



**World Health
Organization**

ESSENTIAL MEDICINES //
ANNUAL REPORT 2006



THE PHARMACEUTICAL SCENE IN 2006 //



Dr Margaret Chan was appointed **Director-General of WHO** in November. Dr Chan recognizes the need for continued targeted action to tackle AIDS, tuberculosis and malaria. But she also intends to refocus international public health efforts on primary health care (PHC), in order to reach patients most in need, such as women and children, and especially in Africa. This choice may herald the return of a more horizontal and comprehensive approach to health care provision. Essential medicines have always constituted an important element of PHC.

Dr Chan's agenda for WHO has six components: promoting development; fostering health security; strengthening health systems; harnessing research, information and evidence; enhancing partnerships; and improving performance.

International support for activities relating to essential medicines

continued to grow. Global funding mechanisms now include not only the Global Fund to Fight AIDS, TB and Malaria and the Global Drug Facility, but also UNITAID. UNITAID was launched officially in 2006 following a decision by Brazil, Chile, France, Norway and the United Kingdom to create an international drug purchasing facility focusing on treatment for high-burden diseases, to be financed with sustainable, predictable resources. Dr Chan has stipulated that WHO's role regarding such initiatives is to provide a sensible and convincing global health agenda, supported by evidence.

WHO's essential medicines activities continued to be based on the *WHO Medicines Strategy 2004–2007*. This annual report highlights some of the activities carried out in 2006. In late 2006, development of the next WHO medicines strategy started, with close attention being paid to the direction and contents of the *WHO Medium Term Strategic Plan for 2008–2013*. Medicines work will thus be firmly integrated with WHO's overall strategies and work plans.



Key essential medicines achievements in 2006 //

- Technical medicines support was provided to over 80 countries, and to sub-regional structures, to develop, implement and monitor national medicine policies. Emphasis was on strengthening capacity for procurement and supply management, and regulation of medicines.
- WHO tools for **national pharmaceutical situation assessment** were updated and *Using Indicators to Measure Country Pharmaceutical Situations: Fact Book on WHO Level I and Level II Monitoring Indicators* was published. The latter contains indicator-based pharmaceutical information for over 100 countries.¹
- WHO is an active participant in **UN reform**.² Through the Interagency Pharmaceutical Coordination (IPC) group, WHO worked intensively with UNAIDS, UNFPA, UNICEF, the World Bank and the Global Fund to Fight AIDS, TB Malaria to harmonize pharmaceutical policies. 2006 marked the 10th anniversary of IPC.
- Numerous **global policies and standards for pharmaceuticals** were issued, with a focus on priority medicines for HIV/AIDS, tuberculosis, malaria and reproductive health.
- The **WHO/UN Prequalification Programme** prequalified 44 new products and secured major donor support for ongoing activities.
- The standard **WHO/Health Action International medicine pricing survey methodology** continued to be widely applied. A summary report on medicine prices for chronic diseases was presented at the World Health Assembly.³
- The **International Medical Products Anti-Counterfeiting Taskforce (IMPACT)**⁴ was launched, to help national authorities safeguard their populations from the dangers of counterfeit medicines.
- Several innovative studies and reports were published, including a study of the medicines supply systems of faith-based organizations in Africa⁵ and two papers on access to essential medicines as part of the fulfilment of the right to health.⁶⁻⁷

POLICY

Indicator-based assessment of pharmaceutical situations //

Improvement of tools for promoting evidence-based pharmaceutical policy development and implementation continued. Working groups are strengthening three assessment tools: the global survey tool; the facility-based survey; and the population-based household survey. A fact book with information from over 100 countries was published and a (third) global pharmaceutical survey is planned for 2007.

Country support on medicines policy development //

Development and implementation of a national medicines policy remains a key component of national essential medicines programmes, and continues to be promoted in all regions. Support was provided to 15 African countries to develop, plan and implement national medicines policies, while a pharmaceutical business plan was developed for 14 Southern Africa Development Community countries. In the Americas, the Caribbean countries focused on creating a sub-regional medicines policy. In Asia, a regional meeting on medicines policies was organized in Fiji for 11 Pacific Island Countries. Brunei, the Cook Islands and Niue were supported to develop their national medicines policies. An international essential medicines conference was organized in Mongolia, to review experiences in implementing national medicines policies.

Pharmaceutical sector assessments were performed in the Republic of the Congo, Djibouti, Fiji, Gambia, Nicaragua and Zambia.

The second year of the European Commission–WHO Partnership on Pharmaceutical Policies was completed successfully. Over 40 countries were assisted, either through direct country assistance and/or subregional collaboration.

In Europe, WHO collaborated with the Austrian Health Institute on the European Union-funded Pharmaceutical Pricing and Reimbursement Information project.

Access to essential medicines as a human right //

Three papers were published on this topic. In May, the *WHO Bulletin* published a paper on how human rights principles should be incorporated into national medicine policies and programmes.⁶ In August, *The Lancet* published the results of a WHO study on whether access to essential medicines, as part of the fulfilment of the right to health, could be enforced.⁷ The study identified 71 court cases from 12 developing countries in which appellants demanded access to essential medicines based on constitutional rights or international human rights treaties signed by their government; 59 of these cases were won. In September, the UN Special Rapporteur on the Right to Health, Paul Hunt, submitted a report to the UN General Assembly on maternal mortality and access to essential medicines as a human right.⁸

POLICY

Good governance for medicines //

The value of the global pharmaceutical market is estimated at over US\$ 500 billion. These funds are an obvious target for abuse. Indeed, an estimated 10–25% of public procurement spending in the health sector is lost to corruption. In 2005, in response to this serious problem, WHO initiated the Good Governance for Medicines Programme. The Programme's overall goal is to curb corruption in the public pharmaceutical sector by increasing transparency and accountability in the regulation and supply management of medicines. It is being implemented at country level in three phases: **(1)** national assessment of the level of transparency and vulnerability to corruption; **(2)** development of a national good governance infrastructure; and **(3)** promotion of the good governance infrastructure by key actors within the pharmaceutical sector. By late 2006, activities were under way in nine countries in Asia and Latin America.

POLICY

Example of UN reform: 10 years of pharmaceutical coordination //

Since 1996, the pharmaceutical advisers of WHO, the World Bank, UNAIDS, UNFPA, UNICEF and, more recently, the Global Fund to Fight AIDS, TB and Malaria, and UNDP/IAPSO, have met every six months to coordinate the pharmaceutical policies underlying the technical advice on medicines that they give to countries.⁹ This has led to increased consistency in technical advice, and to the development of several interagency policy documents, such as the *Guidelines for Drug Donations*¹⁰ and *The Interagency List of Essential Medicines for Reproductive Health*.¹¹ Recent IPC initiatives include prequalification of reproductive health items and better essential medicines for children. The very successful annual *WHO/UNICEF Technical Briefing Seminar on Medicines* was launched by the IPC group in 1997 and continues to attract many participants from UN agencies.

Integration of traditional medicine into national health-care systems //

The 2003 World Health Assembly urged Member States to formulate and implement national policies and regulations on traditional medicine, and to integrate these into national health-care systems. The *WHO Traditional Medicine Strategy 2002–2005*¹² provided a framework for action.

At a meeting on integration of traditional medicine into national health systems, questionnaire results from 22 countries demonstrated a clear and positive change in the status of traditional and complementary and alternative medicine (see table), with respect to national health policies, national programmes and expert committees.

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Change in status of traditional medicine/complementary and alternative medicine (TM/CAM): 2002 and 2006 //

Area	"No" in 2002 and "Yes" in 2006
Existence of national law/regulations for TM/CAM	Brazil, Saudi Arabia, Sweden, United Arab Emirates
Existence of national TM/CAM policy	Brazil, Mali
Existence of TM/CAM unit within Ministry of Health	United Kingdom
Existence of national expert committee on TM/CAM	Republic of Korea, Saudi Arabia, United Arab Emirates, United Kingdom
Existence of national TM/CAM research institution	Australia, Brazil, Ghana, Iran
Existence of national TM/CAM programme*	Brazil, Iran

* A national TM/CAM programme is any programme undertaken at local or national level by the Ministry of Health, other ministries or local bodies, whose mandate is to take specific action in order to achieve objectives in line with national policy or legislation.



ACCESS

Intellectual property and access to medicines //

WHO continues to work to enhance developing country capacity to ensure effective participation in trade negotiations. It also continues to encourage countries to ensure that public health interests are adequately taken into account when national policies and legislation are developed. Regional and national training workshops for developing country policy-makers were held: for example in Argentina, the Republic of the Congo and Pakistan. WHO also participated in four regional workshops organized by the World Trade Organization in China, Costa Rica, Kuwait and Turkey.

The WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property held its first session in December in Geneva. The Working Group will draw up a draft global strategy and plan of action for needs-driven essential health research and development, focusing on the diseases that disproportionately affect developing countries. At its December meeting, it considered eight elements of a draft plan of action: prioritizing research and development needs; promoting research and development; building and improving innovative capacity; transfer of technology; management of intellectual

property; improving delivery and access; ensuring sustainable financing mechanisms; and establishing monitoring and reporting systems. The WHO South-East Asian Regional Office held a preparatory meeting for the IGWG to discuss a regional position on these issues. Consultations at regional and subregional levels will continue in preparation for the next session of the IGWG in November 2007.

Regional and country support //

Surveys for assessing production, procurement and supply management capacity were performed in 32 African countries, and regional frameworks for collaboration and recommendations for policy interventions produced. Fourteen countries were supported in strengthening the coordination and planning of procurement and supply management, and improving the availability of quality medicines. Countries of the East African Community were assisted in creating a model for pooled procurement.

In South-East Asia, a workshop reviewed regional collaboration on production of oseltamivir, as part of pandemic preparedness. Workshop discussions demonstrated that the region has the

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capacity to produce sufficient oseltamivir supplies and that clear guidelines on stockpiling would encourage manufacturers to produce adequate quantities.

Tools for assessing procurement and supply management were presented at a regional workshop for Pacific Island Countries in Fiji, in August, and are now being applied.



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Multi-country studies on supply systems //

The report of a multi-country study on the medicine supply and distribution activities of 16 faith-based organizations in 11 sub-Saharan African countries was published.⁵ The study found that these organizations play a crucial role in increasing access to medicines, especially in rural and remote areas, and provide a “safety net” for when government supply systems fail. Based on this experience, a second study on public supply systems was carried out in 18 African countries.

Medicine pricing surveys, pricing policies and medicines financing //

The WHO/Health Action International standard methodology for medicine pricing surveys has now been used in at least 50 low- and middle-income countries to measure the prices and availability of generic and branded products in the public, private and nongovernmental organization sectors.¹³ Affordability is measured by comparing medicine costs with the wage of the lowest-paid worker in the public sector.

Pricing surveys were carried out in 14 African countries and a stakeholders workshop was organized for 10 African countries, to analyse survey results and plan for policy and advocacy interventions. A pricing survey was also carried out in Viet Nam. Kenya, Malaysia, Mali, Uganda, Tanzania and Viet Nam received assistance to develop medicine prices monitoring mechanisms. In Asia, a regional consultation on medicine prices was attended by 13 countries.

With support from the WHO Eastern Mediterranean Regional Office, a summary report on prices of medicines for chronic diseases was presented at the World Health Assembly in May.³ The report concludes that availability in the public sector is generally very poor and that prices in the private sector are frequently unaffordable for patients with chronic diseases. The work has received international recognition and become an important component of a new plan for increasing transparency in governance (MeTA), launched by the United Kingdom’s Department for International Development.¹⁴ In December, the

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overall methodology was reviewed, on the basis of lessons learnt during country surveys.

A regional workshop on financing essential medicines was held in October, which recommended development of national health accounts for medicines expenditures. Analysis of public and private medicines financing was undertaken in the Cook Islands, Fiji, Mongolia and Papua New Guinea.

In Europe, technical support to supply and reimbursement systems was provided to Azerbaijan, Bosnia Herzegovina, Kyrgyzstan, Latvia, Malta, Poland, Slovakia and the former Yugoslav Republic of Macedonia. Through networking among countries on cost-effectiveness evaluations of new drugs, WHO also provides input to west European countries on their national reimbursement policies and decisions.



QUALITY AND SAFETY

Global effort to combat counterfeit medicines //

Counterfeit medical products are a growing global menace to people's health, causing death, disability and injury. They also destroy the credibility of health systems, and waste precious human and financial resources. In order to strengthen the fight against them, WHO launched the global IMPACT (International Medical Products Anti-Counterfeiting Taskforce Initiative (IMPACT)).⁴ Supported by national medicines regulatory authorities, IMPACT aims to coordinate the activities of all stakeholders. In November, the IMPACT Secretariat was established within WHO. Five working groups are looking at: legislative and regulatory infrastructure; regulatory implementation; enforcement; technology; and communication.

The human cost of counterfeit medicines //

Verónica Díaz lived in Viedma, Argentina. She was 22 and healthy, except for a mild ferropenic anaemia (insufficient iron in her blood) for which she was receiving injections of an iron preparation. After the 7th of a 10-injection treatment, she became very sick and was hospitalized. She died of liver failure on 23 December 2004. While hospitalized, samples of the medicine that she had been taking were tested. On the day she died, the medicines authority of Argentina (ANMAT) ascertained that she had been given a highly toxic counterfeit. (ANMAT) ordered immediate recall of the product, established a 24-hour hotline to receive and provide information, and started an investigation. By 27 December (ANMAT) had traced the source of the counterfeit product to a distributor. Investigations and laboratory tests continued in January 2005, and led to tracking and recovery of most of the counterfeit product, and to the prosecution of four individuals. Yet the highly fragmented distribution system was not fully responsive to the recall. In May 2005, a 22-year old pregnant woman was injected with the same counterfeit iron preparation. She survived, but gave birth to a 26-week premature baby weighing only 1300 grams.

QUALITY AND SAFETY

Regulatory support to countries //

The five-year regional strategic plan for strengthening medicines regulatory authorities in Africa – developed in October 2005 – provided an effective framework for providing direct technical support to countries on assessing and strengthening their medicines regulatory authorities. Collaboration also continued with sub-regional structures on harmonizing medicines regulations. In Africa, sub-regional groups formulated plans to tackle problems associated with access and availability of medicines.

A regional meeting was held for the African and Eastern Mediterranean regions on local production, and included adoption of a framework for strengthening local production capacity in about 30 countries.

In Asia, medicines regulatory assessment was undertaken in Fiji, Papua New Guinea, Samoa, the Solomon Islands, Tonga and Vanuatu. In Europe, WHO worked closely with the European Medicines Evaluation Agency and supported DRUGNET, the network of drug regulatory authorities that aims to improve regulation of medicines in the Commonwealth of Independent States (CIS). Direct country support and regulatory training in bioequivalence

studies were provided to all CIS countries. The Russian good manufacturing practice inspectorate was trained, as were inspectors from Armenia, Azerbaijan, Belarus, Georgia, Moldova, Kazakhstan and Ukraine, in inspection procedures. Specialists from Kazakhstan's medicines regulatory authority were trained in good laboratory practices.

INNs and methodological developments //

An International Nonproprietary Name (INN, generic name) is a unique name – which is globally recognized and constitutes public property – for an active pharmaceutical ingredient. INNs thus facilitate identification of pharmaceutical ingredients and enable exchange of information about them. In 2006, WHO assigned and published 103 INNs, using standardized global consultation procedures. The newly developed nomenclature system for gene-therapy products was used for the first time, to assign six gene-therapy medicine names. Methodological work to develop global nomenclature systems for biological medicinal substances continued. In collaboration with the Chinese Pharmacopoeia Commission and the WHO Collaborating Centre for Drug Registration and Regulation in Tunisia, all existing INNs in Chinese and Arabic were checked and, where necessary, corrected.

QUALITY AND SAFETY

Essential global quality standards HIV/AIDS and malaria medicines //

In view of the demand for new global pharmaceutical norms and quality standards, the WHO Expert Committee on Specifications for Pharmaceutical Preparations now meets every year. The report of the 41st meeting includes the revised procedures for assessing pharmaceutical products for procurement by UN agencies, and for assessing the acceptability of quality control laboratories. It also includes new guidance regarding variations (“changes”) to the dossiers of prequalified products.¹⁵ Additionally, the Committee adopted 16 new monographs for inclusion in *The International Pharmacopoeia* and four new International Chemical Reference Standards. General guidelines for the establishment, maintenance and distribution of chemical reference substances were revised to improve guidance on official secondary reference standards. Work progressed well on a system to waive in-vivo bioequivalence requirements for generic versions of some essential medicines.

Prequalification activities //

The WHO/UN Prequalification Programme assesses the quality, safety and efficacy of priority medicines for HIV/AIDS, tuberculosis, malaria and reproductive health. The web-based list of prequalified products is used by an increasing number of UN agencies, national treatment and medicines programmes, and nongovernmental organizations to guide them in their procurement decisions. In 2006, 44 additional products were added to the list.

During 2003–2005 the Programme operated with only two WHO staff and a budget of less than US\$ 1 million per year. But in 2006 it received considerable long-term financial support from donors. This enabled recruitment of additional staff. Key statistics for the Programme for 2005–2006 are given below. In both years, more generic than branded products were prequalified, illustrating the Programme’s continuing success in capacity building in the generic sector. The Prequalification Programme has also become one of the main vehicles for technical support to national medicines regulatory authorities.

QUALITY AND SAFETY

The WHO/UN Prequalification Programme in 2005–2006 //

	2005	2006
Dossier assessments		
Assessment sessions (number of days) in Copenhagen	9 (45)	6 (42)
Total number of assessment reports	342	496
Number of reports on HIV/AIDS-related products	222	389
Number of reports on TB products	50	78
Number of reports on malaria products	70	29
Inspections	52	49
Inspections of manufacturing sites of finished products	20	17
Inspections of manufacturing sites of active ingredients	10	10
Inspections of contract research organizations	14	15
Inspections of drug quality control laboratories in Africa	8	7
Products and laboratories prequalified		
Total number of products prequalified	32	44
Number of HIV/AIDS products prequalified	29	42
Number of TB products prequalified	0	0
Number of malaria products prequalified	1	2
Number of quality control laboratories prequalified	3	0

Safety of medicines used in public health programmes //

The detection, assessment and prevention of adverse drug reactions (ADRs) through pharmacovigilance improves patient care and safety. Collecting reports of ADRs is key to pharmacovigilance. The WHO Programme for International Drug Monitoring, together with the Uppsala Monitoring Centre in Sweden, facilitates the rapid identification and communication of ADR “signals” via a global electronic database housed in the Monitoring Centre. By the end of 2006, the database contained 3.7 million case reports. Belarus, Nepal and Uzbekistan joined the Programme, increasing the number of full member countries to 81 and the Programme’s capacity to collect ADR reports.

In Barbados, a regional training course on safety monitoring of antiretrovirals (ARV) was held, to introduce HIV/AIDS programme managers and other health professionals to a common system of pharmacovigilance, to provide access to the WHO ADR database and to initiate pilot ARV pharmacovigilance projects in the respective countries. A national pharmacovigilance training course was also organized in Botswana.

QUALITY AND SAFETY

Strengthening quality and safety of blood and blood products //

The world's population is increasingly mobile, which in turn increases national vulnerability to communicable disease threats. The need to improve cooperation among regulatory agencies on quality and safety standards for blood and blood products is now urgent. A strategic plan to develop work on quality assurance and safety of blood products and related biologicals¹⁷ was agreed by the 57th WHO Expert Committee on Biological Standardization (ECBS) in October, as were the terms of reference for the WHO Blood Regulators Network. ECBS also established WHO international biological reference standards,¹⁸ aimed at the control of blood safety diagnostic tests. These standards will contribute to international harmonization of safety regulations for blood products.

Special efforts were also devoted to coordinating WHO standardization activities with those of other standard-setting organizations, WHO Collaborating Centres for biological standards, and the standardization committees of international scien-

tific societies. Additionally, WHO guidelines and standards for the production, control and regulation of plasma for fractionation were widely distributed to support countries in ensuring preparation of quality plasma for the fractionation of plasma derivatives.¹⁹

Equally important, a WHO project was developed to increase access to therapeutic sera and to strengthen quality production in developing countries. Effective treatment for rabies and snake bites is critically dependent on therapeutic sera, but they are often unavailable or unaffordable in the countries where they are most needed.

QUALITY AND SAFETY

Regulation of herbal medicines //

Following WHO's recommendation to use artemisinin-based combination therapies to treat malaria, widespread shortages of the medicinal plant *Artemisia annua* were experienced. In order to optimize use of supplies of this plant, the *WHO Monograph on Good Agricultural and Collection Practices for Artemisia annua* was developed and published, in cooperation with the WHO malaria programme.²⁰ *Supplementary Guidelines on Good Manufacturing Practices for the Manufacture of Herbal Medicines* were also published.²¹



SELECTION AND RATIONAL USE

Country support //

WHO continued to provide support on essential medicines selection to many countries. For example, in Europe, training was supported in the Baltic countries, on the economic evaluation of medicines to be included in national reimbursement lists. Technical support was provided on updating of national essential medicines lists in Kyrgyzstan, Macedonia, Moldova, Tajikistan and Uzbekistan, and on developing and updating national formularies in Armenia, Azerbaijan Georgia and Tajikistan.

Interagency Emergency Health Kit 2006 //

Revision of the *New Emergency Health Kit 98* concluded with the endorsement by 10 UN agencies and international nongovernmental organizations of the *Interagency Emergency Health Kit 2006*. This third edition takes into account the treatment of HIV/AIDS in emergency situations, increasing parasite and antimicrobial resistance, and practical field experience gained during use of previous versions of the kit.

Interagency List of Essential

Commodities for Reproductive Health //

An *Interagency List of Essential Medical Devices for Reproductive Health* was developed,²² following the example of the *Interagency List of Essential Medicines for Reproductive Health of 2005*. This new list was based on years of work between many organizations. The problem was that organizations were using different specifications and different nomenclature systems for their non-drug items (devices, disposable supplies, instruments, etc.). The list resolves this problem by providing a single reference point.



SELECTION AND RATIONAL USE

Essential medicines for children //

The latest *WHO Model List of Essential Medicines (2005)* does not include all essential paediatric formulations. Work therefore started in earnest in 2006 on identifying missing essential medicines for children and promoting their development. A survey carried out in 40 low- and middle-income countries revealed widespread problems with availability, dosing and cost of paediatric medicines. Activities are being carried out in close collaboration with UNICEF and with the WHO/UN Prequalification Programme. The latter will be actively supporting regulators and manufacturers to develop and assess the quality and safety of new formulations for children.

Country support //

Promoting rational use of medicines by prescribers and consumers can generate health gains and financial savings. Yet many countries do not make full use of the potential benefits of proven interventions. Several regional training courses were held to stimulate action in this area. This included a course on promot-

ing rational use of drugs in the community, held in Jaipur, India and organized in collaboration with India's Institute of Health Management Research.

New publications were developed in the South-East Asian Region, including *The Role of Education in the Rational Use of Medicines*.²³ In India, revision of the medical curriculum as part of the effort to improve rational use of medicines was undertaken together with the Indian Pharmacological Society. Also in India, applied research projects on community surveillance of antimicrobial resistance and use continued to be supported. A particularly worrying finding is that fluoroquinolones are the most frequently used antibiotics within the community, and often used inappropriately for coughs and colds.

In the Western Pacific Region, an indicator-based intervention for improving rational use of medicines, called Monitoring Training and Planning, was initiated in Zhuhai Province, in China, and Mongolia. (The intervention has already been applied successfully in Cambodia and Laos.) In Africa, a situational analysis was undertaken in Sudan and recommendations made on containing antimicrobial resistance.

SELECTION AND RATIONAL USE

In Europe, support in developing and implementing clinical guidelines was given to Armenia, Azerbaijan, Croatia, Moldova, Romania and Uzbekistan. WHO also completed an external review of the clinical guidelines programmes of the National Institute for Health and Clinical Excellence in the United Kingdom. It also participated in European Parliament discussions on development of a Europe-wide plan to contain antimicrobial resistance.

Operational research and policy guidance//

The WHO database on use of medicines at primary health care level in low- and middle-income countries was updated to include all surveys between 1990 and 2005. Trends in medicines use over time and by different criteria were then analysed. The analysis showed that more than half of all medicines in low- and middle-income countries are used inappropriately. Analysis was also made of use of policies and tools that can improve the use of medicines. It found that, frequently, essential medicines lists and clinical guidelines have not been updated, that drug and therapeutic committees do not function, that independent drug information is unavailable and that independent continuing medical education

is not obligatory. This information formed the basis of the WHO Secretariat's report to the Executive Board in May.²⁴

A major study on adherence to ARVs in Botswana, Tanzania and Uganda was completed and presented at the World AIDS conference in Toronto.²⁵ It showed that even when availability of ARVs is assured, patient adherence is often severely hampered by poverty, hunger, long waiting times in facilities and shortage of health professionals. Adherence is rarely measured or recorded.

WHO and the International Pharmaceutical Federation launched *Developing Pharmacy Practice – a Focus on Patient Care* to provide a policy perspective on the role of the pharmacist and a practice perspective on pharmaceutical care.



MANAGEMENT

Financial situation and management //

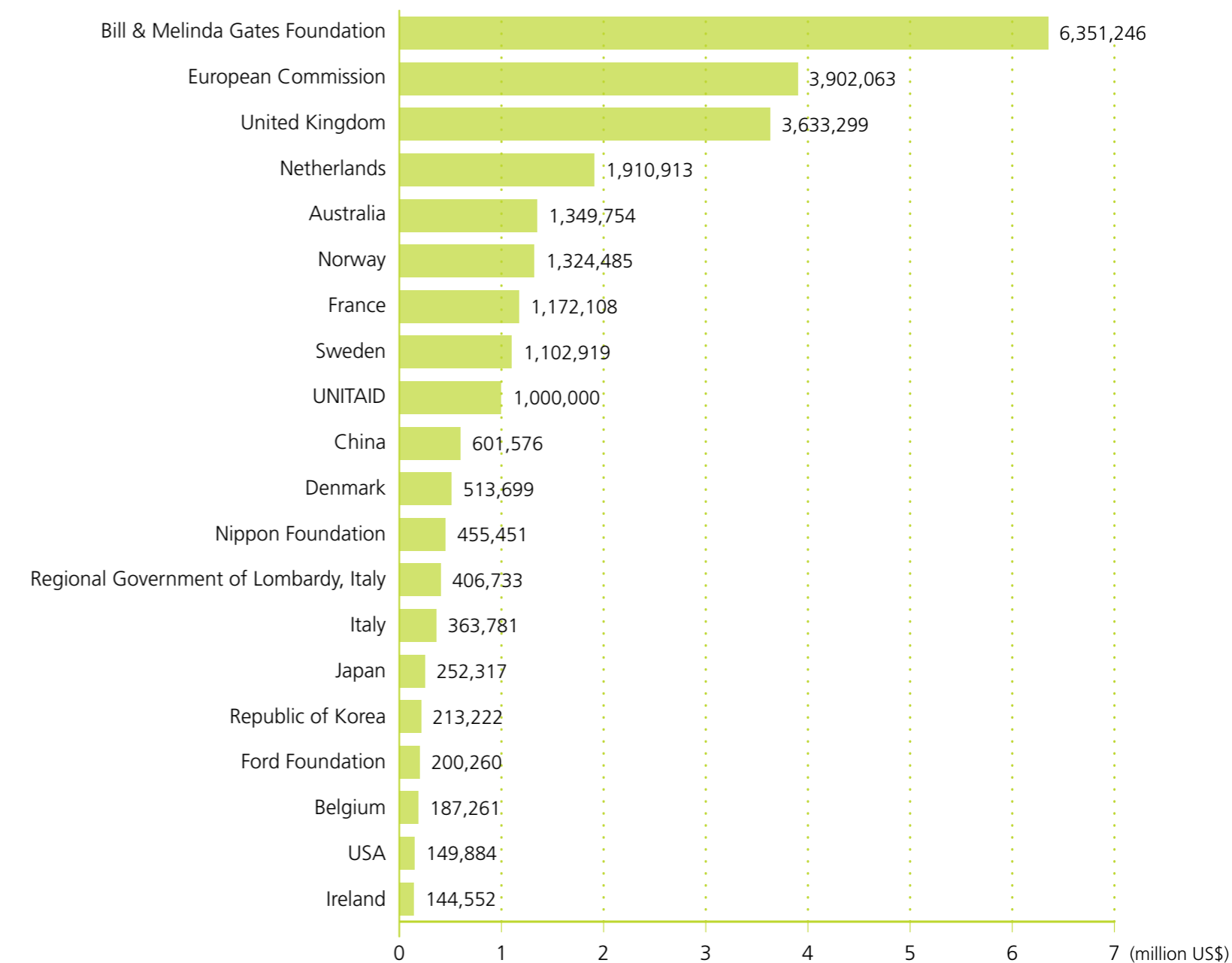
The original 2006–2007 biennial budget for country, regional and headquarters work in essential medicines amounted to US\$ 61 million. By November, US\$ 26 million had been obligated, including US\$ 15 million (37%) for normative work, global policy guidance and other activities carried out at headquarters. The remainder was assigned to country and regional programmes. By the end of 2006, the working budget had increased to US\$ 71.7 million, largely on account of the increased need (and funding obtained) for the Prequalification Programme.

About 25% of the biennial budget is funded through the Regular Budget, about 13% through unspecified funds and the remaining 62% from specified contributions. The unspecified contributions are increasingly being channelled as “core funding” through the WHO corporate account. The level of unspecified support has slowly decreased over the last few years. All recent increases in funding (such as the support received from the Bill & Melinda Gates Foundation, The Nippon Foundation and UNITAID) are specified. (The main extrabudgetary donors are listed in the table and their contributions to the work of WHO are gratefully acknowledged.) Overall, the medicines area in WHO remains under-funded vis-à-vis the magnitude of the global pharmaceutical agenda.



MANAGEMENT

Top 20 donors in 2006 //



FUTURE DIRECTION

The Departments of Medicines Policy and Standards (PSM) and Technical Cooperation for Essential Drugs and Traditional Medicine (TCM), together with regional and country teams, are jointly responsible for the medicines area of work. Six-monthly senior staff meetings, and frequent contact in between, ensure intensive collaboration on planning and implementing national, regional and global medicines programmes.

In 2006 work started on development of the WHO-wide Medium-term Strategic Plan for 2008–2013. Strategic Objective 11 of the new plan covers access, quality and rational use of all essential medicinal products and technologies. Development of the Plan is leading to greater coordination between WHO's policies and its support to activities relating to blood and blood products, diagnostics, medicines, vaccines and other health technologies.



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- ¹ <http://www.who.int/medicinedocs/collect/edmweb/index/assoc/s14101e/s14101e.pdf>
- ² <http://www.un.org/reform/>
- ³ *Price, Availability and Affordability: an International Comparison of Chronic Disease Medicines*. See: <http://www.who.int/medicines/publications/PriceAvailAffordability.pdf>
- ⁴ http://www.who.int/medicines/services/counterfeit/faqs/count_q-a/en/index.html
- ⁵ *Multi-country Study of Medicine Supply and Distribution Activities of Faith-based Organizations in Sub-Saharan African Countries*. See: <http://www.who.int/medicinedocs/collect/edmweb/index/assoc/s14089e/s14089e.pdf>
- ⁶ "Essential medicines and human rights: what can they learn from each other?" in *Bulletin of the World Health Organization*, May 2006, 84(5):371–375.
- ⁷ "Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts", in *The Lancet*, Vol 368, July 22, 2006:305–311.
- ⁸ http://www2.essex.ac.uk/human_rights_centre/rth/docs/GA%202006.pdf
- ⁹ http://www.who.int/medicines/publications/IPC_En.pdf
- ¹⁰ <http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip52e/whozip52e.pdf>
- ¹¹ <http://www.who.int/medicinedocs/collect/edmweb/index/assoc/s14099e/s14099e.pdf>
- ¹² <http://www.who.int/medicinedocs/library.fcgi?e=d-01dedmweb--000-1-0--010---4---0--0-10l--1en-5000-0--50-about-01en-5000-01131-0011xyl4uDve9ee80ca80000000459bc6c2-0utfZz-8-0-0---01001-001-110utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.6&d=Js2297e>
- ¹³ <http://www.haiweb.org/medicineprices/>
- ¹⁴ <http://www.dfidhealthrc.org/MeTA/documents/MeTA%20overview%201Mar07.pdf>
- ¹⁵ WHO Technical Report Series No. 943, available at http://www.who.int/medicines/areas/quality_safety/quality_assurance/TRS943_PharmPrep.pdf
- ¹⁶ <http://mednet3.who.int/prequal/>
- ¹⁷ The area of blood products and related biologicals was transferred into the Department of Medicines Policy and Standards (PSM) in December 2005.
- ¹⁸ <http://www.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=10&codcch=941>
- ¹⁹ <http://www.who.int/biologicals/publications/ECBS%202005%20Annex%204%20Human%20Plasma%20Fractionation.pdf>
- ²⁰ <http://www.who.int/medicinedocs/collect/edmweb/index/assoc/s14074e/s14074e.pdf>
- ²¹ http://www.who.int/medicines/publications/pharmprep/TRS_937.pdf#page=97
- ²² <http://www.who.int/medicinedocs/library.fcgi?e=d-010edmweb--000--1-0--010---4---0--0-10l--11en-5000---50-about-0---01131-001-110utfZz-8-0-0&a=d&c=edmweb&cl=CL2.1.3&d=Js13486e>
- ²³ SEARO Technical Publication Series No. 5. Delhi, WHO, 2006 (ISBN: 92 9022 278 6).
- ²⁴ http://www.who.int/gb/ebwha/pdf_files/EB118/B118_6-en.pdf ; http://www.who.int/gb/ebwha/pdf_files/EB120/b120_7-en.pdf
- ²⁵ From *Access to Adherence: the Challenges of Antiretroviral Treatment – Studies from Botswana, Tanzania and Uganda*. Geneva, WHO, 2006; <http://www.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=685>

Further information on WHO essential medicines activities can be found at: <http://www.who.int/medicines/en/>.



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