

essential drugs *in brief*

A bulletin on major WHO Country and Regional work in the field of Essential Drugs and Medicines Policy

Issue No. 13, June 2004

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.



Department of Essential Drugs
and Medicines Policy

Health Technology
and Pharmaceuticals Cluster

World Health Organization

WTO's Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

A WHO guide on how to use it

It is often said that there are many reasons why extraordinarily large numbers of people in developing countries lack access to treatment. Just as often lack of availability and the high cost of medicines are cited as two of the main reasons. The use of generic ARVs provides a useful example of how to tackle the access problem. Introducing generic ARVs has increased availability and choice of treatment, helping to reduce the cost of therapy and increasing the potential for more patients to be treated.

But from January 2005, developing countries, which had previously not provided product patents for pharmaceuticals, will be required to grant both process and product patents for pharmaceuticals for a minimum of 20 years. Under the TRIPS Agreement, new medicines and medicines for which "mailbox" patent applications were filed after 1 January 1995 will be patentable in these developing countries. It is feared that this will reduce the supply of generic ARVs, particularly affecting India with its thriving generic drugs industry and those countries that import the more affordable generic medicines from India.

The impact of patents on access to medicines has caused the TRIPS regime to come under international scrutiny and debate. In 2001, WTO Members adopted the *Doha Declaration on the TRIPS Agreement and Public Health*, which reaffirmed the right of countries to make full use of TRIPS flexibilities in order to protect public health and promote access to medicines. Paragraph 6 of the Doha Declaration highlighted the problem faced by countries with insufficient or no manufacturing capacity in the pharmaceutical sector. While these countries may issue compulsory licences to import generic versions of patent-protected medicines, TRIPS rules impose constraints on the ability of countries to authorize exports of such products. The *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* adopted on 30 August 2003 by the WTO's General Council, promised a solution to the problem.

Consistent with its mandate,¹ WHO has been assisting Member States to implement TRIPS obligations, in line with public health objectives of promoting access to medicines. WHO's latest paper, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*,* examines ways in which the August Decision can be implemented, to meet these objectives.

The paper's analysis is informed and guided by the need to meet the following public health objectives: a rapid and effective response to public health needs; equality of opportunities for countries in need, irrespective of the patent status of a drug in the importing country, and without regard to its membership of the WTO; the

¹ Since 1999, World Health Assembly resolutions have requested WHO to undertake work that ensures that its medicines strategy addresses the impact of international trade agreements on public health and access to medicines.

* *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Health Economics and Drugs, EDM Series No. 16.*

sustainability of quality supply at affordable prices; the facilitation of a multiplicity of potential suppliers, both from developed and developing countries, which can compete to drive prices down; and provision of a wide range of pharmaceutical products to meet an array of health problems. ■

Copies of the document may be requested from:

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The document is also available on the Internet at:
<http://www.who.int/medicines/>

AFRICAN REGION

EDM/NPOs planning and evaluation meeting

BRAZZAVILLE, 10–14 MAY 2004

In April 2001, it was decided to strengthen the EDM programme in AFRO, and as a result National Professional Officers (NPOs) were recruited, with financial support from DFID. Their remit is to respond more effectively to requests from countries, and to improve access to essential medicines for priority health problems, such as malaria, HIV/AIDS, TB and childhood diseases.

In March 2002, the NPOs had their first technical briefing session in Pretoria, South Africa, followed in April 2003 by a meeting in Dakar, Senegal, to review and evaluate NPO's strengths and weaknesses in implementing their work plans one year after their recruitment, and to make recommendations on revising and implementing plans for 2003. The Brazzaville meeting in May brought together 25 participants, including EDM/NPOs, their national counterparts, and staff from EDM/DAP, EDM/QSM, HIV/AMDS/HQ and EDM/AFRO. It evaluated the results obtained by the NPOs in implementing their 2003 action plan and their use of allocated funds, looking at the lessons learnt, provided guidance to NPOs on planning, implementation and action plan

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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evaluation, and also discussed the contribution of EDM to the 3 by 5 Initiative. Participants reviewed WHO/EDM priority areas of work in Africa, identified priority activities in country work plans for 2004–2005 and discussed reporting procedures and administrative matters. The meeting concluded with the following recommendations:

To WHO Country Offices

- Create positions for EDM NPOs in WHO country offices using regular budget funds.
- Create a 3 by 5 Task Force in WHO country offices, composed of NPOs working on HIV/AIDS, EDM, health systems and other relevant areas.

To WHO AFRO and Headquarters

- Ensure the timely and adequate release of funds for NPO activity implementation.
- Increase the capacity of NPOs and their counterparts through various capacity building initiatives (training, meetings and workshops).
- Schedule monitoring missions to follow programme implementation and to foster increased collaboration at country level.

To EDM/NPOs

- Focus primarily on implementing the EDM work plan while ensuring that a reasonable balance is maintained with other activities in the WHO country office.
- Ensure prompt, consistent, complete and regular reporting of activities using approved formats and taking into account feedback from AFRO.
- Reduce duplication of efforts and optimize resources through effective coordination of interventions with all partners, in support of the MOH. ■

EASTERN MEDITERRANEAN REGION

Recovery of Sudan's health sector

Following the workshop organized by WHO and the Sudan People's Liberation Movement (SPLM) in Nairobi, Kenya, in February 2004 focusing on health sector reconstruction in South Sudan, a workshop to prepare a recovery plan for Sudan's health sector was held in Khartoum on 8–9 March 2004. There were 150 participants from WHO, the World Bank and other UN organizations, NGOs and the MOH, among others. During the workshop three strategic papers were discussed: health policies, management and finance; health care provision and rehabilitation of the health infrastructure; and human resource development and medical education.

Situation analysis of the pharmaceutical sector shows that many procurement systems operating in the country hospitals are erratic and do not follow a specific scheme. Although there is an agreed list of essential drugs, it is not followed by all health care providers and access to essential medicines is estimated at only 49% in the whole country. There are

marked deficiencies in human resources (pharmacists and pharmacy assistants). In general, sustainable public pharmaceutical provision is weak in the North and almost absent in the South.

Among recommendations made for the pharmaceutical sector were the updating of the National Drug Policy and improving the Central Medical Stores, the main national medical supply body for the public sector, in order to cover the whole of Sudan in the near future.

A final plan for rehabilitation and reconstruction of Sudan's health sector will be finalized by WHO and the Ministry of Health. ■

EUROPEAN REGION

Scaling-up access to ARVs in Russia

In order to improve access to ARVs in Russia, WHO has assisted the Russian authorities in preparing a proposal for submission to the Global Fund. As Eastern Europe is experiencing some of the fastest growing HIV-AIDS epidemics, access to ARVs is of cardinal importance. Currently fewer than 1,000 patients receive ARVs in Russia, and this project should scale up treatment to more than 50,000 over the coming five years. The project specifically addresses possible strategies for price reductions of ARVs in Russia, through direct negotiations, using safeguards in the patent law, generic competition and increased efficiency in logistics. ■

Baltic cooperation on pharmaceutical policies

In June 2004, more than 20 experts from ministries of health, health insurance institutions and academia from the three Baltic countries, Estonia, Latvia and Lithuania, met in Tallinn, Estonia, for a follow-up training course on clinical and cost-effectiveness evaluation of medicines for reimbursement. The course was organized within the framework of the Baltic cooperation on reimbursement of medicines, which has already resulted in a common guideline on drug evaluation.

During the course, a one-day meeting was organized to discuss pharmaceutical policies in the Baltic countries. Opened by Estonia's Minister of Health, this attracted more than 120 participants, including many industry representatives and experts from Denmark, Norway and the United Kingdom, who contributed to the debate. This was the third Baltic conference on medicines, and it provided an excellent opportunity for an open dialogue on pharmaceutical issues with the industry. ■

Progress in developing Romanian clinical guidelines

Clinical experts from the Ministry of Health, the Health Insurance Fund, hospitals and academia met in Bucharest, Romania, from 10 to 12 May 2004 to agree on further

steps in developing the national clinical guidelines. The programme was supported by the Open Society Institute, with input from WHO and the Guidelines International Network (GIN). Firm decisions were made on the formation of technical groups, the selection of topics, the review process and a timeframe for guideline development. ■

SOUTH-EAST ASIA REGION

New Medicines Act for Bhutan

Until 2003, Bhutan regulated all pharmaceutical activities by a notification called the "Drug Control Rules of Bhutan 1974", which did not cover all aspects of the pharmaceutical sector. In recent times, with the increasing availability of counterfeit drugs in neighbouring countries, the rising trends of irrational sales of medicines and self-medication, as well as drug misuse, the need to regulate the quality, safety and efficacy of medicinal products was inevitable.

Drafting of the Act was begun in 1996 by a WHO consultant and the work was subsequently taken over by the Principal Pharmacist, who later involved other national pharmacists. The draft was discussed and reviewed in many ministerial and inter-ministerial committee meetings, and then presented to the Lhengye Zhungtshog (Commission of Cabinet Ministers) for approval. Finally, the Act was sent to the Legislative Committee of the National Assembly to be presented during its 81st session, and was passed as the Medicines Act of the Kingdom of Bhutan 2003 on 5 August. The main activities following this enactment will be:

1. Drug Regulatory Authority (DRA) to be put in place.
2. Appointment of officials for the DRA (completed in May 2004).
3. First meeting of the Bhutan Medicines Board (held in June 2004).
4. Drafting of the Bhutan Medicines Rules and Regulations by the DRA. The first draft to be completed by September 2004.
5. Review meetings on the draft, to be completed by November 2004.
6. Final approval of the draft by the Bhutan Medicines Board by December 2004.
7. Printing and distribution of the Bhutan Medicines Rules and Regulations.
8. Training of DRA staff on the Bhutan Medicines Rules and Regulations.
9. National level training for stakeholders in the government and private sectors.
10. Enforcement and implementation of the Bhutan Medicines Rules and Regulations. Proposed, tentative timeframe for this is June 2005. ■

WESTERN PACIFIC REGION

National consultation on China's Medicines Policy

Currently, China has no comprehensive national medicines policy document, although there is a statement related to this issue in the 1998 Health Declaration. In November 2001, participants at a national consultation on the essential medicines programme agreed on the need for a comprehensive national medicines policy. Now another national consultation on medicines policy has moved the process forward. Organized on 24–25 June 2004 by the State Food and Drug Administration (SFDA) and the Policy Research Office of the State Council, the meeting was attended by representatives of numerous relevant government agencies. These included the Policy Research Office of the State Council, the Ministry of Health, the Ministry of Finance, the Ministry of Labour and Social Security, the Intellectual Property Rights Office, National Development and Reform Commission, the State Administration of Chinese Traditional Medicines (SATCM), military logistics experts and experts from universities and research institutions.

The first day of the meeting was devoted to presentations in which different government agencies described their roles and relevance to the National Medicines Policy, while the second day was spent in general discussions on what China needs in such a policy and on a work plan. The State Council will officially designate the SFDA as the leading agency to coordinate policy formulation and once this has been done the Administration will develop a detailed work plan in co-ordination with other agencies. A national committee will be formed, representing the government agencies responsible for drafting the policy document and undertaking regular consultations. WHO will provide technical supports based on the Chinese work plan for developing its National Medicines Policy. ■

WHO and AUSAid collaborate on a rapid regional alert system to combat counterfeit medicines

Counterfeiting of medicinal products in the Western Pacific region is increasing, yet there is widespread lack of awareness about counterfeit medicines among consumers. In many countries there is also a lack of collaboration between regulatory authorities, the police, customs and others in the justice system in enforcing laws and regulations. In many areas, counterfeit drugs are a cross-border problem, distributed illegally through open national borders, but there is little if any intercountry collaboration. Even when counterfeit medicines have been detected, in some countries no action may be taken. Procedures for investigation and prosecution need to be established and the impact of the actions taken should be monitored.

A rapid regional alert system is now being established to ensure more effective and faster responses to combat counterfeit medicines. WPRO is collaborating in this joint WHO/AUSAid project which will continue proactively supporting countries by creating a rapid alert and follow-up system for counterfeits, and improve national regulatory capacity to detect and eliminate them. The system will have the following components:

- intensified surveillance of counterfeit drugs in high-risk areas, targeting high-risk products;
- a rapid alert system for information exchange on counterfeit drugs through an electronic communication network and website;
- provision of guidance on follow-up actions need to be taken;
- creation of a regional database on counterfeit drugs;
- monitoring of actions taken by countries when counterfeits are detected;
- evaluation of the impact on the rapid alert system and follow-up.

The IT system for the project will be developed with the WHO Collaborating Centre for Drug Information in Malaysia. ■

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