

The pharmaceutical scene in 2008–2009

In times of economic crisis the supply of medicines is often the first component of the health-care budget to be cut. Since January 2009 the World Health Organization (WHO) has been monitoring the health impact of the economic crisis through quarterly reports of medicine consumption and prices in over 80 countries. These data are collected by the Essential Medicines and Pharmaceutical Policies Department (EMP) in collaboration with IMS Health.

EMP has also contributed to mitigating the effects of the H1N1 pandemic. EMP was actively involved in the development of the clinical guidelines for the treatment of H1N1 influenza; a monitoring tool (PaniFlow) was developed in cooperation with Swiss regulators to monitor adverse events following immunization or the use of medicines; and key antiviral medicines were prequalified, thereby increasing competition and supplier security, and reducing the price of these medicines for low- and middle-income countries by half.

The positive effects of the merger of the two WHO medicines departments and the move of EMP to the Health Systems and Services Cluster have become increasingly apparent. The three functions of EMP (global normative work, technical support to countries and innovative public health thinking) are now fully integrated. In addition to the ongoing collaboration between the medicines programmes at headquarters, regional and country offices, several cluster-wide projects have started, such as the development of performance indicators for renewed Primary Health Care.

Meanwhile, international interest in the quality and regulation of medicines has never been so great. In addition to its continuing role in the development of new medicine quality standards and prequalification of large numbers of new products for UN procurement, WHO is now involved, together with several international donors, in a new initiative to promote regional harmonization of medicine regulatory systems within and between African regional economic communities. Many years of successful collaboration with other UN agencies active in pharmaceutical support have resulted in a situation where all agencies increasingly speak with one voice – a practical example of the concept of “One UN”.



ESSENTIAL MEDICINES

BIENNIAL REPORT 2008–2009

“The concept of essential medicines is one of the major public health achievements in the history of WHO. It is as relevant today as it was at its inception over 30 years ago.”

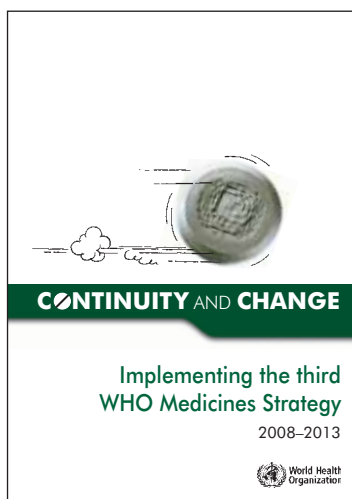
Dr Margaret Chan
Director-General
World Health Organization

KEY ACHIEVEMENTS IN 2008–2009

- Over 90 countries were supported by EMP in 2008–2009, with over 80 countries and sub-regions receiving technical support to develop, implement and monitor national medicine policies.
- The WHO/UN Medicines Prequalification Programme prequalified 84 medicines, including 14 paediatric formulations and medicines for H1N1 influenza and reproductive health.
- Global indicators for access to essential medicines were established.
- The 13th International Conference of Drug Regulatory Authorities (ICDRA) brought together over 300 representatives from 96 countries.
- The Essential Medicines Monitor was relaunched as an electronic newsletter on the web.
- The first WHO Congress on Traditional Medicine adopted the Beijing Declaration calling for further integration of traditional medicine into national health systems.
- Quarterly assessment and reporting of the impact of the financial crisis on access to essential medicines were initiated.

Continuity and change: Implementing the 3rd WHO Medicines Strategy (2008–2013)

Following the successful outcome of the previous Medicines Strategies, EMP held global consultations with many different stakeholders to prepare *Continuity and change: Implementing the 3rd WHO Medicines Strategy (2008–2013)*.



Strong data and information sharing are essential to building good policy: pharmaceutical surveys

During 2008–2009, data from the 2007 WHO Global Pharmaceutical Survey of 156 Member States on pharmaceutical sector policies and structures were analysed, and a global fact book was published. Based on this data, specific reports have been produced for the Region of the Americas, including for Caribbean countries. An assessment of the pharmaceutical sector was carried out in 2009 in the 15 Southern African Development Community countries and individual country profiles were produced. The results showed that per capita annual public expenditure on medicines varied from less than US\$ 1 to over US\$ 130. Regulation of medicines showed significant differences, for example in terms of the number of registered medicines (ranging from 4000 to 12 000)

and fees for medicines registration (from US\$ 150 to US\$ 15 000). WHO together with the European Commission Pharmaceutical Pricing and Reimbursement Information network and the Pharmaceutical Health Information System project, (1) have produced more than 20 comprehensive pharmaceutical profiles of individual European Union (EU) Member States as well as a comparative study, (2) and have also contributed to networking among EU countries on medicines reimbursement policies and cost-effectiveness evaluations of new medicines.

An in-depth pharmaceutical sector assessment was completed in 16 developing countries using WHO Level 2 survey tools. The newly developed Household Survey tool assesses access to essential medicines and patient perceptions on quality and use of medicines. Its use in eight countries has revealed that access to essential medicines remains challenging for most households in developing countries, with significant differences between rich and poor. A survey is currently under way in Jordan and the report for Uganda is already available on the EMP web site. (3)

Assessment of impact of the financial crisis

At the request of the Executive Board in January 2009, WHO has issued quarterly reports on the impact of the international economic situation on health. (4) In collaboration with IMS Health, EMP has collected data from 83 countries in each quarter comparing: consumption of all medicines, medicines for acute and chronic conditions, and branded and generic medicines; total medicines expenditure; and average medicine price per supply unit. Most countries appear to have weathered the economic recession without major changes, except in the Baltic countries, where major declines in consumption of medicines have been identified.

Technical briefing seminars

Annual general technical briefing seminars on essential medicine policies were held in English and French as well as an advanced seminar on quality and safety. The seminars were attended by 68 participants from 43 countries. All materials from the seminars are publicly available on the web for use in national and other teaching programmes. (5)

The Essential Medicines Monitor

The *Essential Drugs Monitor* which was published for more than 25 years as an important source of practical information on essential drugs was relaunched in 2009 as an electronic newsletter with a new name – the *Essential Medicines Monitor*. (6)



Essential medicines publications and documentation library

Over 30 publications, in addition to translations, periodicals and other information products were issued during 2008–2009. The EMP electronic publications and documentation library now contains over 950 medicines-related publications. In a further improvement, the search tools have been modified to make finding information easier. (7)

Country support for national medicine policy development

Development and implementation of a national medicine policy remains a fundamental building block of national essential medicines programmes, and continues to be promoted in all regions. Over 80 countries and sub-regions received technical support to assess, revise, or develop national medicine policies and implementation plans and to monitor progress, particularly in strengthening capacity for provision, use and reimbursement of medicines, in procurement and supply management, and in better regulation of medicines. A sub-regional medicine policy was developed in the Economic and Monetary Community of Central Africa. To facilitate this process, the WHO Regional Office for Africa has coordinated the revision of the Regional Guidelines for the Formulation, Implementation, Monitoring and Evaluation of National Medicine Policies. The revised guidelines include additional components such as good governance, effective medicine regulation, monitoring the impact of trade agreements on access to essential medicines, institutionalization of traditional medicine in health systems, clinical trials, and technical cooperation and harmonization. Much of this work has been supported by the European Union. In addition the AMRO/PAHO office in the Americas has supported the Andean region in the development of a sub-regional medicine policy, which was adopted by the Ministers of Health of Andean countries in 2009.

Ministers of Health of all European countries attended the June 2008 Ministerial Conference on Health Systems, and signed up to the Tallinn Charter, calling for access to and effective use of medicines through strengthened health systems.⁽⁸⁾ Similar conferences were held in other regions, including the

Americas (Buenos Aires) and Africa (Ouagadougou). Medicine policy support was provided to EU Member States and countries in Eastern and South-Eastern Europe and the Eastern Mediterranean region in analysing pharmaceutical sector policy issues and in supporting their implementation.

Countries at the core: WHO National Medicines Advisers

Over 40 National Medicines Advisers in WHO country and regional offices provide expertise and support for health policy-makers, civil society, the private sector and regulatory authorities, and build stakeholder collaboration. A 2009 review shows that countries with WHO National Medicines Advisers are more likely to: undertake pharmaceutical reforms; review existing and endorse new regulatory guidelines; carry out pricing and availability studies; have updated national drug policies and essential medicines lists; and engage in institutional and capacity building activities to strengthen health systems. This network has been strengthened and expanded to new countries with the support of the European Union and the UK Department for International Development. Collaboration with civil society has grown in the African Region. In Ghana, Kenya and Uganda the Ministry of Health, WHO National Medicines Advisers and Health Action International (HAI) Africa work together to improve the availability and affordability of medicines.⁽⁹⁾

“WHO brings the normative role, HAI Africa the consumer perspectives, and the Ministry of Health the mandate and authority to get things moving. The combination increases credibility and the chances of making things work better.”

Ministry of Health, Kenya

Transparency and good governance for medicines

Member States' interest in implementing WHO's Good Governance for Medicines (GGM) programme has exceeded expectations.⁽¹⁰⁾ This innovative initiative helps countries strengthen their health systems by increasing transparency, accountability and integrity in their pharmaceutical systems.

Launched in 2004 in four Asian countries, GGM is now a global programme implemented in 26 countries. The programme is already having a visible impact. Successes in Jordan, Malaysia, Mongolia and Thailand include improved best practices in medicine procurement, revised national pharmaceutical laws and regulations, more transparent pharmaceutical activities, information publicly available on Ministry of Health web sites, and the inclusion of good governance in university curricula. In 2009, in response to increasing demand from countries, WHO established and trained a human resources pool to provide technical support in this area.

WHO, together with the World Bank, supports the work of the complementary UK Department for International Development-led Medicines Transparency Alliance (MeTA). To date seven countries^a are involved in MeTA pilot projects with the aim of improving access to medicines through ensuring greater transparency and efficiency in pharmaceutical systems. WHO is supporting MeTA countries in efforts to collect, disclose and analyse evidence on the pharmaceutical sector and promote a more transparent and inclusive policy dialogue for improving the availability and affordability of medicines through a multi-stakeholder approach.

^a Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda and Zambia

First WHO Congress on Traditional Medicine

In 2008 WHO celebrated its 60th anniversary and the 30th anniversary of the Alma-Ata Declaration. The Alma-Ata Declaration was significant for traditional medicine as the first recognition by WHO and its Member States of the role of traditional medicine and its practitioners in primary health care. Since then the use of traditional medicine has grown. The number of Member States with a national policy on traditional medicine rose from 5 in 1990 to 48 in 2007, and the number of Member States with regulation of herbal medicines rose from 14 in 1986 to 110 in 2007.

The first global WHO Congress on Traditional Medicine was held in Beijing, China, from 7-9 November 2008. The "Beijing Declaration" adopted by 74 countries calls for the integration of traditional, complementary and alternative medicine into national health systems to strengthen primary health care. In May 2009, the World Health Assembly adopted WHA 62.13 based on the "Beijing Declaration".⁽¹¹⁾

Traditional medicine in primary health care and national health systems

Volume 4 of the WHO monographs on selected medicinal plants was published in 2009 and includes 28 monographs, bringing together important scientific information on common plants used in traditional medicine.⁽¹²⁾

The International Regulatory Cooperation for Herbal Medicines (IRCH), comprised of national regulatory authorities and regional/sub-regional bodies responsible for the regulation of herbal medicines, works to protect and promote public health and safety through improved regulation of herbal medicines. The IRCH network, which held its third annual meeting in Canada in 2009, has 22 members and eight technical working groups.

Regional and country support

In order to improve access to medicines it is essential to understand the current pharmaceutical situation in countries. In the European Region, assessments of medicines supply systems and of medicine prices versus quality of medicines were carried out in a number of countries.^a

Elsewhere, in the African Region the tool for mapping partners, financial flows to medicines, and in-depth assessment of the procurement and supply systems was used in 11 countries.^b The results of this work are being used to advocate for more coordination between partners working in the supply chain.

Over 40 countries were supported in strengthening procurement and supply management. Among them, 13 Pacific Island countries were supported through assessment of the medicines supply system; development of a training module on supply management, supervisory and monitoring visits to outer islands; and the development of a pharmaceutical management information system.⁽¹³⁾ Five African countries are also conducting quarterly monitoring of medicine prices and availability.

A number of sub-regional communities were also supported to: improve access to quality medicines through the development of common policies and regulations (e.g. Good Manufacturing Practices (GMP) in West African Economic and Monetary Union countries); establish pharmacovigilance systems (VigiCarib in the Caribbean); and carry out feasibility studies for regional procurement of medicines (East African Community, Southern African Development Community and Pacific Island countries). In Europe direct technical support was provided to many of the transitional countries^c

a Belarus, Kazakhstan, Kyrgyzstan, the Former Yugoslav Republic of Macedonia and Ukraine

b Burundi, Cameroon, Congo, Democratic Republic of the Congo, Ghana, Mali, Nigeria, Rwanda, Senegal, United Republic of Tanzania and Zambia

c Armenia, Azerbaijan, Estonia, Kazakhstan, Kyrgyzstan, Latvia, Romania, Slovakia, Tajikistan, Ukraine and the Former Yugoslav Republic of Macedonia

on strengthening the provision of medicines and streamlining reimbursement systems.

The cost of access: medicine pricing surveys, pricing policies and medicine financing

Medicine pricing and financing are important components of ensuring access to medicines. The WHO/HAI standard methodology for medicine pricing and availability 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 other sectors.⁽¹⁴⁾

In 2008, the second edition of the survey manual for measuring medicine prices and availability was launched.⁽¹⁵⁾ Pricing and availability surveys were carried out in a number of countries.^d In addition, price components studies were conducted in Ghana, Kenya and Uganda; an in-depth study of medicine procurement prices and price components was conducted in the Philippines; reviews of medicine financing and expenditures were completed in eight Pacific Island countries to determine trends, using national health account principles⁽¹⁶⁾; and other countries continue to routinely monitor prices and availability.

A number of studies on key policies impacting medicine prices and availability have been completed and policy guidance provided for improving medicine prices, availability and affordability. For example, several countries^e participated in an advanced technical briefing seminar on medicine pricing and financing; 18 countries in the Western Pacific Region participated in the regional medicine prices information exchange; an in-depth analysis was conducted on current pricing policies in China; and two

d Bolivia (Plurinational State of), Brazil, Burkina Faso, Colombia, Ecuador, Iran, Jordan, Malawi, Mauritius, Morocco, Nicaragua, Oman, Rwanda, Sao Tome and Principe, Thailand, Ukraine and Zambia

e China, India, Indonesia, Maldives and Sri Lanka



■ Countries where medicine prices and availability surveys have been conducted using the WHO/Health Action International standard methodology

regional consultations were held in Brazil on the challenges faced by middle-income countries in financing and pricing policies for newer, high-priced medicines. The Regional Office for the Americas has published guidelines and recommendations for countries to promote access, and rationalize the use of such medicines within health systems.

Global indicators for access to essential medicines

Medicine prices and availability data enabled secondary analyses across regions⁽¹⁷⁾ and internationally,⁽¹⁸⁾ revealing that poor public sector availability and unaffordable prices in the private sector can make medicine unobtainable. In 2008, WHO reported on global progress towards meeting Millennium Development Goal 8, Target 8.E: *In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries.*^(19,20) National data from price and availability surveys are included in WHO's annual World Health Statistics Report.⁽²¹⁾ The work on pricing and financing of medicines helped estimate the level of additional funding needed in order to improve access to medicines for noncommunicable diseases, mental health and parasitic diseases in the 49 lowest-income countries.

Improving access to controlled medications

The Access to Controlled Medications Programme (ACMP) was launched in 2007 to improve access to essential medicines controlled under international drug conventions. These medicines include opioid analgesics, methadone and buprenorphine for treatment of opioid dependence and abuse, a number of antiepileptic medicines and medicines used in emergency obstetrics and psychiatry. Eighty per cent of the world's population do not have access to morphine, an essential medicine to relieve moderate to severe pain.⁽²²⁾ The ACMP focuses on removing educational, policy, regulatory and supply barriers that impede access to controlled medicines. The programme is raising awareness on the extent of the problem through advocacy, therapeutic and policy guidance, and country support, and recently held a special meeting during the Eastern Mediterranean Regional Committee meeting. The programme is currently developing tools to help countries implement policy and legal changes to address these barriers.

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Combating counterfeiting of medicines

In efforts to combat counterfeiting of medicines, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), whose Secretariat is hosted by WHO, has strengthened collaboration between: national and interregional medicines regulatory authorities; national and international enforcement authorities; associations representing pharmaceutical manufacturers and wholesalers; health professionals; and patients' groups.

IMPACT's five working groups focus on: *legislative and regulatory infrastructure* – to protect and sanction against counterfeits throughout the medicine chain; *regulatory implementation* – promoting good distribution, procurement, and national assessments; *enforcement* – coordinating and strengthening operations among participating countries; *technology* – assessing



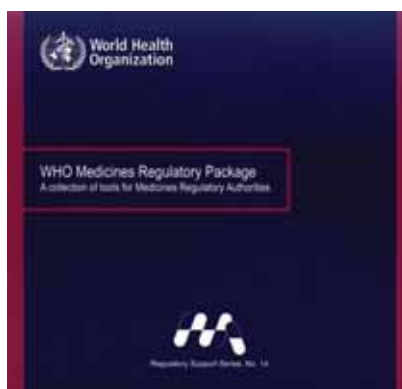
Internationally coordinated enforcement operations, carried out in cooperation with national medicines regulatory authorities, are launched in order to seize products and stop counterfeiting operations which pose a significant public health risk. Operation STORM, which began in 2009, brought together INTERPOL, WHO, the World Customs Organization and national authorities in Cambodia, China, Indonesia, Lao People's Democratic Republic, Myanmar and Viet Nam to combat counterfeit medicines. These included anti-malaria, anti-tuberculosis and anti-HIV medicines as well as antibiotics for pneumonia and child-related illnesses.

Photo © INTERPOL

technologies to prevent, deter or detect counterfeit medicinal products; and *communication* – addressing health professionals, distributors, patients, enforcement and media. In addition to working group meetings, IMPACT held its third annual meeting in Hammamet, Tunisia, in 2008.⁽²³⁾ WHO's Good Distribution Practices (GDP) have been revised and reviewed by both IMPACT and the WHO Expert Committee on Specifications for Pharmaceutical Preparations, leading to a consensus document being considered by third parties for adoption and implementation.

Complex and changing environment: regulatory support to countries

Increasing globalization and more complex manufacturing and product specifications have created additional challenges for national medicines regulatory authorities (NMRAs) and manufacturers. This requires that national regulatory capacity is regularly assessed using a standardized WHO tool. During 2008-2009 assessments were performed on 20 NMRAs.^a



To support the work and decision-making processes of NMRAs a Model Medicines Regulatory Package was developed, field-tested and implemented in seven African countries as a tool for exchange of regulatory information and for building regulatory capacity.⁽²⁴⁾

Given the continuous learning needs of NMRA staff, WHO delivered training courses on the assessment of quality, safety and efficacy in the marketing authorization process in all WHO regions, involving participants from over 50 countries.

The African Medicines Regulatory Harmonization Initiative has been established to address the increased responsibilities placed on national regulatory systems. WHO is working with the Bill & Melinda Gates Foundation, the Clinton Foundation and UK Department for International Development to improve health in Africa by increasing the availability of medicines that meet safety, efficacy and quality standards through medicines regulatory harmonization. The issue was discussed at a pre-meeting of the second African Medicines Regulators Conference which brought together 54 heads and staff of NMRAs of 40 countries.

WHO continued to work closely with NMRAs from developing and developed countries from all WHO regions in supporting information exchange and knowledge transfer. Cooperation with regional networks such as DRUGNET has facilitated the provision of regulatory support to many countries.^b Training was offered to inspectors in conducting GMP inspections, while quality control laboratories have received training in GMP in laboratory practice. Capacity building workshops were organized with regulators on new pharmaceutical legislation – in line with EU legislation – and a workshop was organized on regulating medicines promotion.

Building networks and information exchange: 13th International Conference of Drug Regulatory Authorities

The 13th International Conference of Drug Regulatory Authorities

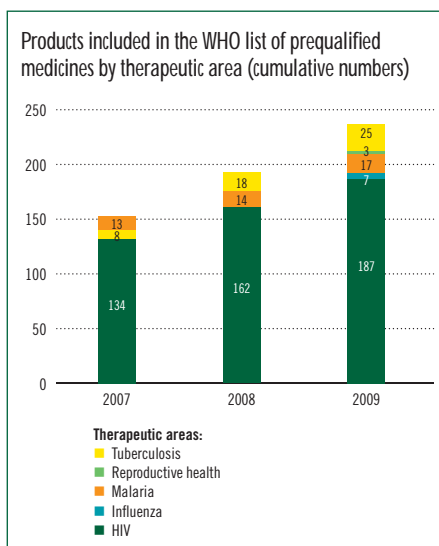
(ICDRA) brought together over 300 representatives from 96 countries.⁽²⁵⁾ During the week-long meeting regulators discussed and adopted recommendations for assuring the quality, safety and efficacy of medical products including: better collaboration and information exchange among regulators; safety and pandemic preparedness; strategies to fight counterfeit medicines; innovative ways of regulating medicines for children; and regulation of blood products, biosimilars and radiopharmaceuticals. A pre-meeting on Better Medicines for Children focussed on the regulatory challenges and opportunities to improving access to safe, quality medicines for children. The next ICDRA will be held in Singapore in 2010.⁽²⁶⁾

Prequalified medicines: value for money

The WHO/UN Prequalification of Medicines Programme ensures the quality of many of the medicines being used to meet the demand for treatment for HIV/AIDS, tuberculosis and malaria in developing countries. It also helps to maximize the use of funding for these treatments by stimulating quality generic medicines supply and competition. During 2008-2009, the Programme prequalified 84 medicines, including 14 paediatric formulations, and its first reproductive health and influenza products. Additionally, nine laboratories were prequalified and 32 training workshops were organized for 659 manufacturers, 583 regulators, and 54 laboratory staff. A new business plan for the Programme completed by PricewaterhouseCoopers will help direct the programme in the coming years. The plan comments, "It is clear that in the context of today's disease landscape the Programme has a vital, pivotal and ongoing role" and projects an economic return on investment of 170:1 for the period 2009–2013.

^a Argentina, Bangladesh, Benin, Burundi, Central African Republic, Chile, Colombia, Cuba, Congo, Democratic Republic of the Congo, Djibouti, Egypt, Gabon, Kyrgyzstan, Niger, Seychelles, Sudan, Turkmenistan, Uganda and Yemen

^b Inspections training: Armenia, Belarus and Kazakhstan; GMP laboratory practice training: Azerbaijan and Kyrgyzstan; legislation capacity building: Bosnia Herzegovina and Montenegro; and in Poland a workshop was organized for neighbouring countries on regulating medicines promotion



The majority of prequalified medicines are currently manufactured in the WHO South-East Asia Region. However, it is anticipated that medicines prequalification activities will expand in other regions, such as the WHO Eastern Mediterranean Region, and that prequalification of quality control laboratories will expand in the WHO Americas Region. Elsewhere, in the Western Pacific Region the medicines prequalification team will work with the WHO China Country Office, with a particular focus on improving the quality of fixed-dose combination antituberculosis medicines.

What's in a name? INNs and methodological developments

This is a unique and essential function of WHO, as no new medical products can be marketed without an International Nonproprietary Name (INN) assigned by WHO. An INN is a generic name assigned to an active pharmaceutical ingredient, either chemical or biological, which is public property and globally recognized. INNs facilitate the exchange of information among all parties involved in medicines research, production, regulation and use and are important product identifiers in pharmacovigilance systems. In 2008-2009, WHO assigned and published 254

Proposed INNs (172 chemicals and 82 biologicals) and 255 Recommended INNs (177 chemicals and 78 biologicals), through a broad consultative process.^a An INN nomenclature scheme has been adopted for monoclonal antibodies (mAbs). The new web-based INN Integrated Data Management Information System enables online INN consultation and an integrated publication process.

Production, control and regulation of snake antivenoms

The lack of effective snake antivenoms to treat the specific types of envenomings encountered in various regions of the world is a critical but neglected global health issue. A new WHO Guideline for the Production, Control and Regulation of Snake Antivenom Immunoglobulins helps manufacturers and regulators ensure that only good quality, effective antivenoms reach patients. While global and regional consultations have highlighted the issue, and training and technical assistance were provided to regulatory authorities and manufacturers from 34 countries, more effort is needed to overcome the shortage of quality products.



Papuan taipans (*Oxyuranus scutellatus*) are found in southern Papua New Guinea and south-eastern West Papua Province, Indonesia. They have one of the world's most potent venoms, causing haemorrhage and irreversible neurotoxic paralysis. Without medical treatment the fatality rate is 100%. Antivenom is manufactured in Australia.

Photo © David Williams, WHO

Essential global quality standards for medicines

The WHO Expert Committee on Specifications for Pharmaceutical Preparations meets annually to respond to the demand for new global pharmaceutical norms and quality standards. The reports of meetings held in 2008⁽²⁷⁾ and 2009,⁽²⁸⁾ include 11 new and revised quality assurance guidelines for GMP topics, including guidelines for sterile products, active substances and products containing hazardous materials. In addition, the GDP and Good Practices for Quality Control Laboratories were revised. Guidelines for the preparation of a Contract Research Organization Master File (CROMF), requalification of prequalification dossiers and regulatory guidance on stability testing requirements were also finalized. These independent quality standards and guidelines enable WHO Member States and other parties to meet the challenges of increasing globalization, and are implemented and used within the WHO/UN Prequalification of Medicines Programme. Altogether 66 monographs of new essential medicines have been finalized for inclusion in *The International Pharmacopoeia*, including medicines for HIV and related conditions, malaria and tuberculosis; medicines such as oxytocin, mebendazole and oseltamivir phosphate, with respective dosage forms; radiopharmaceuticals; and numerous monographs that apply to paediatric formulations. The WHO guidelines for regulatory guidance on stability testing are now on the national regulatory authority web sites of Europe, Japan and the USA, underlining the recognition of WHO as the global standards-setting organization and marking a significant step towards harmonization of regulatory requirements.⁽²⁹⁾

^a As requested by the INN Revised Procedure (EB115/11, December 2004)

Safety of medicines used in public health programmes

The detection, assessment and prevention of adverse drug reactions 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 adverse drug reactions signals via a global electronic database. In 2008-2009, 30 ADR signals were published. By the end of 2009, the database contained over 5 million case reports. With the addition of seven new countries the Programme now has 96 full member countries and an increased capacity to collect adverse drug reactions reports.^a

Training courses and workshops on pharmacovigilance, and adverse drug reactions and their monitoring were held in both English and French.^b Following the courses in Ghana, two Cohort Event Monitoring Programmes have provided safety information on antimalarial medicines.^c PaniFlow, a new tool for monitoring adverse events – either vaccine- or medicine-related – during influenza pandemics, has been developed by the Uppsala Monitoring Centre together with Swissmedic, and is being made available for all countries using vaccines donated by WHO.

Strengthening quality and safety of blood and blood products

Blood products and associated diagnostics help save millions of lives every year. (Blood products are defined as any therapeutic substances derived from human blood, including whole blood, labile blood components and plasma-derived medicinal products). It is

essential that these products and technologies are of good quality, safe, effective and available. WHO works with Member States towards the goal of strengthening regulatory systems to ensure that only blood-derived medicines of assured quality are used in national health systems.

WHO biological reference preparations for blood products and related in vitro diagnostics provide guidance for national regulatory authorities and manufacturers on the production and quality control of safe and effective products. During 2008-2009 reference preparations for hepatitis B genotypes were developed, which will help improve the quality of hepatitis B diagnostic and tracking devices. Reference materials for blood products and the diagnosis of genetic diseases such as haemophilia were also established. Additionally, 18 new or replacement global reference preparations were developed, providing a benchmark for industries to develop diagnostics and for regulators to control them.⁽³⁰⁾

A number of medicinal products derived from blood and plasma are included in the WHO Model List of Essential Medicines. Regional workshops to help strengthen the capacity of developing countries to manufacture life-saving plasma-derived medicinal products were held in the Eastern Mediterranean Region, involving 16 countries.

Academic awards to EMP staff

Dr Richard O. Laing received an Honorary Doctorate of Science of the University of Utrecht (the Netherlands) on 26 March 2009, for his achievements in promoting international public health. This is a rare honour as the nearly 400-year old university awards only two honorary doctorates per year.

Dr Hans V. Hogerzeil received the 2008 Public Service Award of the Institute of Genomics of the University of North Carolina at Chapel Hill (USA) on 2 October 2008, in recognition of his contribution towards the promotion of national medicine policies based on the concept of essential medicines.

Supporting essential medicines selection

During 2008 the WHO Model List of Essential Medicines for Children (EMLc) was reviewed by the second meeting of the Subcommittee on medicines for children and progress was made on tuberculosis medicines for children. The meeting of the 17th Expert Committee on the Selection and Use of Essential Medicines updated the EML and reviewed the work of the Subcommittee. As a result two new EMLs were published, the general EML and the 2nd EMLc.

Essential medicines list development and revision is regularly supported by WHO. Specific training on the economic evaluation of medicines to be included in national reimbursement lists and medicines selection was organized with health authorities in a number of countries,^d and WHO actively supports the exchange of information and experience on medicines selection for reimbursement schemes. A regional workshop in South-East Asia focussed on the need to include medicines for children on national lists of essential medicines.



a Botswana, Madagascar, Montenegro, Namibia, Saudi Arabia, Senegal and Sudan

b Ghana, Mozambique, Sierra Leone, Switzerland and the United Republic of Tanzania. The second and third pharmacovigilance training courses in French were held in Morocco

c Nigeria and the United Republic of Tanzania

d Latvia, Estonia, Slovakia; and European Union

Getting the most out of medicines: improving their use and containing resistance

Promoting rational use of medicines by prescribers and consumers can generate health gains and financial savings. 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 2008, and findings from an analysis of the database were published.⁽³¹⁾ The 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 sector than in the public sector.

More than half of all medicines in low- and middle-income countries are used inappropriately.

Work on developing a rapid appraisal tool for national stakeholders to assess their own health systems started in 2009. The assessments will be the basis for evidence-based recommendations on health system strengthening and reform for inclusion in national health plans.

Recent findings show that community-based surveillance of antimicrobial resistance in resource-constrained settings is possible but that substantial capacity building is required. Baseline data showed high levels of resistance and inappropriate antibiotic use.⁽³²⁾ Studies in India revealed that inappropriate pharmaceutical promotion, commercial pressures and patient demand were contributing to antibiotic overuse and a sector-wide intervention is proposed to improve this situation.

Country support

Over 30 countries have been supported to improve rational use of medicines and address antimicrobial resistance through the development of essential medicines lists, standard treatment guidelines and national action plans and strategies. Support has also been given for health worker training, support to drug and therapeutics committees, the creation of medicines information centres, and information campaigns for consumers.



Essential medicines for children: accomplishments and next steps

Together with UNICEF and other partners WHO has made progress towards improving access to children's medicines to treat the major diseases which account for most child deaths.⁽³³⁾

Strengthening the pharmaceutical workforce

Despite its critical importance, information about the pharmaceutical workforce in developing countries is often scarce or non-existent. This lack of comprehensive data often results in a gap in national human resources policies. WHO is working with its Regional Offices for Africa and for the Eastern Mediterranean and the International Pharmaceutical Federation (FIP) to fill this gap in evidence. A survey on human resources for the pharmaceutical sector has been carried out in four African countries and is under way in a fifth.^a The results will be used to develop a human resources framework for the pharmaceutical sector.

A literature review on the competencies, training and workforce requirements of health workers involved in medicines supply management in Pacific Island countries was undertaken as a basis for the development of training modules on supply management.

Promote research and development of essential medicines for children:	
<p>Done:</p> <ul style="list-style-type: none"> ✓ "Missing" essential medicines for children identified ✓ Ideal dosage forms for children defined 	<p>To do:</p> <ul style="list-style-type: none"> ☐ Build global consensus for standards of conducting research involving children ☐ Promote an increase in the number of quality clinical trials involving children
Filling knowledge gaps:	
<p>Done:</p> <ul style="list-style-type: none"> ✓ Evidence for optimal use of antibiotics in children established ✓ Optimal doses for medicines to treat tuberculosis in children defined ✓ EML reviewed to identify which medicines are safe and effective for use in children 	<p>To do:</p> <ul style="list-style-type: none"> ☐ Identify medicines to recommend for treating pain and chronic diseases in children ☐ Learn what parents and child-care providers think about giving medicines to children and their preferences for dosage forms and use
Promote access to medicines for children:	
<p>Done:</p> <ul style="list-style-type: none"> ✓ EMLc developed to advocate for purchasing and supply changes ✓ Survey of access and availability of medicines for children completed 	<p>To do:</p> <ul style="list-style-type: none"> ☐ Promote country level adoption of EMLc ☐ Encourage changes in medicine policy and purchasing at the national level
Promote better use of medicines in children:	
<p>Done:</p> <ul style="list-style-type: none"> ✓ Identify interventions shown to improve use of medicines in children 	<p>To do:</p> <ul style="list-style-type: none"> ☐ Determine why medicines for children are not properly prescribed and used in two pilot countries

^a Ghana, Nigeria, Sudan, United Republic of Tanzania and Rwanda respectively.

Country support in the field of Essential Medicines, 2008–2009

- Part-time WHO medicines adviser
 - Full-time WHO medicines adviser
 - Advocacy (1–2 nationals attended an international meeting and/or <\$25,000 activity budget for this subject in the country)
 - Support (3 or more nationals attended an international meeting and/or > \$25,000 activity budget for this subject in the country)
- NPO National Professional Officer
 P National policies on access, quality and use of essential medicines
 S National procurement and/or supply systems
 B National strategies and regulatory mechanisms for blood and blood products and/or infection control
 Q National regulatory authorities have been assessed and/or supported
 R Promoting sound and cost-effective use of medical products and/or technologies

COUNTRY	NPO	P	S	B	Q	R
Afghanistan						
Albania						
Algeria						
Andorra						
Angola						
Antigua						
Argentina						
Armenia						
Australia						
Austria						
Azerbaijan						
Bahamas						
Bahrain						
Bangladesh						
Barbados						
Belarus						
Belgium						
Belize						
Benin						
Bhutan						
Bolivia						
Bosnia and Herzegovina						
Botswana						
Brasil						
Brunei Dar						
Bulgaria						
Burkina Faso						
Burundi						
Cambodia						
Cameroon						
Canada						
Cape Verde						
Central Africa						
Chad						
Chile						
China						
Colombia						
Comoros						
Congo						
Cook Islands						
Costa Rica						
Cote d'Ivoire						
Croatia						
Cuba						
Cyprus						
Czech Republic						
Denmark						
Djibouti						
Dominica						
Dominican Republic						
DPR Korea						
DR Congo						
Ecuador						
Egypt						
El Salvador						
Equ. Guinea						
Eritrea						
Estonia						
Ethiopia						
Fiji						
Finland						
France						
Gabon						
Gambia						
Georgia						

COUNTRY	NPO	P	S	B	Q	R
Germany						
Ghana						
Greece						
Grenada						
Guatemala						
Guinea						
Guinea Bissau						
Guyana						
Haiti						
Honduras						
Hungary						
Iceland						
India						
Indonesia						
Iran						
Iraq						
Ireland						
Israel						
Italy						
Jamaica						
Japan						
Jordan						
Kazakhstan						
Kenya						
Kiribati						
Korea, Republic of						
Kuwait						
Kyrgyzstan						
Lao PDR						
Latvia						
Lebanon						
Lesotho						
Liberia						
Libya						
Lithuania						
Luxembourg						
Madagascar						
Malawi						
Malaysia						
Maldives						
Mali						
Malta						
Marshall Islands						
Mauritania						
Mauritius						
Mexico						
Micronesia						
Monaco						
Mongolia						
Montenegro						
Morocco						
Mozambique						
Myanmar						
Namibia						
Nauru						
Nepal						
Netherlands						
New Zealand						
Nicaragua						
Niger						
Nigeria						
Niue						
Norway						
Oman						
Pakistan						

COUNTRY	NPO	P	S	B	Q	R
Palau						
Palestinian SRA						
Panama						
Papua New Guinea						
Paraguay						
Peru						
Philippines						
Poland						
Portugal						
Qatar						
Republic of Moldova						
Romania						
Russian Federation						
Rwanda						
St Vincent & the Grenadines						
Samoa						
San Marino						
Sao Tome & Principe						
Saudi Arabia						
Senegal						
Serbia						
Seychelles						
Sierra Leone						
Singapore						
Slovakia						
Slovenia						
Solomon Islands						
Somalia						
South Africa						
Spain						
Sri Lanka						
St Kitts & Nevis						
St Lucia						
Sudan						
Suriname						
Swaziland						
Sweden						
Switzerland						
Syria						
Tajikistan						
Tanzania						
Thailand						
FYR Macedonia						
Timor Leste						
Togo						
Tonga						
Trinidad & Tobago						
Tunisia						
Turkey						
Turkmenistan						
Tuvalu						
United Arab Emirates						
Uganda						
Ukraine						
United Kingdom						
United States						
Uruguay						
Uzbekistan						
Vanuatu						
Venezuela						
Vietnam						
Yemen						
Zambia						
Zimbabwe						

Financial situation and management

The essential medicines programme is part of WHO Strategic Objective 11 (SO-11): *To ensure improved access, quality and use of vaccines, medicines and health technologies*. The biennial global budget for SO-11 was US\$ 178.3 million, of which US\$ 153.7 million (86%) was funded and US\$ 130.6 million (73%) implemented. In the global budget, US\$ 95.2 million (54%) was planned for global normative functions and US\$ 83.1 million (46%) for country support activities. The global normative components under SO-11 were fully awarded but only 74% of regional and country budgets could be resourced, reflecting the fact that few donors and regional offices are interested in funding country support activities under SO-11. As a result, US\$ 81.0 million (62%) of actual expenditure was on global normative functions and US\$ 49.6 million (38%) on country support.

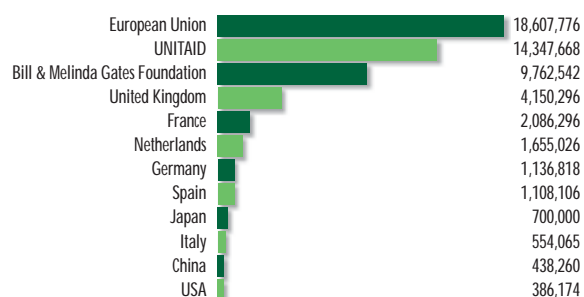
The approved budget for 2008–2009 for the Essential Medicines and Pharmaceutical Policies department at Headquarters was US\$ 53.6 million, of which US\$ 45.5 million (85%) was implemented. About 15% of the department’s budget was funded from Regular Budget (US\$ 6.8 million), 15% from unspecified (core voluntary) contributions (US\$ 6.8 million) and 70% from specified (project) contributions (US\$ 31.9 million). Separate expenditure figures for medicines work within SO-11 at the regional and country level are not available.

While the bar graph opposite shows the top donors for specified funding, the work of the Essential Medicines and Pharmaceutical Policies department is made possible through the contributions of many additional donors and through the in-kind support of a large number of Collaborating Centres, national quality control laboratories, regulatory and health authorities, and an extensive network of experts.



The Global Medicines Council brings together the six Regional Medicines Advisers with the EMP Director and five team coordinators from Geneva, to review all major pharmaceutical policy issues. In April 2009 the meeting was held in the Regional Office for the Americas in Washington. Standing left to right: Zafar Mirza (Eastern Mediterranean), Richard Laing (Medicine Information and Evidence for Policy), Budiono Santoso (Western Pacific), Krisantha Weerasuriya (South-East Asia), Lembit Rago (Quality and Safety: Medicines), Clive Ondari (Medicine Access and Rational Use) and Kees de Joncheere (Europe). Sitting left to right: Jean-Marie Trapsida (Africa), Gilles Forte (Medicine Programme Coordination), Hans Hogerzeil (Director, EMP), James Fitzgerald (Americas) and Xiaorui Zhang (Traditional Medicine). Photo © WHO

Top donors of specified funds 2008–2009 (US\$)



The chart shows the voluntary funds EMP had available for spending in 2008-2009 for all programmes in HQ and regions/countries. These figures differ from those reported in the previous biennium in the following ways: the source of unspecified funds is not included as it is no longer known to us; the figures include specified pledges for 2008-2009, carry over of specified funds available from the previous biennium, secondments and in-kind contributions, as well as programme support costs which are managed centrally by WHO.

Future direction:

Continuity and Change

The next biennium will see more results from a mature department operating within a logical organizational framework. The title of the new WHO Medicines Strategy for 2008-2013, *Continuity and Change*, reflects both the challenges and the opportunities ahead. Many of WHO’s global normative functions should be continued and defended in a situation of ever-reducing general income. Technical country support is also greatly valued by Member States – and yet mobilizing the necessary donor funds remains a challenge.

At the same time new initiatives must be developed in response to changing needs, such as technical guidance to district hospitals and medicine reimbursement as part of social health insurance. Activities in promoting good governance in medicine registration and supply will also continue, as well as work in support of medicine price monitoring and pricing policies, and medicine regulatory harmonization in Africa. In general terms more emphasis will be put on promoting equity, transparency, accountability and good governance. These objectives remain very much in line with the promotion of access to essential medicines as part of the fulfilment of the right to health, and as a condition for universal access to people-centred health care.



National Medicines Advisers met with staff from WHO headquarters and regions in Geneva in October 2009. Photo © E. Georget, WHO

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

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