Assessment-based planning and interventions in countries in Africa

Monitoring and evaluation of the national pharmaceutical situation has not always been a regular activity of ministries of health in Africa. To promote a culture of monitoring, WHO is building capacity in health ministries and with relevant stakeholders, such as WHO country staff and NGOs. The WHO Operational Package for Monitoring and Assessing Country Pharmaceutical Situations contains Level I and Level II indicators, and over the last year it has been used to evaluate the pharmaceutical situation in 11 African countries.

Level I indicators are collected using a short questionnaire, and are used to assess existing structures and processes in a national pharmaceutical system, including implementation of the components of national medicines policies. Level II indicators focus on outcomes at facility and household levels, and although they rely on field surveys they can be collected without extensive human or financial resources. Focused surveys are conducted at five central/district medicines warehouses, 30 public health facilities, 30 private pharmacies/drug outlets, and 900 households spread across five districts/regions per country. Level II indicators focus on access, quality and rational use of medicines. At the household level, information is also collected on patients’ care-seeking behaviour and barriers to accessibility of medicines.

Preliminary reports are being finalized in the countries where the Operational Package has been implemented, and in the coming months national stakeholder workshops will be held to analyse and discuss the data and plan interventions that will help strengthen national capacity and improve access to medicines. Preliminary results have already been used by the countries concerned to develop plans for specific interventions for 2003 and for 2004–2005. Plans centre on improving selection, availability and affordability of medicines, including those for HIV/AIDS, through advocacy, policy development and capacity building. By this exercise, WHO hopes to encourage countries to incorporate monitoring into their programmes, enabling evidence-based planning, development and implementation of national medicines policies.

Mali, provides one example of a country already taking action, as the Level II survey there revealed that adherence to the national standard treatment protocol for non-bacterial diarrhoea in children was 0.5%, even though 70% of facilities had a copy of the standard treatment guidelines available. Only 47% of children with non-bacterial diarrhoea were given ORS, while 78% received an antibiotic and 68% were given other medicines. Mali has identified rational selection of medicines and training of prescribers and dispensers as priority areas for interventions. Training courses on rational selection and use of medicines are part of WHO’s work to build capacity in these areas, and this year WHO has helped to organize courses in Kigali (held in...
June) and Algiers (being held in September), with representatives from Mali participating in both.

Figure I shows data obtained from exit interviews with patients dispensed medicines at public health facilities in four countries. Based on the results, these countries have identified the need to train pharmaceutical supply managers and dispensers at health facilities. This training will focus on improving labelling practices and information for patients, to ensure that patients know the correct dosage and the duration of their treatment, and that this information is written on the label of all dispensed medicines.

AFRICAN REGION

Regional Workshop on Regulation of Traditional Medicines

JOHANNESBURG, SOUTH AFRICA, 1–3 APRIL 2003

The workshop’s objective was to review the Draft Guidelines for Registration of Traditional Medicines in the WHO African Region, prepared by WHO/AFRO and circulated to participants before the meeting. Nineteen people from fifteen countries attended the workshop, which adopted a four-category classification system for traditional medicines.

Participants agreed on the minimum general regulatory requirements for traditional medicines, in terms of the safety, efficacy and quality issues related to the import and export of these medicines within the region. Member States would develop their own national minimum specific regulatory requirements for the registration of each category of traditional medicine, based on the general minimum requirements adopted in Johannesburg.

The workshop recommended Member States to develop/review their national laws/policies, and their registration and regulatory frameworks. Countries should also support research on traditional medicines, expedite action on the integration of traditional medicine into national health systems and establish/strengthen agencies that regulate traditional medicine practice. Recommendations to WHO included reviewing their national requirements for the registration of each category of traditional medicine, based on the general minimum requirements adopted in Johannesburg.

The meeting concluded that:

- NPOs should focus on improving collaboration with ministries of health and other partners, including information sharing, and concentrate on implementing activities in the plans of action. They should also take full advantage of available training courses at country offices.
- WHO/EDM and WHO/AFRO should engage in resource mobilization to forestall any budgetary constraints in implementing activities. They should provide documentation on roles and functions at the various levels of WHO, and ensure that communications to and from NPOs in the African Region flow through WHO/AFRO. Proper integration of NPOs at country offices, and increased opportunities for capacity building for NPOs were also recommended.

REGION OF THE AMERICAS

Successful price negotiations on antiretrovirals for 10 Latin American countries

In June 2003, 10 Latin American countries (Argentina, Bolivia, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru, Uruguay and Venezuela) invited manufacturers of HIV/AIDS antiretrovirals (ARVs) and diagnostic kits to participate in a regional negotiation to set maximum reference prices for the region as a whole. This was the culmination of a process during which the countries had met at regional level a number of times to analyse issues of product access, to formalize commitment to lowering drug prices, and to develop a framework for action.

During the June meeting, countries rejected proposals presented through the Accelerated Access Initiative, but instead signed a significantly more favourable agreement with manufacturers presenting unconditional prices, and satisfying regional criteria for ARVs and diagnostics. The agreement was signed by a number of brand companies, principally suppliers of diagnostics but also of ARVs, as well as by Indian and Argentinian generic ARV manufacturers.

As a result of the agreement, countries achieved significant reductions in the price of 37 drugs, with 15 prices now below the previous lowest reference price in the region. The cost of treatment using a first-line triple therapy, such as AZT+3TC+NVP, was reduced between 30 and 92% – from US$1,100 (the previous lowest regional price) to US$5,000 (the previous highest regional price) to US$365. The negotiations also resulted in major price reductions of between

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9 and 90% for HIV diagnostic kits at regional level. Estimates are that an additional 150,000 patients will be able to receive treatment if the predicted economies of scale are used to provide first-line ARV therapy.

Latin America’s approach has attracted considerable interest globally, as a means of accessing essential medicines and diagnostics for the care and treatment of HIV/AIDS patients at a more affordable price.

Correction to issue Nº9: Price negotiations between the governments of Central America and pharmaceutical companies have led to a minimum 55% reduction in the prices of HIV/AIDS antiretroviral medicines in Central America, not 5% as was reported.

**EASTERN MEDITERRANEAN REGION**

**2nd Traditional Medicines Workshop**

**ABU DHABI, UNITED ARAB EMIRATES, JUNE 2003**

In October 2002, the WHO Regional Committee for the Eastern Mediterranean requested the Regional Director to take the necessary action to develop guidelines for the preparation of national policies and regulation on traditional medicine. As a follow up, two workshops were arranged on regulation of herbal medicines, with the first held in Iran in December 2002 and the second in Abu Dhabi, United Arab Emirates, from 7 to 9 June 2003. The Abu Dhabi workshop focused on controlling safety, quality and efficacy through regulation and standards governing the registration, production and distribution processes. It also provided an opportunity for countries that are primarily importers of herbal medicines and repositories of traditional medicinal knowledge to share their experiences in developing and implementing national regulatory policies, and to develop common goals towards regional harmonization in regulation and policy. The workshop was another opportunity for WHO to continue its support to Member States in their efforts to establish effective regulatory systems for registration and quality assurance of herbal medicines. In addition, one of the participants’ main tasks was to initiate the development of “EMRO Regional Guidelines”. These are based on a series of WHO technical guidelines on the safety, efficacy and quality control of herbal medicines and on their regulation, as well as meeting specific regional requirements. Member States are being encouraged to develop or update their national action plans for regulating herbal medicines in line with the “EMRO Regional Guidelines”.

**EUROPEAN REGION**

**WHO/EURO reviews UK NICE**

At the request of the UK Government, the WHO/EURO Pharmaceuticals Programme is undertaking an external review of the National Institute for Clinical Excellence, (NICE), the body responsible for evaluating medicines to be paid for through the country’s National Health Service. The final report, with recommendations on methods and procedures in the complex technology appraisal process, will be available on the EURO website.

**Reform and development of pharmaceutical education in the Central Asian Republics**

The 7th meeting of the Network on Reform and Development of Pharmaceutical Education in the Central Asian Republics took place in Karaganda, Kazakhstan, on the 7th and 8th of July 2003. The meeting brought together deans of the schools of pharmacy and the relevant experts in the ministries of health to discuss further development of university pharmaceutical education.

**Final inspection of Russian TB drug manufacturers**

In July, the last joint inspection by the team of international and Russian GMP inspectors assessed two Russian manufacturing sites for compliance with WHO GMP standards, with a positive outcome. Inspection of the other two TB drug manufacturers resulted in recommendations on the required corrective actions to improve compliance. The inspections were carried out with a view to the possible participation of Russian TB drug manufacturers in the international competitive bidding for the procurement of TB drugs within the World Bank AIDS/TB project in Russia.

**Access to HIV/AIDS medicines reviewed in Romania**

Romania has approximately 6000 AIDS patients, and in May a joint mission of WHO/HQ, WHO/EURO Pharmaceuticals and the HIV/AIDS Programme visited the country to review the level of access to HIV/AIDS medicines. Romania is one Central European country that has made a firm commitment to treat its AIDS patients, and its negotiations with pharmaceutical companies have resulted in price reductions, with all patients now receiving ARV treatment.

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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. 10, July 2003
Assessment of the essential drugs and pharmaceutical situation in Timor-Leste

Timor-Leste, currently facing major drug supply problems, started out addressing the issue with a sound initial master plan, funds for procuring drugs, a very good Central Warehouse and had also hired an institution to manage the drug supply system.

Despite these efforts, the assessment found that the supply system may still face major stock-outs in the coming months and precipitate a crisis in the health service. Current stock-outs have prevented hospitals functioning normally – for example, lack of intravenous fluids at the National Hospital have forced the postponement of routine operations. The ultimate goal is for an Autonomous Medical Store to service government health care institutions. The mid-term review encouraged consulting appropriate pharmaceutical expertise. Recommendations from the most recent assessment, which may help the Government to decide on the future course of action, include:

- Holding more frequent meetings between the Ministry of Health and the CMS, to ensure better coordination.
- Purchasing a software programme for managing drug supply in the CMS.
- Defining the list of essential medicines by level of health care.
- Providing drug supply management training, both at the CMS and at health care institutions, in Bhasa.

Effective Medication Counselling Between Pharmacists and Consumers

WPRO and the Western Pacific Pharmacy Forum are collaborating on developing and undertaking training on Effective Medication Counselling Between Pharmacists and Consumers. WPRO is funding the development of materials, field-testing and a training workshop. Activities will be carried out in the Philippines, in collaboration with the national pharmacists association, as part of a communications programme, ‘Asking Questions About Medicine’. The programme’s overall objectives are to:

- Inform consumers that by using medicines correctly they can maximize benefits and minimize risks.
- Educate consumers to see their pharmacist as a valuable resource and source of expert information.
- Empower consumers to speak to their pharmacist about their medicines.

Western Pacific develops a regional strategy for improving access to essential medicines

Responding to requests from Member States, WHO/WPRO is in the process of developing a regional strategy for improving access to essential medicines in the region. The overall objective is to provide operational and practical guidance for Member States and for WPRO on improving access to essential medicines. The strategy development process involves wide consultations, both within WPRO and externally – with partners in essential medicines and national medicine policies, Member States and relevant experts. The strategy was discussed at an expert consultation meeting in July.

The Second Asian Course on Problem-Based Pharmacotherapy Teaching

The Second Asian Course on Problem-Based Pharmacotherapy Teaching has been organized successfully by the Department of Pharmacology, Universiti Kebangsaan Malaysia (UKM), in collaboration with WHO. Held from 6 to 15 March 2003, the course objectives were to provide pharmacology and therapeutics teachers with the knowledge and skills necessary for problem-based teaching; and to help them develop action plans to implement the problem-based methodology in their own institutions. The course was attended by 29 participants from China, India, Malaysia, Mongolia, Saudi Arabia, Sri Lanka and Thailand. It was coordinated by the Department of Pharmacology UKM, and faculty included a WHO consultant, and a number of pharmacology and clinical teachers from Malaysia.