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.

In January 2003, DAP will finalize a new survey package to facilitate monitoring and assessing country pharmaceutical situations. This package provides a cost-effective means for countries to determine the extent of access and proper use of quality essential medicines. Policy makers and managers can use results from the surveys to identify strengths and weaknesses of the pharmaceutical sector and prioritize areas of work. Follow-up surveys can assess the impact of interventions and monitor trends over time.

The package minimizes the investment of time, personnel and financial resources. The 14 surveys that make up the package are completed with data from public health facilities and their pharmacies, private pharmacies, central/district warehouses and households. In all, the surveys take 10 people a total of 12 days to complete and provide quality information for making comparisons between facilities, regions and countries.

The package has been field-tested in 17 countries representing every WHO region. Data from these surveys are noteworthy:

- The number of drugs allowed to be sold on the market varies considerably between countries. In Chad, 453 drugs may be sold on the market. In Bulgaria, the figure is 4,475, in Guatemala 10,000 and in Malaysia 24,916.

- In Iran's public health facilities the percentage of patients able to recognize each dispensed drug, its indication and its use ranged from 38% to 84% between regions.

- In public health facilities in China, the percentage of patients receiving antibiotics varied between 17% and 80%.

- In Uganda, availability of essential medicines varied twofold among public health facilities and fivefold among warehouses.

This is valuable information that countries can use to prioritize action in the pharmaceutical sector. Each country is encouraged to organize workshops tailored to stakeholders' needs at facility, national and regional levels. At these workshops, the report of the baseline survey will be presented and stakeholder experiences will be discussed. Stakeholders will be asked to use the results as an impetus to direct actions, priorities and strategies to address problem areas.
Study on the quality screening of antimalarial products in some countries of the African Region

The AFRO Essential Drugs Programme in collaboration with the Roll Back Malaria initiative, launched the present pilot study, with the objective of determining the content and dissolution characteristics of the active ingredient(s) in antimalarial samples from different locations in six countries. The WHO Collaborating Centre for the Quality Assurance of Medicines, Potchefstroom, South Africa, carried out the analysis.

The antimalarials selected were the solid dosage form of sulfadoxine/pyrimethamine combination products as well as the solid and liquid dosage forms of chloroquine. In each country, samples were collected from the following levels: teaching and district hospitals, pharmacies, medical stores, health centres, shops, street vendors and households. In total, 213 samples were collected.

In all the countries except one, more than 75% of the samples of chloroquine syrup tested had acceptable chloroquine content: 90–110% of the label claim. In all the countries except one, more than 85% of the samples of sulfadoxine/pyrimethamine tablets were within the limits for both ingredients. In all the countries, more than 80% of the samples of chloroquine tablets tested had acceptable dissolution properties. However, in all the countries, only 58% had an acceptable content of chloroquine (97–103% of the label claim) and more than 75% of the samples of sulfadoxine/pyrimethamine tablets had unacceptable dissolution properties with regard to pyrimethamine.

Various problems were encountered with the samples and sampling procedures despite a briefing session in which all the principal country investigators participated.

However, despite the evident constraints of the study and notwithstanding the statistical analysis yet to be carried out, these results point to a need for stricter surveillance of products put on the market. This is important information for all involved in the drug supply chain as well as for drug regulatory authorities. A more systematic surveillance study will be launched, taking into account lessons learnt from the present initiative, and this will be extended to other therapeutic classes.

Good Manufacturing Practices: first priority for drug regulators in the Region

Within the framework of the Pan American Network for Drug Regulatory Harmonization, the implementation of Good Manufacturing Practices (GMP) was identified as the first priority for the Region and educational activities were identified as the most relevant strategy for technical cooperation.

In this context, in April 2001, a 10-day workshop on GMP took place in Jamaica for the CARICOM countries. The workshop was attended by 18 participants from regulatory authorities, ministries of health, universities and other institutions. The training programme covered all the modules on the Basic Principles of GMP and included a manufacturing site visit to a small local factory.

The educational modules were translated into Spanish. From August 2001 to September 2002, 18 national seminars on GMP were held in 18 out of the 19 Latin American countries of the American Region. Six professors from pharmacy schools in Colombia, Costa Rica, Mexico and Venezuela and two independent experts were selected as trainers for the seminars.

More than 500 professionals from governments, academia, the pharmaceutical industry and related organizations were trained. This multi-institutional participation was widely recognized by both the public and private sectors as appropriate technical cooperation in this area.

Evaluations from each seminar indicate a high level of satisfaction among participants. The main recommendations include follow-up national seminars in specific specialized areas such as: validation of analytical methods, validation of processes, sterile compounds, documentation, bioequivalence and other subjects according to the particular need of each country.
Essential Drugs

**EASTERN MEDITERRANEAN REGION**

**Implementation of National Drug Policy in Somalia**

The National Authorities in Hargeisa recently adopted a national drug policy (NDP) as well as several related policy (donor guidelines) and legislative (regulation of imports) decisions. A one-day workshop on the implementation of the NDP was held in July 2002. Various stakeholders representing the government, private sector, academia, NGOs, the UN and service providers agreed on a strategic package of interventions to begin implementing the NDP. These include establishing a national steering committee and a NDP secretariat to guide the implementation process, developing a national drug regulatory authority, organizing short in-service training courses, and publishing and disseminating national donor guidelines and the updated national essential drugs list.

WHO is working closely with national authorities to re-establish the national drug distribution systems in Somalia. The Medical Stores in Hargeisa are currently being renovated to introduce an appropriate physical environment for storage and distribution. They will also serve as WHO’s depot for distribution of medicines and other supplies throughout Somalia.

**Forty-ninth Session of the Regional Committee discussed traditional medicine and antimicrobial resistance**

Two technical papers related to medicines were discussed by the Ministers of Health.

- “Antimicrobial Resistance and the Rational Use of Antimicrobials” led to an intense discussion. Particular concern was expressed about the use of antimicrobials in the food industry as growth promoters. A resolution was passed calling, *inter alia*, on Member States to establish a national intersectoral task force on antimicrobial resistance containment.

**EUROPEAN REGION**

**Health as a Human Right – the WHO Response**

In conjunction with its 11th annual meeting, the EuroPharm Forum held a symposium entitled “Health as a Human Right – the WHO Response”, in Copenhagen on Saturday, 5 October 2002. The overall aim of the symposium was to present the key priority areas of WHO and to open a debate on how pharmacists can link or incorporate these areas in their activities. Seventy pharmacists from 26 countries attended. Material from the symposium, as well as abstracts of the speeches, will soon be available on the Forum’s Web site: [http://www.euro.who.int/eprise/main/WHO/Progs/EPF/Home](http://www.euro.who.int/eprise/main/WHO/Progs/EPF/Home).

The meeting reaffirmed access and appropriate use of medicines as part of the human right to health.

**Annual course on drug policy issues for transitional countries**

From 27 October to 9 November 2002, in Tashkent, Uzbekistan, more than 40 experts, mainly from the NIS and CCEE, participated in the annual course on Drug Policy Issues for Transitional Countries. The course was organized by the Boston University School of Public Health with the support of WHO/EDM, EURO and the Tashkent-based, USAID-supported, Zdrav Plus Project. The course addressed different policy areas and built on the extensive experiences of the participating countries now that more than 10 years of drastic changes have occurred in eastern Europe.

Bulgaria’s new drug policy focuses on access to medicines

More than 100 experts from all parts of the pharmaceutical sector participated in the National Drug Policy meeting in Sofia, Bulgaria, on 26 September 2002, and provided input to the Ministry of Health’s policy proposal. The new policy will now be further developed and provide the framework for a comprehensive approach to maintaining access to medicines for the population.
SOUTH-EAST ASIA REGION

Post-International Conference on Drug Regulatory Authorities (ICDRA) Meeting, 28 June 2002, Hong Kong

Regulators from the Region identified Good Clinical Practice (GCP) and counterfeit drugs as priority issues to be addressed. GCP had become important as a fall-out from globalization. Clinical trials for new drugs are now being done in developing countries and the countries in SEARO are no exception. Counterfeit drugs are an increasing problem and the authorities felt that, although it was well known to the DRAs, general awareness among the population and decision-makers was insufficient. National activities to raise the awareness were considered a priority.

Fifty-fifth Session of the Regional Committee discussed traditional medicines and essential medicines

The WHO Traditional Medicine Strategy 2002–2005 was discussed extensively as the Region has a rich heritage in that area. The Regional Committee adopted a resolution on “Accessibility to Essential Medicines”, which reiterated the importance of Essential Medicines and their rational use. Additionally, it emphasized the importance of pre-qualification in drug procurement systems as a means of ensuring the quality of drugs.

SOUTH-EAST ASIA REGION

Solomon Islands

The use of cannabis is increasing in the Pacific as in the rest of the world. This triggered the Ministry of Health to take a closer look at the relevant legislation regulating controlled substances. Consequently the Dangerous Drugs Act of 1947 was revised to reflect current needs and to be in line with international conventions on narcotic drugs, psychotropic substances and illicit traffic in drugs. After a round of hearings with all involved parties, it is hoped that new legislation will soon be approved.

Tonga

Several activities have taken place in Tonga in recent times to improve the pharmaceutical sector. The National Drug Policy of the Kingdom of Tonga was approved by the Cabinet in 2001. The old drug legislation was revised, resulting in the Therapeutic Goods Bill 2001. This bill provides the legal basis for registration of pharmaceutical products. The first steps towards registration of pharmaceutical products have been taken. Standard Treatment Guidelines are underway.

WESTERN PACIFIC REGION

The Vietnamese Pharmacopoeia

Quality testing of drugs has for many years received much attention from the Vietnamese Ministry of Health. A system for quality control of drugs has existed in Viet Nam since 1958. Quality control is carried out by the National Institute of Drug Quality Control in Hanoi, the Sub-Institute of Quality Control in Ho Chi Minh City and the drug quality control laboratories of the provincial health departments. This countrywide network of quality testing laboratories was established to, among other duties, detect substandard and counterfeit drugs on the market.

The Vietnamese Pharmacopoeia was developed, published and distributed in early 2002. It ensures that testing is carried out consistently throughout the country. It contains 678 monographs (specification and test methods) for pharmaceutical active ingredients, herbal material and dosage forms. The Vietnamese Pharmacopoeia will be a valuable tool for the drug quality control laboratories in the government’s efforts to ensure the quality of medicines on the Vietnamese market.

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