process is different from the patented one.

The Agreement provides for a delay in implementation of most of the provisions from one year for industrialized countries, five years for developing countries, to eleven years (extensible) for the least-developed countries. Where developing countries have to extend patent protection to a field of technology not previously protected, they are allowed an additional five-year transitional period. None the less, special provisions are made for the protection of pharmaceuticals and agrochemicals: patent applications may be filed as from the date the Agreement entered into force and, under certain conditions, a product subject to a patent application will be granted exclusive marketing rights for five years.⁸⁴

In view of the technology gap between groups of countries, the industrialized countries agree to provide incentives to their enterprises and institutions for the purpose of promoting and encouraging the transfer of technology to least-developed countries to enable them to build up a sound and viable technological base.

The provisions of the Agreement will directly affect the health sector because for the first time patenting of **pharmaceuticals** has become compulsory, although there are now few countries which do not yet provide product patent protection for such products. The new regulations may entail higher prices for patented medicines as pharmaceutical companies recoup research and development costs. This may imply economic and social costs in developing countries⁸⁵, and a possible transfer of income from South to North in the form of royalties from the licensing of patented medicines.⁸⁶ On the other hand, any impact on prices would be considerably delayed, as drugs which met the criteria for patentability after the Agreement came into effect will generally not reach the market for another ten to twelve years. The potential effect would also depend on government price control policies at that time.⁸⁷

⁸³ See Correa C. *Los acuerdos de la Rueda Uruguay y los medicamentos*.

⁸⁴ For a detailed explanation of the new regulations for patent protection, see Correa C, *The GATT Agreement on Trade-related Aspects of Intellectual Property Rights*.

⁸⁵ See, for example, *Los medicamentos ante las nuevas realidades económicas*.

⁸⁶ Evans P. *op. cit.*

⁸⁷ For a discussion of the possible effects of the TRIPS Agreement on pharmaceutical prices, see Ouen A, *The GATT TRIPS Agreement and health care in India*.



What will happen to essential drugs and vaccines?

One of WHO's objectives is to collaborate with Member States to ensure the regular supply - at the lowest possible cost - and the rational use, of a selected number of safe and effective drugs and vaccines. It was largely with this in mind that the Declaration of Alma-Ata in 1978 identified access to essential drugs as a basic element of primary health care.

In order to provide a framework to ensure such access, WHO advocates that every country should have a national drug policy - in turn an integral part of its health policy. It was for the purpose of supporting countries in drawing up and implementing national drug policies that WHO launched its Action Programme on Essential Drugs in 1981.

One of the basic components of a country's drug policy is a national list of essential drugs. Recognizing the need for the most necessary drugs to be available at a modest price, WHO drew up in 1977 a Model List of Essential Drugs containing over 200 pharmaceuticals and vaccines which would ensure a reasonable level of health care for as many people as possible. All the drugs on the List are of proven safety and efficacy; most are no longer protected by patent and can be produced inexpensively in quantity. Revised every two years,⁸⁸ the List provides a basis for countries to identify their priorities and to make their selection according to national health needs. Over 110 countries have drawn up their essential drug list.⁸⁹

The List contains the vaccines required for EPI. Established in 1974, the goal of the Programme is to provide universal childhood immunization, targeting - initially - poliomyelitis, diphtheria-pertussis-tetanus, tuberculosis and measles. Most of the vaccines listed are not protected by patent and can be produced by any manufacturer - often public research institutes - without payment of royalties.

Might the objective of ensuring a regular supply of low-cost drugs be jeopardized by stronger patent protection? The new provisions should not have an immediate effect on the price or availability of pharmaceuticals on national lists of essential drugs. As most of them are off-patent, they can be manufactured freely under their generic, or international nonproprietary, name and can usually be bought at a much lower price. In 1994, 95% of the 200 most widely prescribed drugs in the United States were out of patent;⁹⁰ the situation was similar in India.⁹¹

In those developing countries with a domestic pharmaceutical industry, such as Argentina, Brazil, China or India, manufacturers are likely to concentrate on the

⁸⁸ The current List is contained in *The use of essential drugs: sixth report of the WHO Expert Committee*. Geneva, World Health Organization, 1995. WHO Technical Report Series No. 850.

⁸⁹ Essential drugs: action for equity. Geneva, WHO Action Programme on Essential Drugs, 1992. Unpublished document WHO/DAP 92.5.

⁹⁰ Dukes M. Change and growth in generic markets in developed and developing countries.

⁹¹ Karandikar SM. *Indian drug industry after GATT*.



production of generics, and might be able to take advantage of lower production costs to increase exports of off-patent bulk drugs.⁹² WHO, in collaboration with the International Trade Centre, issues a monthly bulletin, the 'Pharmaceuticals raw materials/essential drugs report', to inform developing countries of purchasing prices of raw materials for production of essential drugs, in order to improve importers' opportunities for negotiation.

With regard to the development of new drugs for diseases afflicting specifically people in poor developing countries - the diseases of poverty - research has tended to depend on economic considerations, in other words, the value of the potential market.⁹³ Although patent protection is an incentive to drug development in industrialized countries, it will take time to determine whether it has a similar effect on R&D efforts in developing countries.

In the case of vaccines, the demand for the off-patent EPI vaccines is met to a considerable extent by local manufacture in developing countries. In general, though, vaccine production tends to be segmented between the traditional, non-patented vaccines intended for developing countries and the new products sold with higher profit margins in industrialized countries.⁹⁴ Yet there can be outstanding exceptions, such as the one described in the box below.

Malaria vaccine developed in Colombia

A breakthrough on several counts, the malaria vaccine developed and patented by Manuel Patarroyo of the Institute of Immunology of Bogota is currently undergoing trials in Gambia and Thailand. The vaccine, known as SPf66, is the first against malaria, the first against any parasitic disease of humans, and the first active vaccine against any organism to be based on synthetic peptides - fragments of proteins - which mimic peptides from the malaria parasite *Plasmodium falciparum*.

In an agreement signed in May 1995, the inventor granted WHO an exclusive, worldwide, royalty-free licence to his patent and know-how. The agreement is part of wider discussions between WHO, Dr Patarroyo and the Colombian Government for the bulk manufacture of the vaccine in Colombia, at cost, by a nonprofit organization. Subject to further trials and development, and the definition of a public health policy on the vaccine, SPf66 would be distributed globally, at the lowest possible cost, particularly for public sector use in developing countries.

New Scientist, 5 November 1994; WHO Press (Press Release WHA/6. 4 May 1995)

The fact, however, that the Agreement has introduced the patenting also of processes is a cause of concern. If a new and more efficient technique were to be invented for producing an off-patent drug, that process could be patented; the new product

⁹² Karandikar SM, *Indian drug industry after GATT*.

⁹³ See Implications of GATT for WHO'S international health work.

⁹⁴ Guérin N, Kaddar M, de Champeaux A, *op. cit.*



might then be in a dominant market position. Hence, when incorporating the provisions of the Agreement into national legislation, consideration could be given to using relevant stipulations for the purpose of encouraging competition among products that are essential for public health and of ensuring that they are accessible to everyone.⁹⁵ For example, the possibility could be examined, if necessary, of introducing compulsory licensing in order to discourage anticompetitive practices.

Biotechnology left in doubt

Queries arise, however, concerning products resulting from the application of biotechnology, involving such processes as gene transfer, cell manipulation or recombinant DNA technology. Biotechnology is making a significant contribution to increasing the availability, for example, of therapeutic human proteins (such as insulin, interferon, growth hormone, or tissue plasminogen activator) through *in vitro* production, and of antibiotics, enzymes, or purified blood products. It is having particular impact on the introduction of new and improved vaccines, such as the recombinant vaccines prepared using monoclonal antibodies or genetic engineering - products and processes which are patented.

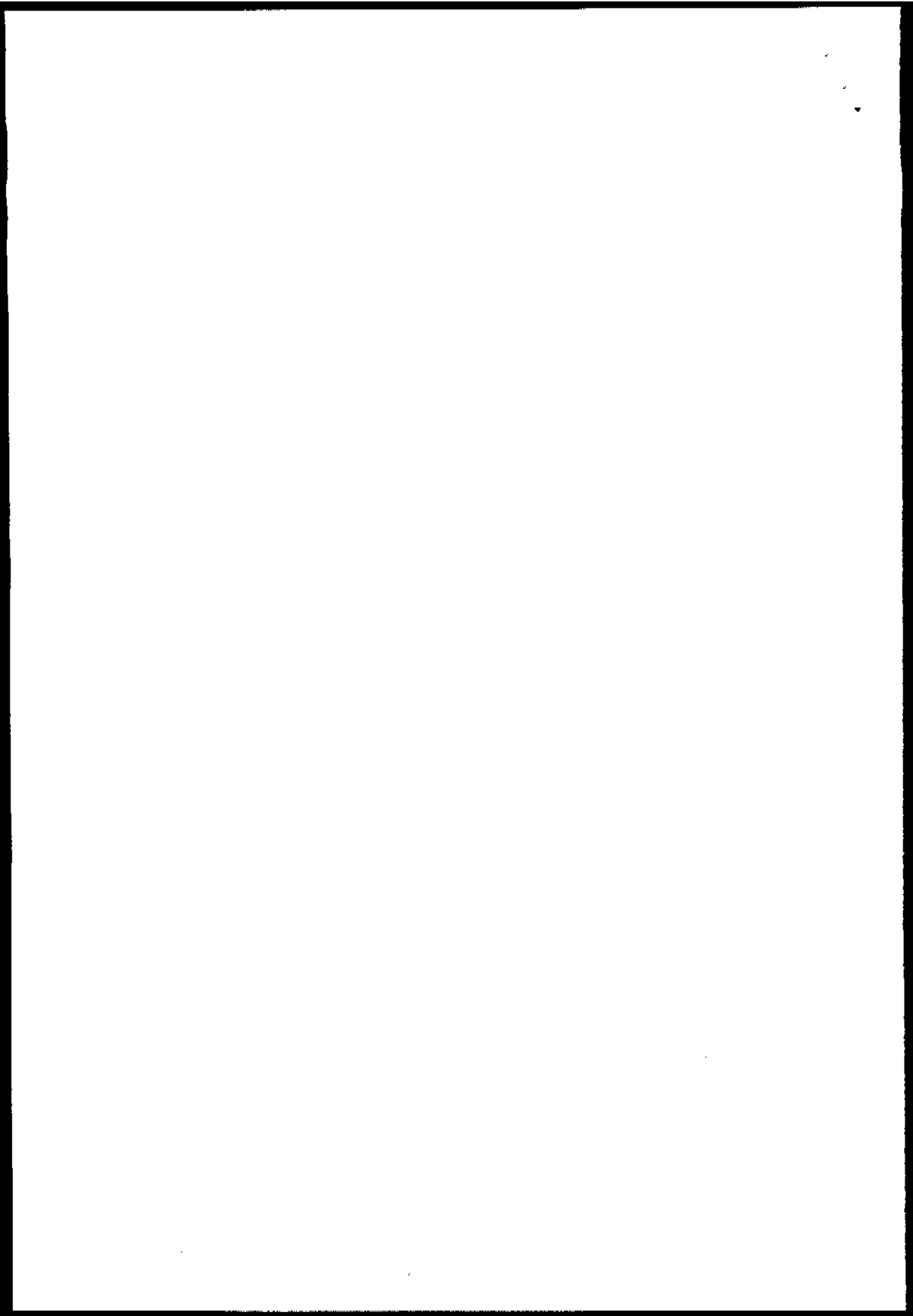
The provision of the Agreement concerning biotechnology is subject to debate. It does not specify, for example, if replication of a naturally existing gene for a human protein should be patented or not, so is open to different interpretations. Some Western countries recognize that such a substance can be patented, if and when it is produced and isolated in a purified form from a foreign cell. Other countries consider that in this case there is no "invention", simply a "discovery" that cannot form the basis for claiming intellectual property rights. One commentator has expressed the view that the Agreement admits the interpretation that such substances are not inventions, thus excluding from patent protection drugs and vaccines based on substances existing in nature.⁹⁶ Local production is likely to depend on the extent to which individual countries make use of the possible exclusions in this domain. This provision is also significant for countries, like China, which make considerable use of plant-based medicaments.

It is worth noting, however, that this provision is subject to revision four years after the Agreement enters into force, i.e. before the end of the transition period for developing countries. Regulations might therefore be modified before they can be implemented.

In matters relating to health aspects of pharmaceuticals and patent protection, WHO would be in a position to collaborate where appropriate with the Council for Trade-Related Aspects of Intellectual Property Rights, which monitors the operation of the Agreement and governments' compliance with it.

⁹⁵ For a development of this subject, see C. Correa, *Los acuerdos de la Rueda Uruguay y los medicamentos*.

⁹⁶ *Idem*.





9 POLICY CONSIDERATIONS

The expected outcome of the new agreements is a boost to trade throughout the world within a stable and regulated trading environment, which should contribute to the prosperity of all partners. For developing countries the stakes are higher; even - or especially - for the poorest, increased export earnings would represent an opportunity to improve the living conditions of their people.

None the less, whether rising exports have an impact on standards of living throughout the population will depend on such factors as the kind of goods exported, the extent to which the activities concerned generate employment, their linkages with other sectors of the economy, and the way in which new income is distributed. Together, they determine the degree to which export earnings will benefit ordinary people, rather than reinforce existing inequalities. In other words, the goal of broad-based income growth would be combined with measures to improve the conditions of the very poor.

Only participation of the health sector in framing national development policies can ensure not only that additional resources are channelled to health and directed especially at the poorest and most vulnerable groups, but also that existing health finances are used in the most cost-effective way. Such policies would thus contribute to achieving improved health status and greater equity in health.

Special attention to the poorest

Although increased export earnings resulting from greater market access should contribute to alleviating poverty, specific actions may be needed to protect the poorest people as economies become more market-oriented.

Sri Lanka, for example, launched the 'Janasiviya' programme, a set of interventions intended to help the poorest people to improve their well-being, and to provide them with the means of doing so, including assurance of a stable nutritional intake and promotion of income-generating self-employment. A special component has been built into the programme to improve - on the basis of community participation - the health of all marginalized people, especially the most vulnerable groups. The scheme provides an integrated package of services centred around a network of preventive and community health activities so as to meet basic health needs at a relatively low cost.

Evaluation shows that this component was able to encourage even poor households to use part of their resources for improving living conditions, sanitation and nutrition, helping to improve and sustain their well-being.

Poverty and its effects on health: alleviation of poverty through TCDC and health intervention. Geneva, World Health Organization, 1995. Unpublished document ICO/19/NAM/95.4

The new trade agreements render particularly relevant one of WHO's major policy orientations proposed as a focus for action by the health community, that of **protecting health**.⁹⁷ In fact, they provide a special opportunity to strengthen and to further

⁹⁷ See *Ninth General Programme of Work*.



WHO's normative work. The formulation, application and enforcement of regulatory measures are essential to protect workers from health hazards and to prevent and control risks to environmental health. For them to be effective implies the ability to collect and analyse information on working conditions and to monitor and assess environmental risks for health. Close collaboration with other sectors is therefore indispensable to ensure that health considerations are at the fore when framing policies for development of agriculture, manufacturing and industry.

Health is further protected by the adoption and application of international standards that assure the quality of pharmaceutical and biological products and foodstuffs. Effective enforcement will depend on adequate control facilities and technically competent staff to ensure that relevant international requirements are met. The result should be not only the use of high-quality products, but also establishment of the necessary quality assurance infrastructure.

At the same time, if countries take part in the work of normative bodies they can ensure not only that appropriate standards are set for products of interest to them, but also that they are set with the technological possibilities of both developing and industrialized countries in mind. The ability to participate actively in, for example, relevant expert committees or the work of the Codex Alimentarius Commission, will underpin efforts to achieve a balance between technological capacities of different groups of countries, thereby avoiding a situation of potential dependency.

A second major policy orientation - **that of ensuring equitable access to health services** - is especially relevant if countries opt for greater private provision of health services, whether domestic or foreign. Such a decision implies both a judicious choice regarding the mix of private and public suppliers, and priority to assuring the coverage of those unable to afford health care, whether provided publicly or privately. Further, it will require setting - in line with a country's needs - the conditions under which services may be provided by a foreign supplier, while being fully regulated by national authorities.

When countries harmonize their efforts

In 1993 the five Members of the Andean Pact⁹⁸ defined a common pharmaceutical policy for the Andean region. Reaffirming that the State is responsible for guaranteeing availability of and equal access to good-quality drugs at affordable prices, it contains two main lines: promotion of essential drugs as the most equitable approach, and use of generic drugs as the best commercial alternative. The Members are drafting a common drug law that reflects these choices.

In order to select the products that may enter the subregional pharmaceutical market, the countries are drawing up a common list of essential drugs and harmonizing their pharmacological standards and registration requirements. They all agreed on joint implementation of good manufacturing practices as the most effective way to ensure quality. Their approach to supply and marketing combines the advantages of decentralization with a stronger negotiating position resulting from pooled purchasing.

Pharmaceutical policy of the Andean subregion. Geneva, World Health Organization, 1993. Unpublished document WHO/DAP/93.7

⁹⁸ Bolivia, Colombia, Ecuador, Peru and Venezuela



Similarly, with changes in patent protection, assuring that the poorest are not excluded from access to necessary drugs and vaccines will also be a priority. New patent laws will need to be regulated in a way compatible with the interest of public health, minimizing the economic and social costs of changes in production and trade of pharmaceuticals. Establishment of comprehensive national drug policies, addressing all aspects of selection, manufacture, quality assurance, financing, distribution and rational use in the public and private sectors, will help to strengthen the regulatory functions of ministries of health and to ensure universal access to, and rational use of, safe, effective and low-cost drugs.

An outward-looking approach, at both national and regional level, will be needed for health concerns to be considered when policy decisions are made. Participation of the health sector in national policy-making will help to ensure that legislation incorporating new commitments on trade include the measures necessary to protect public health. Further, the position of the sector can be strengthened within regional groupings, for improving, through cooperation, not only health status within countries, but also defence of public health concerns when decisions affecting health are taken on an international basis.

Given the limited references to health in the new trade agreements, WHO could well play a pivotal role in analysing links between trade policy and health development, an area which has so far received little attention. This analysis would provide **opportunities** for WHO to bring health concerns to the forefront of current political debate, reaffirm its **commitment** to achieving improved health status and greater equity in health, and set out a range of **options** for action.

WHO is well placed to open a dialogue within the international community in order to present the health and related aspects of the new agreements to institutions in different spheres of activity, contributing to a balanced view of the development process. It would thus broaden its advocacy campaigns so that health gains visibility in new areas. It is also in a position to place its specialized scientific and technical knowledge and expertise at the service of the international community for application in a broader context.

The Organization is setting about informing and raising awareness of health authorities of potential effects of the new agreements, so that governments may duly appraise the possible health and related consequences of increased trade. It is doing so in line with one of its foremost policy orientations: **integrating health and human development in public policies**. Its purpose is to strengthen the ability of the health sector to gain political commitment and to promote intersectoral cooperation so that economic development may contribute to improving health status. In short, WHO is leading new conceptual and practical efforts geared to convincing all sectors of government of the priority to be given to health, and consequently to allocate appropriate resources to its protection and promotion.⁹⁹

⁹⁹ See, for example, Rodriguez-Garcia R, Goldman A (eds.), *The health-development link*.



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ACRONYMS AND INITIALS

- EPI Expanded Programme on Immunization
GATS General Agreement on Trade in Services
GATT General Agreement on Tariffs and Trade
ILO International Labour Organisation
IPCS International Programme on Chemical Safety
OECD Organization for Economic Cooperation and Development
SPS Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement on Technical Barriers to Trade
TRIPS Agreement on Trade-Related Aspects of Intellectual Property
UNCED United Nations Conference on Environment and Development
UNEP United National Environment Programme
UNESCO United Nations Educational, Scientific and Cultural Organization
WFP World Food Programme
WMO World Meteorological Organization
WTO World Trade Organization