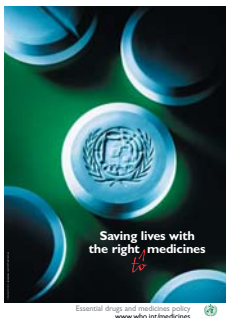
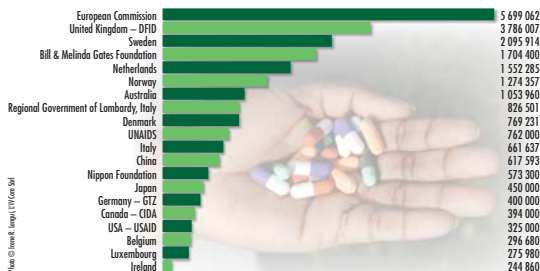


### Financial situation of the essential medicines area of work

According to plan, the 2004–2005 biennium started with a healthy carry-over balance of about US\$ 5 million. The 2004–2005 budget for the essential medicines area of work (i.e. the total country, regional and headquarters budgets for essential medicines activities) amounted to US\$ 51.5 million, of which 37% was funded through the Regular Budget and the rest from other sources. Of this budget, US\$ 29 million (58%) was spent on normative work, global policy guidance and other activities undertaken at headquarters; the remainder was assigned to country and regional programmes.

By the end of 2004, 57% of the extrabudgetary resources needed for the biennium had been secured and 47% of the budget had been obligated. The main extrabudgetary donors are listed in Table 2. Their contributions to the work of WHO are gratefully acknowledged. Over the years, a shift from unspecified to specified extrabudgetary support has become evident. This includes increasing extrabudgetary income from foundations such as the Bill and Melinda Gates Foundation.

Table 2: Top 20 donors of extrabudgetary revenue in 2004 (US\$)



Further information on WHO essential medicines activities can be found at: <http://www.who.int/medicines/en/> or by contacting the Department of Technical Cooperation for Essential Drugs and Traditional Medicines ([tdm@who.int](mailto:tdm@who.int)) or the Department of Medicines Policy and Standards ([psm@who.int](mailto:psm@who.int)).

### Changes in direction

In January 2004, Dr Jonathan Quick, director of the Department of Essential Medicines (EDM), left WHO to become President and Chief Executive Officer of Management Sciences for Health, in Boston. In December 2004, EDM was restructured to create the Department of Technical Cooperation for Essential Drugs and Traditional Medicine, and the Department of Medicines Policy and Standards. Mrs Malebona Matsoso and Dr Germán Velásquez were appointed as director and associate director, respectively, of TCM, while Dr Hans Hogerzeil was appointed director of PSM.



Dr Hans Hogerzeil



Mrs Malebona Matsoso



Dr Germán Velásquez

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### Introduction: 1999 baseline data and achievements for 2003

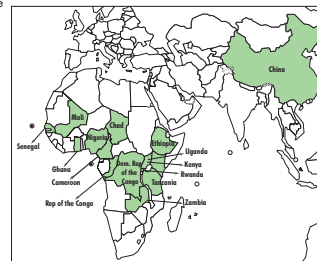
2004 marked the start of implementation of the second WHO Medicines Strategy. The strategy was the result of a two-year consultation process with global medicines stakeholders. The new strategy covers activities for 2004–2007. It incorporates 1999 baseline data, data showing progress in medicines activities as at the end of 2003, and target indicators for 2007.<sup>1</sup> Selected country progress indicators are given in Table 1.

Table 1: Selected country progress indicators 1999–2003	1999	2003	Target for 2007
Countries with an official national medicines policy implementation plan — new or updated within the last 5 years	41/106* 39%	49/103 48%	61%
Countries with a national list of essential medicines — updated within the last five years	129/175 74%	82/114 72%	75%
Countries implementing basic medicines regulatory functions	70/138 51%	90/130 69%	74%
Countries regulating herbal medicines	48 37%	82/127 65%	75%
Countries with public spending on medicines of less than US\$ 2 per person per year	38/103 37%	24/80 30%	20%
Countries with public sector procurement limited to national essential medicines lists	71/133 53%	84/127 66%	74%
Countries in which generic substitution is allowed in private pharmacies	83/135 61%	99/132 75%	81%

\* Number of countries reporting

### Country support: too much to report

WHO continued to provide tailor-made technical collaboration to more than 80 Member States. To facilitate this important work, about 30 countries now have full-time national programme officers working on essential medicines issues. Two regions (Eastern Mediterranean and the Americas) saw the appointment of new regional advisers for pharmaceuticals. The DFID-supported programme for African countries continued, and a new EC-supported programme was started, with significant direct country support to Africa, the Pacific and the Caribbean. Standardized medicine pricing surveys were undertaken in many countries, including 13 African countries. The surveys provide reliable data on availability, prices, affordability and price components. This information has been published on the Health Action International web-site to promote transparency of medicines prices information.<sup>2</sup> Regional harmonization of medicine regulation was intensified in the Americas and West Africa, and among the Commonwealth of Independent States. The interregional project to combat counterfeiting in Asia was intensified, with financial support from Australia, through launching of a rapid alert system in Western Pacific countries. The system will be extended to South-East Asian countries in 2005.



## ESSENTIAL MEDICINES ANNUAL REPORT 2004

### The World Medicines Situation

After years of painstaking work, the second report on the *World Medicines Situation* was issued.<sup>3</sup> This large volume of data was based on WHO pharmaceutical surveys, data collected from other UN agencies and commercial data on pharmaceutical markets. The book presents current country figures and global trends, and is intended to support public health research and policy analysis. Trends from 1985 to 1999 indicate that the value of medicines production has grown four times more rapidly than the world's income, and the 10 best-selling medicines account for 12% of the value of all medicines production.

### A public health approach to innovation

Following a request and a grant from the Netherlands Government, WHO researched and made recommendations on *Priority Medicines for Europe and the World*,<sup>4</sup> focusing on the best use of public research funds for pharmaceutical development. This included in-depth analysis of the future global burden of disease and identification of "missing essential medicines". The report was very well received by both the scientific community and the research-based pharmaceutical industry.<sup>5-6</sup> European-level discussions will decide on how its recommendations can be implemented.

- <http://www.who.int/medicines/areas/policy/en/index.html>
- <http://hwhb.org/medicines/areas/>
- WHO/EDM/PAR/2004.5; <http://hwhb.org/temppubmainframe.com/gsdl/cgi-bin/edemweb/library.fcgi>
- Priority Medicines for Europe and the World*. Geneva, WHO, 2004; <http://medicines.who.int/prioritymeds>
- Editorial. *Europe's Health Priorities for the World*. *Lancet* 2004; 364: 1912.
- Editorial. *Neglected diseases*. *Br Med J* 2005; 330:376-377.

### Support to "3 by 5"

WHO continued to give strong support to pharmaceutical activities relating to the "3 by 5" initiative. Important contributions included: development of pharmacopoeial monographs for antiretroviral medicines (ARVs) (essential for quality assurance and product assessment); information and training in quality assurance and control developed under the prequalification programme; collection (with Médecins Sans Frontières and UNAIDS) of market intelligence information on the patent status of priority medicines;<sup>7</sup> collection (with UNICEF and UNAIDS) of information on sources, prices and registration status; development of tools for forecasting medicines needs; and participation in "3 by 5" country assessments. A course on *Promoting Rational Drug Use*, held in Pretoria, led to a number of studies on adherence to ARV treatment.<sup>8</sup>

At country level, the general approach is to promote the integration of medicines for "3 by 5" within general pharmaceutical supply systems. During 2004, it became clear that the medicines supply side of "3 by 5" activities worked most effectively in those countries where full-time essential medicines national programme officers are operational. The number of national programme officers is now being expanded further, particularly to "3 by 5" priority countries.

### TRIPS and globalization: practical guidance to Member States

In the field of Trade-Related Intellectual Property Rights (TRIPS) practical guidance was prepared for Member States regarding the General Council Decision of the World Trade Organization on implementation of paragraph 6 of the Doha Declaration.<sup>9</sup> Several regional awareness and training courses were organized in Africa and Asia, and medicines staff participated in similar training courses organized by the World Trade Organization. Technical support was given to the Government of Nigeria in drafting its patent law.

Additionally, the TRIPS Network refined standard monitoring tools, methods and selected indicators for monitoring and analysing the impact of the TRIPS Agreement on access to medicines. The Network has been coordinating its work with that of the joint WHO-Health Action International project on medicine prices, to ensure coherent and systematic data collection. Network meetings are attended by experts from WHO Collaborating Centres, as well as other advisers and researchers.

### Prequalification of medicines for high-burden diseases

WHO continues to manage a major global project to assess potential suppliers and priority products for treating HIV/AIDS, tuberculosis and malaria. The project was strongly endorsed by the World Health Assembly in 2004.<sup>10</sup>

The list of prequalified products is used by UN agencies, the Global Fund for HIV/AIDS, TB and Malaria, and the World Bank to guide procurement decisions.<sup>11</sup> It is also increasingly being used by Member States, national treatment programmes and nongovernmental organizations. A critical moment occurred in mid-2004 when some pre-qualified products had to be temporarily withdrawn from the list and additional quality assurance requirements relating to bioequivalence instituted. The manufacturers of the delisted products responded by carrying out new bioequivalence studies. The studies confirmed that the delisted products are in fact as effective as their respective brand-name counterparts. By the end of 2004 several delisted products were back on the list.

The programme is being expanded to cover prequalification of active pharmaceutical ingredients and quality control laboratories. This is of especial relevance to medicines for treating TB. Many of the quality problems identified by the project for TB medicines concern poor-quality active pharmaceutical ingredient (APIs). An increased number of prequalified APIs needed in the production of TB medicines would enable manufacturers to eliminate many existing quality problems.

### Generic names, good manufacturing practices and fixed-dose combinations

Every new medicine needs an International Non-proprietary (i.e. generic) Name (INN). INNs are assigned by WHO, following an extensive global consultation procedure. In 2004, new INN procedures were developed and approved by the WHO Executive Board, and nearly 150 new INNs assigned, in six languages.

The areas covered by the Expert Committee on Pharmaceutical Specifications are extensive. They range from good manufacturing practices, regulatory guidance texts (e.g. regarding the interchangeability of medicines, fixed-dose combination products and stability testing), to counterfeit and substandard medicines. Quality control specifications and International Chemical Reference Substances are developed, focusing on essential medicines and on those medicines used in the treatment of large populations, often for which no international quality requirements are publicly available. In 2004, the Committee developed additional Good Manufacturing Practices guidelines for sampling starting materials, and guidelines for registration of fixed-dose combinations. The latter are of great practical relevance for production and registration of priority medicines for HIV/AIDS, tuberculosis (DOTS) and malaria (artesunate-based combinations).

### Traditional Medicine: many innovative materials

The traditional medicine team at headquarters continued to develop a wide range of global technical guidance documents aimed at promoting the efficacy, safety and rational use of traditional medicine. Many of these cover subjects for which no other guidance exists. Examples are: guidelines on good agricultural practices for medicinal plants;<sup>12</sup> guidelines on safety monitoring of herbal medicines;<sup>13</sup> and guidelines on the development of consumer information.<sup>14</sup> A very special piece of work was a report on clinical trials on the treatment of SARS with a combination of traditional Chinese medicine and Western medicine.<sup>15</sup> The experts who reviewed the trials recognized the difficulties and challenges in conducting treatment on SARS while the epidemic of this new disease was spreading. Due to the relative scarcity of medical resources and the heavy clinical workload, clinical research on SARS faced difficulties never previously encountered.

Each of these documents critically reviews evidence that has been put forward for the safety and efficacy of traditional medicine, and provides practical guidance for national regulators.

### ICIUM: how to promote the rational use of medicines

The second International Conference on Improving the Use of Medicines (ICIUM) was held in Thailand in March 2004. The first ICIUM (1997) had identified successful strategies to promote rational medicines use in developing countries and listed several questions for further research. Over 500 international experts (mostly from developing countries) attended ICIUM-2, reviewed the evidence accumulated over the last seven years and identified additional successful intervention strategies recommended for national scale-up. Outstanding research questions were also considered, such as the most effective means of promoting adherence to chronic treatment in developing countries. This issue is now of great urgency in view of ARV treatment of HIV/AIDS. Following a request from Sweden, the main ICIUM-2 recommendations on rational use of medicines in general, and on containing antimicrobial resistance in particular, were presented to the WHO Executive Board and World Health Assembly.



- 7 *Sun, Determining the Patent Status of Essential Medicines in Developing Countries*. Health Economics and Drugs/EDM Series No.17. Geneva, WHO, 2004 (document WHO/EDM/PAK/2004.6).
- 8 [http://mednet3.who.int/PROUD/CourseReport/PROUD\\_Report.pdf](http://mednet3.who.int/PROUD/CourseReport/PROUD_Report.pdf)
- 9 *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. Geneva, WHO, 2004 (document WHO/EDM/PAK/2004.4).
- 10 WHA resolution 57.14.
- 11 <http://mednet3.who.int/prequal/>
- 12 *WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants*. Geneva, WHO, 2002.
- 13 *WHO Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems*. Geneva, WHO, 2004.
- 14 *Guidelines on Developing Consumer Information for the Proper Use of Traditional, Complementary and Alternative Medicine*. Geneva, WHO, 2004.
- 15 *SARS: Clinical Trials on Treatment Using a Combination of Traditional Chinese Medicine and Western Medicine*. Geneva, WHO, 2004.