The purpose of *Essential drugs in brief* is to share information on the latest country support provided or coordinated by the extended Drug Action Programme team (country, regional and HQ offices). It is an informal instrument aiming to share our experiences with colleagues within and outside WHO, who are active in the implementation of national drug policies at national and regional levels.

**SOUTH AFRICA**

**Access to essential drugs in international trade agreements**

WHO Medicines Strategy for 2000–2003 aims to provide technical support to countries in implementing their national drug policy. Priority components include maintaining access to essential drugs within international trade agreements, by advising countries on their options regarding pharmaceuticals and trade under the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement. The recent court case in South Africa concerning the 1997 Medicines Act 90 drew considerable media attention and became highly symbolic for both the AIDS community and for developing countries with respect to globalization, international trade agreements, and access to medicines. WHO’s view was clearly stated by the Director-General, Dr Gro Harlem Brundtland, in her remarks presented on 12 March to the Ambassadors of the Organization of African Unity in Geneva:

“...all of us would take the view that an effective regime for international trade is one which allows countries to implement workable systems that secures people's basic needs—including their health needs—while respecting intellectual property, the process is difficult. Along the road, there will be disputes about how trade agreements are to be interpreted. There will be challenges to those national drug policies which seek to change the ways in which patent rights are applied. These can only be solved by testing their limits through a legal process: this is costly and frustrating to all concerned, but the stakes are very high indeed. Over the past weeks, we have seen the beginnings of just one such legal process—in South Africa...WHO fully supports the intent of the 1997 Medicines Act 90, which is to operationalize key elements of the National Drug Policy, including generic substitution, greater competition in public drug procurement, improved drug quality, and more rational use of medicines. We recognize that language within parts of the act is seen as a challenge by some companies. During the past few years we have worked with the different interests involved as numerous attempts have been made to find a way forward that is acceptable to all...”

WHO played an instrumental role in the formulation and implementation of the South Africa National Drug Policy of 1996 whose objectives are “to ensure an adequate and reliable supply of safe, cost-effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers.” The 1997 Medicines Act 90 was an embodiment of many key principles of the National Drug Policy which included: parallel importation, generic substitution, quality control of imported medicines, voluntary price reduction, international competitive tendering for the public sector, essential drugs list and standard treatment guidelines.

The court case in South Africa was initiated at the behest of 39 pharmaceutical companies which challenged parts of the 1997 Medicines Act 90, contending that the law would destroy patent protections by giving the health minister overly broad powers to produce, or import more cheaply, versions of drugs still under patent.

At the request of the South African Ministry of Health, WHO identified relevant international legal expertise to support, and report, to the Government of South Africa. The 39 pharmaceutical companies eventually dropped the case unconditionally on 18 April 2001. In a joint state-
African Region

Monitoring and evaluating national drug policies in Africa: a feedback approach to implementing strategies and work plans

In Africa, implementation of the WHO Medicines Strategy is being linked to monitoring and evaluation to assess whether people have access to essential drugs and medicines that are safe, efficacious and of good quality, and whether these drugs are used properly. Assessment covers country capacity such as available infrastructure, logistics and human resources, the process and strategies used in implementation, outcomes and impact. The approach has already been implemented in South Africa and Namibia and is now being adopted in Chad.

A monitoring package, including an operational system on how to prepare and co-ordinate monitoring and evaluation, plus the technical support that the country may need, has been created. The package also includes a simple training guide for conducting systematic field surveys.

The next step will be to implement the feedback loop and to encourage and demonstrate the use of the information collected in policy decisions relating to synchronising of, for example, health and economic policies. The policy-makers and implementers in health facilities will then have a clearer picture of national and institutional problems for reassessing strategies and priorities.

The monitoring package is now being used in Chad where national health professionals are carrying out a practical operational procedure. This activity is being implemented in close co-operation with the WHO country office and the Ministry of Health. Training of staff, field-testing/practice, and the review of test results have been carried out and a national survey and assessment of the pharmaceutical sector are ongoing. The results of the national survey will improve the focus of the technical input for national drug policy implementation. A problem-based approach to training for prescribers and dispensers of primary health facilities, using the results of national monitoring, is scheduled for early May 2001.

Region of the Americas

New medicines developments in MERCOSUR

During the Protempory Secretariat of MERCOSUR (Brazil, Argentina, Uruguay and Paraguay) in Brazil, two important decisions were made during the year 2000. The first was the approval of a document on Drug Policy for MERCOSUR, Bolivia and Chile. The drug policy has a very comprehensive approach, covering access, quality, rational use and research. The policy element is based on the essential drug concept and in terms of access includes the preparation of a common Essential Drugs List, implementation of legislation on generic substitution and therapeutic equivalence, and the obligation of governments to finance essential drugs for priority health programmes. The quality element emphasizes the one-quality standards concept for all medicines, whether essential, generic or patented, the need for all countries to implement approved agreements on good manufacturing practice (GMP), inspections, and the required social and sanitary functions of pharmacies as part of the drug distribution chain. The rational use element stresses the need for joint action on prescription and dispensing practices, the promotion of the pharmacy care concept and the need to implement ethical criteria for drug promotion with specific mention of over-the-counter drugs. Finally, the common drug policy also establishes the need to promote clinical research and to disseminate good clinical practice (GCP) guidelines.

The second important decision taken by MERCOSUR was to approve the creation of a database on drug prices. Brazil will be responsible for preparing the proposal, which will cover drug prices at pharmacy level, indicating the cost that has to be paid by the patient to obtain the medication, and drug prices paid by governmental institutions undertaking drug procurement. This database is expected to form the basis of national drug price policies in MERCOSUR member countries.

Both decisions are expected to influence the process of drug regulatory harmonization in other subregions of the Americas, mainly the Andean Community group and the Central America subregion.

The Department of Essential Drugs and Medicines Policy (EDM) is comprised of four teams:

- Drug Action Programme (DAP); Policy, Access and Rational Use (PAR);
- Quality Assurance & Safety: Medicines (QSM); and Traditional Medicine (TRM).
- Support to countries is provided in coordination with WHO Regional and Country Offices.

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Issue No. 4, April 2001
**EASTERN MEDITERRANEAN REGION**

**United Arab Emirates to join the EMRO countries with National Drug Policies**

The United Arab Emirates has, with WHO technical assistance, started the process of developing its national drug policy. The administrative framework for this process has been established, as has a plan of action for the soon to be appointed Task Force. The Task Force will prepare a situation analysis of the pharmaceutical sector and convene stakeholder meetings, with adoption of the policy in 12 months time as its major milestone.

**Joint visit by EDM and VAB to review regulation of medicines and biologicals in Tunisia**

In the context of establishing a policy to support national institutions in regulation of drugs and vaccines, WHO's Departments of Essential Drugs and Medicines Policy (EDM) and Vaccines and Biologicals (VAB) have planned a series of country evaluation missions during 2001. The first country evaluated was Tunisia during February. The mission evaluated the performance of systems for regulating pharmaceutical products and vaccines in Tunisia (main objective), tested and used WHO performance indicators for evaluating drug regulation systems, and made proposals for better WHO coordination of policies to strengthen national drug and vaccine regulatory authorities.

The missions are multidisciplinary, and involve staff from WHO headquarters and the regions. In most countries, the system for regulating biologicals, including vaccines, is based on a single institution and staff for both regulation and control of pharmaceuticals or drugs. It was seen as important to coordinate support for the respective policies of WHO EDM and VAB.

**Health workers in Somalia express need for continuing education**

Doctors and nurses attending a series of training workshops on rational drug use organized by WHO in various parts of Somalia expressed the need for continuing education and reference materials. The pre- and post-assessment of the workshops showed dramatic improvements in the participants' understanding of appropriate drug use and the essential drugs concept (scores went up from 7 to 30 out of 40 for doctors and from 2 to 25 for nurses) as well as a desire by all for more training and professional literature. Before the training course only 10% of physicians interviewed had access to formularies or treatment guidelines.

**Drug supply management course in Sudan**

Twenty-three supply officers attended a national training course on drug supply management in Arabic and English organized by EMRO. The training programme covered the basic functions relating to selection, procurement and distribution of medical supplies in general, and drugs in particular. Topics covered included national drug policy, store administration, quantification, supplier selection, inventory management, finance management, systematic cost reduction and quality assurance.

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**EUROPEAN REGION**

**Data on drug use patterns in Western European countries**

Health authorities of western European countries met in December to discuss closer collaboration in the exchange of data of drug use patterns. This would assist countries in implementing their national programmes to improve drug use, and also help them to carry out their pricing and reimbursement policies and decisions. Follow-up will be carried out in collaboration with other European partners, including the European Union.

**National drug policy meeting in Bratislava**

A national drug policy meeting took place in Bratislava, Slovak Republic, with stakeholders from all sectors, including the pharmaceutical industry and the parliamentary health committee. A national working group will continue shaping the current national policy, and turn it into one comprehensive policy.

**Reimbursement of drugs in Baltic countries**

Pharmaceutical authorities of the Baltic countries met recently in Riga to discuss and analyse current issues and policies concerning reimbursement of drug costs in their countries, and in particular to consider drug assessment issues.

**Training seminar on pharmacy-based services**

In January, EuroPharm Forum held a two-day training seminar on managing and implementing pharmacy-based services. Twenty-six participants were introduced to the four stages of project management and motivation for changing practice, and provided with toolkits.
essential drugs in brief

SOUTH-EAST ASIA REGION

Monitoring the impact of globalization and TRIPS on access to essential drugs

Resolution WHA52.19 gave WHO the mandate to analyse the current situation with respect to pharmaceuticals and trade, particularly in developing countries, and to develop monitoring methods to assess the impact of new trade agreements on access to essential drugs.

A meeting was held in Bangkok in February and attended by representatives from four WHO collaborating centres (Bangkok, Barcelona, London and Rio de Janeiro) and international experts on issues relating to health, access and intellectual property, continuing WHO’s implementation of this resolution. The outcome of the meeting resulted in:

- creation of a steering committee to monitor the impact of globalization and TRIPS on access to essential drugs through four WHO collaborating centres; and
- harmonization of selected model indicators to be adapted according to the particular characteristics of each region.

Dr Supachai Panitchpakdi, the incoming Director-General of the World Trade Organization, made the opening remarks. Highlights of his speech include the following:

- “[T]here are a large number of countries around the world who think that we must review the TRIPS Agreement…Some countries which cannot meet the commitment of the TRIPS Agreement, are now vying for support to revise TRIPS before the next Round, the 9th Round, which will commence sometime this year. There is already some kind of movement to look into the consequences of TRIPS particularly on developing countries. I am sure that you are also doing this, that you are looking at TRIPS particularly at its impact on the supply of pharmaceutical products. This is one thing that needs to be brought into the bigger picture.”

- “There are many things in the TRIPS requirements that we need to reconsider, so that the requirements would not place an unnecessary burden on the poor countries. It would also enable the poor countries to pursue their developmental goals, for example educational development and health care development.”

- “So we are looking at implementation and I am sure that before the next Round, which I will call the Development Round, we would have some sort of agreement to look into some of the requirements of TRIPS. I am sure that there will also be some review of the requirements connected to patent rights and the protection of patent rights, that must have some bearing on certain kinds of essential drugs.”

WESTERN PACIFIC REGION

Intercountry workshop on national drug policy

Over the years, WPRO has provided technical and financial support to Member States in the formulation and implementation of national drug policies (NDP). Support has been focused on policy formulation and revision, drug regulation and registration, drug legislation, improving manufacturing practices and quality assurance, improving pharmaceutical supply and management, and promoting rational drug use. More than half of the 37 countries and areas in the region are carrying out NDP implementation. A review of years of experience in implementing NDP in developing countries in WPRO suggests that some areas require further strengthening. Innovative strategies need to be identified in each country to efficiently implement NDP. Exchange of experience is important in pursuing such strategies.

An inter-country workshop on national drug policy took place in Manila from 21–23 November 2000, involving 14 countries which have actively implemented or are in the process of formulating their NDP. WHO organized the workshop in collaboration with the Philippine National Drug Policy Program of the Department of Health. The workshop highlighted a number of priority areas such as regional perspectives of NDP and current challenges, country experience in implementing and monitoring NDP, drug regulation and quality assurance, trade globalization and its impact on the pharmaceutical sector, pharmacoeconomics and drug financing, reform process in pharmaceuticals and the public pharmaceutical supply system, and promoting rational drug use.

The workshop recommended relevant actions to be followed up by Member States and WHO, including the need for a monitoring system for NDP implementation and impact evaluation (with appropriate indicators to demonstrate evidence of change at country level); development and field-testing of innovative approaches in rational drug use, combined with financing interventions; inter-country collaboration to combat counterfeit drugs; and increased attention to public health interest in pharmaceutical sector reform. Finally, participants agreed to hold a regional workshop every two years to evaluate NDP implementation.