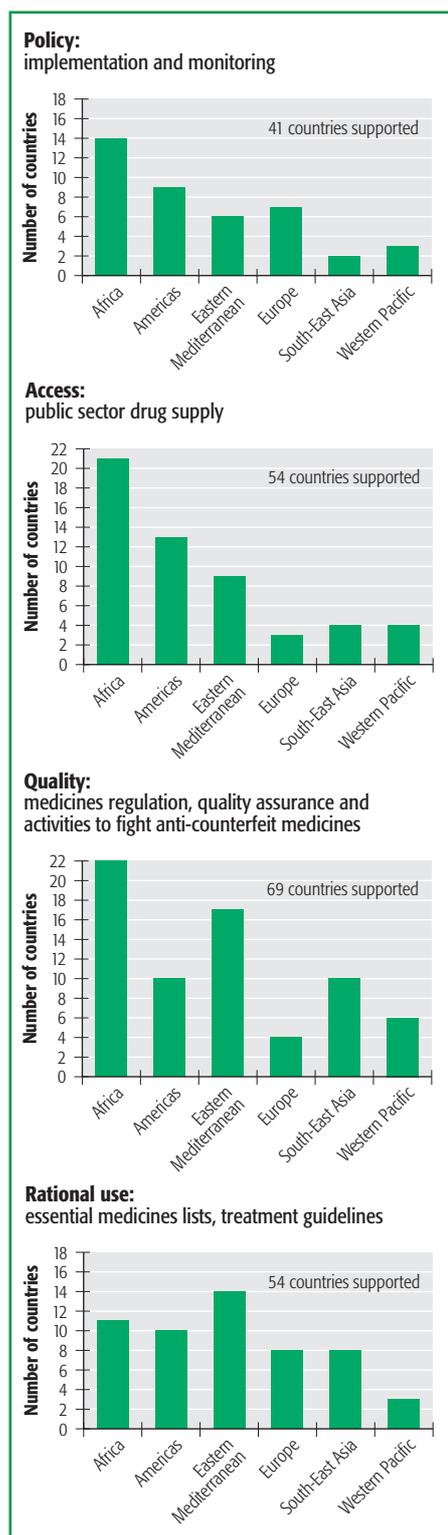




# Annual Report 2002

## Essential Drugs and Medicines Policy: Supporting countries to close the access gap

In each WHO region, areas of support are tailored to specific country needs



The year 2002 marked the 25<sup>th</sup> anniversary of the first WHO Model List of Essential Medicines. It also marked the 25<sup>th</sup> annual meeting of the WHO International Monitoring Network for Medicines Safety. In 25 years, much has been achieved: 100 countries have national drug policies in place or under development; 156 countries have national or provincial essential medicines lists; 135 countries have



turned the essential medicines concept into clinical practice with national treatment guidelines and/or formulary manuals; over 90 countries have introduced the essential drugs concept into curricula for medicine and pharmacy students; the WHO Programme for International Drug Monitoring now includes 76 member and associate member countries; and a major global effort has been launched to assure medicines quality. Most significantly, the number of people estimated to have regular access to essential drugs has risen from 2.1 billion in 1977 to over 4 billion today.

But despite these gains, a huge unfinished agenda remains. Roughly two billion people – one-third of the world’s population – still lacks regular access to essential medicines of affordable price and assured quality. Irrational use of medicines, unfair financing, unreliable delivery systems, inadequate regulatory systems and high medicines prices are critical factors in this access gap.

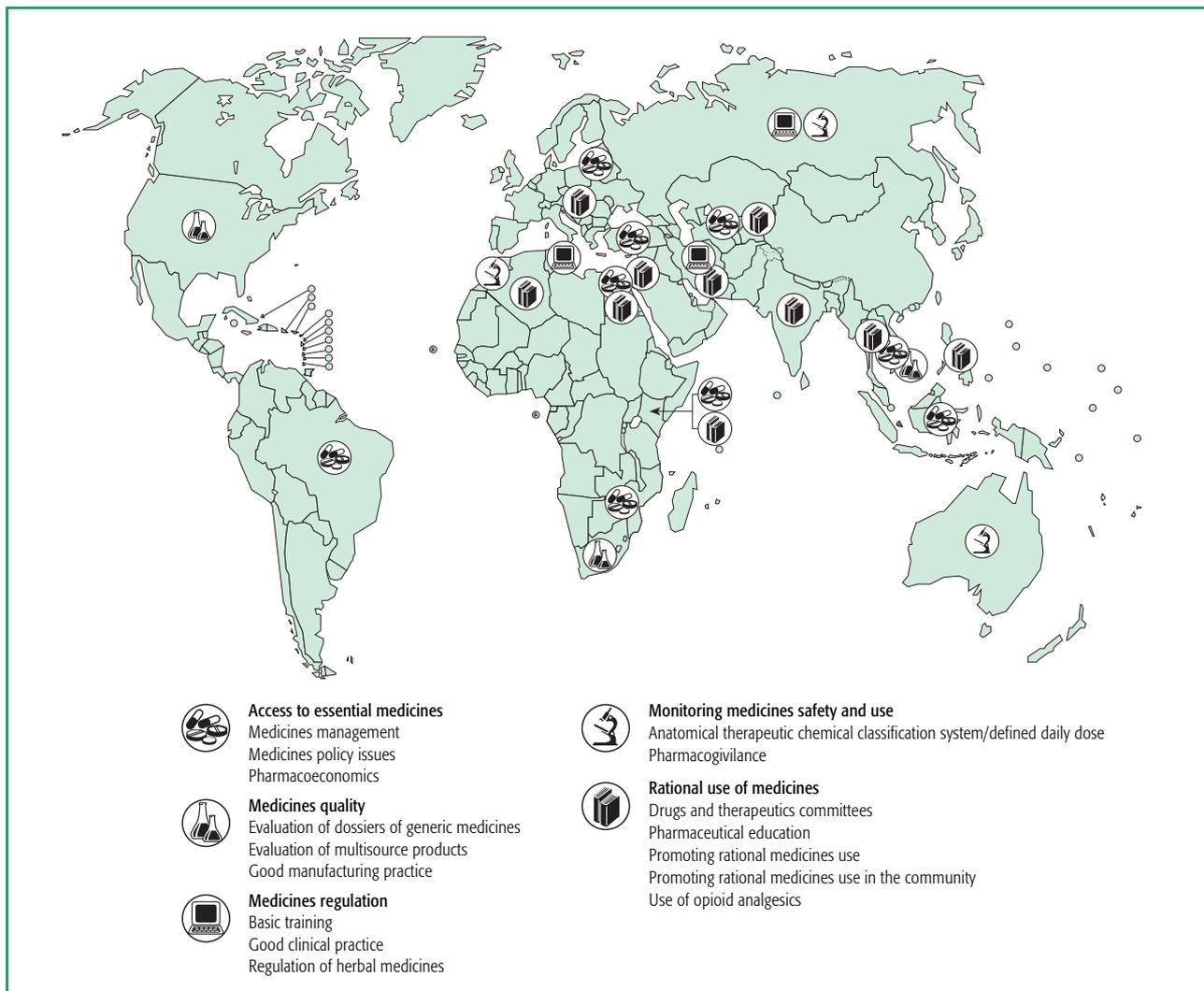
This report focuses on WHO country support activities aimed at closing the access gap. In line with the WHO Medicines Strategy, WHO provided support to countries on: medicines regulation, quality assurance and anti-counterfeit activities (69 countries); rational use of medicines by health professionals (54); public sector drug supply (54); overall national drug policy development and monitoring (41); medicines financing and pricing (27); improving medicines use by consumers (25); and setting of pharmaceutical norms and standards (21). This support included training in these areas to nearly 900 health professionals.

WHO supported comprehensive medicines programmes in 22 countries, specific technical support in 85 countries and situation analysis in 6 countries. Afghanistan, Bangladesh, Bolivia, Brazil, Cape Verde, China, the Democratic People’s Republic of Korea, Ethiopia, Haiti, India, Indonesia, the Islamic Republic of Iran, Myanmar, Nepal, Nicaragua, Nigeria, South Africa and Sudan received the most intensive support in financial terms.

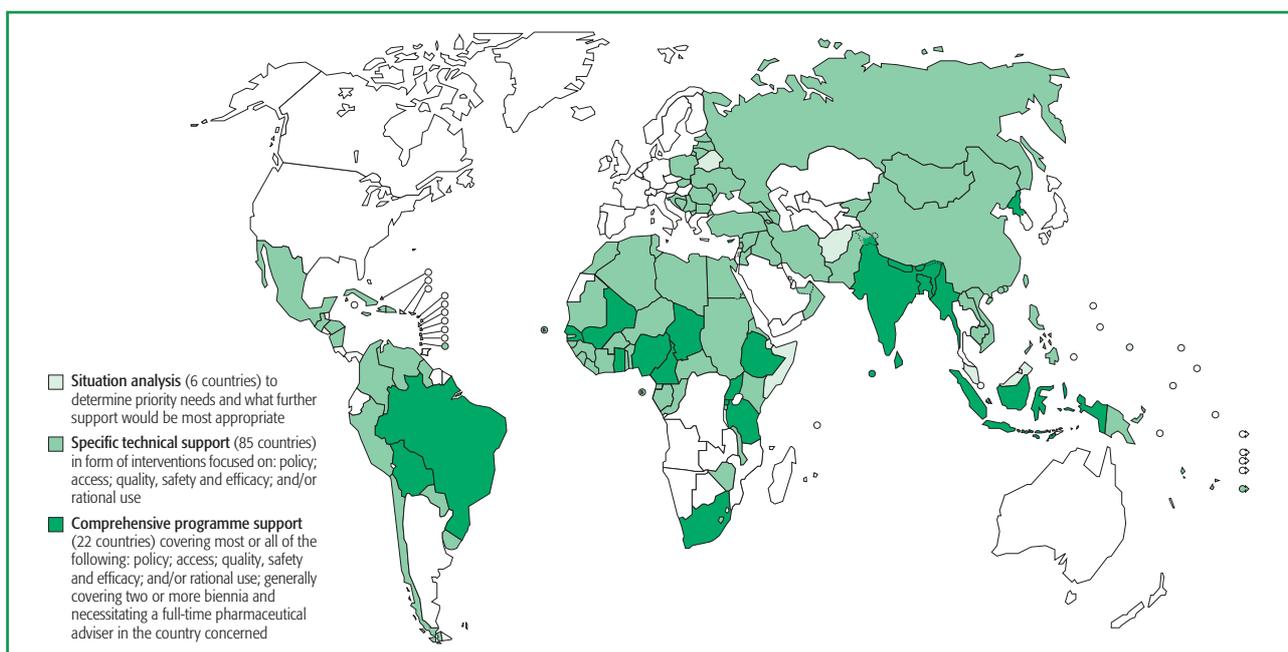
Country experiences reported here confirm that when sound policies and guidelines are actively implemented, substantial improvements can be achieved in affordability, availability, quality and rational use of medicines. Progress is often greatest when local officials and development partners work closely together.

**Dr Anarfi Asamoah-Baah, Executive Director  
Health Technology and Pharmaceuticals**  
**Dr Jonathan Quick, Director  
Essential Drugs and Medicines Policy**

**Nearly 900 health professionals around the world received training in medicines areas through 28 regional and international courses and workshops, covering all six official UN languages**



**WHO provided direct support on essential drugs and medicines policy to 113 countries, of which 22 benefited from comprehensive programmes**



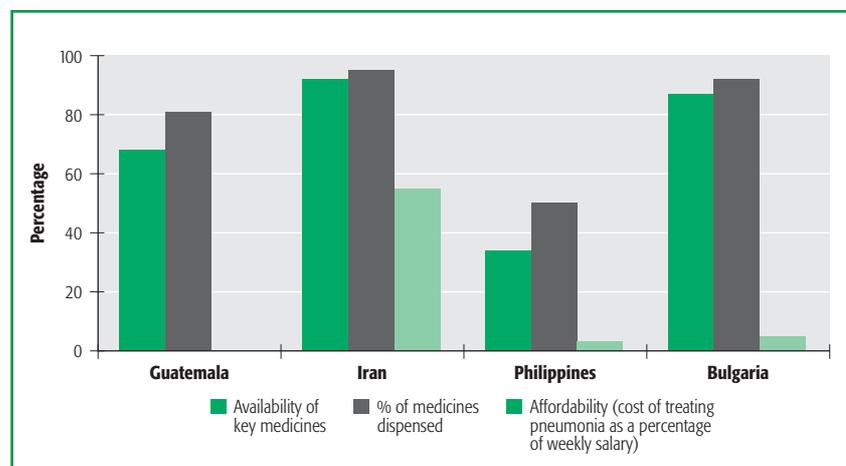
# Developing a monitoring culture to improve impact

A WHO survey package to facilitate monitoring and assessment of country pharmaceutical situations was further developed in 2002. It provides a cost-effective means of determining availability of essential medicines, the safety, efficacy and quality of those medicines, and whether they are used rationally. So it can help countries pinpoint the strengths and weaknesses of their pharmaceutical sector and prioritize areas for intervention. Follow-up surveys can be undertaken to assess the impact of interventions and to monitor pharmaceutical trends over time. Common use of the package will facilitate comparisons between facilities, districts/regions and countries. By the end of 2002, the package had been field-tested in 16 countries, representing all six WHO regions.

## Looking at access and rational use

Use of the package in Bulgaria and the Philippines not surprisingly yielded different performances for the key indicators. Although Bulgaria does not yet have a national drug policy (NDP) in place, a pharmaceutical programme is included in its national health plan. This is reflected in the availability of key essential medicines, which is high, and which

**The affordability of essential medicines varies widely in the four countries surveyed, while prescribing data indicate that key medicines are not available in sufficient quantity**



has increased since 1995. However, further efforts are required in rational medicines use, given that less than 50% of medicines prescribed are on Bulgaria's essential medicines list.

In the Philippines, availability of key medicines in rural health facilities has gone down – possibly due to decentralization of health services. Prescription of medicines on the essential medicines list has also declined. Worryingly, the percentage of patients being prescribed antibiotics has increased to over 50%, although other prescribing practices

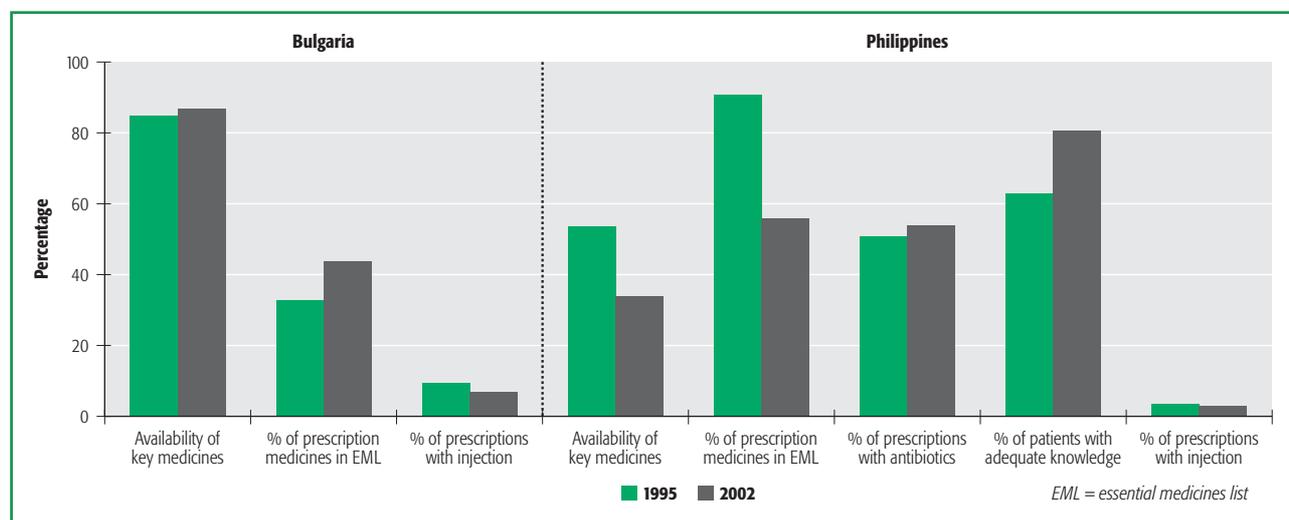
have improved. Training and continuing education in rational medicines should therefore remain a focus of support provided by government to provinces and towns.

Looking at access indicators for four countries – Bulgaria, Guatemala, Iran and the Philippines – it can be seen that availability of key medicines and dispensing do not concur. This suggests that prescribing of non-essential medicines may be occurring.

## Field-testing in Africa

In Africa, field-testing of the monitoring package was carried out in

**Comparing 1995 and 2002 indicators for Bulgaria and the Philippines shows progress in some areas but that enhanced efforts needed in others**



Ghana, Mali, Nigeria, Tanzania and Uganda by newly-appointed national programme officers (NPOs) working with their Ministry of Health (MoH) counterparts. The package was particularly welcomed by MoH staff given that previous pharmaceutical situation surveys had generally been carried out by external consultants. In carrying out the surveys with the NPOs, MoH policy-makers and health officials could appreciate first-hand the impacts – good or bad – of pharmaceutical decisions they have made. Results of these surveys are now guiding implementation and or modification of NDPs.

For most of the countries, the role of the private sector in providing health care and medicines is increasing. So including private pharmacies and drugs outlets in the surveys was very important. In so doing, the surveys made possible the comparison of the availability and affordability of medicines in the public and private sectors.

**Household surveys**

The monitoring package includes a one-page questionnaire for carrying out a household survey. The questionnaire covers: health-seeking behaviour and whether it leads to use or non-use of medicines; whether needed medicines are available and affordable; and, if used, whether they are used rationally. Household surveys are key to measuring access to medicines since it is only through these that we can obtain information to determine

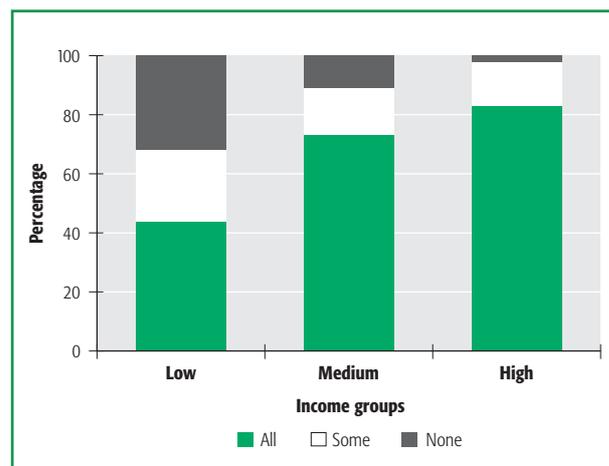
whether households can obtain all the medicines they need and how much they can afford to pay for them.

In Tanzania, use of the household survey showed that households are most likely to self-medicate and use public health facilities, and that use of public health facilities is not confined to lower economic groups. Nevertheless, it was seen that many households, especially those in the lowest economic groups, are unable to obtain all the prescribed medicines that they need. More than 50% of the lowest economic group could not obtain all the medicines that it needed. Access to medicines was observed to be limited primarily by lack of income for purchasing medicines, high prices of medicines and/or unavailability.

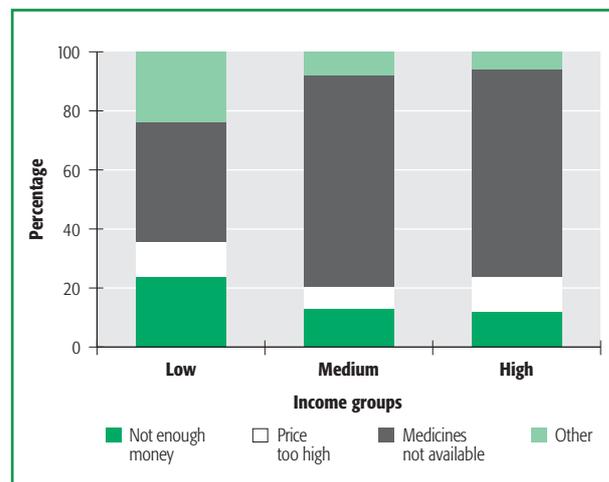
Such information can be used by policy-makers to design policies, programmes and interventions to meet essential medicines needs.

*Copies of the monitoring package can be requested from: [edmdoccentre@who.int](mailto:edmdoccentre@who.int). The package will also be posted on the WHO Essential Drugs and Medicines Policy website at: [http://www.who.int/medicines/strategy/policy/indicators\\_op.shtml](http://www.who.int/medicines/strategy/policy/indicators_op.shtml)* ■

**Tanzania 2002: what percentage of the medicine prescribed was obtained by households within 5 kilometre radius of public facilities and public private pharmacies**



**Tanzania 2002: why households – within 5 kilometre radius of public facilities and public private pharmacies – did not obtain all the medicines they required**



# Traditional and complementary medicine: putting policy into action

The WHO Traditional Medicine Strategy 2002–2005 was launched at the World Health Assembly, receiving wide coverage in the international press. It aims to promote development of national traditional and

complementary medicine (TM/CM) policies and programmes, improve the safety, efficacy and quality of TM/CM by expanding the knowledge base on TM/CM, and provide guidance on regulatory and quality assurance

standards. *Traditional Medicine in Asia* (SEARO Regional Publication No. 39), published in 2002, complements the WHO Traditional Medicine Strategy by exploring policy issues such as harmonization of

traditional and modern medicine, the role of TM in national health care systems, cost-benefit analysis and training programmes.

In the African and Western Pacific Regions, regional TM strategies are already guiding Member States on regional TM issues. In the Eastern Mediterranean Region, a WHO Regional Committee resolution was passed in 2002, calling on Member States to adopt the WHO Traditional Medicine Strategy 2002–2005 as a framework for developing national TM programmes.

### Tools for institutionalizing traditional medicine

In the African Region, several tools for institutionalizing TM were developed, including:

- guidelines for formulating a national master plan for developing TM
- a tool to help countries document the status of African TM
- guidelines for documenting ethnomedical evidence data
- guidelines for registering traditional medicines in the African Region, as part of an effort to accelerate the registration and circulation of standardized African traditional medicines within the African Region.

### Regulating herbal medicines

The global WHO Traditional Medicine Strategy indicates that rapidly increasing use of herbal medicines throughout the world has made regulation of herbal medicines an urgent issue. A series of workshops – for Africa, the Americas, the Eastern Mediterranean, Europe and South-East Asia – was therefore launched to help drug regulatory authorities develop the expertise required for regulating herbal medicines. The first workshop was held in Teheran in December, for Eastern Mediterranean countries. The aim is to familiarize national drug regulatory

### Even in China, the number of traditional Chinese medicine (TCM) hospitals, beds and research institutions is soaring

	1952	1957	1963	1975	1980	1985	1990	1995
Number of TCM hospitals	19	257	124	160	647	1414	2037	2371
Number of beds in TCM hospitals	224	5684	9254	13 675	49 151	101 418	160 899	206 812
Number of TCM research institutions	–	16	33	29	47	54	55	65

Source: *Traditional Medicine in Asia*. New Delhi, WHO, 2002 (SEARO Regional Publication No. 39).

authorities with the principal policy, safety and quality control issues regarding regulation and registration of herbal products, including development and implementation of national regulations. The workshops will also work towards development of common regional requirements for registration of herbal medicines.

In the Western Pacific Region, such harmonization is in fact already under way. The first meeting of the

Western Pacific Region Forum for the Harmonization of Herbal Medicine was held in March 2002. It drew up a work plan to deal with: harmonization of nomenclature for herbal medicines; harmonization of methods and guidelines for the registration and regulation of herbal medicines; harmonization of agricultural and field collection practice procedures; and communication of information on herbal medicine regulation. ■

### In 2002 WHO supported a range of countries on numerous traditional medicine (TM) issues

**China:** to set up a computerized database on endangered medicinal plants in China; to establish a clinical research centre in the Chinese Academy of Traditional Chinese Medicine; to assess the role of Chinese medicines and its use within a market economy and reformed health service system; to prepare guidelines on safe use of Chinese herbal medicines.

**Burkina Faso and Zimbabwe:** to evaluate medicines for treating HIV/AIDS.

**China and Korea:** to collect and analyse data on effectiveness of acupuncture through review of existing literature in Chinese and Korean.

**China, Mongolia and Viet Nam:** to organize training courses on use of TM for treatment of selected diseases.

**Ghana, Kenya and Nigeria:** to review results of clinical trials for antimalarial herbal medicines.

**Guinea, Philippines, Sao Tome and Principe, Tanzania, Uganda and Viet Nam:** to develop national policies/masterplans and programmes for TM.

**Papua New Guinea:** to collect local information on use of medicinal plants.

**Philippines:** to develop a curriculum on traditional and alternative health care for seven health science disciplines.

**Uganda:** to develop a national code of ethics for traditional health practitioners.

**Viet Nam:** to advise on methodology of clinical research, and development of TM curricula in universities; to assess quality control of herbal medicines and standardization of plant materials; to organize a training course and lectures on quality control of herbal medicines.

# Key country support in Africa and Eastern Mediterranean

Countries receiving substantial WHO support in 2002 included Afghanistan, Somalia, South Africa and Uganda. In both Afghanistan and Somalia, pharmaceutical support was an important element of health system reconstruction. In South Africa, intensive WHO support facilitated sound implementation of the country's national drug policy. In Uganda, the results of a WHO-assisted pharmaceutical situation analysis were used to reorient access and rational use activities.

## Afghanistan: rebuilding the pharmaceutical sector

The arduous process of reconstructing Afghanistan's health system is now under way. WHO made a preliminary assessment of the pharmaceutical sector in early 2002. Shortly afterwards, it recruited a national programme officer to assist the Ministry of Public Health (MoPH) on pharmaceutical issues.

### Key activities

Key MoPH/WHO activities in 2002 included:

- creation of a department of pharmaceuticals within MoPH
- staffing of the department of pharmaceuticals
- selection of essential medicines focal points in 20 provinces of Afghanistan
- creation of a national drugs and therapeutics committee
- adaptation and adoption of WHO *Guidelines for Drug Donations*
- process of updating and revising national essential medicines list started, via consultation with health professionals in Kabul, the regions, provincial hospitals and health centres
- review of Afghanistan's generic medicines law
- further development of standard treatment guidelines.

## Framework agreement with Iran

Evidently, building national pharmaceutical capacity is a long-term process, but collaboration with Iran will greatly facilitate it. A framework agreement between Afghanistan's Ministry of Public Health and Iran's Ministry of Health was signed in 2002, under which Iran will provide a training programme for staff of the Afghan drug regulatory authority, the national quality control laboratory and the faculty of pharmacy.

## Somalia: long-term development follows emergency

Constant civil war in Somalia destroyed almost all the country's public health services. A WHO situation analysis was carried out in 2001. It described the lack of a national drug policy, the poor condition of the country's medical stores, overuse of antibiotics and injections, and a pharmaceutical supply system that was completely dependent on donations. But WHO now has an office in Hargeisa and in 2002 started to work with the national authorities to lay the groundwork for health sector development.

A national drug policy (NDP) workshop was held and a strategy for NDP implementation was agreed upon. This includes setting up a national steering committee and NDP secretariat, establishing a national medicines regulatory authority, and publishing and disseminating national donor guidelines and an updated national essential medicines list.

WHO also worked closely with national authorities to re-establish Somalia's medicines distribution system. The immediate goal was defined as creating a unified pharmaceutical policy among the many NGOs and international organizations

currently providing health care in Somalia. The long-term goal will be to create an integrated essential medicines system for the whole country, responsibility for which can later be passed to the national government.

## South Africa: comprehensive support sees results

In December 2002, the South Africa Drug Action Programme (SADAP) concluded six years of intensive support for implementation of South Africa's National Drug Policy. SADAP was a project attached to the South African Department of Health, funded by the South African Department of Health and the United Kingdom Department for International Development.

Much was achieved during the six years. SADAP supported the South African Government throughout its involvement in the highly contentious international debate surrounding essential medicines, patents and affordability of medicines. SADAP also generated widespread understanding of the rationale and operation of an essential medicines list in terms of health policy-making and management, and contributed to the successful production and dissemination of standard treatment guidelines, particularly at primary health care level. Additionally, a number of workshops on medicines supply management – which trained over 700 pharmaceutical assistants – were held. These were an important contribution towards developing norms and standards for procurement, stock control, distribution, financing and staffing.

In late 2002, the Department of Health created the Pricing Working Group, preparatory to establishing the Pricing Committee, mandated by the 1997 Medicines Act 90. WHO

will provide technical advice to the Pricing Working Group during 2003.

### Uganda: from assessment to action

Medicines advisers are national professional officers with specialized pharmaceuticals expertise. Their brief is to help monitor country pharmaceutical sectors, assist countries in identifying priorities, and coordinate WHO pharmaceutical assistance. In 2002, medicines advisers began work in 11 WHO Country Offices in the African Region, including Uganda.

The medicines adviser in Uganda, WHO's Regional Office for Africa and WHO Headquarters assisted the Ugandan Ministry of Health (MoH) in carrying out a baseline survey to assess Uganda's pharmaceutical

situation. The assessment helped build capacity in monitoring and also created an evidence base for developing collaborative work plans. Collaboration between the MoH and the WHO Country Office for Uganda led to significant achievements in the pharmaceutical sector in three of WHO's key medicines areas: access, rational use, and quality and safety.

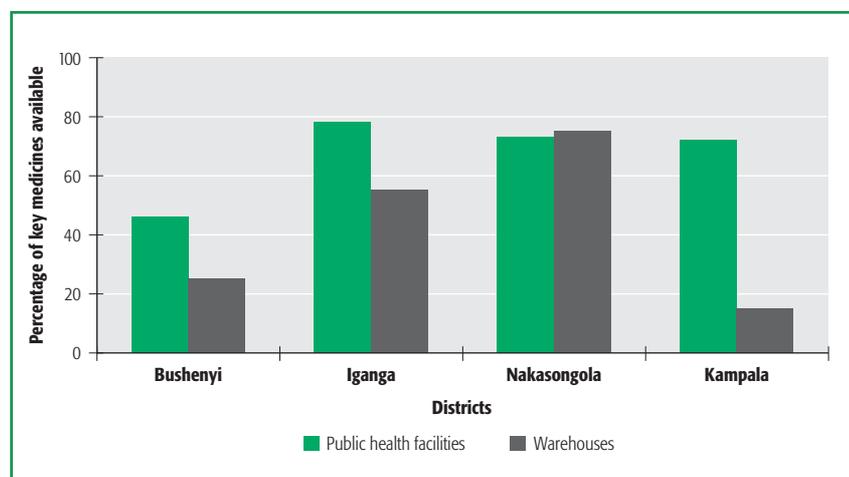
In terms of access, the situation assessment revealed that availability of key medicines varied nearly two-fold among public health facilities and five-fold among district warehouses. To improve this situation, district drug managers were trained in drug information management, and National Medical Stores personnel and district drug managers were trained in the selection and procurement of essential medicines and

medical supplies. Under Uganda's decentralization policy, districts are required to procure medicines according to their local needs. The WHO Country Office and MoH therefore supported districts in switching to a needs-based system for essential medicines procurement. Outstanding success has been achieved in this area, with 53 out of the 56 districts (95%) placing orders for essential medicines and supplies according to their local quantified needs for the first quarter of 2003.

In the area of rational use, the WHO Country Office supported the MoH to develop the *National HIV-ART Treatment & Care & Implementation Planning Guidelines* for scaling up HIV/AIDS care and support in the country. Support was also provided for dissemination of HIV/AIDS information and the setting up of the National Drug Information Centre. One of the major findings of the national assessment of the pharmaceutical sector was high use of antibiotics and injections in health facilities. Accordingly, the MoH/WHO work plan includes strategies for promoting rational use of drugs to reverse this trend.

To help ensure the quality and safety of medicines, WHO provided support for setting up a database system at the National Drug Quality Laboratory (NDQCL). This was in addition to procuring chemicals for use by NDQCL in analysing medicines samples. ■

### The 2002 pharmaceutical situation assessment in Uganda revealed that availability of key medicines varied two-fold among public health facilities and five-fold among medicines warehouses



## WHO Collaborating Centres: supplying active support for medicines work

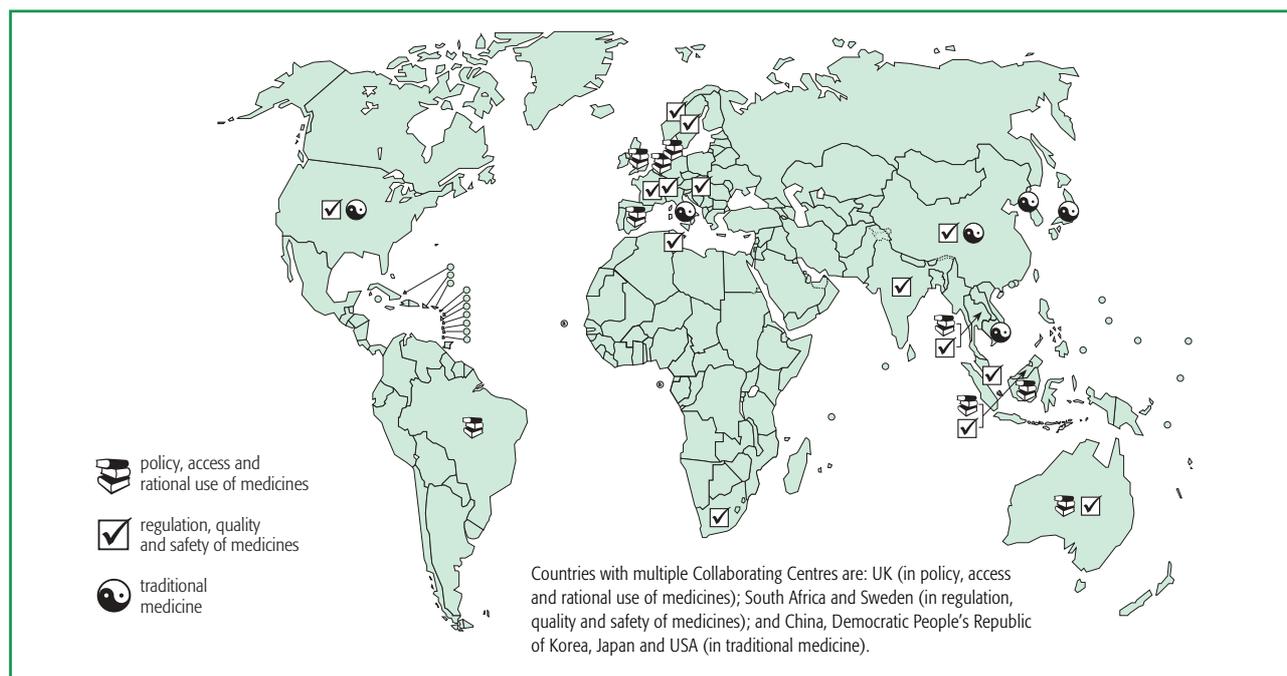
More than 40 WHO Collaborating Centres (CCs) now work with WHO on medicines priorities. Three examples of CCs working with WHO on WHO Medicines Strategy objectives are based in Chicago, Tunis and Rio de Janeiro.

### WHO Collaborating Centre for Drug Regulation Direction de la Pharmacie et du Médicament, Tunis

WHO's collaboration with Tunisia's Direction de la Pharmacie et du Médicament (Pharmacy and Medicines

Directorate – DPM) started in the early 1990s, when it helped DPM to improve its capacity to carry out medicines regulation activities, and to provide training and support to other countries. This included training DPM staff, providing reference

**WHO Collaborating Centres provide valuable technical support in: policy, access and rational use of medicines; regulation, quality and safety of medicines; and traditional medicine**



books, and developing operating procedures and a comprehensive computer-based drug registration system. In 1995, DPM started to train regulatory officials from francophone African countries in technical and administrative measures for effective medicines regulation.

In 1998, the German Foundation for International Development joined forces with WHO and organized a training course on medicines registration in collaboration with DPM. External experts and DPM staff taught the course, attended by 17 participants, representing 13 countries. That same year, DPM became a WHO Collaborating Centre for Drug Regulation. By the end of 2002, 23 drug regulation officers from 10 countries had received training from DPM in medicines registration.

DPM is now an established reference and technical support centre for countries that have adopted or intend to adopt WHO's model system for computer-assisted drug registration (SIAMED). DPM staff install the system, train users, undertake remote maintenance of the system and make follow-up visits. During the period 1996 to

2002, 12 African countries benefited from DPM assistance in installing and using SIAMED.

**South-North-South interchange and collaboration**

In 1999, the European Medicines Evaluation Agency decided to use DPM's computer system for medicines registration (developed in collaboration with WHO) as a model for developing its own computer system. EMEA's new system became available for wider distribution in 2002. Tunisia has itself adopted this new system, the end result of a rare instance of South-North-South interchange and collaboration.

Also in 2002, DPM pioneered a standardized evaluation method for assessing the safety and efficacy of new chemical entities in developing countries. It will be more broadly tested in 2003 and the subject of a training course.

**WHO Collaborating Centre for Traditional Medicine College of Pharmacy, University of Illinois at Chicago**

In 2002, the College of Pharmacy – designated a WHO CC for Traditional

**Data sourcing in traditional medicine: over half a million accessions to the NAPRALERT\* database were made by developing countries in 2002**

	Number of accessions
Africa	115 795
Europe	226
Mediterranean	12 699
Americas	146 172
South-East Asia	205 026
Western Pacific	21 620

\* Natural PProducts ALERT database

Medicine in 1981 – enhanced developing country research capacity in traditional medicine in two ways. It enrolled 22 graduate developing country students in its Pharmacognosy Graduate Program, and provided post-doctoral research training on medicinal plants for 15 developing country visiting scientists.

The College of Pharmacy also improved information exchange on traditional medicine by providing information free of charge to scientists and non-profit organizations in developing countries through its NAPRALERT (NATURAL PProducts ALERT) database. NAPRALERT contains nearly 170 000 bibliographic records with information on over 140 000 natural products and over

160 000 organisms. This CC also made the final revisions to Volume 3 and initiated preparation of Volume 4 of the WHO *Monographs on Selected Medicinal Plants*. It also constructed a website capable of being hot-linked to WHO headquarters, WHO Regional Offices, and other CCs, to further facilitate information exchange.

**WHO Collaborating Centre for Pharmaceutical Policies  
Nucleus of Pharmaceutical Assistance,  
National School of Public Health,  
Rio de Janeiro**

Part of Brazil's National School of Public Health, the Nucleus for Pharmaceutical Assistance (NAF) has been a designated WHO Collaborating Centre for Pharmaceutical Policies since 1988. Its mandate derives from the Brazilian National Drug Policy and the WHO Medicines Strategy. In partnership with all levels of government in Brazil, as well as nongovernmental organizations, bilateral and multilateral agencies, and donors, NAF contributes to important national and international initiatives to improve access to health care.

In 2002, NAF activities included setting the pharmacological and clinical basis for medicines in Brazil, advising ANVISA (the drug regulatory authority) on generic medicines issues, seminars and educational activities, translation of WHO guidelines into Portuguese, research and evaluation. National elements of this work included evaluating hospital pharmacy and pharmaceutical services within primary health care, making a pharmaco-economic assessment of drug selection, and assessing indicators for measuring access to essential medicines. Other activities had an international focus – such as examination, for Latin American and Caribbean countries, of financing for HIV/AIDS medicines, and the impact of patent protection and the TRIPS Agreement on access to medicines. ■

## How is TRIPS affecting access to medicines?

The Network for Monitoring the Impact of Globalization and TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) on Access to Medicines consists of four WHO Collaborating Centres in Brazil, Spain, Thailand and the United Kingdom. Additional input is provided from experts in appropriate pharmaceutical selection, intellectual property and economics.

The Network has developed indicators and an assessment tool to conduct baseline surveys and ongoing monitoring of: national intellectual property laws; pharmaceutical consumption; pharmaceutical pricing; medicines regulatory systems; and investment in pharmaceutical research, development and manufacturing. The tool is currently being revised based on results from field tests and will be published in 2003.

To date, assessment has been carried out in 11 countries in East Asia,

Eastern Europe and Latin America. It provides valuable information on country situations as well as a means of comparative analysis. The data shed light on key policy questions, including: whether country reliance on quality generics is increasing or decreasing; the extent to which countries are making use of flexibility built into the TRIPS Agreement; the extent to which TRIPS and globalization is spurring foreign investment and technology transfer in developing countries; and the extent of pharmaceutical patenting in particular countries. As it accumulates, the data will become increasingly important in monitoring the impact of the TRIPS Agreement on access to medicines, making it possible to analyse changes in policies, prices and consumption over time.

Further data will be collected in additional countries, including in Africa, in 2003 and 2004. ■

### Illustrative data for Eastern Europe from the Network for Monitoring the Impact of Globalization and TRIPS

	Bulgaria	Croatia	Turkey
Has legislation been modified to conform with TRIPS?	Yes	Yes	Yes
Did or will the country use the transition period?	No, modified IP law before WTO accession	No, modified IP law before WTO accession	Yes, until 1999
Does the Ministry of Health intervene in the patent review process?	No	No	No
Have compulsory licenses been granted for pharmaceuticals	No	No	No
Can the drug regulatory authority approve or register a pharmaceutical from a person, company or other entity that is not the patent holder?	–	Yes	No
Can the health authority rely on information submitted by a prior registrant to approve a subsequent application to make a generic product?	Yes	Yes	Yes

IP = intellectual property      WTO = World Trade Organization

Development  
of the essential  
drugs concept  
over the past  
25 years

Pharmaceutical promise  
and dangers

**New and powerful drugs emerge**

**1899**

- Aspirin first marketed

**1941**

- Penicillin isolated – first clinical use

**1943**

- Chloroquine trial against malaria

**1944**

- Streptomycin first effective TB drug

**1948**

- Antibiotics tetracycline and chloramphenicol introduced

**1951**

- Isoniazid introduced against TB

**1952**

- Erythromycin introduced for patients with penicillin allergy

**1954**

- Sulfonylureas introduced as first oral anti-diabetic and nystatin as first antifungal agent

**1955**

- Field trials of oral contraceptives

**A powerful pharmaceutical industry develops**

- Automated high-volume manufacturing processes create large profits
- Patent protection creates long periods of market exclusivity
- Mergers create large companies

**Significantly increased and widespread concern about safety: thalidomide**

**1961**

- Thalidomide withdrawn from US and European markets after association with serious birth defects observed, leading to global recognition of need for drug regulation and safety assessment

Growing recognition that medicines can bring dangers as well as great promise

The concept of essential  
drugs emerges

**General picture**

- Few countries have essential drugs lists
- Very little independent information on drugs and prices publicly available
- Few countries allow generic substitution
- No systematic teaching on prescribing
- No regulation of drug promotion
- Early start of safety monitoring

**Early 1970s**

- Developing countries complain that up to 40% of health budgets is spent on drugs
- Public protest at promotional practices of pharmaceutical industry

**1975 First definition of essential drugs**

- WHO Director-General Dr Halfden Mahler puts drugs issues on international development agenda by defining essential drugs as “those considered to be of utmost importance and hence basic, indispensable and necessary for the health needs of the population”

**1976**

- WHO collects drug lists from Member States, prepares criteria for drug selection and produces first draft list of essential drugs

**1977 WHO Model List of Essential Drugs**

- First Model List includes 206 active substances – Model List revised every two years thereafter

**1978**

- 31<sup>st</sup> World Health Assembly urges Member States to establish essential drugs lists and demands creation of Action Programme on Essential Drugs

**1978 WHO/UNICEF Conference in Alma Ata**

- Adopts essential drugs concept as 8<sup>th</sup> component of primary health care

**Late 1970s: economic crisis starts**

- Reduced health budgets and limited availability of convertible currency result in drug shortages, leading to renewed discussion about need for national drug policies



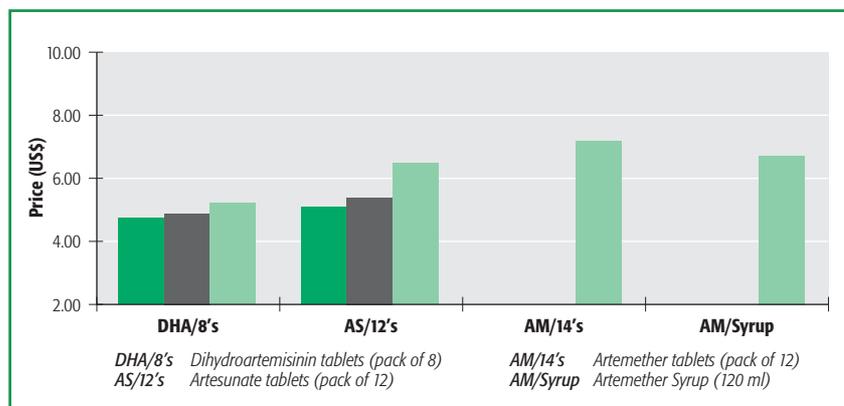
# Measuring access to antimalarials

In 2000, the Abuja Declaration issued by the African Summit on Roll Back Malaria, called on African countries to “Make appropriate treatment [of malaria] available and accessible to the poorest groups in the community.” With increasing problems of resistance, this means ensuring access not only to 1<sup>st</sup>-, 2<sup>nd</sup>-, and 3<sup>rd</sup>-line antimalarial treatments, but also to the new, and hence more expensive, artemisinin-derived antimalarials.

But in order to devise effective strategies to improve access to antimalarials, a clear picture must first be drawn of their current availability, funding for procurement, capacity for medicines regulation and control, and mechanisms for ensuring rational selection and use. While some of the related data are available within the ministries of health of malaria-endemic countries, they are often not disaggregated, which means that they cannot be used optimally in planning, budgeting or reporting.

To tackle this problem, a survey tool was developed and pilot-tested in Kenya. The tool incorporated

**Price (US\$) of 8 artemisinin antimalarial products varied widely in the private sector in Kenya in 2002**



elements of a drug pricing methodology already developed by Health Action International and WHO (see Working Out the Cost of Medicines on page 14). Survey results showed that:

- resources for procuring antimalarials are limited
- shortcomings exist in the quality of prescribing, but dispensing of antimalarials is often appropriate
- antimalarials are widely available
- antimalarial prices in private health facilities vary considerably
- post-marketing surveillance for quality assessment of antimalarials is sporadic

- patients who suspect that they have malaria mainly consult public health facilities
- 83% of those seeking medical care for malaria were diagnosed as having malaria
- 86% of patients diagnosed with malaria obtained the medicines they were prescribed
- 77% of those who obtained medicines took them as prescribed.

A similar survey will be carried out in 2003 in Ghana, Tanzania, Uganda and Zambia. ■

## Strengthening regional and national bulk procurement

**Africa:** a regional workshop on strengthening national medicines supply systems was held in Harare, Zimbabwe in July to develop a framework for improving national essential medicines procurement and distribution systems in Africa. The 36 participants from 20 anglophone countries were drawn from national medicine supply agencies, departments of pharmacy within ministries of health, nongovernmental organizations and donor agencies.

**South-East Asia:** Following discussion at the Health Secretaries Meeting of April 2002, a resolution on bulk purchasing was passed at

the SEARO Regional Committee in September 2002. SEARO's role is to bring together countries with similar situations and requirements – be these countries such as India, Indonesia and Thailand with sophisticated manufacturing capacity, or countries such as Bhutan, the Maldives and Timor Leste with no manufacturing capacity, or countries such as Nepal and the Democratic People's Republic of Korea, which do have manufacturing capacity, but which need to tackle quality problems. Additionally, SEARO will work with countries to develop common medicines specifications.

**Western Pacific:** In 2002, a workshop on pooled medicines procurement for smaller island states (SIS) was held in Nadi, Fiji. The workshop evaluated implementation of a procurement action plan developed at an earlier workshop, and identified means of improving collaboration between the SIS and Fiji. Also in 2002, *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies* were published by the Western Pacific Regional Office to demonstrate how small procurement agencies can minimize costs and ensure product quality. ■

# Learning from successful supply systems

Many governments have introduced supply reform strategies to increase availability of safe, effective and affordable medicines. But little evidence has been collected that establishes if and to what extent they have succeeded. Experience in a number of countries in Africa, Asia and Latin America suggests, however, that contrary to what is often asserted, some supply systems are working well.

Meanwhile, vastly increased funds for medicines procurement are becoming available at global level. To be used effectively, much clearer understanding is needed of country experiences with alternative approaches to medicines supply

management. Moreover, examination of vertical versus comprehensive approaches to increasing access to medicines is long overdue.

In 2002, WHO launched two complementary studies. The first of these is a multi-country study to assess reform strategies introduced by governments to centralized medicines supply systems. A start-up stakeholders meeting produced a situation analysis and status report on innovative supply systems, and developed a study protocol. The study will identify why certain strategies have succeeded – i.e. the criteria and social and political conditions that would need to apply in order for success to be replicated.

The results will help generate guidance for governments and agencies working to improve medicines supply.

A second study will map the supply and distribution activities of faith-based nongovernmental organizations in Sub-Saharan Africa. A questionnaire has been developed and will be field-tested and applied in 2003 by medicines supply staff of faith-based organizations. In addition, a regional network of medicines supply experts working for faith-based organizations will be created, to promote exchange of expertise, and to serve as a source of mutual assistance and support. ■

## Autonomous medicines supply agencies – three examples

### Benin

The Benin Central Purchasing Office (BCPO) for essential medicines supplies was established in 1991. An autonomous supply agency, with a monopoly position, it is responsible for providing medicines to public health facilities and the private not-for-profit sector. BCPO has a management committee, which monitors financial operations, while a steering committee ensures that the agency's objectives are met. In 1993, after devaluation of the CFA franc, procurement of essential medicines by generic name was initiated. Management principles were also adopted, such as cash-only sales, no credits, responsibility for medicines collection and distribution assigned to clients, and minimum operations budget and personnel. Staff are selected through competitive application and recruited under contract rather than as permanent civil servants. Government regulations and medicines policies are followed, and BCPO's performance is monitored regularly by the government.

### Sudan

In 1991, the Central Medical Stores became an autonomous agency under the name of CMS Public Corporation (CMSPC) and was capitalized with a government grant. The number of staff was reduced considerably. It has no direct government involvement but works closely with the government. CMSPC has its own independent bank accounts and operates as a monopoly. Funds are received from cash-and-carry sales. It operates an open tendering procurement system to obtain the required bulk quantities of essential medicines by generic name, in accordance with the national list of essential medicines. Following decentralization policies, each of Sudan's 28 states – including those ravaged by war – has been obliged to organize its own medicines collection and distribution system, as well as its own cost-recovery system. "People's pharmacies" (semi-private community pharmacies), nongovernment organizations, and sometimes private pharmacies, purchase medicines from CMSPC, which operates a price policy for the various buyers. Government regulations and medicines policies are adhered to. CMSPC's performance is monitored by the government. But the prevailing economic situation prevents CMSPC from functioning more effectively.

### Zimbabwe

Commercialization of the Government Central Stores in Harare was approved in July 1997. NatPharm was created in 1998, capitalized with a government grant and operates as a commercial company. It has a Board of Directors that monitors operations. It operates in accordance with a Memorandum of Understanding and within Articles of Association, and has signed a performance agreement with the Ministry of Health. Its main customers are the country's 1300 public health institutions, but it can also make sales to the private sector. Its tender system is directed at obtaining the required bulk quantities of essential medicines by generic name, in accordance with the national list of medicines.

## Working out the cost of medicines

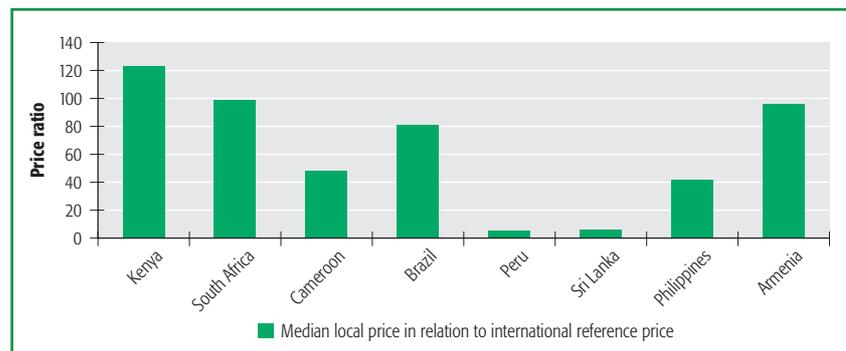
Civil society organizations took a prominent early lead in drawing attention to the need to increase access to medicines in the fight against poverty. Dialogue between such organizations and WHO led to a joint WHO–Health Action International project to promote greater openness and better information on medicines prices and availability, as a means of tackling access problems.

The first phase of the project was completed in December 2002. This included development of a methodology for monitoring medicines prices and publication of a manual on how to apply that methodology in individual developing country settings. The methodology can be used to establish whether prices are high or low, availability, price differences between branded medicines and generics, and between sectors, and the elements of price composition. A worksheet enables investigators to measure the affordability of treatment for 9 common conditions.

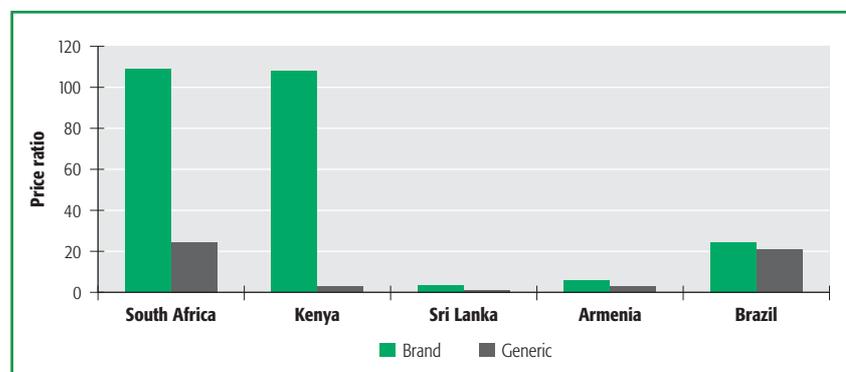
### Field test results and potential impacts

Results from the field tests showed, for example, that in Kenya's private retail sector the median "brand premium" (median price ratio of branded to generic medicines) was "over 5" –

**Private sector retail prices in 2002 for innovator brand ciprofloxacin, varied widely across 8 countries indicating considerable scope for more effective price regulation**



**In 2001, innovator brand and generic furosemide prices in relation to the international reference price varied considerably across five countries, indicating scope for improving the affordability of medicines**



meaning that innovator brands cost, on average, over 5 times more than the most-sold generic equivalents. In Brazil, by contrast, the "brand premium" was much lower – close to 0.33. Nevertheless, in Brazil's private sector, as in Kenya, big differences

were observed between international prices for individual medicines (the price of brand ciprofloxacin was over 80 times higher than the international reference price). The methodology is also being used in Africa to investigate prices of antimalarials. ■

## Supporting MDG target on access to essential medicines

The Millennium Development Goals (MDG) are an ambitious agenda for reducing poverty and improving lives that world leaders agreed on at the Millennium Summit in September 2000. For each goal one or more targets have been set – most for 2015, using 1990 as a benchmark. MDG target 17 is, "In co-operation with pharmaceutical companies, provide access to affordable essential drugs in developing countries" and the indicator for monitoring progress is "the

*proportion of population with access to affordable essential drugs on a sustainable basis*".

WHO's engagement to achieve the MDG access target involves four components. Helping countries achieve **better prices** is pursued through price information services and technical assistance on effective price regulation, as well as by enlarging the supplier base for essential drugs. Careful **selection** is

supported through the Model List of Essential Medicines process, and its use at country and health facility level. Better medicine **supply** systems are supported by procurement information and advice. Strategies to raise and improve the fairness of medicines **financing** include providing guidance and technical support for ensuring subsidies for key medicines for poor people, and inclusion of drugs in expanded health insurance schemes. ■

# Common guideline for evaluating new medicines in Baltic countries

Since 1997 WHO has provided sustained medicines support, including courses on pharmaco-economics, assistance for the Baltic Medicines Conferences of 1997 and 2001, and technical input for developing reimbursement systems, to Estonia, Latvia and Lithuania. As a result, these three Baltic countries succeeded in bringing together the expertise and necessary political support for developing and adopting a common guideline on pharmaco-economic evaluation of new medicines. The Ministry of Welfare of the

Republic of Latvia, the Ministry of Social Affairs of Estonia and the Ministry of Health of the Republic of Lithuania signed a Memorandum of Understanding in September 2002 agreeing to:

- strengthen co-operation between institutions working on pricing and reimbursement of pharmaceuticals and pharmacoeconomic analyses at national level
- use a common methodology for assessing costs and cost-effectiveness of pharmaceuticals in order to support decision-making on

resource allocation for health care

- exchange information on prices and pricing of pharmaceuticals
- exchange information on legislative changes relating to pricing and reimbursement of pharmaceuticals, and application of cost-containment measures.

The three countries will now be able to build on each other's assessment of applications for reimbursement, reducing duplication and leading to more informed and consistent decision-making on reimbursement. ■

# NGO toolkit for improving access to HIV/AIDS treatment

Developed in 2002, the *Handbook on Access to HIV/AIDS Treatment* is a resource for the various groups involved in providing treatment for HIV-related conditions. It is also intended to be a concrete acknowledgement that, without the work of nongovernmental organizations (NGOs), the global response to AIDS would have been much smaller and less effective than it is today.

While the International HIV/AIDS Alliance, WHO and UNAIDS Secretariat will provide the finished product, the essential "raw material" was provided by dozens of individuals and groups in Africa and Asia. Their participation during design and field-testing gave the handbook the benefit of their experience and expertise, and kept it focused on the practical needs and challenges of providing treatment to people living with HIV/AIDS.

Groups of persons living with HIV/AIDS, NGOs and community based organizations (CBOs) have been at the forefront of prevention and care

since the world first became aware of the epidemic two decades ago. Instead of leaving these tasks to the medical profession or public health authorities, they became partners in providing HIV-related commodities and services – in some places, they have been the only providers. They have also built roles for themselves as advocates and teachers, changing the way the world thinks about HIV/AIDS and responds to the people who live with it. In so doing, they have built hope, spread important skills and ensured better delivery of HIV/AIDS-related services and commodities.

The handbook aims to widen the participation of these groups yet further by providing a collection of information and tools for understanding, planning and undertaking work on HIV/AIDS-related treatment.

Initial feedback suggests that the handbook is serving its purposes well:

**Dr Chhim Sarat, Senior Project Officer Care and Support, Khmer**

**HIV/AIDS NGO Alliance (KHANA), Cambodia:** We use the handbook in all of our care and support workshops, taking some parts of it to develop the curriculum and to discuss the issues related to access to treatment, etc.

**Chanda Fikansa, former Assistant Programme Manager of the Intergrated AIDS Programme of the Catholic Diocese of Ndola, Zambia:** We used the handbook in a workshop setting involving home-based care programme staff... [It] has also been used with specific target groups of community volunteers. We used the handbook to look at ways of improving the quality of the care delivery that the home-based care programmes were providing. By looking at the barriers to treatment we could look at what things we could do to improve care and support. The handbook was particularly useful for facilitating the discussion and flow of ideas. It's also useful for those who are not experienced in care and support, but familiar with some of the issues. It is a useful tool to show

what information you need to provide good care and support and to think through the issues involved.

**David Musendo, Deputy Director, Family AIDS Caring Trust (FACT), Zimbabwe:** So far, we've used the handbook in two regional workshops and at one national workshop. FACT staff have also adopted some of the sections from the toolkit for local training workshops in their different projects. The toolkit is user-friendly and easy to adapt for local use. The language is simple and relates to what people can realistically do at the grass-roots level. There is little medical jargon.

**Boithumelo Huma, Vukuzenzele Project Co-ordinator, AIDS Consortium, South Africa:** We used the handbook at a workshop for community volunteer facilitators from CBOs in the Gauteng and Mphulalanga Provinces, NGO workers from Swaziland and Lesotho, and lecturers from WITTS University. After the workshop, the community facilitators shared information in the handbook with caregivers in their communities, most of whom are illiterate. This was important in helping families know what is available to them and to encourage them to demand that it becomes accessible. The handbook also helped facilitators to improve relationships with other care providers – they've reached out to social workers and priests, and visited clinics to discuss access issues with nurses. The handbook has shown caregivers the importance of different service providers working together to cover all aspects of care for people living with HIV/AIDS. This has resulted in more respect between service providers and more cross-referrals. The WITTS University lecturers now include access to treatment in their curricula and have developed a programme with the AIDS Law Project. ■

The pre-publication version of the handbook can be accessed at: <http://www.unaids.org/publications/documents/health/access/NGOtoolkit/index.html>.

## Harmonizing medicines regulation in the Americas

In the Americas, harmonization is considered key to ensuring the production of good-quality pharmaceutical products by the region. WHO's Regional Office for the Americas/Pan American Health Organization (AMRO/PAHO) promotes and facilitates harmonization by integrating the various stakeholders in the harmonization process.

Every two years, a Conference on Drug Regulatory Harmonization is held as an open forum for discussing and endorsing proposals presented by technical expert groups. The 3<sup>rd</sup> Pan American Conference on Drug Regulatory Harmonization took place in April 2002. The Conference recommends actions that countries can undertake to promote harmonization. The 3<sup>rd</sup> Conference made many proposals, including:

### Good Manufacturing Practice

- giving priority to training activities to improve GMP implementation
- adopting the WHO 1992 GMP guideline
- promoting implementation of a WHO-type Certificate of Quality

of Pharmaceutical Products Subject to International Commerce

### Bioequivalence

- using the same reference product for bioequivalence studies

### Good clinical practice (GCP)

- harmonizing procedures for evaluating clinical trial protocols
- developing inspection guidelines for audits on GCP.

Based on studies on implementing and enforcing GMP in the region, the 2<sup>nd</sup> Conference (1999) recommended that GMP be the first priority in the harmonization process. AMRO/PAHO was especially active in GMP training – between April 2001 and September 2002, it organized 18 workshops on GMP in 18 countries. The workshops were attended by nearly 600 health professionals. Instructors were mostly professors of Latin American universities, with experience in GMP, pharmaceutical technology and quality systems. The courses are now being replicated by pharmacy schools of universities in Bolivia, Colombia, Honduras and Nicaragua. ■

## Good manufacturing practice in China: rapid progress

In the *Annual Report 2001: Essential Drugs and Medicines Policy*, the number of pharmaceutical manufacturers that would be compliant with good manufacturing practice (GMP) by the end of 2002 was estimated at 1200. In fact, by the end of 2002, 1600 pharmaceutical manufacturers were compliant with GMP. This rapid progress is due to China's concerted effort, with WHO assistance, to organize GMP training and to translate

WHO's GMP basic training modules into Chinese (see: <http://www.who.int/medicines/organization/qsm/activities/qualityassurance/gmp/trainingmodules/whobasictrainingmodulesgmp.htm>). An article by K. Morimoto et al. entitled Promoting GMP implementation: developing training materials for the international audience, will appear in *Quality Assurance: Good Practice, Regulation, and Law*, 2003, 10(1). ■

# Pharmacovigilance: detecting and reporting adverse drug reactions

**Safety of Medicines: A Guide to Detecting and Reporting Adverse Drug Reactions. Why Health Professionals Need to Take Action<sup>1</sup>** presents some alarming information. Problems with medicines – known as adverse drug reactions (ADRs) – are the 4<sup>th</sup> to 6<sup>th</sup> largest cause of mortality in the USA. WHO is promoting pharmacovigilance<sup>2</sup> to help prevent medicines-related morbidity and mortality. Collecting reports of ADRs is key to pharmacovigilance.

WHO's international ADR monitoring database was made available for national pharmacovigilance centres in 2002. It is the cornerstone of the WHO Programme for International Drug Monitoring operated by the Uppsala Monitoring Centre (UMC) in which 68 countries now participate. The programme held its 25<sup>th</sup> annual meeting in 2002. A new procedure introduced by UMC in 2002 focuses on detecting serious ADRs associated with newer drugs and drug-ADR combinations.

In the last two years, special efforts have been made to improve pharmacovigilance in the Newly Independent States (NIS), following a request from eight NIS countries for assistance. Widespread economic and social changes had affected health care in general and the pharmaceutical sector in particular in these countries, with negative impacts on not only availability, but also the quality of essential medicines.

In 2000, a project – Development of National Systems for Drug Monitoring in Newly Independent States –

## Country progress in collecting information on adverse drug reactions (ADRs)

**Cuba** became a member of the WHO Programme for International Drug Monitoring in 1994. In 1998, the Cuban system of pharmacovigilance collected around 900 reports. In 1999, responsibility for drug safety monitoring and promotion of ADR reporting became part of continuous education activities, resulting in a dramatic increase in the number of reports. In 2001, the national pharmacovigilance centre received 16 295 ADR reports. The reporting rate per capita is now the world's highest.

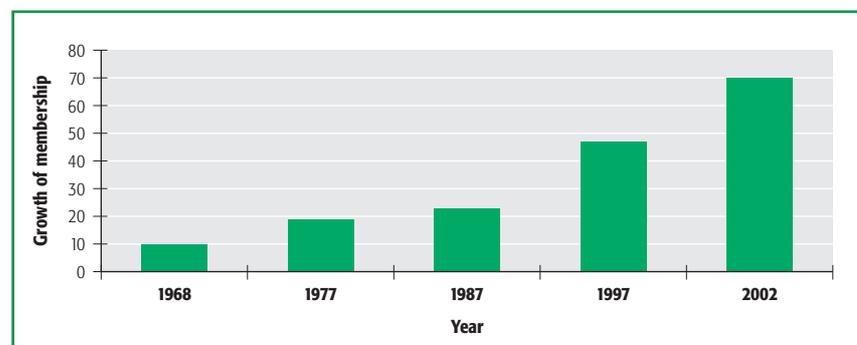
**Ghana** became a full member of the WHO Programme for International Drug Monitoring in 2001. The spontaneous reporting system in Ghana is reported as going well, with increasing acceptance of the programme by prescribers, dispensers and the general public. Training courses on ADR reporting have been held.

**New Zealand** was one of the founding members of the WHO Programme for International Drug Monitoring. New Zealand's national monitoring centre for adverse reactions collects and evaluates spontaneous reports of adverse reactions to medicines, vaccines, herbal products, dietary supplements, and blood products. Its database now holds over 48 000 reports and provides New Zealand-specific information on adverse reactions to these products, and serves to support clinical decision-making when unusual symptoms are thought to be therapy-related.

was launched, covering Armenia, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Ukraine and Uzbekistan. Evaluation showed that monitoring and evaluation of ADRs varied enormously. For example, Armenia, the Russian Federation and Ukraine each had a pharmacovigilance system in place, but these were not highly developed. Recommendations were made to countries

depending on their population size, economic and social conditions, and level of existing expertise. For example, since Kazakhstan, the Russian Federation and Ukraine each have a large population and extensive territory, it was recommended that they each establish several regional pharmacovigilance centres, as well as a national pharmacovigilance centre.

## Growth of membership of International Drug Monitoring Programme since its inception in 1968



<sup>1</sup> Published in 2002. See also *The Importance of Pharmacovigilance*, published in 2002 and available at: <http://whqlibdoc.who.int/hq/2002/a75646.pdf>.

<sup>2</sup> Pharmacovigilance consists of methods to identify and quantitatively assess the risks related to the use of medicines in the entire population, or in specific population subgroups.

To help in this task, WHO guidelines on setting up and running a pharmacovigilance centre were translated into Russian and distributed. Additionally, four pharmacovigilance training seminars, using the “train-the-trainers” principle, were conducted. A further 200 educational and information seminars and meetings on pharmacovigilance

were organized for health care providers.

Concurrently, national pharmacovigilance systems were established in all eight countries through passing of special legislation and/or regulations. Five of the countries also joined the WHO International Drug Monitoring Programme. In Kazakhstan, Russia and Ukraine, 30, 15 and 25 regional

ADR centres respectively have also been set up. Reporting of ADRs is now well under way and a national database to collect information on ADRs has been established in each country. Armenia and Russia now publish special bulletins on drug safety, while the other countries include drug safety information in their drug bulletins. ■

## Variations in prescribing information in 26 countries

An international comparative study<sup>1</sup> on regulatory medicines information conducted in 2002 by WHO, the Mario Negri Research Institute (Milan, Italy), the Institut Català de Farmacologia, Universitat Autònoma (Barcelona, Spain) and the International Society of Drug Bulletins (Paris, France), showed that medicines recommendations used by prescribers and patients vary considerably between countries. Disagreement was found even within a single country, when written materials from different brands of the same drug were compared. The discrepancies arise because national regulatory authorities do not or may not have the resources to conduct full and systematic assessments of data from clinical studies and post-marketing surveillance, before approving prescribing information materials. The discrepancies are worrying because they can mislead prescribers and patients regarding medicines use, and researchers seeking to compare medicines use patterns across countries.

Summaries of product characteristics, package inserts and data sheets were assessed for 26 countries for ciprofloxacin, fluoxetine and nifedipine. These three medicines were chosen because they were among the top 30 medicines in

terms of global sales in 2000, and cover three therapeutic areas of worldwide relevance in terms of mortality and morbidity. For the four variables considered – indications, dosage range in adults, side-effects and cautions – an information checklist was created, using the British National Formulary (BNF).

Out of 26 countries, 11 had information that matched BNF indications for nifedipine. For ciprofloxacin,

materials from 3 countries did not match the dose range recommended by the BNF, while for nifedipine and fluoxetine, materials from 7 countries and 9 countries respectively did not match. Also for ciprofloxacin and fluoxetine, none of the materials from the various countries reported all major side-effects listed in the BNF. None of the materials from any of the countries reported all the cautions included in the BNF for nifedipine. ■

## 10<sup>th</sup> ICDRA: an international basis for medicines regulation

The International Conference of Drug Regulatory Authorities (ICDRA) was set up by WHO to develop international consensus on medicines regulation issues. Given new regulation issues brought about by globalization and development of free markets, and increased regulatory responsibilities – for instance, in relation to the introduction of innovative treatments – such a forum is essential.

The 10<sup>th</sup> ICDRA (see: <http://www.who.int/medicines/organization/qsm/activities/drugregul/icdra.shtml>) took place in June in Hong Kong and was marked by recognition that access to medicines is a global and shared issue, commitment to improving medicines quality in developing countries, and concern

regarding how to ensure the safety of traditional and complementary medicines. Recommendations were made on: access to drugs and vaccines; regulatory reform; medicines safety; regulation of clinical trials; harmonization; combating counterfeiting; herbal medicines; homeopathy; new technologies and e-commerce. The recommendations are now serving as a basis for action on medicines regulation by WHO Member States and WHO.

A pre-ICDRA workshop entitled, The Impact of Regulation on the Safe Use of Drugs, provided a venue for drug regulatory authority staff to discuss new trends in medicines safety and to prioritize issues for discussion and recommendations during the ICDRA sessions. ■

<sup>1</sup> International Comparative Study on Drug Information (ICSODI) Collaborative Group. Prescribing information in 26 countries: a comparative study. *European Journal of Clinical Pharmacology*, in press.

## Fighting poor-quality drugs

Medicines to improve the quality of life of people with HIV/AIDS, to cure tuberculosis (TB) and to fight malaria are needed more than ever before. Increased financial commitment to supplying those medicines means that the resources for procuring these medicines are more readily available. But impacts will only be seen at country level if sufficient quantities of medicines of good quality can be procured and distributed.

Systematic procurement can both speed up medicines distribution and help maximize treatment outcomes – as well as optimize use of resources. WHO launched a project in 2001 to create unified standards for performing inspections at suppliers, and assessing regulatory information about product quality, before pharmaceuticals are sourced. In short, it created a Model Quality Assurance System. The vastly enhanced rate of “pre-qualification” now possible with this system has speeded up adjudication and contract award, and hence access to medicines. It has also helped to eliminate or vastly reduce the risk of sourcing sub-standard, counterfeit and/or contaminated medicines.

The initial focus of the project was on medicines for treating HIV/AIDS (but it has since been expanded to cover anti-TB medicines and antimalarials). By the end of 2002, 69 products, for treating HIV/AIDS, had been pre-qualified. Just as importantly:

- developing country capacity to produce good-quality antiretrovirals (ARVs) had been increased
- developing country regulatory capacity to assess ARVs had been strengthened
- international cooperation on medicines quality had been enhanced. ■

## Improving medicines use in hospitals in Cambodia and Lao PDR

In 1997, the first International Conference on Improving the Use of Medicines (ICIUM) presented and discussed interventions from around the world that aimed to promote appropriate use of medicines. It concluded that a successful intervention should:

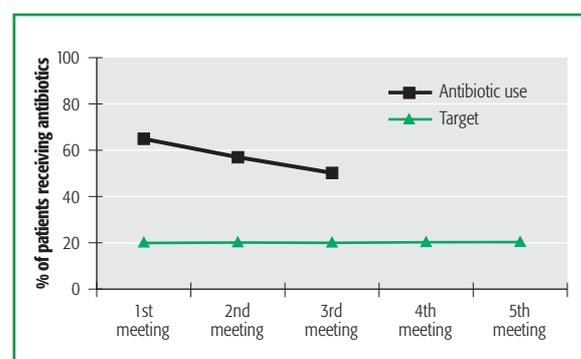
- focus on a specific problem
- address the underlying factors
- use a problem-solving approach
- repeat the intervention
- be interactive
- provide feedback to prescribers
- be followed by monitoring and supervision
- develop peer group commitments or guidelines.

In 2001, the percentage of patients receiving antibiotics was 60–100% in Cambodia and approximately 70% in Lao PDR, while injection use in both countries ranged from 60–100%. A review by WHO indicated that monitoring and supervision of medicines use in the two countries did not incorporate problem-solving approaches, and was neither generating prescriber, commitment to nor setting specific targets for improved medicines use. In other words, the precepts recommended by ICIUM were not being comprehensively followed.

Following the ICIUM recommendations, and working with the Ministries of Health in Cambodia and Lao PDR, WHO introduced and field-tested an innovative monitoring, training and planning strategy (MTP) for improving rational use of medicines. A group of providers identifies medicines use problems, quantifies them using suitable indicators, identifies their possible causes, and

selects appropriate solutions. They then implement the chosen solutions using available scientific information and other resources, and measure their (hopefully) improved performance. Additionally, the group of providers holds a regular monthly meeting to monitor the levels of the defined problem, discuss improvements made and target levels of improvement for the following month.

**The percentage of patients receiving antibiotics at Hinboun District Hospital, Cambodia, fell immediately after implementation of the monitoring, training and planning strategy**



The MTP strategy was field-tested in Cambodia and Lao PDR in a number of, mostly provincial, hospitals (6 in Cambodia and 8 in Lao PDR), and later expanded to district hospitals (21 district hospitals in Lao PDR). Evaluation of implementation in the pilot hospitals showed that it was effective in improving medicines practices and that hospitals can adopt the strategy easily. The Ministries of Health in Lao PDR and Cambodia are now seeking to extend use of this strategy to additional provincial and district hospitals, with donor support.

MTP was earlier adopted by the WHO Collaborating Center for Research and Training on Rational Drug Use in Yogyakarta, Indonesia, for implementing rational medicines use interventions in Indonesia. ■

# WHO-India Essential Drugs Programme: multiplying impact

WHO expanded its support to the WHO-India Essential Drugs Programme in 1997. This was to enable the Programme to extend the success of its Delhi Capital Territory Essential Medicines Programme, largely implemented by the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD). DSPRUD's activities during 1997–2002 were externally evaluated in October 2002.

The hallmark of DSPRUD activities has been close cooperation with the Delhi State Government. DSPRUD has also assisted nongovernmental organizations (NGOs) in other states, such as Rajasthan, and large institutions such as the Municipal Corporation of Mumbai, with activities to promote rational use of medicines. The evaluation found that DSPRUD's design and implementation of a transparent pooled procurement and distribution system had resulted in a consistent supply of good-quality essential medicines for Delhi State's public health facilities. It also noted that execution of the programme through an NGO had minimized bureaucracy and encouraged flexibility for developing linkages with medical schools, universities and other institutions.

By the end of 2001, the WHO-India Essential Drugs Programme was operating comprehensive essential drugs programmes in 6 states and partial programmes in a further 8 states. In 2002, partial programmes were introduced in Bihar, Chattisgarh,

Kerala, Orissa and Uttar Pradesh, and significant progress made in developing standard treatment guidelines (STGs). STGs were developed as follows:

- **Delhi State:** STGs were prepared by DSPRUD, for treating patients with specific clinical conditions, following an extensive consultative process involving 70 clinicians, from all levels of health care, and including some private practitioners.
- **Karnataka State:** STGs for primary health care facilities were prepared and distributed to district health officers.
- **Madya Pradesh State:** STGs were developed for reproductive and child health.
- **Maharashtra State:** STGs for treating in-patients of secondary and tertiary health-care facilities in the Municipal Corporation of Greater Mumbai were prepared and published by the Department of Clinical Pharmacology, BYL Nair Charitable Hospital.
- **Uttar Pradesh State:** STGs were prepared with technical support from DSPRUD and will be distributed by the Government of Uttar Pradesh to doctors in hospitals and primary health centres. ■

## Oman: improving antibiotic use in primary health care

With assistance from WHO's Eastern Mediterranean Regional Office, the Department of Rational Drug Use in Oman conducted a national survey of antibiotic use. It identified inappropriate use in primary health care (PHC) centres in particular. A pilot study was thereafter conducted at the Muscat Health Centre to develop a national tool for improving antibiotic use. The study was conducted over six months and covered use of three antibiotics in two dosage forms. Doctors were encouraged to read selected scientific materials about evidence-based use of antibiotics for the most common clinical conditions encountered in

PHC practice. Simultaneously, they were monitored, evaluated and informed about any nonconformity observed between their prescriptions and the evidence-based materials they had been given.

At the end of the study, a 53% reduction in the consumption of antibiotics was observed. The six-month follow-up period showed a similar antibiotic consumption trend. A similar approach for reducing antibiotic consumption in other PHC centres will accordingly be incorporated into the 2003 national annual plan for promoting rational use of antibiotics. ■