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 medicines policies at national and regional levels.

**Eleventh International Conference of Drug Regulatory Authorities**

Over 240 participants from drug regulatory authorities in 113 countries were present at the 11th International Conference of Drug Regulatory Authorities (ICDRA), held in Madrid from 16 to 19 February 2004. In collaboration with WHO, the ICDRA was hosted by the Ministry of Health of Spain and the Spanish Agency for Medicines and Health Products (http://www.agemed.es), with the Minister of Health and the Director-General of WHO opening the proceedings.

Drug regulatory authorities are continually challenged by the rapid development and sophistication of medicinal products and new technologies. Such developments create a heavy demand on regulatory control systems, which are often unable to respond due to inadequate resources. The enlargement of distribution and access channels, growing use of the Internet, and penetration of substandard and counterfeit medicines into many markets compound the problem, and mean that the regulator’s task is becoming increasingly daunting. One objective of the ICDRA is to give regulators the opportunity to exchange information, leverage collaboration and strengthen vital links with agencies experiencing similar problems.

The four-day programme covered many important topics affecting public health. WHO reported on progress in implementing recommendations from the 10th ICDRA. Among the subjects discussed were:

- Regulatory assessment of combination products
- Public health needs versus the market-place
- Strengthening regulatory frameworks for medicinal products
- Harmonization updates.

Recommendations from the 11th ICDRA will form a basis for future collaboration among WHO Member States, drug regulatory authorities, WHO, and interested agencies and institutions. They also set priorities for WHO actions and support. The recommendations are available in full in *WHO Drug Information*, Volume 18, Number 1, 2004. (http://www.who.int/druginformation).

**Associated events**

Three meetings associated with ICDRA were held prior to the Madrid Conference: the Second Regional Workshop on Regulation of Traditional Medicines (see below); the Pan American Network for Drug Regulatory Harmonization initiative (PANDRH); and the pre-ICDRA Workshop on Counterfeit Drugs. The latter was attended by 90 major players from diverse institutions and agencies, including regulators, representatives of the World Customs Organization, the World Intellectual Property Organization and Interpol, industry and NGOs. Discussions focused on their experiences in combating counterfeit drugs, and participants debated the feasibility of formulating an International Framework Treaty on Counterfeit Drugs.

The ICDRA remains an important forum for WHO and drug regulatory authorities to discuss problems and the latest developments in medicines regulation. It continues to review and analyse collaborative initiatives, with a focus on harmonization of medicines control, in order to improve the safety, efficacy and quality of medicines worldwide.
Johannesburg, South Africa, hosted a Regional Workshop on Traditional Medicines Research & Development, Intellectual Property Rights and Biodiversity from 24–27 November 2003. The meeting brought together 47 experts from 22 African countries involved in R&D of traditional medicines (TM) to share experiences and review progress in managing the following priority diseases: malaria, sickle cell anaemia, diabetes, HIV/AIDS and hypertension. New and promising data were presented on malaria (Burkina Faso, Ethiopia and Uganda), sickle cell anaemia (Burkina Faso and Nigeria), diabetes (Ghana), HIV/AIDS (Nigeria and South Africa) and hypertension (Ethiopia and Madagascar). The meeting identified specific interventions needed to move forward. The draft regional framework on intellectual property rights (IPR) of TM generated lively discussion in the plenary. It was agreed that a consultant should revise the document in line with the valuable suggestions made at the Workshop.

The WHO draft document, Guidelines for Clinical Observational Studies on Traditional Medicines in the WHO African Region was carefully reviewed and the title was changed to Guidelines for Clinical Evaluation of Traditional Medicines in the WHO African Region. The meeting recommended that once published the document should be widely distributed among institutions involved in TM R&D. Other recommendations were that Member States should support clinical assessment of TM using the protocol adopted at the Workshop, and develop relevant IPR laws to protect traditional medical knowledge and biodiversity. Member States were also urged to mobilize funds to support TM R&D and to evolve policies and practices promoting conservation and cultivation of medicinal plants and their sustainable use. Participants suggested that collaboration between WHO and the African Union should continue, and asked the Union to support the establishment and strengthening of national institutions on TM R&D. There was also a call for collaboration between ARlPO and OAPI to be strengthened. Additional recommendations were that WHO should support countries on clinical assessment of TM, and finalize the clinical protocol and IPR documents reviewed during the Workshop.

for the last three years, WHO has worked with pharmaceutical associations to promote health by using pharmacists as health agents. One way of doing this is to develop pharmaceutical care projects in which community and hospital pharmacists play a key role in following-up patients with chronic diseases such as hypertension and diabetes, which have associated drug utilization problems resulting in poor treatment adherence. The initial focus is on hypertension, as it is estimated that cardiovascular diseases are responsible for almost one third of deaths, and hypertension is a major associated risk factor, with a prevalence of between 8–30% in Latin American and Caribbean countries. Hypertension is underdiagnosed and only a third of patients using antihypertensive treatment manage their blood pressure values correctly.

A group of professors from the Americas has completed the design of the Pharmaceutical Care Project in Hypertensive Patients, involving pharmacists in following-up patients, dealing with drug-related problems and undertaking surveys. The project will verify if this helps to reduce medication problems, particularly lack of adherence, and so improve control of blood pressure. The project requires:

- setting up a National Group to support implementation in each country (composed of the different partners: Ministry of Health, University, Pharmaceutical Association, WHO);
- implementing the same protocol to enable comparison of results;
- training and sharing educational activities for pharmacists before they begin on the project.

The protocol was tested last year in a pilot study in Ouro Preto, Brazil. Implementation started with seminars in Buenos Aires, Santiago de Chile and Rio de Janeiro, which were attended by 100 professionals. The Regional Expert Group on Protocol Design has published a review of some hypertension topics on the Web, for use in the project, and seminars are being scheduled at various times. Uruguay and Venezuela have agreed to join the National Groups and will begin the programme next May. By the end of 2004 it is expected that some 140 pharmacies and 1300 patients will be involved in this innovative project.

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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**EASTERN MEDITERRANEAN REGION**

**Recovery and reconstruction of the health sector in South Sudan**

As part of the preparation process for the post-conflict period in Sudan, WHO is supporting the Sudan People’s Liberation Movement (SPLM) Secretariat of Health to prepare a strategic framework and a transitional plan for health sector recovery in Southern Sudan. A series of meetings and workshops are being facilitated by WHO to support this process, including an international technical conference on Sudan, which will take place once a comprehensive peace agreement is signed.

On 19–20 February 2004, WHO held a workshop in Nairobi focusing on the reconstruction of the health sector in South Sudan. Approximately 100 participants attended, including representatives from the SPLM Secretariat of Health, WHO and other international and national organizations (UN & NGOs). Thematic papers were presented, including one on the pharmaceutical sector, and working groups reviewed each theme, making recommendations for short- and mid-term action.

The situation analysis presented by the working group on pharmaceutical policies depicted a severely disrupted pharmaceutical sector, with very low access to essential medicines for the majority of the population. UNICEF and Pharmaciens Sans Frontières are responsible for most procurement and distribution, but many other NGOs maintain their own procurement systems, with no proper coordination mechanism between the various parties. There is no official essential medicines list, and quality control mechanisms are non-existent. Education levels are extremely low, and training of health professionals remains severely limited, leading to irrational prescribing and wastage of medicines. Availability of human resources in the health sector as a whole, and more particularly in the pharmaceutical sector, is disturbingly low.

Immediate recommendations included the creation of a Pharmaceutical Coordination Group to coordinate activities among all those involved, and a rapid assessment of the pharmaceutical situation focusing on the procurement and distribution systems. Other priorities include developing an essential medicines list by level of health care, a national medicines policy with an implementation plan for 2004–2010, and national guidelines on medicines donations.

**EUROPEAN REGION**

**Boost for evidence-based medicine in Kyrgyzstan**

A Workshop on Evidence-Based Medicine (EBM) in Education and Medical Practice took place in Bishkek, Kyrgyzstan, in February 2004, and was followed by training for trainers on the principles of EBM. This signalled a breakthrough in Kyrgyzstan’s approach to medical education and practice, and gave an opportunity for open discussion among the country’s academics and experts from NIS countries. The Russian branch of The Cochrane Centre, the Moscow Evidence-Based Medicine Centre and Moscow Medical Academy contributed greatly to the event, particularly with ideas on promoting the principles of EBM. The Workshop showed a great demand for this type of education, and the project will be continued in the current biennium. The Zdravplus/USAID Project in Central Asia, the WHO/EURO Special Project on Pharmaceuticals in the NIS and the WHO/EURO Programme on Human Resources for Health jointly organized this successful event.

**SOUTH-EAST ASIA REGION**

**Timor-Leste: the world’s youngest nation goes essential**

When Timor-Leste regained its independence all medical stores and stock had been burnt, and it was difficult to find storage for donations and other supplies. Construction of a new state-of-the-art medical store (with World Bank support) solved one problem but there was a need to deal with a large variety of (not always essential) supplies. Standard Treatment Guidelines and an Essential Medicines List were drafted, but still stocks and treatment did not match the country’s real needs. Competing agencies and professionals continued using their own lists and sources of supply. The confusion meant certain items were available in as many as eight different forms or formulations, others only as substitutes or not at all. Consequently, the Ministry of Health adopted the Interagency Guidelines for Drug Donations, but with additions to cover medical sundries and equipment. This did not immediately prevent undesired donations but helped the Ministry to decide what to do with unannounced, unwanted or oversupplied goods. A series of meetings were held with hospital and district staff to explain

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**Wide-ranging discussions on Turkey’s pharmaceutical sector**

In February 2004, the Turkish General Directorate of Pharmaceuticals in the Ministry of Health, with support from the WHO Regional Office, hosted a meeting to discuss access to medicines, the WTO and the TRIPS Agreement and their implications for the country’s pharmaceutical sector, including manufacturers. Representatives from various ministries (health, economics, justice, finance, and the patent and competition offices) academia, and the pharmaceutical industry discussed presentations on TRIPS and data protection, the new EU pharmaceutical legislation, implications for Turkey (especially in relation to data exclusivity), and the country’s review of reimbursement. Agreements were made with the Ministry of Health to further support, develop and streamline reimbursement arrangements within the framework of the Health Transformation Plan.

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**essential drugs in brief**
the essential medicines concept. Under the guidance of an experienced pharmacist, the stock lists and medical staff requirements were examined to determine their pharmacological value in the national setting. As a result about 150 formulations were deleted from the Medicines List. While there are still some medicines included for use by relevant specialists only, the Ministry has adopted a “standard” List.

The Standard Treatment Guidelines are being changed to reflect decisions made on the availability of medicines, and, because medical literature is so scarce in local languages, the Guidelines will be developed in such a way that they can also be used as a teaching manual. A summary for use at the lower levels of care will be prepared. Already a catalogue of standard medicines, consumables and equipment available to different levels of the health system is being field-tested. About 1000 items have been identified from the highest (referral) to the lowest (health post) level (200 items). As there is no national pharmaceutical production, all procurement will follow these guidelines, and the recommendation is to create a simple quality assurance laboratory to test imported drugs.

WESTERN PACIFIC REGION
Progress in improving access

An informal consultation on the Draft Regional Strategy for Improving Access to Essential Medicines in the Western Pacific was held in Manila in February 2004. As a follow up to discussions at the 54th Session of the Regional Committee of WHO Western Pacific, a small group of experts from selected Member States (Cambodia, France, Japan, Fiji, Malaysia, People’s Republic of China, Philippines, USA), NGOs (Médecins Sans Frontières), industry (World Self-Medication Industry) and WHO met in Manila to review and revise the existing draft strategy. The draft will be presented at the 55th session of the Regional Committee, and if endorsed will serve as a guide for WHO and Member States to improve access to essential medicines in the Western Pacific.

Government endorses Samoan National Medicines Policy

The Government of Samoa has endorsed the National Medicines Policy (NMP), which was drafted in 1999. WHO assessed the pharmaceutical situation in February 2004 and supported the Government in improving policy implementation. Seven key areas were identified for implementation activities: drug provision; ensuring safe, effective and specified good quality; access to drugs and drug supply; affordability, drug financing and pricing; human resources; organization and management; and a prescribing system.

Cambodia’s pharmaceutical strategic plan

With WHO support, Cambodia is currently developing its pharmaceutical strategic plan, using it as a tool in a sector-wide approach to coordinating technical and financial assistance for implementing priority activities. The National Medicines Policy is being revised to facilitate its integration in the country’s Health Policy – a major objective of the strategic plan.

Drug regulation in Brunei Darussalam

Brunei Darussalam is reviewing its regulatory system for medicines, with assistance from WHO. The relevant legislation is being examined, and a new Medicines Order has been drafted. The Government’s intention is to establish a system for registering medicines based on the outcome of ongoing discussions within member states of the Association of Southeast Asian Nations (ASEAN) on a common technical dossier containing administrative and technical requirements for licensing medicines.