

The pharmaceutical scene in 2006–2007

International support for activities relating to essential medicines continues to grow. Global funding mechanisms now include not only the Global Fund to Fight AIDS, TB and Malaria and the Global Drug Facility, GAVI and others, but also UNITAID. UNITAID was launched in 2006 following a decision by France, Brazil, Chile, Norway and the United Kingdom to create an international drug purchasing facility targeting treatment for high-burden diseases, to be financed with sustainable, predictable resources. Since then, many other countries have joined in the effort.

WHO's essential medicines activities continued to be based on the *WHO Medicines Strategy 2004–2007*. This report highlights some of the activities carried out in 2006–2007. In 2006, work began on developing the next WHO medicines strategy, with close attention to the direction and contents of the *WHO Medium Term Strategic Plan for 2008–2013*¹. Medicines work will thus be firmly integrated with WHO's overall strategies and work plans.

Strong country data are essential to building good policy

Improvement of tools for promoting evidence-based pharmaceutical policy development and implementation continued. Several working groups are strengthening three assessment tools: global pharmaceutical survey, the facility-based survey, and the population-based household survey. A fact book with information from over 100 countries was published in 2006.⁴ The third global survey was started in 2007 and responses from more than 100 countries are already complete. The facility survey tool is finalized and ready for publication. The working version of the population based survey has been developed and tested in three countries.

Country support for medicines policy development

Development and implementation of a national medicines policy remains a fundamental building block 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, which includes traditional medicine,

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 and lessons learned in implementing national medicines policies.

The second and third year of the European Commission–WHO Partnership on Pharmaceutical Policies were completed successfully. Over 40 countries were assisted, either through direct country assistance and/or subregional collaboration. Pharmaceutical sector assessments were performed in Angola, Burundi, Republic of the Congo, Djibouti, Fiji, Nicaragua and Zambia. In Europe, WHO collaborated with the Austrian Health Institute on the European Union-funded Pharmaceutical Pricing and Reimbursement Information project (PPRI), which produced more than 20 comprehensive pharmaceutical profiles of European member states plus a comparative study⁵ and contributed to networking among the EU countries on medicines reimbursement policies. Technical assistance was provided to Iraq in medicine selection, supply systems, and national medicine policy implementation.

ESSENTIAL MEDICINES

BIENNIAL REPORT 2006–2007

KEY ACHIEVEMENTS IN 2006–2007

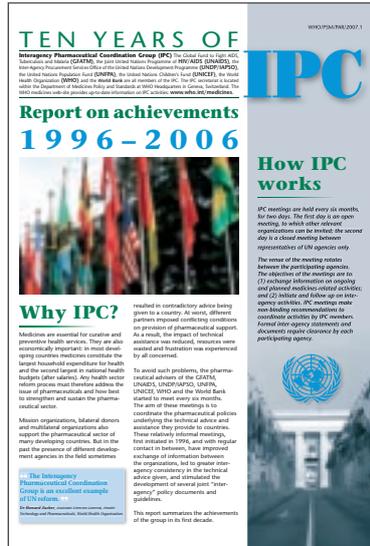
- Over 80 countries and sub-regions received **technical support** to develop, implement and monitor national medicine policies, particularly in strengthening capacity for provision and reimbursement of medicines, procurement and supply management, and on better regulation of medicines.
- The **WHO/UN Prequalification Programme** prequalified 65 new products and secured major donor support for its expanding activities.
- The **Model list of Essential Medicines (EML)** celebrated its **30th birthday** in 2007. In 2007, the first-ever **EML for children** and its companion **Promoting the Safety of Medicines for Children** were published and WHO launched 'make medicines child size', a global initiative to improve access to quality, safe and affordable medicines for children.
- WHO is active 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 and Malaria to harmonize their pharmaceutical policies. In 2006, the IPC marked its **10th anniversary**.
- The **International Medical Products Anti-Counterfeiting Taskforce (IMPACT)** was launched to help national authorities safeguard their populations from the dangers of counterfeit medicines.³

Access to essential medicines as a human right

Three steps were taken on the issue of access to essential medicines as a human right. A paper was developed on the practical implications of the rights-based approach to access to essential medicines, detailing how human rights principles should be incorporated into national medicine policies and programmes.⁶ A study was completed on whether access to essential medicines, as part of the fulfilment of the right to health, could be enforced through the courts, describing 71 court cases from 12 developing countries.⁷ The UN Special Rapporteur on the Right to Health submitted a report to the UN General Assembly on maternal mortality and access to essential medicines as a human right.

Good Governance for Medicines programme

The global pharmaceutical market is estimated to be over US\$ 600 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.⁸ In 2005, WHO initiated the Good Governance for Medicines Programme which aims to curb corruption in pharmaceutical sector systems through the application of transparent and accountable administrative procedures and the promotion of ethical practices among health professionals. 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 national good governance for medicines programmes; and (3) promotion of the good governance practices by key actors within the pharmaceutical sector. By the end of 2007, activities were under way in nineteen countries, covering all WHO regions.



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 as the **Interagency Pharmaceutical Coordination (IPC) Group** to coordinate the pharmaceutical policies underlying the technical advice on medicines that they give to countries. This has led to increased consistency in technical advice, and the development of several interagency policy documents, such as the *Guidelines for Drug Donations* and the *Interagency List of Essential Medicines for Reproductive Health*. 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 launched by the IPC group in 1997 continues to attract many participants from UN agencies.

Integration of traditional, complementary and alternative medicine into national health systems

The most recent resolution on traditional medicine (TM), adopted at the World Health Assembly in 2003, urged Member States to develop and implement national policies and regulations on traditional medicine and to integrate them into national health-care systems, depending on the circumstances in their countries. After four years of implementation of the **WHO Traditional Medicine Strategy (2002–2005)**, country progress has been made and all targets have been accomplished or exceeded. Therapies and practice of TM/CAM are recognized by more countries through regulation and registration. In 2006, a WHO working group discussed the integration of traditional medicine into national health systems.

In Africa, Cameroon, Central African Republic, Congo, Côte d'Ivoire, Rwanda, United Republic of Tanzania, Uganda, Zambia and Zimbabwe developed national policies on traditional medicine. Draft guidelines on national policy for the protection of traditional medical knowledge and access to biological resources, and WHO draft model law for the protection of traditional medical knowledge and access to biological resources in Africa were developed. WHO guidelines for training health sciences students in traditional medicine and for training traditional health practitioners in primary health care were field-tested in Cameroon, Congo, DRC, Ghana, Mali, Senegal, South Africa, United Republic of Tanzania and Uganda.

International harmonization on promotion of regulation of herbal medicines

The results of the WHO 1st Global Survey showed that challenges in the field of regulation of herbal medicine are related to the lack of four key elements: research data, appropriate control mechanisms, education of providers and expertise. More than 120 Member States have

requested support from WHO for: information sharing on regulatory issues and databases, training workshops on the regulation of herbal medicines and herbal medicines safety monitoring, and technical guidelines on research and evaluation of herbal medicines. WHO is continuing to promote the effective regulation and safe use of herbal medicines globally. In 2007, the international network of International Regulatory Cooperation for Herbal Medicines (IRCH), established by WHO between 16 countries and 3 regional organizations in 2005, held its third annual meeting.

Technical guidance on traditional medicines

Since WHO recommended artemisinin-based combination therapies against malaria in 2001, the medicinal plant *Artemisia annua* has been in great demand. "WHO guidelines for good agriculture and collection for *Artemisia annua* plant" were published in 2006. In 2007, "Supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines", "WHO guidelines on assessing quality of herbal medicines with reference to contaminants and residues" and other guidelines were published.



Artemisia annua

Intellectual property and access to medicines

WHO continues 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 in a number of countries including: **Argentina, the Republic of the Congo, Pakistan and the Philippines**. WHO also participated in four regional workshops organized by the World Trade Organization in **China, Costa Rica, Kuwait and Turkey**.

The **WHO Inter-Governmental Working Group** on Public Health, Innovation and Intellectual Property (IGWG), established in 2006, held two sessions. The second session in November 2007 was attended by 140 member states and stakeholders. The Working Group's draft global strategy and plan of action for needs-driven essential health research and development, focuses on diseases that disproportionately affect developing countries. The draft plan's eight elements include: 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 global strategy and plan of action will be submitted to the 61st World Health Assembly in 2008.

Access to Controlled Medications Programme ACMP

Each year tens of millions of people suffer from lack of access to opioids, or pain relieving medicines. To address this problem and in response to resolutions at the World Health Assembly and the United Nations' Economic and Social Council in 2005, WHA58.22 and ECOSOC 2005/25 respectively, WHO developed the Access to Controlled Medications Programme (ACMP) in consultation with the International Narcotics Control Board and a number

of NGOs. The ACMP was launched in 2007 to improve legitimate medical access to all medications controlled under the drug conventions. The ACMP focuses on lifting barriers that impede access to controlled medicines and includes development of policy guidelines, country specific analysis, legislation review, and training for making estimates, statistics, procurement and monitoring.

Regional and country support

To improve access to medicines in countries it is essential to understand the current situation. 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.

Tools for mapping partners, financial flows to medicines, and in-depth assessment of the procurement and supply systems were developed and pre-tested in Ghana and Senegal. Using these tools, **9 African countries (Burundi, Cameroon, Ghana, Mali, Nigeria, Rwanda, Senegal, United Republic of Tanzania and Zambia)** undertook mapping and in-depth assessment of procurement and supply systems. Similar tools were presented at a regional workshop for **Pacific Island Countries** in **Fiji** and are now being applied. In **Europe** technical support was provided to transitional countries on strengthening the provision of medicines and streamlining reimbursement systems, including **Azerbaijan, Bulgaria, Czech Republic, Hungary, Kyrgyzstan, the former Yugoslav Republic of Macedonia, and Tajikistan**. The PPRI project has mapped the medicines reimbursement systems of



most EU countries. In the Americas, 11 countries received technical support in integrated strengthening of procurement and supply management systems. Through the PAHO/AMRO Strategic Fund 9 of these countries drew on regional capacity in the acquisition of strategic medicines.

Multi-country studies on medicine supply systems

A multi-country study on medicine supply and distribution activities of 16 faith-based organizations in 11 sub-Saharan countries in Africa⁹ 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 government supply system failure. Subsequently a second comparative study was undertaken to assess alternative medicine supply strategies to the highly centralized medical supply system in 18 countries in Africa¹⁰. The study identified good practices in medicine supply and management operations across the selected countries and distinguished between the various types of supply strategies these countries use.

Medicine pricing surveys, pricing policies and medicines financing

Medicines pricing and financing are important components of ensuring access to medicines. The WHO/Health Action International standard methodology for medicine pricing surveys has been used in over 50 low- and middle income countries to measure the prices, affordability and availability of generic and branded products in the public, private and nongovernmental organization sectors.¹¹

Pricing surveys were carried out in 14 African countries and Viet Nam. A stakeholders’ workshop organized for 10 African countries, analysed survey results and planned policy and advocacy interventions. Kenya, Malaysia, Mali, Uganda, United Republic of Tanzania and Viet Nam received assistance to develop routine medicines prices and availability monitoring mechanisms.

In Asia, a regional consultation on medicines 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 2006.¹² The work received international recognition and became an important component of a new plan for increasing transparency in governance (MeTA), being launched by the United Kingdom’s Department for International Development.¹⁸ The Philippines was chosen as the first pilot country for MeTA. A regional workshop on financing essential medicines was held in 2006, 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 for supply and reimbursement systems was provided to Azerbaijan, Bosnia Herzegovina, Kyrgyzstan, Latvia, Malta, Poland, Slovakia and the former Yugoslav Republic of Macedonia. WHO also provides input to west European countries on their national reimbursement policies and decisions through direct networking among countries on information exchange, reimbursement arrangements, and cost-effectiveness evaluations of new drugs.

Global effort to combat counterfeit medicines: IMPACT

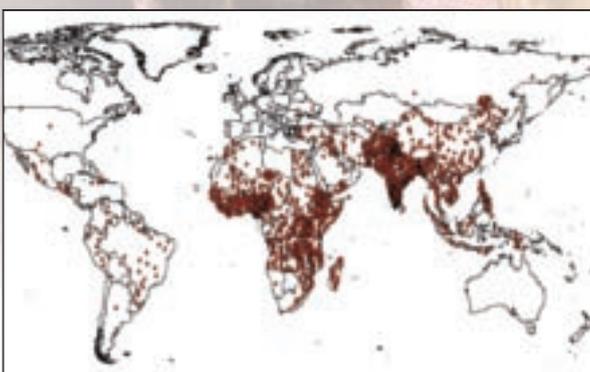
Counterfeit medical products are a growing global menace to people’s health, causing death, disability and injury. They also destroy the credibility of health systems, and waste precious human and financial resources. In order to strengthen the fight against counterfeits, WHO launched the global IMPACT (International Medical Products Anti-Counterfeiting Taskforce) Initiative³ in 2006, and established its Secretariat within WHO.

Supported by national medicines regulatory authorities, IMPACT aims to coordinate the activities of stakeholders ranging from Interpol to industry, in five key areas. Five working groups are looking at: 1) legislative and regulatory infrastructure – to protect and sanction against counterfeits throughout the development and distribution chain; 2) regulatory implementation – promoting good distribution, procurement, and national assessments; 3) enforcement – coordinating and strengthening operations among participating countries; 4) technology – assessing technologies to prevent, deter or detect counterfeit medicinal products; 5) communication – address health professionals, distributors, patients, enforcement and media.

Regulatory support to countries

The five-year regional strategic plan for strengthening medicines regulatory authorities in Africa, developed in October 2005, provided a framework for delivering technical support to countries on assessing and strengthening their medicines regulatory authorities. Collaboration continued with sub-regional structures on harmonizing medicines regulations. A regional meeting was held for the African and Eastern Mediterranean regions on local production, and adopted a framework for strengthening local production capacity in about 30 countries.

Medicines regulatory system assessments were undertaken in Botswana, Burkina Faso, Cameroon, Chad, Côte d’Ivoire,



GLOBAL DISTRIBUTION OF CHILD DEATHS

Each dot represents 5000 deaths. About 30,000 children die each day, most of these could be prevented with access to essential medicines.

Source: Black et al., Lancet 2003; 361: 2226-34

Kenya, Malawi, Mali, Mozambique, Rwanda, Senegal and Zambia. In Asia, Fiji, Papua New Guinea, Samoa, the Solomon Islands, Tonga and Vanuatu undertook medicines regulatory system assessments. In Europe, WHO worked closely with the European Medicines Evaluation Agency (EMA) and supported South East European countries and 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 and inspectors from Armenia, Azerbaijan, Belarus, Georgia, Republic of Moldova, Kazakhstan and Ukraine received training.

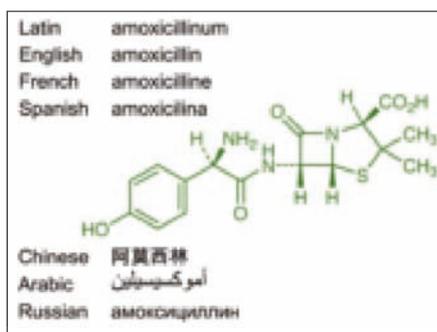
In the Americas, the Pan American Network for Drug Regulatory Harmonization (PANDHR) advanced the development of important technical guides based on WHO norms, including: Good Manufacturing Practices (GMP), Good Clinical Practices and harmonization of requirements for the registration of vaccines. Training in GMP was provided to Brazil, Argentina, Uruguay, and Paraguay. National regulatory authorities in Argentina, Brazil, Chile, Colombia, Cuba, Mexico and Venezuela are coordinating an "Informal Mechanism of Dialogue among NRAs" to implement PANDRH harmonized guidelines, participate in joint GMP inspections and incorporate new themes for discussions such as: biosimilars and pharmacoeconomics.

INNs and methodological developments

An International Nonproprietary Name (INN, generic name) is a unique name for an active pharmaceutical ingredient, which is globally recognized and constitutes public property. INNs facilitate the identification of pharmaceutical ingredients and enable exchange of information about them. INNs are also very important product identifiers in pharmacovigilance systems and their use contributes to and promotes patient safety. In 2006–2007, WHO

"Some activities undertaken by WHO are largely invisible, quietly protecting the health of every person on this planet, every day. By assigning a single international name to drugs, WHO helps ensure that a prescription filled abroad is what doctor ordered back home."

Dr Margaret Chan, Director-General
Working for Health: An introduction to WHO



INN and chemical structure for amoxicillin

assigned and published 240 Proposed INNs and 228 Recommended INNs, using standardized global consultation procedures. This is particularly important for a group of biological products whose patents and other exclusivity rights expire. Copies of these, commonly known as biosimilars or follow-on proteins are reaching the market. These "new" biological products pose a number of regulatory and safety challenges, including the use of the correct INN.

In collaboration with the Chinese Pharmacopoeia Commission, the Russian Centre for Drug Information (Pharmedinfor) and the WHO Collaborating Centre for Drug Registration and Regulation in Tunisia, all existing INNs in Chinese, Russian and Arabic were checked and, where necessary, corrected.

Essential global quality standards for medicines

Due to the demand for new global pharmaceutical norms and quality standards, the WHO Expert Committee on Specifications for Pharmaceutical Preparations now meets annually. The reports of the 41st and 42nd meetings held in 2006¹³ and 2007¹⁴, include revised and new procedures for assessing pharmaceutical and reproductive health products for procurement by

UN agencies, and for quality control laboratories. New guidance for the variations of dossiers of prequalified products and the assessment of active pharmaceutical ingredients for use in medicines were also developed. In 2006 and 2007, the Committee adopted 27 new monographs for inclusion in *The International Pharmacopoeia* for anti-malarial, anti-tuberculosis, antiretroviral and medicines for children; 11 new International Chemical Reference Standards; and a policy on how related substances will be tested in future monographs for dosage forms.

In 2006, the 4th edition of *The International Pharmacopoeia* was published in print, CD-ROM and online.¹⁵ All WHO good manufacturing practices (GMP) and related guidelines were published in one comprehensive volume¹⁶ and a study pack with training materials for GMP was developed.¹⁷ These independent quality standards and guidelines enable Member States and other parties to meet the challenges created by increasing globalization.

Prequalification of medicinal products

The WHO/UN Prequalification of Medicines Programme, supported by the Bill & Melinda Gates Foundation and UNITAID, assesses the quality, safety and efficacy of priority medicines for HIV/AIDS, tuberculosis, malaria and reproductive health. The web-based list of prequalified medicines¹⁸ is a "public good" used by UN agencies, national treatment and medicines programmes, nongovernmental organizations and national regulatory agencies as guidance in procurement and regulatory decisions. By the end of 2007, the list included about 156 individual products and related manufacturing sites. To achieve this 46 inspections and 511 assessment reports were written. During 2006–2007, 65 new products were prequalified, including 5 anti-tuberculosis and 3 anti-malarial medicines, representing a considerable increase in the choice of prequalified medicines for these diseases. A programme of field sampling and testing showed extremely low quality failure rates for prequalified products.¹⁹

Recognizing the importance of **capacity building** for manufacturers, laboratories and national regulatory authorities through training and hands-on practice, the WHO Prequalification Programme doubled the number of training workshops in 2007. Thirteen courses were organized in nine countries, training 523 participants. Since 2006, the Programme has provided practical and targeted **technical assistance** for manufacturers and quality control laboratories. In 2007 alone, the WHO Prequalification programme provided 13 technical assistance sessions in nine countries, compared to six in four countries in 2006.

Safety of medicines used in public health programmes

The detection, assessment and prevention of adverse drug reactions (ADRs) through **pharmacovigilance** improve patient care and safety. 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. In 2007, 45 ADR signals were published. By the end of 2007, the database contained nearly **4 million** case reports. **Belarus, Nepal, Suriname, Togo, Uganda** and **Uzbekistan** have increased the Programme's number of full member countries to 84 and its capacity to collect ADR reports.

Training courses and workshops in pharmacovigilance, adverse drug reactions and safety and monitoring were held in **Barbados, Botswana, Ghana, Philippines** and **Zambia**. The first pharmacovigilance training course in **French** was held in **Morocco**. As a result of the courses in Ghana, two projects for collecting data from anti-malarials have been started in **Nigeria** and the **United Republic of Tanzania**. These activities reflect the increasing international interest in **targeted pharmacovigilance** for new essential medicines for priority diseases in developing countries, such as malaria and HIV/AIDS. The programme works closely with disease programmes and is building a system of international cooperation and coordination.

Strengthening quality and safety of blood and blood products

The world's population is increasingly mobile, increasing national vulnerability to communicable disease threats. Improving cooperation among regulatory agencies on quality and safety standards for blood and blood products is urgent. A strategic plan on quality assurance and safety of blood products and related biologicals (transferred into the Department of Medicines Policy and Standards in December 2005) was agreed by the 57th WHO Expert Committee on Biological Standardization (ECBS) in 2006, as were the terms of reference for the **WHO Blood Regulators Network**. The ECBS also established WHO international biological reference standards, for the control of blood safety diagnostic tests and to improve international harmonization of safety regulations for blood products.

Efforts were made to coordinate WHO standardization activities with those of other standard-setting organizations, WHO Collaborating Centres for biological standards, and the standardization committees of international scientific 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. 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. In response a programme of work was developed to increase **access to therapeutic sera** and to strengthen quality production in developing countries.



A woman with a sick child in a rural health clinic in India, and the medicines given to the child

Supporting essential medicines selection

Training was provided in **South Africa** on the economic evaluation of medicines to be included in the national reimbursement lists. A multi-country workshop was held for countries of the **South-East Asia** region, with a particular focus on the need to include medicines for children on national lists of essential medicines. A workshop for eastern **European countries** was held in **Croatia** on the development of treatment guidelines for reproductive health, in combination with essential medicines lists. Networking among European countries on drug selection for reimbursement was supported and a regional workshop was organized with **Poland, Hungary, the Czech Republic** and **Slovakia** to exchange information and explore closer cooperation. A sub-regional standard list of essential medicines is being finalized in **Central America** as part of the sub-regional medicines policy initiative.



Essential medicines for children

Each year about 10 million children die from diseases that could be treated with access to safe and effective essential medicines. The World Health Assembly in 2007 adopted WHA resolution 60.20 calling for action to ensure 'Better Medicines for Children'. WHO together with UNICEF are taking action. Thirty years after the first WHO Model List of Essential Medicines, the Expert Committee endorsed the first **Model List of Essential Medicines for Children**. In December 2007, WHO launched 'make medicines child size'²⁰ to increase awareness and galvanize stakeholder action to address the global need for paediatric medicines.

Interagency Emergency Health Kit 2006

Thirteen UN agencies and international nongovernmental organizations endorsed the *Interagency Emergency Health Kit 2006*. This third edition takes into account the treatment of HIV/AIDS in emergency situations, increasing parasite (malaria) and antimicrobial resistance, introducing disposable syringes and needles as best practice, and practical field experience gained during use of previous versions of the kit.



Dr Hans Hagerzeil, Director of the WHO Medicines programme, in a clinic in rural China

Rational use and policy guidance

The WHO database on use of medicines in primary health care in low- and middle-income countries was updated to include all surveys published between 1990 and 2006. An analysis showed that more than half of all medicines in low- and middle-income countries are used inappropriately and that the situation is worse in the private compared to the public sector. Many countries are not implementing basic policies to encourage more rational use of medicines, such as: updated essential medicines lists and clinical guidelines, drug and therapeutic committees in most hospitals, availability of independent drug information and obligatory independent continuing medical education. This information formed the basis of the WHO Secretariat's report²¹ to the World Health Assembly in May 2007, during which Resolution WHA60.16 was adopted.

Several training courses, workshops and technical assistance to stimulate action in this area, included: two courses held in **India**, promoting rational use of drugs in the community; courses on Drug and Therapeutic Committees in **Brunei** and two provinces in **China**; promoting rational use of medicines in **14 African countries**; two courses in the **Caribbean**; a national Congress on Promoting Rational Use in **Brazil**; and support in developing and implementing clinical guidelines was given to **Armenia, Azerbaijan, Croatia, Republic of Moldova, Romania and Uzbekistan**.

In **Sudan**, a situation analysis resulted in recommendations on containing antimicrobial resistance. In the **Western Pacific Region**, an indicator-based intervention for improving rational use of medicines was initiated in **China and Mongolia**, having already been applied successfully in **Cambodia and Laos**.

In the **South-East Asia Region**, revision of the medical curriculum to improve rational use of medicines was undertaken in **India**. In **Europe**, WHO completed an external review of the clinical guidelines programmes of the National Institute for Health and Clinical Excellence (NICE) in the **United Kingdom** and participated in European Parliament discussions on development of a **Europe-wide** plan to contain antimicrobial resistance.

An inter-institutional approach to rational use of medicines is being supported in the **Americas**. **Brazil** has established a National Committee to Promote the Rational Use of Medicines. **Guatemala** has put similar mechanisms in place and other countries are also taking steps. Studies on the use of antibiotics in the community have been conducted in **Honduras, Nicaragua, Paraguay and Peru**.

In **India**, applied research projects on community surveillance of **antimicrobial resistance** found that fluoroquinolones are the most frequently used antibiotics within the community, and often used inappropriately for coughs and colds. This type of use can lead to future

resistance. A major study on adherence to ARVs in **Botswana, United Republic of Tanzania and Uganda**, 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.

Strengthening the pharmaceutical workforce

The pharmacist is an integral member of the health care team with varied functions ranging from the procurement and supply of medicines to pharmaceutical care services ensuring optimal patient health outcomes. In collaboration with the International Pharmaceutical Federation (FIP) the first edition of an innovative handbook *Developing pharmacy practice — A focus on patient care* was launched in 2006. The handbook is designed to meet the changing needs of the pharmacist, setting out a new paradigm for pharmacy practice and presents a step by step approach to pharmaceutical care within a general practice environment.

Financial situation and management

The 2006–2007 biennial budget for country, regional and headquarters work in essential medicines amounted to US\$ 61 million. By November, US\$ 59 million had been obligated, including US\$ 35.5 million (60%) 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 2007, the working budget had increased to US\$ 80 million, largely due to the increased need and funding obtained for the Prequalification Programme and the programme on Better Medicines for Children.

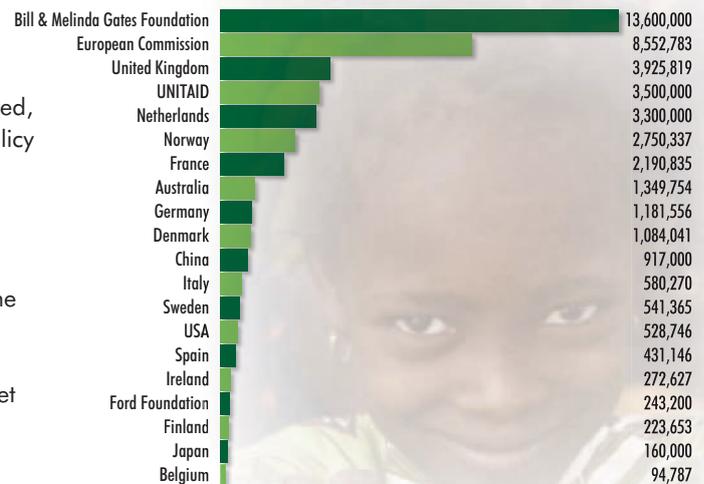
Approximately 25% of the Medicines Department biennial budget is funded through the Regular Budget, 13% through unspecified funds and 62% from specified contributions. Unspecified contributions are increasingly being channelled as “core funding” through the WHO corporate account. While the level of unspecified support has decreased over recent years there has been an increase in specified funding, such as the support received from the Bill & Melinda Gates Foundation, European Commission, The Nippon Foundation and UNITAID. While the bar graph shows the top 20 extrabudgetary donors, the contributions of all donors to the work of WHO are gratefully acknowledged. However, given the magnitude of the global pharmaceutical agenda, the medicines area in WHO remains under-funded.

Future direction

The WHO-wide **Medium-Term Strategic Plan for 2008–2013** Strategic Objective 11 addresses access, quality and rational use of all essential medical products and technologies. Development and implementation 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.

In December 2007, the decision was taken to merge the Departments of Medicine Policy and Standards (PSM) and Technical Cooperation for Essential Drugs and Traditional Medicine (TCM) into one **Department of Essential Medicines and Pharmaceutical Policies**; and to move the new department into the cluster of Health Systems and Services. These organizational reforms open the way for further integration of work in the field of medicines, and for closer coordination with health systems. Key areas for further collaboration are essential medicines as part of Primary Health Care systems, medicine financing and good governance.

Top 20 donors in 2006–2007 (US\$)



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