Essential drugs save lives and improve health — but only if they are available, affordable, safe and properly used. In 2000 significant progress was made in: strengthening national pharmaceutical programmes, with notable achievements in countries in each of the six WHO regions; developing effective drug regulation; maximizing the impact of WHO clinical guidelines; helping countries respond to the impact of trade on their pharmaceutical sector; promoting safe and effective use of traditional medicine; and monitoring WHO’s work in essential drugs and medicines policy.

WHO’s current priority in medicines is to expand access to essential drugs, particularly for low-income and disadvantaged populations. Considerable progress is being made on drug selection and drug pricing. In 2001, greater focus is being put on financing, supply systems and quality assurance — areas in which effective work with countries and partnerships with other international organizations, aid agencies and nongovernmental organizations are crucial for achieving sound, sustainable results.

Dr Yasuhiro Suzuki, Executive Director
Health Technology and Pharmaceuticals
and
Dr Jonathan Quick, Director
Department of Essential Drugs and Medicines Policy

**Policy: vital for health systems development**

*Direct policy and technical support to countries* was strengthened to better support Member States in this critical area of health systems development. This included creating a five-person essential drugs and medicines policy unit in the Regional Office for Africa and initiating a process to select WHO national essential drugs advisers for seven African countries. In the Americas, 17 full-time professionals are now working on essential drugs issues.

Armenia, Azerbaijan, Bolivia, Brazil, Chad, China, Colombia, Costa Rica, Egypt, Georgia, Guatemala, Jamaica, Kyrgyzstan, Laos, the former Yugoslav Republic of Macedonia, Mongolia, Namibia, Oman, Pakistan, Papua New Guinea, Peru, Romania, South Africa, Swaziland, Tajikistan and Yemen were among the countries who received support for national drug policy development and implementation. Additionally, a comprehensive national drug policy monitoring system was established in Cambodia, Chad, Kyrgyzstan, Mongolia, Namibia and several of India’s largest states (Box 1).

**Capacity to develop and implement national drug policy** was increased by
international two-week courses — one in Lebanon and another in Brazil — and by a regional workshop in the Philippines. At a meeting in Vienna, policy-makers and drug regulators of the Newly Independent States reviewed progress and next steps in pharmaceutical reform for their region.

Anglophone and francophone network meetings for essential drugs programme managers were held in South Africa and Togo and resulted in further strengthening of the African Intensified Essential Drugs Programme. In the Americas, national essential drugs programme managers met in Panama to revise activities in light of the WHO Medicines Strategy. Other means of tackling policy issues included the Director-General’s round-

table process with the research-based pharmaceutical, generic drug and self-medication industries, and public-interest nongovernmental organizations (NGOs). The roundtables have led to work on increasing access to antimalarials, improving drug quality, combating counterfeit drugs, developing drug price survey methodology, and documenting and critically evaluating drug promotion. Work on traditional medicine policy was also expanded, including efforts to validate this type of health care (Box 2).

At international level, work to coordinate pharmaceuticals policy and activities continued via the Interagency Pharmaceutical Coordination (IPC) group and through closer collaboration with the European Commission. The IPC group now includes all four United Nation agencies most concerned with access, quality and rational use of pharmaceuticals (UNFPA, UNICEF, UNAIDS, WHO) and the World Bank. In 2000, IPC met twice and started to develop interagency guidelines for accepting drug price discounts or donations of single-source pharmaceuticals.

**Access: framework for collective action**

Extensive efforts were made to increase access to essential drugs for treating specific diseases in particular, and to develop tools and methods for increasing access to essential drugs in general. A global framework for collective action to increase

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### Box 1: Monitoring to improve national drug policy performance

Evaluating the impact of national drug policy (NDP) formulation and implementation is part of WHO’s assistance to countries. The aim is to provide information and feedback to improve NDP performance. Core indicators have now been identified and are being used in some countries. In Cambodia, NDP monitoring is providing feedback for improving access to and use of medicines. In Namibia, indicators and targets were identified for each component of the country’s NDP implementation plan. An operational package has also been developed and is being used in Chad.

In Chad, the official NDP document and implementation plan were approved and adopted in 1998. As can be seen, strategies to improve public sector financing, drug pricing and management of drug donations have improved access to essential drugs for the population. The two indicators, “% of key drugs available in health facilities” and “stock-out duration of key drugs,” are being closely observed since fluctuations may indicate reduced access to essential drugs. Other indicators show that although Chad’s standard treatment guidelines were updated, no improvements have been observed in antibiotic and injection use. This is particularly worrying given that a public education campaign in rational drug use was carried out. A meeting on rational drug use to discuss the results and identify strategies is scheduled for 2001. Work in Chad is the result of cooperation between the Chad Government, WHO and the World Bank, and bilateral assistance.

<table>
<thead>
<tr>
<th>Core indicators monitored in Chad</th>
<th>1995</th>
<th>2001</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Access</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of population with access to essential drugs</td>
<td>46% (1999)</td>
<td>60%</td>
</tr>
<tr>
<td>% of medicine dispensed to patient at health facility</td>
<td>88%</td>
<td>89%</td>
</tr>
<tr>
<td>Public per capita expenditure on drugs</td>
<td>US$ 0.04</td>
<td>US$ 0.12</td>
</tr>
<tr>
<td>% of key drugs available in health facilities</td>
<td>80%</td>
<td>70%</td>
</tr>
<tr>
<td>Stock-out duration of key drugs</td>
<td>41 days</td>
<td>59 days</td>
</tr>
<tr>
<td>Affordability (cost to treat pneumonia/food basket):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>public pharmacies</td>
<td>18%</td>
<td>6%</td>
</tr>
<tr>
<td>private pharmacies</td>
<td>82%</td>
<td>39%</td>
</tr>
<tr>
<td>Implementing drug donation guidelines</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Rational drug use</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average number of drugs/prescription</td>
<td>2</td>
<td>2.4</td>
</tr>
<tr>
<td>% antibiotics use</td>
<td>56%</td>
<td>54%</td>
</tr>
<tr>
<td>% injection use</td>
<td>23%</td>
<td>29%</td>
</tr>
<tr>
<td>Essential drugs list &lt; 5 years</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>% of drugs prescribed that are on essential drugs list</td>
<td>91%</td>
<td>97%</td>
</tr>
<tr>
<td>Standard treatment guidelines &lt; 5 years</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>% doctors’ offices with standard treatment guidelines</td>
<td>61%</td>
<td>47%</td>
</tr>
<tr>
<td>Essential drugs concept included in medicine/pharmacy curricula</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Public education campaign on rational drug use</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>NA not applicable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
access to essential drugs at all levels of health systems has now emerged. It has four components: (1) rational selection and use of drugs; (2) affordable prices; (3) sustainable financing; and (4) reliable health and supply systems.

Based on this framework, considerable work was carried out with UNAIDS Cosponsors and Secretariat to increase access to HIV-related drugs. Over 30 African countries have now established national action plans to implement HIV-care programmes based on their national HIV/AIDS strategies. A technical meeting on Access to Drugs for HIV/AIDS within National Essential Drugs Programmes was held in Pretoria, South Africa. Representatives of national HIV/AIDS control programmes, essential drugs programmes and ministries of finance or planning from African countries, including the six Phase I countries under the International Partnership Against AIDS in Africa, met to review their national situations and develop action plans within the four-part framework described above.

WHO also worked with its partners on: financing and price reduction for HIV-related drugs; the impact of the TRIPS agreement on access to HIV-related drugs in francophone Africa; and development of a pilot project on quality-related issues for antiretrovirals (following a public announcement by UNAIDS Cosponsors and Secretariat seeking expressions of interest from research-based and pharmaceutical manufacturers of medicines). The project is intended to lead to a uniform pre-qualification system for procuring HIV-related drugs, with a list of pre-qualified suppliers, and a WHO model quality assurance system for procurement.

In partnership with Roll Back Malaria, work was also undertaken — in Gabon, Ghana, Kenya, Mali, Mozambique, Sudan, Tanzania and Zimbabwe — on quality and availability of antimalarials. Work also intensified on access, quality and rational use of drugs for tuberculosis (TB), childhood illness and other priority health problems. The pharmaceuticals and TB programmes of the Western Pacific Regional Office, for instance, worked with their counterparts in China to conduct joint assessment of good manufacturing practices (GMP) used in production of anti-TB drugs.

Box 2: Achievements in traditional medicine

Traditional medicine is an accessible and affordable health care resource for many developing country populations, and increasingly used in developed countries. However, although promising evidence of efficacy exists for some products and practices, substantial work is needed to assess efficacy adequately.

In 2000, the WHO Strategy for Traditional Medicine 2001-2005 was drafted to enable traditional medicine to play the most appropriate role in health care delivery. Additionally, WHO organized a meeting of the African Forum in Harare, Zimbabwe, to strengthen the role of traditional medicine in health systems in Africa.

Traditional medicine activities undertaken in 2000 focused on investigating and promoting effective and safe treatment with traditional medicine. They included: support for three national clinical studies on herbal antimalarials; drafting of a Technical Update for HIV/AIDS Programme Managers on Clinical Validation of Traditional Medicine in cooperation with UNAIDS; publication of General Guidelines for Methodologies on Research and Evaluation of Traditional Medicines; and organization of a meeting in Jamaica on regulation of herbal medicines by Headquarters and the Regional Office for the Americas, and by the African Regional Office of a regional workshop in Antananarivo, Madagascar on evaluation of traditional medicines.

Other activities included an inter-regional workshop in Thailand, organized by Headquarters and the Eastern Mediterranean, South-East Asian and Western Pacific Regional Offices on intellectual property rights in the context of traditional medicine, and country support to Burkina Faso, China, Ethiopia, Mongolia, Namibia, Pakistan, Papua New Guinea, Samoa, Singapore, Syria, Viet Nam and Zambia.

Use of traditional medicine for primary health care is extensive in many developing countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage of population using traditional medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uganda</td>
<td>80%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>100%</td>
</tr>
<tr>
<td>Benin</td>
<td>40%</td>
</tr>
<tr>
<td>Rwanda</td>
<td>0%</td>
</tr>
<tr>
<td>India</td>
<td>60%</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>20%</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>80%</td>
</tr>
</tbody>
</table>

Box 2: Achievements in traditional medicine for primary health care is extensive in many developing countries.
Table 1: Example of price information for HIV-related drugs from one of three regular pharmaceutical price information services

<table>
<thead>
<tr>
<th>Antibacterials</th>
<th>Manufacturers</th>
<th>Indicative prices (US$, 1999)</th>
<th>List prices*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No./countries</td>
<td>Unit</td>
<td>Max</td>
</tr>
<tr>
<td>Ceftriaxone</td>
<td>5</td>
<td>vial</td>
<td>2.24</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>14</td>
<td>tab</td>
<td>0.95</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>3</td>
<td>cap</td>
<td>0.15</td>
</tr>
<tr>
<td>Sulfadiazine</td>
<td>1</td>
<td>amp</td>
<td>7.89</td>
</tr>
<tr>
<td>Tablet, 250 mg</td>
<td>6</td>
<td>tab</td>
<td>0.77</td>
</tr>
</tbody>
</table>

* The UK price (which is the public sector consumer price set by the National Health Service for reimbursement) and the Spanish price (which is the ex-works price) are not directly comparable and provided for information only.

As a tool for making drug prices affordable, **drug price information** is crucial. WHO continued to make it widely available through: the International Drug Price Indicator Guide (with Management Sciences for Health); Selected Drugs Used in the Care of People Living with HIV: Sources and Prices (with Médecins Sans Frontières, UNICEF and UNAIDS); and the Pharmaceutical Starting Materials/Essential Drugs Report (with the International Trade Centre — UNCTAD/WTO) (Table 1). The relevant documents are available in print form and on the web-sites of sponsoring organizations.

Increasing the quantity, quality, comparability and transparency of information on essential drug prices also contributed to access efforts. Together with several NGOs and a private foundation a project was initiated to develop **standardized drug price survey methodology**.

**Box 3: The Americas: fighting corruption to improve access to medicines**

International experts, nongovernmental organizations (NGOs) and the international pharmaceutical industry joined forces to fight corruption that hinders poor people’s access to medicine in Latin America and the Caribbean. A workshop in Washington on ethical business practices, organized by the Regional Office for the Americas (PAHO — the Pan American Health Organization) and the World Bank, examined corruption in the pharmaceutical sector.

Participants learned that officials sometimes sell health cards or demand payment of “commissions” as a condition for purchasing products from a supplier. Similarly, some companies pay kickbacks in exchange for registration of their products. Senior economist on health, William Savedoff, of the Interamerican Development Bank, commented; “When public funds are diverted, society pays twice: once, when the funds are stolen and again when someone needs medical attention and cannot get it.”

Workshop participants discussed the causes and manifestations of corruption, and ongoing reforms and regulations in the region designed to prevent it, such as those in Brazil, Chile, Colombia and Mexico. Participants agreed to establish an inter-institutional working group with the pharmaceutical industry and NGOs to promote transparency in the sector in the region, and to assess the vulnerabilities in the system of AIDS drugs provision especially.

Meanwhile, in the Western Pacific Region, a survey was initiated to assess the availability and prices of anti-TB drugs. In the European Region a sample price comparison of recently introduced drugs in 25 countries found little evidence that prices are lower in less affluent, eastern European countries than in wealthier western European countries.

As a method for increasing access, **sustainable financing** mechanisms and promotion of optimal resource allocation based on a mix of funding channels also received much attention. The WHO/South-East Asian Regional Office working group on drug financing met in Nepal for the third time and reviewed prepayment schemes for health and drugs operating in their countries, and proposed strategies for developing national social health insurance systems and for improving drugs benefits in health insurance schemes. In the Eastern Mediterranean region, considerable activity took place...
place around reimbursement for drug expenditure. The health authorities responsible for the pharmaceutical policies of 29 countries (all Western European and most CCEE) created the Pricing and Reimbursement Information Network on Medicines in Europe (PRIME) to extend use of pharmacoeconomic guidance in making reimbursement decisions.

Reliable procurement, distribution and dispensing of pharmaceuticals are also key to access. Country support and activity were extensive. In Armenia, procurement procedures were developed and formalized, in Kyrgyzstan pooled procurement was expanded to cover many more hospitals, and in Georgia, pooled procurement was introduced for selected state programmes covering both primary and hospital patients. Pooled procurement has also been notably applied among the Maghreb countries (Algeria, Morocco and Tunisia) and the countries of the Gulf Cooperation Council (GCC). In Tajikistan, workshops were held in each of the country’s four regions to examine the main factors influencing access to essential drugs.

Considerable training on making supply systems more effective was also undertaken. Training in good storage and dispensing practices was held for the inspection service of the National Pharmaceutical Products Directorate and for hospital pharmacists working for Peru’s Ministry of Health. In Colombia, training was given in drug supply and improving pharmaceutical care services in public hospitals and community pharmacies. And in Sudan a national training course was held for drug supply officers covering procurement, donations and disposal. WHO was also involved in international supply training, including the Commonwealth Pharmaceutical Association course, and the annual training programme of Management Sciences for Health and the International Dispensary Association. Other efforts to promote reliable health and supply systems involved tackling corruption (Box 3).

Rebuilding supply systems has been another area of major activity. In Kosovo, a hospital drug supply and management system was created and a procurement and supply office established within the Department of Health and Social Welfare (Box 4). Similarly in East Timor, WHO contributed to efforts to manage drug donations during the emergency phase and thereafter to rebuild drug supply systems (Box 5). Country support was also given to Palestine and Yemen, the latter involving support for creation of a revolving drug fund, and collaboration with many partners.

Ensuring the reliability of health and supply systems also means taking due account of wider economic and social conditions, and initiating action, be this to counter or benefit from them. Nowhere is this more necessary than in the area of trade and pharmaceuticals. Amidst much debate WHO continued to help countries develop their own informed approaches to health and trade.

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**Box 4: WHO Kosovo Pharmaceutical Project fully operational**

During 2000 the WHO Kosovo Pharmaceutical Project made progress in all four strategic areas of the Medicines Strategy, including:

**Policy**
- Integration of essential drugs and medicines policy into Kosovo’s health policy.

**Access**
- Establishment of Corporation of Pharmacies of Kosovo for securing primary health care supplies.
- Creation of hospital drug supply and management system, and procurement and supply office within Department of Health and Social Welfare.
- Access surveys of essential drugs in primary health care facilities.

**Quality and safety**
- Drug donations management and drug disposal management.
- Guidance on good manufacturing practices to pharmaceutical manufacturers.
- Drafting of regulations for manufacturing, importing, wholesaling and retailing of pharmaceutical products, narcotics and psychotropics, and support for their implementation.

**Rational use**
- Development of essential drugs list for primary health care, model essential drugs list for hospitals and drug information formulary.
- Rational drug use indicator study.
- Creation of drugs and therapeutics committees in four out of six of Kosovo’s hospitals.
- Translation of Guide to Good Prescribing into Albanian and prescribing skills training for 100 family medicine trainees.
Ministers of Health of the Southern African Development Community (SADC) were briefed on the implications for African countries of international trade agreements. Also, policy guidance on patent issues and revision of national pharmaceutical legislation including incorporation of public health safeguards, to make it compliant with TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) was provided, in close collaboration with relevant organizations, to several individual countries, to ASEAN1 and SADC countries, and at a joint ASEAN-WHO workshop on the TRIPS Agreement (Box 6). WHO also provided input on TRIPS to meetings of the Arab Ministers of Health and the GCC, and briefed the participants of the Eastern Mediterranean Regional Committee on TRIPS.

Concurrently, WHO initiated monitoring and analysis of the impact of trade agreements on essential drugs in partnership with four WHO Collaborating Centres (in Brazil, Spain, Thailand and the United Kingdom). In 2000, the World Trade Organization (WTO) Council for TRIPS accorded WHO observer status. WHO can now follow relevant issues under discussion at the WTO that may have implications for the health sector.

Quality and safety: information for action

The growing complexity of pharmaceutical products and markets means that

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1 Association of South East Asian Nations

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Box 5: WHO Drug Donation Guidelines having an impact in East Timor

In early 2001, a joint evaluation team led by the World Bank, including participants from WHO, the European Agency for Health and Development, and the Partnership for Quality Drug Donations, assessed drug donations made during and after the post-referendum emergency period (September 1999 to February 2000) in East Timor. It concluded that the Guidelines for Drug Donations (revised and reissued by WHO and 15 international humanitarian agencies in 1999), had had a positive impact on those drug donations, and outlined several lessons learned:

1. Effective management and coordination of the drug donation process are essential.
2. Emergency health kits — usually easier to track, distribute and monitor than individual drugs — are very useful in the initial phases of emergencies, provided they are well planned and appropriate.
3. Proper management, storage and distribution are critical, otherwise even good donations may lie unused, spoil and/or expire.
4. Effective and safe drug disposal systems are as important as a good system for managing drug donations.
5. Drug donations must be managed within an overall framework for pharmaceutical and health care service delivery, and within the broader context of an emergency response system.

Drug supply in post-emergency phase, March 2000–March 2001, East Timor


Page 6: Highlights of the year 2000 in Essential Drugs and Medicines Policy
WHO’s leadership in quality and safety assurance is needed more than ever before. In 2000, the three pillars of WHO’s work in this area were: development of internationally recognized norms and standards; establishing and maintaining effective drug regulation; and information support for pharmaceutical regulation.

Work on **norms and standards** included: producing the first draft of screening tests for antimalarials and anti-TB drugs; drafting and/or review of ten new quality assurance guidelines; outlining guidance on global good trade and distribution practices; producing a guideline on establishing a pharmacovigilance centre; and continued selection of international nonproprietary names (INNs). (More than 120 new names were published as proposed and a further 150 as recommended INNs.) Also, a panel of experts of safety issues was informally established with the intention of creating a WHO Advisory Committee on Safety of Medicinal Products. In South Africa, country staff assisted with development of national guidelines for good practice in the conduct of clinical trials in human participants.

### Country support for drug regulation

***Strategies for effective drug regulation*** was provided to Armenia, Cambodia, Egypt, Fiji, Georgia, Iraq, Kazakhstan, Kyrgyzstan, Lebanon, the Russian Federation, Syria, Uzbekistan and Yemen. Several courses were held — for instance, on drug regulation and quality assurance in Ghana for African drug regulatory authorities, and on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce in Zimbabwe for drug analysts. Additionally, WHO and the national drug regulatory authorities of Spain and Portugal co-sponsored the Annual Conference of Ibero-American Drug Regulatory Authorities in Costa Rica.

In Bangkok, WHO ran a workshop — with assistance from Tunisia — to improve monitoring and control of drug importation for all South-East Asian regional countries. At operational level, the ***WHO Multicountry Working***

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**Box 6: Developing informed approaches to trade and pharmaceuticals**

The aim of the joint ASEAN-WHO workshop, *The TRIPS Agreement and its Impact on Pharmaceuticals* was to examine the TRIPS Agreement and its implications for ASEAN countries. The workshop was attended by over 30 participants — including representatives of Ministries of Health, Ministries of Trade and patent offices, as well as of the World Trade Organization, the World Intellectual Property Organization, nongovernmental organizations and the pharmaceutical industry. Participants were provided with an overview of intellectual property rights, WHO’s perspective on globalization and access to drugs, the history of the TRIPS negotiations, country experiences with patents and development of TRIPS-compliant legislation, and special issues such as traditional medicine knowledge and intellectual property rights. Participants recommended that ASEAN countries should:

- when reviewing their legislation, ensure compliance with the TRIPS Agreement, define criteria or standards of patentability, and include provisions related to safeguards provided by the TRIPS Agreement
- develop new instruments to protect traditional knowledge (as this is not covered by TRIPS)
- establish an expert group on the impact of globalization and trade liberalization on the health sector.


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**Box 7: Strategies for effective drug regulation**

Fewer than one in six countries have effective drug regulation. Analysis of the WHO Multicountry Working Group on Effective Drug Regulation shows, however, that there are many strategies for promoting effective drug regulation. For example, by:

- Developing a clear sense of mission for the regulatory agency.
- Ensuring adequately comprehensive and up-to-date drug laws for all drug products and information.
- Making a single agency accountable for the overall effectiveness of drug regulation.
- Keeping the national drug regulatory agency free from all political and commercial influence.
- Applying the same regulatory standards to all drugs and pharmaceutical sectors.
- Developing appropriate standards and guidelines, using them as tools for all regulatory processes and making them available to all stakeholders.
- Systematically monitoring the regulatory process to identify problems and find solutions.
- Transforming the drug regulatory authority into a learning organization that routinely conducts self-assessment and initiates quality improvement.
- Using a number of different strategies such as prioritization and streamlining of work processes to increase efficiency of resource use.
- Ensuring that the drug regulatory authority communicates regularly with clients and acknowledges the right of citizens to accurate, appropriate information on drugs marketed in their country.

Group on Effective Drug Regulation completed its study, covering 10 countries, of the most effective approaches to drug regulation (Box 7).

Development of the capacity of drug regulatory authorities to evaluate pharmaceutical quality included promotion of GMP implementation. The WHO GMP Basic Training Modules were finalized, a GMP video and CD-ROM produced, and GMP campaign materials in all 6 UN languages distributed. National GMP workshops were organized in Cambodia, China, Cyprus (attended by both Cypriot nationals and representatives of Palestine), Myanmar, the Philippines and South Africa, and country support in GMP provided to Libya and Oman.

A workshop on harmonizing drug registration was held in South Africa for SADC drug regulators. A comprehensive joint ASEAN-WHO project — ASEAN Drug Regulatory Harmonization: A Tool to Ensure Drug Quality, Safety and Efficacy — was developed and will be launched in 2001. Additionally, GMP training was provided by Pharmakon (a Danish Collaborating Centre for drug policy and pharmacy practice) for a number of countries in Europe.

Meanwhile, WHO continued to participate as an observer in the Steering Committee of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This enabled WHO to continue to liaise between non-ICH and ICH countries. Options for the continued involvement of WHO in international harmonization activities were evaluated by a WHO independent review team. A report will be finalized in 2001.

With WHO assistance, the GCC countries, in particular, worked hard to harmonize licensing and inspection functions.

WHO also continued to provide support to drug regulatory networks including AFDRA, CADREAC, Drugnet, EMDRAC, EMEA, and the drug regulatory networks of ASEAN and SADC countries (Figure 2).

At the other end of the drug regulation spectrum,
Highlights of the year 2000 in Essential Drugs and Medicines Policy

In terms of dependence-producing drugs, six psychoactive substances were assessed and a recommendation made to the UN Commission on Narcotic Drugs to place four of the drugs under international control. Other related activities included development and promotion of balanced drug control policies and guidelines to improve access to opioid analgesics.

Information support for pharmaceutical regulation was undertaken with the European Agency for the Evaluation of Medicinal Products, principally to develop use of SIAMED (the

Box 8: Comprehensive drug information system operational in Syria

With support from WHO, and bilateral assistance, the Directorate of Pharmaceutical Affairs and the Quality Control Laboratory of the Syrian Ministry of Health completed development of a comprehensive drug information system consisting of:

- A drug registration system — using SIAMED, the WHO model system for computer-assisted drug registration.
- The WHO Model Package for Quality Control Laboratories.
- The WHO/Syrian Arabization system — for translation of WHO computer packages into Arabic.
- A drug quality system — a national pharmacovigilance database.
- An inspections system — for following up inspections of manufacturing sites and pharmacies.
- The ISO 9002 system — the ISO standard system for quality control laboratories.

Nearly 3000 applications have now been entered in SIAMED, and the quality control laboratory is fully computerized and has received ISO certification. Drug consumption data are being collected and will be fed into the Drug Consumption Information System, for more accurate estimation of drug needs. Ultimately, this comprehensive drug information system will lead to increased access to safe drugs of good quality and better use of health resources.

Figure 3: Sixty countries now participate in the WHO Programme on International Drug Monitoring
WHO model system for computer-assisted drug registration. WHO also helped Burkina Faso, Cameroon, Guinea, the Maldives, Laos, Mauritania, Mexico, Mongolia, Nepal, Papua New Guinea, South Africa, Syria, Tanzania, Tunisia and Venezuela to strengthen or initiate computer-assisted drug registration (Box 8).

Three more countries — Cyprus, Sri Lanka and Yugoslavia — joined the WHO Programme on International Drug Monitoring operated by the Uppsala Monitoring Centre, which collects data for generating early warning signals of potential adverse drug reactions. The 23rd annual meeting of representatives of national centres participating in the Programme was held in Tunisia (Figure 3).

Additionally, two drug information projects were launched — to create a WHO Model Website for National Drug Regulatory Authorities to make drug regulatory information more transparently and more widely available, and to carry out an international comparative study on drug information (Box 9).

**Rational use: action at all levels of care**

Irrational drug use typically involves the wrong drug given in the wrong dose or for the wrong duration. Escalating health care costs in many countries, a growing range of pharmaceutical treatments for individual conditions, and the increasing threat of antimicrobial resistance are now magnifying the impacts of such irrational use, making therapeutically sound and cost-effective use of drugs by health workers and consumers both medically and economically necessary.

Support to individual countries in rational selection and use of drugs was given to Afghanistan, Armenia, Egypt, Georgia, several states in India, Kyrgyzstan, Mongolia and Tajikistan in particular.

In Armenia and Georgia, substantial efforts have been put into improving drug prescribing practices by introducing problem-based pharmacotherapy, clinical and social pharmacy teaching into the medical and pharmacy curricula at both undergraduate and continuing education levels, and development and use of

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**Box 9: Rapid, wide and cost-effective distribution of quality and safety information**

In 2000 considerably more quality and safety guidance information was posted on WHO's web-site. The following information is now available at http://www.who.int/medicines:

- International nonproprietary names (INNs) in Arabic, Chinese, English, French, Spanish and Russian, as well as Latin — now available to subscribers, currently numbering more than 200.

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**WHO Drug Alerts** — issued on an ad hoc basis when a safety concern arises and the relevant information needs to be disseminated rapidly.

**WHO Drug Information** — communicating pharmaceutical information that is either developed and issued by WHO, or transmitted to WHO by research and regulatory agencies worldwide.

**WHO Pharmaceuticals Newsletter** — containing information on safety and efficacy of pharmaceutical products and medical devices, including regulatory decisions, and recently remodelled and improved to incorporate material from the Uppsala Monitoring Centre in Sweden (a WHO Collaborating Centre for International Drug Monitoring).
standard treatment guidelines for priority diseases in primary and hospital care. Generic drug prescribing is now strongly promoted through essential drug lists and formularies at all health care levels, and pilot hospital pharmacies have substantially strengthened their function as providers of drug information.

In Tajikistan, WHO worked with the National Pharmaceuticals Taskforce to improve drug use in particular. Also with WHO assistance, the Directorate for Rational Use of Drugs was established in the Ministry of Health of Oman.

While work was under way on revising WHO treatment guidelines (Box 10), an open consultative process was also being undertaken to propose changes to the revision process of the WHO Model List of Essential Drugs.

Courses, workshops and regional coordination continued to be important means of developing rational use skills. Courses to promote rational drug use were held in Nigeria and Indonesia in collaboration with the International Network on Rational Use of Drugs (INRUD). In Kazakhstan, Kyrgyzstan and Uzbekistan, rational drug use courses were held for family medicine teachers. Drug selection workshops were held in Peru (for pharmacy and therapeutics committee representatives) and Sudan.

Additionally, the drug evaluation and selection capacity of the pharmacy and therapeutics committee responsible for promoting rational drug use in 12 of Colombia’s 34 provinces was strengthened. The first version of a manual on establishing and running drug and therapeutics committees was also produced.

Other workshops included national rational drug use training and advocacy workshops in Kuwait, Pakistan, Somalia and Sudan. A national workshop to improve ongoing supervision and monitoring of drug use and drug supplies was also held in Cambodia.

In the European region, rational use was promoted via cross-country collaboration. Health professionals from Ministries of Health and health insurance institutions from 20 countries of Western and Central and Eastern Europe met to compare national approaches to rationalizing drug use through formulary and guidelines development, innovative use of drug information and information technology, and local structures for prescribing support. Direct country support was provided to Armenia, Croatia, Kazakhstan, Kyrgyzstan, the Russian
Federation, Tajikistan, Turkmenistan and Uzbekistan for developing formularies and standard treatment guidelines. Also in the European region, the EuroPharmForum network of pharmaceutical associations and the Regional Office for Europe now consists of 33 country members, and implements disease management and health promotion projects through community pharmacies.

Much activity also took place around the problem of antimicrobial resistance (AMR). An interdisciplinary group on AMR consisting of different programmes was established in the Western Pacific Regional Office, and also in the Eastern Mediterranean Regional Office.

In terms of promoting rational use among households, consumers and patients, new training modules on public education in rational drug use in the community were tested at a first international two-week course in Thailand. Developed by WHO and the University of Amsterdam, the course taught participants how to: identify and prioritize community drug use problems; choose and develop appropriate intervention strategies and communication channels; pre-test materials; evaluate impact; and fundraise and network for support and sustainability (Figure 4).

Figure 4: Steps in an effective communication intervention to promote more appropriate drug use by consumers

STEP 1: Describe drug use and identify problems

STEP 2: Prioritize problems

STEP 3: Analyze problems and identify solutions

STEP 4: Select and develop intervention

STEP 5: Pretest intervention

STEP 6: Implement intervention

STEP 7: Monitor and evaluate intervention

Improve analysis

Improve intervention

Development and implementation of community-based intervention projects to promote more rational use of antibiotics for infectious diseases at household level also continued as part of an initiative with several universities and NGOs. □

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