Annual Report

Essential Drugs and Medicines Policy

2003
The year in focus: medicines for HIV/AIDS, tuberculosis and malaria

In 2003, the number of people living with HIV/AIDS reached 38 million, 9 million developed tuberculosis (TB), while malaria inflicted 300 million cases of acute illness. Sometimes these diseases combine to deal a double blow: HIV fuels the TB epidemic in ways that were unimaginable 20 years ago.

Roll Back Malaria, Stop TB and, more recently, the 3 by 5 effort to get antiretroviral treatment to 3 million people by the end of 2005, each represent the determination of WHO and its partners to fight back — to slow if not halt the suffering, loss and economic declines caused by these diseases.

Essential medicines underpin these efforts. They prolong and improve quality of life for people living with HIV/AIDS. They cure TB and malaria. But they need to be affordable, of good quality and used properly in the right dosage at the right time.

Knowledge and capacity exist

Twenty-six years of promoting and implementing the essential medicines concept mean that WHO has developed the most diverse and extensive concentration of essential medicines expertise in the world. The organization can advise on getting good-quality medicines to where they are needed, and how to get them administered and taken correctly. This in turn means generating the capacity to implement a national medicines policy, developing expertise in supply chain management, transferring knowledge of pharmaceutical norms and standards, making information on sources and prices freely available, strengthening regulatory capacity, and promoting good prescribing skills.

Yet for far too many people, essential medicines remain unaffordable. Sophisticated counterfeit medicines are a real danger. Confusion remains about what medicines supply systems work best and where. Quality and safety issues threaten treatment regimes and patient health. But as this report shows, solid progress is being made.

Progress is indeed possible as a result of the sustained support and collaboration of WHO’s partner agencies, governments and nongovernmental organizations.

More over, the momentum, energy and passion generated around medicines for fighting HIV/AIDS, malaria and TB will be channelled into other ongoing efforts to ensure that all essential medicines reach the people who need them.
WHO is pioneering a “hierarchical” approach to monitoring medicines policy impacts at country level. Level I consists of a structured national pharmaceutical situation questionnaire and Level II consists of a systematic survey of health facilities and pharmacies. By moving from the general to the particular, the potential for making effective medicines policy decisions is increased.

In 2003, 145 countries completed the national pharmaceutical situation questionnaire. The questionnaire can be rapidly and easily completed with information collected mostly from health ministries and departments, and medicines regulatory authorities. Analysis of the 2003 questionnaire results has indicated which countries would benefit most from increased WHO support for medicines activities.

Are countries implementing and updating their national medicines policies?

Questionnaire results showed that countries that have updated their national medicines policy (NMP) within the previous 10 years increased from 49 in 1999 to 57 in 2003, and that 16 countries succeeded in moving from a draft NMP document in 1999, to an official NMP in 2003. But nine countries have still not managed to turn their draft NMP documents into official NMP documents. Implementation is progressing, though — whereas only 40% of countries had developed an NMP implementation plan in 1999, this figure had increased to 52% by 2003.

How do we know if NMP implementation is effective? By monitoring levels of access to medicines, and how rational those medicines are being procured, paid for and used. Questionnaire results have given both cause for optimism, and a strong indication that greater efforts must be made by countries and their international partners to enhance medicines impact for public health.

Where are we in terms of access?

WHO is tracking the number of countries where more than 50% of the population has previously been reported as having no regular access to medicines. Questionnaire results showed that 11 of the countries surveyed (seven of which are in Africa) that reported less than 50% regular access in 1999, now report more than 50% access. However, five countries reported regular access as having declined from more than 50% in 1999 to less than 50% in 2003.

Strategies to improve access to medicines include: public financing; generic procurement; health insurance; and appropriate procurement and medicines management schemes. Data collected showed that Eritrea, Mongolia and Sudan have all increased per capita public medicines expenditure to more than US$ 2.00, while in Bahamas and Belize, the increase was substantially higher. Fourteen countries that had not stipulated generic substitution in private pharmacies by 1999 had done so by 2003, while Benin, Guinea, Rwanda and Samoa have adopted public health insurance schemes that reimburse medicines expenditure. A further 11 countries now limit public procurement to medicines on their essential medicines lists. These include three countries in the Americas and three countries in Africa.

Rational to what extent?

Standard treatment guidelines, essential medicines lists (EMLs) and medicines information centres, each contribute significantly to ensuring that medicines are used to best effect, both therapeutically and financially. In 1999, only 23 countries reported having updated their standard treatment guidelines within the previous five years, but by 2003 this figure had risen to 31. And while in 1999 only 35 countries reported having medicines information centres that provided medicines information both to prescribers and dispensers, a further seven countries had established such an information centre by 2003. Still, the figures suggest that greater effort needs to be put into encouraging many other countries to make available the...
to be compared across different years, areas of concern to be pinpointed and progress to be monitored.”

She notes that, “the culture of monitoring is quickly gaining ground. Before it was difficult to motivate countries to do assessments and monitoring to find out whether people are accessing medicines, where they are accessing them, and if they aren’t able to do so, why not. But countries increasingly understand the benefits of collecting such data, and the impetus it gives to health policy-makers and managers to undertake further NMP development and implementation.”

Results can be both encouraging and discouraging, pointing to the difficulties involved in tackling medicines issues. In the Philippines, the cost of treatment in many public health facilities (PHF) is lower than that available in private retail outlets. However, only one-third of essential medicines are available at all in PHFs, and are frequently out of stock. Moreover, only 20% of the PHFs use standard treatment guidelines and not one health facility had an EML. The negative results might be attributable to decentralization, which appears to have slowed NMP implementation.

Monitoring progress in the Americas

In 2003, the WHO Regional Office for the Americas/Pan American Health Organization (AMRO/PAHO) organized a regional Level II/systematic survey training workshop in the Dominican Republic. Participant countries — Bolivia, Brazil, the Dominican Republic, El Salvador, Honduras, Nicaragua and Venezuela, and a representative of the Caribbean — developed an implementation plan for country pharmaceutical assessment and monitoring using Level II indicators.

Level I monitoring had already produced some interesting results. Analysis of the responses indicated areas in which WHO and countries need to focus greater effort. For example, only 11 of the 24 countries that responded indicated that they have a national strategy to combat antimicrobial resistance. And despite increasing use of medicinal plants, most of the countries do not yet include medicinal plants in their national medicines lists.

But questionnaire responses revealed some encouraging signs of progress too. Procurement of essential medicines only by the public sector had increased from 33% in 1999 to 50% in 2003. Several countries have increased their capacity to test the quality of medicines available on their markets. In 1999, only 54% of official laboratories were involved in testing quality control, but by 2003, this figure had risen to 70%. However, the number of samples tested varies widely from country to country, demonstrating that there is still a need to build national capacity to run a systematic and self-financed programme of quality control testing as a key element of national medicines quality assurance.

Medical schools increasingly include essential medicines in their curricula. In 1999, only 25% of medical schools did so. But by 2003, the figure had grown to 41%. Drug information centres are more widely appreciated, and both generic prescription and generic substitution have increased since 1999.

Commented Dr Rosario d’Alessio, AMRO/PAHO’s regional adviser for pharmaceuticals, “The assessments are vital not only for WHO identification of priorities for technical assistance, but also to enable systematic documentation of country-level progress and shifts in pharmaceutical sector priorities.”

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In the Islamic Republic of Iran, survey data revealed that prescribing of medicines is excessive and that the average number of medicines per prescription is high. The Ministry of Health has responded by establishing a rational use centre to promote and monitor rational use of medicines.

Monitoring has highlighted many other areas requiring improvement at national level. In Nigeria, assessment of facilities showed inadequate record-keeping, especially at primary health care level. Thus although 46% of key medicines were available at public health facilities, 7% of them had expired. By comparison, no expired medicines were found on the shelves in private drug outlets.

Results also sometimes indicate when national medicines targets are not being met. In Ethiopia, the national average for availability of key essential medicines in health facilities was 70%, 85% and 91% for public health facilities, regional medicines stores and private medicines retail outlets respectively. The figures are lower than the 100% target set out in the Health System Development Plan.

Priorities for 2004

WHO aims to further institutionalize medicines policy monitoring. It will also encourage use of monitoring results in the planning and implementation of national programmes, and of WHO medicines activities at country and regional levels.

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WHO pharmaceutical situation data can be accessed at: http://mednet.who.int


“In many ways the challenges remain the same. But the knowledge about how to tackle them is improving. If this knowledge was to be combined with political will and enough resources to put policy into practice, WHO could without doubt achieve its medicines objectives,” comments Dr Guitelle Baghdadi. As programme officer in essential drugs and medicines policy at WHO Headquarters, she coordinated a global process leading to the WHO Medicines Strategy 2004–2007.

Five key working groups composed of WHO staff in Headquarters, WHO regions and countries together reviewed medicines challenges and planned WHO responses for addressing them during 2004–2007.

Dr Baghdadi continues, “The new strategy is coherent and easy to follow. We have also included some new areas that were not included in the previous strategy (WHO Medicines Strategy 2000–2003), reflecting the evolution of the environment in which we work. So access to essential medicines as a human right, the promotion of ethical practices in the pharmaceutical sector, the UN prequalification project, our work with the Global Fund, and the promotion of innovation based on public health needs, but especially for neglected diseases, are all now covered.”

The new strategy retains the same four core objectives as the previous strategy (policy; access; quality and safety; and rational use), which are divided into components and expected outcomes, with a clear indication of what is needed in countries to turn WHO’s vision for medicines into reality.

Progress in medicines work will continue to be tracked via a set of country progress indicators. The strategy can be accessed at: http://www.who.int/medicines/strategy/stmission.html.

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The WHO Medicines Strategy 2004–2007 provides guiding principles for medicines activities at country, regional and global levels

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Highlights of WHO work in traditional medicine in 2003

- A global survey of national policy on traditional medicine and regulation of herbal medicines was carried out to: obtain baseline information; assess the impact of the WHO Traditional Medicine Strategy to date; and identify the technical support needs of Member States. Analyses of the survey results and summaries have been prepared for easy consultation. This activity was supported by Japan’s Nippon Foundation. Many other new partners are working with WHO to implement the strategy. In 2003, they included the Regional Government of Lombardy, Italy and the Prince of Wales’s Foundation for Integrated Health.

- A series of regional workshops — supported by the Luxembourg Government — was held to familiarize national regulatory authorities with herbal medicine quality and safety issues, and requirements for registration. More than 60 countries from all six WHO regions participated in the workshops.

- WHO Guidelines on Good Agricultural and Collection Practices for Medicinal Plants were published to promote herbal medicine quality control through good agricultural practices and sustainable collection of medicinal plants.

- A WHO Consultation was held in Milan, Italy in December, to finalize the WHO Guidelines for Developing Consumer Information on Proper Use of Traditional Medicine and Complementary/Alternative Medicine, with support from the Regional Government of Lombardy, Italy.

- Organized largely by the WHO African Regional Office, the first African Traditional Medicine Day was held in August, highlighting the role and value of traditional medicine in African culture.

- The third meeting of the WHO African Regional Expert Committee on Traditional Medicine was held in South Africa to: share country experience regarding traditional medicine R&D for treatment of HIV/AIDS, malaria, sickle cell anaemia, diabetes and hypertension; review draft guidelines for conducting clinical observation studies of use of traditional medicine; review draft guidelines on research methodology for evaluating the quality, safety and efficacy of traditional medicine in Africa; and review a regional framework on intellectual property rights for the protection and benefit-sharing of traditional medicine knowledge and the use of Africa’s biodiversity.

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His Royal Highness the Prince of Wales, President of the Prince of Wales’s Foundation for Integrated Health meets Dr Xiaorui Zhang, team coordinator of the traditional medicine team at WHO Headquarters.
WHO medicines advisers are now working in 11 WHO country offices in Africa. Their task is to work with ministries of health and other stakeholders to plan, implement and monitor national medicines policies. Their ultimate goal is to improve access to and rational use of good-quality essential medicines, especially those for treating HIV/AIDS, tuberculosis and malaria.

During 2003, the medicines advisers supported their respective ministries of health in conducting baseline surveys of the pharmaceutical sector. Through these surveys, national capacity in monitoring and evaluation was greatly strengthened. Ogori Taylor, medicines adviser for Nigeria (see box), comments that, in the case of Nigeria, the pharmaceutical sector review was extensively referred to during revision of the national medicines policy.

In Ghana, Kenya and Uganda the baseline surveys were implemented with the support of the Regional Collaboration for Action on Essential Medicines in Africa. This is a programme that is jointly implemented by WHO and Health Action International Africa (a network of civil society organizations). The Collaboration provides intensified support to increase the coordination and participation of ministries of health, civil society and WHO in planning, implementing, and monitoring medicines policies and programmes.

As well as the baseline surveys, the Collaboration has supported a number of activities related to pricing and intellectual property issues. In 2003, the Collaboration and WHO medicines adviser for Uganda, Joseph Serutoke (see box), provided technical and financial support to the Uganda Coalition for Access to Essential Medicines, to host a national stakeholder workshop on “promoting public health through patent legislation”.

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Medicine prices — measuring the difference

“If you have a peptic ulcer and require a month’s treatment, the originator brand version of ranitidine will cost you the equivalent of 50 days wages in Cameroon, almost 19 days of pay in Armenia and 13 days in the Philippines...If a partner and children get sick, then the medicines bill will rapidly devastate a household income.”

With this truth, the new joint WHO–Health Action International (HAI) project manual Medicine Prices — a New Approach to Measurement was launched in 2003. The manual and accompanying workbook, which are available in Arabic, English, French and Spanish present a rigorous method for data collection and analysis, for use by governments, nongovernmental organizations and others interested in price information.

Applying the methodology at country level

In addition, a series of regional workshops on medicine prices is being organized. The first of these was held in October 2003 in Cairo. Those taking part were split into working groups focusing on data collection (via local pharmacies) and workbook data-entry exercises. The workshop was also a forum to share country-specific price issues.

Two members of the University of Kuwait’s Faculty of Pharmacy attended the Cairo workshop, as preparation for a medicine pricing survey in Kuwait. Dr Douglas Ball, Associate Professor of Pharmacy Practice, commented, “Apart from making contact with other interested groups in the Arabic-speaking countries and learning about their particular concerns and situations, more specific benefits were realized. Hearing Dr Anita Kohwani’s experience in Rajasthan, India, clarified the planning and administration necessary for successfully completing a pricing survey. This was complemented with the mock data collection and entry exercise, which provided insight into the practical difficulties that can be encountered. Overall, the Cairo workshop was a rewarding experience that helped to prepare us for conducting a medicine survey in Kuwait.”

Participants generally conduct country medicine price surveys after attending an initial workshop and then attend a second workshop, to consider data analysis and interpretation issues. Lebanon has already initiated a price survey and other countries are set to follow suit in 2004.

Higher prices in poor countries

Andrew Creese, a health economist working on medicine pricing at WHO Headquarters comments, “What is clear is that manufacturers’ pricing policies and government pricing policies often result in much higher prices in poor countries for the same drug, and the problem is made worse by poor people having to buy their own medicines. This mechanism doesn’t apportion blame. But it does give a good methodology for comparing prices. It also reveals huge differences in the price break you can get with generics. It’s an evidence-based means of empowering policy-makers.”

Margaret Ewen, Director of Health Action International Europe and project coordinator, is categorical about the need for governments to act regarding medicine prices, “No longer can governments stand idle while the poor die because they cannot afford medicines. They must implement sound pricing policies. But to do this, careful diagnosis of prices is needed — that’s where the WHO–HAI methodology is so useful. It can point the way to bringing medicine prices down.”

The project is having other benefits. Ms Ewen continues, “The WHO-HAI project has not only produced a much-needed survey tool. It’s also shown the synergistic value of WHO and civil society working together. We saw this during the development of the methodology and, importantly, when the surveys were undertaken. Most surveys are now undertaken as collaborations between civil society, government, WHO and academia.”

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While working in Rwanda, Ruth Evans — journalist and writer — met and interviewed two young women. She writes...

The 1994 genocide in Rwanda was deliberately planned and systematically executed, resulting in the brutal mass murder of over a million people. Rwandan women and young girls not only witnessed the torture and killing of their families, and destruction and looting of their homes and property. They were also subjected to extreme and brutal forms of sexual violence, raped, deliberately infected with HIV/AIDS and mutilated. Chantal is one of them. Her family were all killed in the genocide, and she was raped and infected with HIV. As the sole survivor, she now struggles to care for five orphaned children, as well as her own child, conceived as a result of the rape. Ten years on, she is sometimes too sick to work or plant her shamba, and then the children go hungry. She knows that treatment with antiretrovirals is available in Rwanda for around US$ 25 a month. But she says she cannot afford even the bus fare to the clinic, let alone the medicines. “Only God can help me,” she says. “The genocide is still a daily reality for women like me, only ours is a slow death. My biggest worry is who will look after the children when I am dead.”

Akimana’s story is just as distressing. When she was ten years old, Akimana’s Hutu parents were killed because they opposed the genocide in Rwanda. Although she herself was shot in the shoulder and left for dead, she survived. Today she looks after her four orphaned brothers and sisters. “Getting treatment is a big problem,” she says. She still has medical complications from her wounds, including fainting attacks and heart problems. But her greatest worry is looking after the other children. “It’s not easy to get money to take them to the clinic about 10 kilometres away. Malaria is the biggest problem. In the rainy season, one of them might fall sick twice a month. It isn’t easy to get treatment and the medicines are too expensive for us to buy.”

These stories portray not only the terrible circumstances some people have been forced to endure as a result of civil strife. They also underscore the continuing gap between the potential that essential medicines offer for improving and maintaining quality of life, and the reality that for millions of people who desperately need them, they remain far beyond reach.

(Editors note: Chantal gave permission for her story to be used to publicize the plight of women who were raped during the genocide.)
WHO’s Constitution states, “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.” The human right to health is also recognized in many international and regional treaties.

The most comprehensive article on the right to health is found in the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12.2 sets out a number of steps for ensuring progressive realization of this right, including provision of health facilities, goods and services.

**Turning treaties into practice**

By the end of 2002, 142 countries had signed the Covenant and 83 countries had signed regional human rights treaties. Over 100 countries have now incorporated the right to health in their constitution. Ratification of an international human rights treaty means that a state becomes a state party to that treaty. As such, it is obliged to meet certain obligations with respect to its population. But are these obligations enforceable in practice?

In 2002, WHO started a study to identify, analyse and summarize court cases in developing countries that individuals or groups had initiated against a government or governmental institution, to secure access to essential medicines, fully or partly on the basis of human rights treaties signed and ratified by their government. Evidently, the study focused on those who had won their case and how their example could be used to empower other individuals and groups to launch similarly successful cases and claim the benefits due to them.

A total of 20 cases from Argentina, Bolivia, Colombia, Costa Rica, El Salvador, South Africa and Venezuela were identified. Of these, seven (35%) cases had been strongly supported by nongovernmental organizations. Eleven (55%) cases contested a social security scheme. In a further six (30%) cases, the defendant was the ministry of health.

The full study has not yet been published, but the boxed examples illustrate the potential for increasing access to essential medicines through legal action based on the state’s obligation to provide access to essential medicines in part fulfilment of the right to health.

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**Claiming the right to access to medicines**

In El Salvador, Odir Miranda and 25 others living with HIV/AIDS filed a complaint in January 2000, before the Inter-American Commission on Human Rights, alleging the state’s failure to provide them with life-saving antiretroviral (ARV) therapy. The Commission solicited the Salvadoran State to comply with its regional obligations and provide the treatment. The Supreme Court in El Salvador supported the claim and in 2001 issued a ruling ordering the Social Security Institute to provide ARV therapy. The ruling was based on the right to life and health as entrenched in the Constitution and international treaties ratified by El Salvador.

In 2001, in South Africa, individuals and health advocacy nongovernmental organizations jointly challenged the decision of the South African Ministry of Health to restrict access to nevirapine, a medicine used to prevent mother-to-child transmission of HIV. The central argument was that restriction of nevirapine to test sites only violated the right to health, to life and to equality. The case was eventually brought before the Constitutional Court. In 2002, it ruled that the restriction on nevirapine was unconstitutional and ordered the government “without delay” to ensure its availability throughout the country.
Ensuring medicines supplies at all levels at all times

The success of new strategies to fight against high-burden diseases depends heavily on effective medicines supply systems. Supply problems must not be the bottleneck that prevents medicines reaching those who need them. WHO is exploring options for using the experience of nongovernmental organizations (NGOs) to create supply systems based on an efficient public-private mix. One example of WHO’s work in this area is an innovative study on medicines supply activities by faith-based organizations.

Throughout 2003, in collaboration with the Ecumenical Pharmaceutical Network, and with funding from the Swedish International Development Agency, WHO surveyed the medicines supply practices of 16 faith-based NGOs in 11 sub-Saharan African countries. One particularly effective feature has been data collection through paired country assessments. Staff from NGOs in one country have systematically researched supply systems in their partner country and later hosted a return visit.

Adding value to supply systems

Commenting on the value of this twinning arrangement, Mrs. Marsha Macatta-Yambi, pharmacist at the Christian Social Services Commission, Dar Es Salaam, Tanzania, said that, “Receiving the visit from the Zambian group was a highlight, and it reinforced just one of the project’s positive outcomes — it has made my colleagues in other departments realize the importance of my pharmacy’s work.”

The country reviews had been completed by December 2003. Preliminary findings indicate that faith-based supply organizations often fill gaps left by government supply systems. One issue that has been highlighted is the negative effect of unexpected drug donations on the sustainability of NGO supply systems. In some cases, donations distributed free of charge, had decreased the sales of revolving drug fund mechanisms, leading to stock wastage and financial loss.1

Data analysis of study results is continuing, and WHO will disseminate the information gathered and its recommendations.

Further commenting on her involvement in the study, Mrs. Macatta-Yambi said, “My initial feeling was one of trepidation at the possible difficulties and extra work, but it has been worth all the effort — being part of the project has definitely added value to my work. The study questionnaires are so well thought out and so comprehensive that the project has given us greater insight into what we do. Also, transparency is so important to us and this project has been one way of ensuring our transparency.”

1 This finding underlines the importance of continued adherence to the Interagency Guidelines for Drug Donations, and a companion volume, Guidelines for Price Discounts of Single-source Pharmaceuticals, the latter published by WHO in 2003. They can be obtained by emailing edm-doccentre@who.int

Collaborators in medicines supply (from left to right): Marlon Banda (lead investigator, Zambia); Stella Feka (Organisation catholique pour la Santé au Cameroun); Marsha Maccata-Yambi (Christian Social Services Commission, Tanzania); Hans Peter Bollinger (Ecumenical Pharmaceutical Network)
Civil society has had a major role in pushing the issue of access to antiretrovirals (ARVs) higher up the global health agenda. Nongovernmental organizations (NGOs) such as Oxfam, Médecins Sans Frontières (MSF) and the Treatment Action Campaign in South Africa, as well as the media, have all actively and repeatedly demanded that HIV/AIDS medicines, including ARVs, be made much more widely available and affordable. Concurrently, WHO is looked to for guidance on how to ensure good-quality and effective medicines.

WHO continues to develop close collaborative relationships with many NGOs working on HIV/AIDS issues, including MSF. “We don’t necessarily always agree,” says Daniel Berman, co-director of MSF’s Access Campaign, “but the working relationships we have developed with WHO have been very productive. We know that some of WHO’s most important work is carried out under considerable pressure. One example is prequalification of medicines. It’s crucial for the countries in which we work, and has revolutionized the purchase and supply of low-cost medicines.”

In October 2003, WHO and MSF jointly published *Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries*. This survey of the availability and use of ARVs in 10 countries found substantial variation in access to ARVs. But it distils the individual procurement experiences of the countries concerned and makes a number of recommendations on how to optimize ARV availability.

### Drug price targets: could try harder

Much remains to be done, however, to get ARVs to all who need them. Although prices of ARVs are now much lower than they have ever been, MSF says they should come down even further still. “WHO’s drug price targets lack ambition and do not reflect prices that are currently available,” claims MSF’s President, Morten Rostrup, referring to an announcement by an Indian drug company that is now offering its triple therapy for US$ 140 per patient per year. “Today, drug prices have fallen another 50%. WHO should encourage this trend so that universal access to AIDS treatments becomes a reality. The full effects of the implementation of TRIPS will not become visible until after 2005, when generic competition will become more difficult. WHO will then need to play an even more active role in ensuring that affordable essential medicines become available.”

Prequalification — vital to global goals for treating HIV/AIDS, malaria and tuberculosis

Increasing treatment options and simplifying treatment regimes

On World AIDS Day 2003, WHO announced that three new generic products for first-line AIDS treatment had been added to the list of prequalified products. The products are fixed-dose triple-therapy combinations and will contribute to simplifying HIV/AIDS treatment regimes. By the end of 2003, over 240 medicines for treating HIV/AIDS had been evaluated, and more than 50 of these products included in the list. The project now also covers medicines for treating tuberculosis and malaria.

The list means that procurement agencies can choose between several manufacturers offering the same quality product. Indeed, the Global Fund to Fight AIDS, Tuberculosis and Malaria considers the list to be vital to ensuring that its funds are spent on medicines of assured quality. Mr Van Zyl points out that, “The Fund is allowing countries who receive funds a period of grace in terms of procuring ARVs and other medicines. But after that funds must be spent only on products that have been prequalified by WHO.” The list saves procurement agencies time since they don’t have to assess the quality of products themselves.

Evaluations and inspections are carried out by a group of qualified external experts from national medicines regulatory agencies providing support to a core team at WHO. At all stages, WHO provides feedback to encourage the manufacturer to meet prequalification standards.

Publicly available standards for independent laboratories

Key also to the success of the prequalification project has been the issuing of pharmacopoeial monographs to provide independent laboratories with the information they need to be able to test product quality. In 2003, draft monographs were issued for some ARVs. Nine monographs were circulated for comments and further validation. Others will follow.

Comments Dr Sabine Kopp, a scientist with the Quality and Safety: Medicines team at WHO Headquarters, “Because ARVs are new substances and products, no internationally validated monographs are publicly available for them. We are collecting information from manufacturers in all regions so that we can develop tests for detecting any impurities. Of course there are commercial sensitivities, but we’ve had a good response from many manufacturers. Hopefully other manufacturers will come to recognize that this will contribute not only ensuring that patients get quality medicines, but also to fighting counterfeiting.”

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Without the right medicines, there can be no effective treatment for malaria, and resistance to antimalarials will continue to grow. A WHO study, The Quality of Antimalarials, published in May 2003, revealed significant problems of substandard products in Africa.

The deeply disturbing results showed that many antimalarials for sale in the countries studied (Gabon, Ghana, Kenya, Mali, Mozambique, Sudan and Zimbabwe) often contain little or insufficient active ingredients. This appears to be due to failure of manufacturers of antimalarials to comply with good manufacturing practice (GMP), and to the high prevalence of counterfeiting.

“Such results cannot be ignored by Roll Back Malaria (RBM) partners — either at the global level or at the level of country action,” says Dr Clive Ondari, one of the report’s authors. He affirmed that WHO’s RBM programme, and others working in malaria prevention, must actively support national regulatory authorities in strengthening GMP as well as good procurement and good distribution procedures.

Quality standards for many antimalarials are now in place. However, for a number of the newer antimalarial products, such standards have yet to be developed. The challenge will be to get the different RBM technical partners (including WHO, UNICEF, USAID and the United States Pharmacopeia) to work effectively together to improve production and distribution of safe, effective and good-quality antimalarials.

Safety tracking of the new antimalarials

Safety issues will be critical to effective use of the new generation of artemisinin-based combination (ACT) antimalarials, now being deployed in countries where resistance to chloroquine and sulphadoxine-pyrimethamine is high.

WHO and RBM are also developing pharmacovigilance reporting programmes for the new artemisinin combinations, in a bid to avoid the quality and resistance issues that have beset past drug responses. Pharmacovigilance identifies and quantitatively assesses the risks related to the use of medicines in an entire population or in specific population groups. It can pinpoint problems relating to misuse of a medicine, poor-quality or counterfeit production, or safety issues not picked up during a drug’s development and initial testing.

Dr Mary Couper, who leads pharmacovigilance activities at WHO Headquarters in Geneva, comments that, “Any new drug on the market needs especial vigilance. No drug is completely safe. But there are certain effects with malaria medicines that we need to be on the look-out for such as blood disorders and Stevens-Johnson allergic skin disorders. This is especially true for African countries for which ACTs represent new products and which have not yet developed capacity to undertake pharmacovigilance.”

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Quality assurance and safety — a cure for counterfeiting

Recent headline stories in the international press on counterfeit medicines touch only the tip of a very large and very dangerous iceberg. They are in part a response to WHO’s efforts to raise awareness of the dangers of counterfeit medicines, defined as medicines that are “deliberately and fraudulently mislabelled with respect to identity and/or source”.

Lucrative trade in counterfeit medicines

Some agencies estimate that up to 25% of all medicines in the developing world are counterfeit or substandard. Counterfeit medicines are often used — particularly in Africa and Asia — to treat life-threatening conditions such as HIV/AIDS, tuberculosis and malaria.

The lack of openness and poor information exchange on this issue means that fighting counterfeits is not easy. Sometimes, of course, the information is simply not available, because the necessary surveillance is not undertaken. And legitimate manufacturers worry that if concerns about counterfeit medicines are publicly highlighted, sales of their products will fall. So they can be reluctant to participate in campaigns against counterfeit medicines. Compounding these problems is the fact that many countries find it difficult to attract qualified personnel for regulatory positions, given that they can offer only low salaries. Law enforcement is another factor — all too often counterfeiting of medicines is classified merely as a trade violation, carrying a minor penalty only.

Awareness campaign

In 2003, WHO intensified its efforts to raise public and government awareness of the dangers of counterfeit and substandard medicines, and to improve collaboration between medicines regulatory agencies and law enforcement agencies in this area. It also continued to strengthen national regulatory authorities, through training, provision of advice, and development of guidelines and tools for improving regulatory systems.

Estetu Wondemagegnehu is a WHO technical officer, working with the Quality and Safety: Medicines team at WHO Headquarters. Although he recognizes that public awareness of counterfeit medicines is increasing, he considers that enhanced country-level regulation, using WHO guidelines and advice, remains an urgent priority. “In most developing countries, there is a shortage of medicines. This encourages smuggling and counterfeiting. What’s more, their regulatory system is often very...”

Fakes in Central and Eastern Europe and the Newly Independent States

Counterfeit medicines plague not only Asia and Africa. Following the collapse of communism, under which the state had been the monopoly supplier and regulator of medicines, ensuring effective medicines regulation in Central and Eastern Europe (CEE), and in the Newly Independent States (NIS), proved to be extremely challenging. Although many of these countries have now created national medicines regulatory authorities, regulatory “gaps” are reflected in reports of increased incidence and variety of counterfeit medicines.

Accurate data on incidence of counterfeit medicines in NIS and CEE countries have yet to be collected. But we do know that in several countries in the Caucasus, Central Asia and South-Eastern Europe, medicines are sold on markets and from kiosks. Ministries of health in the region have limited funds for purchasing medicines and so populations must generally cover their health costs themselves. The temptation to buy medicines from these cheap sources is therefore very strong. Unfortunately, the medicines may be not only cheaper but fake and/or substandard as well. Kees de Joncheere, Regional Adviser for Pharmaceuticals in WHO’s European Regional Office, observes that, “Ministries of health in CEE and the NIS are clearly aware of this problem and very concerned about it, but they lack the resources that would enable them to tackle this issue effectively.”

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weak. So medicines are easily sold over the counter without prescription or even on the street. In other words, we have to look at the whole pharmaceutical supply system, and encourage governments to strengthen and really enforce their medicines regulation and legislation, including where, how and by whom medicines can be sold."

Mr Wondemagegnehu continues, "We are very concerned about the persistence of counterfeits in developing countries. Not surprisingly, for many of them, national policies are driven by economic priorities and the need to ensure safe medicines to promote public health is forgotten. Production and sale of medicines can then take precedence over ensuring the quality and safety of medicines. In general, I think it's a question of political commitment... if the commitment is there it's easy to enforce regulation.

"China is a good example of effective political commitment and allocation of the resources needed. In just five years it has set up an independent regulatory authority (the State Drug Administration) and developed significantly in terms of infrastructure and qualified human resources. It has enacted the Drug Administration Law with provisions prohibiting the manufacture, sale and distribution of counterfeit and substandard medicines, and has also taken action against people and companies convicted of counterfeiting medicines."

Joining forces to fight counterfeits

In 2003, implementation of a WHO multi-country project to combat counterfeit medicines for the greater Mekong sub-region countries (Cambodia, China, Lao PDR, Myanmar, Thailand and Viet Nam) continued, with support from AusAID. The percentage of counterfeit artemisinin-based antimalarials exceeds 50% in parts of this region. Comments Dr Budiono Santoso, regional pharmaceticals adviser in WHO's Western Pacific Regional Office, "It's hard to imagine what the final economic cost will be. The technological investment that will be required if these new artemisinin-based antimalarials become ineffective, and yet another antimalarial has to be developed, is unthinkable."

The project aims to improve collaboration between the pharmaceutical sectors and law enforcement agencies, and raise public awareness of counterfeit medicines. WHO has worked with the countries to not only develop national, cross-sectoral plans to tackle counterfeits, but also to encourage collaboration, exchange of expertise and information-sharing between them.

A meeting in Hanoi between the Mekong countries and a variety of agencies (Interpol, Management Sciences for Health, Aus AID, JICWELS (Japan International Cooperation for Welfare Services), United States Pharmacopeia, Wellcome Trust, Australia's Therapeutic Goods Administration and USAID) was held in November. Dr Santoso says that, "It's becoming increasingly obvious that countries cannot fight counterfeit medicines in isolation but must work together to track incidence of counterfeits and the counterfeiters themselves, as well as encourage each other to enforce legislation against counterfeit medicines."
Quality and safety achievements: 2003

In 2003, many long-term activities aimed at ensuring the quality and safety of medicines — carried out in parallel to efforts to increase access to essential medicines — were completed. Some of them are described briefly below.

• Creation of WHO Advisory Committee on the Safety of Medicinal Products, to respond to the growing number of country requests for guidance on medicines safety issues.
• First training course on pharmacovigilance for new antimalarials, which will serve as a model for similar training for HIV/AIDS treatment programme managers to initiate pharmacovigilance for antiretrovirals (ARVs).
• Volume 5 of the 3rd edition of The International Pharmacopoeia published, including 75 new monographs and test procedures. The specifications for all known artemisinin-based antimalarials are especially important. They mean that vital information for improving manufacturing quality control and helping new manufacturers to start producing good-quality antimalarials, is now publicly available. This will contribute to increased competition and lowering of prices.
• Development of internationally-validated specifications for ARVs used to treat HIV/AIDS initiated, as a move towards making information on quality standards publicly available. This will help national quality control laboratories to test the quality of products and generic manufacturers to produce ARVs of assured quality.
• Finalization of second series of tests for WHO External Assessment for National Quality Control Laboratories, providing independent, international standards for quality-control testing so that national quality-control laboratories can evaluate their level of performance of quality-control testing of medicines.
• Development and adoption of five new and two revised Good manufacturing practice (GMP) texts to take account of country requests for more GMP guidance and of recent advances in pharmaceutical manufacturing.
• Introduction to Drug Utilization Research published, to guide countries on how they can use and benefit from medicines utilization research.
• ASEAN countries agree on single set of technical requirements for medicines evaluation, enabling better technical collaboration among ASEAN member states, facilitating access to medicines in the ASEAN region, and improvement of the regulatory capacity of less well resourced ASEAN member states.
• Tunisia starts publishing prescribing information for all medicines approved by the national medicines regulatory authority and granted a marketing authorization, indicating that developing countries can make correct medicines information available, thus limiting the negative impacts of unethical medicines promotion.

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Working in partnership with the Global Fund to Fight AIDS, Tuberculosis and Malaria

“The Global Fund is already the world’s largest single financier of drugs to fight AIDS, tuberculosis (TB) and malaria. To ensure that these drugs are of good quality and safe, we rely heavily on the expertise of WHO. We greatly appreciate the close collaboration between the Global Fund and WHO’s Essential Drugs and Medicines Policy Department,” comments Professor Richard Feachem, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

On World AIDS Day 2003, WHO announced that three new generic products for first-line AIDS treatment had been prequalified. The products were fixed-dose triple therapy antiretroviral (ARV) combinations containing lamivudine, stavudine and nevirapine. Effective, simple to take as a treatment regimen and easily administered, they are also cost-efficient. By the end of 2003, the list of prequalified products contained more than 50 ARV medicines — in single-drug, two- and three-drug combinations. It also contained first- and second-line treatments for TB and one medicine for malaria. By clearly indicating what medicines can safely be procured where, the list is both reducing the time and effort needed for procurement, and helping to ensure that funds for treating the three major diseases of poverty are used optimally.

WHO is also collaborating with the Global Fund to develop policies and procedures for medicines procurement and supply management, providing technical advice, analysis and data. Global Fund procurement and supply management guidelines now incorporate a number of WHO pharmaceutical norms and standards.

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Easy electronic access to WHO Model Formulary

The WHO Model Formulary was first launched in 2002 and then made available in electronic format on the WHO medicines web site (http://mednet3.who.int/eml/eml_intro.asp) in 2003. This practical tool to assist national drug selection committees has also been released on CD ROM, and translation into Arabic, Russian and Spanish is now under way. In 2004, plans will be made for making the Model Formulary available on a palm computer.

The electronic versions (in both pdf and Word formats) of the Model Formulary are especially useful for countries that would like to develop their own formulary. Rather than starting from scratch, they can now start with a full text and adapt that to their specific needs by omitting or adding other information.

Presenting independent information on all 316 medicines on the WHO Model List of Essential Medicines, the 2004 edition of the Model Formulary will also incorporate updates and changes made during the relevant Expert Committee meeting of 2003. A manual describing how countries can best adapt the Model Formulary to national requirements will be made available in electronic format in early 2005.

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Traditional medicine vs. SARS: expert meeting backs integrated treatment

In July 2003, WHO announced that it had broken the chain of human-to-human transmission of the SARS (severe acute respiratory syndrome) coronavirus. In an epidemic that started in China and lasted a little over 12 months, more than 8400 cases of SARS were reported in 29 countries. Within a few months of the end of the epidemic, it was recognized by a meeting of experts that traditional Chinese medicine (TCM) had helped fight the SARS battle. Why and how was TCM integrated with western medicine (WM) to achieve this success?

A long history of use

China has a long history of traditional medicine use, which often includes herbal medicines, acupuncture or acupressure and spiritual therapies. TCM is frequently used to meet primary health care needs.

When SARS broke out, the Chinese State Administration of Traditional Chinese Medicine (SATCM) initiated clinical research projects on integrated TCM and WM. A total of 21 projects were set up focusing on prevention, treatment and rehabilitation. (More than half of all SARS patients in China were treated with TCM.) At the request of the Chinese Government, and with financial support from the Nippon Foundation, WHO guided SATCM on 13 clinical trials. Working together, WHO and SATCM later organized the International Expert Meeting on Review of Treatment of SARS and the Integration of Traditional Chinese Medicine with Western Medicine. The meeting was held in Beijing, China, in October 2003, and reviewed the reports of the 13 clinical trials.

Dangerous conditions

In all, 68 experts from seven countries attended the meeting. They paid tribute to the TCM professionals who treated SARS patients. They were recognized as having carried out vital data collection in dangerous conditions. They are estimated to have participated in the treatment of SARS in 102 of the 195 SARS-specific hospitals in China.

For SARS patients, data collected indicated that TCM could potentially alleviate fatigue, shortness of breath and other clinical symptoms and enhance immune system functioning. The 13 clinical reports indicated that no negative side-effects on heart, liver or kidney functioning were observed, suggesting that TCM treatment was safe. Moreover, for a group of early-stage SARS patients treated only with TCM, all recovered, without the need for corticoids, antiviral agents or antibiotics. Additionally, no SARS cases were observed among health workers who had been exposed to SARS but who had taken TCM for the purpose of prevention. The meeting report (in press) comments, “TCM is the accumulation of thousands of years of experience of the Chinese nation in fighting against diseases. Facing unknown reasons or complicated pathological causes of diseases, traditional Chinese differentiation cognition theory and treatment principles have obvious advantages.”

However, the experts who attended the meeting noted that the data in the reports were inconclusive. Accordingly, their recommendations were to: continue follow-up of SARS cases, and observation and comparison of the long-term effects of various treatments; improve clinical research design; and strengthen research on health economics and SARS.

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Communicable Diseases Hospital, Beijing, China
One pill to be taken 2 x daily: ground-breaking industry–public health meeting on fixed-dose combinations

"It was a unique and important meeting. By bringing together the large pharmaceutical companies, the generic manufacturers and disease control experts, we were able to get a consensus on the way forward. It was an opportunity for disease control specialists to say to the pharmaceutical industry — this is what we want. And there was a clear willingness by the industry to focus on global public health needs," comments Dr Richard Laing, of the Medicines Policy, Access and Rational Use team at WHO Headquarters. He is describing the meeting on fixed-dose combinations (FDCs) for HIV/AIDS, tuberculosis (TB) and malaria, organized by WHO in December 2003 and supported by the Rockefeller Foundation. Attended by WHO medicines and disease control programmes, nongovernmental organizations, medicines regulatory agencies, and representatives of the pharmaceutical industry, the meeting brought together the full range of stakeholders in FDCs.

FDCs have a long history of development and use. The combined contraceptive pill and the treatment of cancer, infectious diseases, hypertension and neurological disorders, are well-known examples of FDC use. In fact, in the 1960s, in the USA, they accounted for over half of all pharmaceutical products and for 40% of the best-selling medicines. But then followed controversy. Because there were many "irrational" combination products on the market, FDCs fell out of favour with medicines regulators.

"It became clear that FDCs should be used only where combination treatment offered a clear advantage. Since the 1990s we have become increasingly concerned about the rise of antimicrobial resistance. Now we are also concerned about how best to promote AIDS/TB/malaria treatment adherence. In both areas, FDCs have obvious advantages," continues Dr Laing.

"Instead of asking someone to take 12 or 13 tablets a day, if he or she can just take one or two, then there is a much greater chance of compliance. We have seen this in TB control with use of FDCs in DOTS1 programmes. And when we consider the high interaction of TB and AIDS infection, it’s clear that FDCs will become increasingly important to public health programmes."

The meeting was a key point in time. WHO was a forum for all those people to come together, to get a synthesis of ideas. We were able to bring these different groups together because they share the same problems. The consensus was that FDCs are the way forward for HIV/AIDS, TB and malaria treatment, where possible. That is the first choice. If that is not possible, then we use blister packs, which also simplify patient adherence," says Dr Laing.

FDCs also help streamline medicines supply management — theft, wastage and misuse can all be minimized. However, these three- or four-drug combinations can be difficult to produce to quality-assured standards.

The value of FDCs for 3 by 5

Commenting on the use of FDC antiretroviral (ARV) medicines within WHO’s 3 by 5 strategy to fight HIV/AIDS, Dr Vladimir Lepakhin, WHO Assistant Director-General for Health Technology and Pharmaceuticals, emphasizes that the ease of compliance and distribution would prove invaluable. “The 3 by 5 strategy recommends simplified AIDS treatment regimens,” he continues. “These new FDCs will help the countries which are hardest hit by the AIDS epidemic to provide easy-to-take AIDS medicines to the people who need them most urgently.”

Médecins Sans Frontières is currently providing ARV treatment to more than 11,000 people living with HIV/AIDS in over 20 countries. It is a strong advocate of triple-FDCs and comments that, “Compared to ARV drugs used as separate products, triple-FDCs have clear advantages, such as ease of use, reduced risk of drug resistance, competitive prices and the easing of pressure on the supply chain.”

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PHOTO: Irene R Lengui/L’IV Com

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Rational Use

“Until now, surveillance work aimed at understanding and tackling antimicrobial resistance (AMR) was carried out largely at national level, with little local input or feedback. The new approach being developed by WHO, is to gather local data for local action,” explains Dr Kathleen Holloway, medical officer with the Policy, Access and Rational Use team at WHO Headquarters. One of Dr Holloway’s tasks is to encourage rational use of antibiotics to help slow development of AMR. But doing this demands understanding of why and how it develops in the first place.

Dr Holloway continues, “The problem has been that little evidence has so far been collected as to which AMR interventions are the most effective and feasible. Instead, attempts to tackle AMR have tended to be hospital-based, involving only surveillance by microbiologists. Samples analysis has remained at the level of the sample (i.e. bacteria), and has been linked to neither patients nor type of antimicrobial use. Antimicrobials are used not just in hospitals though, but also widely within communities. So what is needed is a broad-based analysis.

“This in turn means using a multidisciplinary approach, whereby health professionals experienced in rational use of medicines and antimicrobial resistance, work with anthropologists and sociologists experienced in working with communities. Only then can we work out the how and why of antimicrobial use. After that, we can choose interventions for containing AMR that are likely to be locally appropriate and feasible.”

But developing countries often lack multidisciplinary capacity. Dr Holloway has therefore assembled a team of researchers, and is supporting five pilot projects in India and South Africa, to encourage its development. Based around local institutions, the projects are helping experts of different disciplines to pool their expertise to collect a wide variety of data on AMR and antibiotic use. The projects have gathered one year’s worth of data from all levels of the health care system, both public and private. These data will be used to formulate local action plans.

Problems and progress

Each project experienced difficulties in getting started, including problems in creating a multidisciplinary team, insufficient sample size of patients, logistical problems in collecting medicines use data and difficulties in performing adequate data analysis. That said, at every project site, project participants have found project involvement to be an invaluable learning experience. “Not only are we creating a standard method for multidisciplinary research into AMR — suitable for use in any country — but we are building understanding about how to do it,” comments Dr Holloway.

Initial results from all projects show an association between high antimicrobial use and resistance, and significant over-use of antimicrobials in the community. Alarmingly, some results demonstrate that trends in increasing use are associated with trends in increasing resistance.

Phase II will broaden this programme of work, so as to identify interventions that can most effectively slow resistance to treatment for HIV/AIDS, tuberculosis (TB) and malaria. Failure to do so could threaten achievement of Millennium Development Goal 4 — to reduce child mortality — and Goal 6 — to combat HIV/AIDS, malaria and other diseases. AMR could also undermine global initiatives such as 3 by 5, Roll Back Malaria and Stop TB, as well as national efforts to tackle infectious diseases.

Further information:

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Local data for local action to fight antimicrobial resistance

In describing the project he supervises in Vellore, India, Dr Kurien Thomas, Professor of Medicine at the Christian Medical College, comments that working with WHO has, “helped us to determine our directions in tackling AMR”. For his clinical pharmacologist colleague, Dr Sujith Chandy, the WHO AMR project has presented, “WHO — a wonderful holistic opportunity. The value of linking data on AMR and on medicines use at local level, of working in urban and rural areas and of bringing colleagues from different disciplines within the hospital to work together on the project is proving to be a great experience for all involved.”

Further information:

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Sources of extrabudgetary revenue received in 2002–2003 (US$)

<table>
<thead>
<tr>
<th>Country</th>
<th>Revenue</th>
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<tbody>
<tr>
<td>Netherlands</td>
<td>7,197,710</td>
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<td>Australia</td>
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Where the money went: financial information 2002–2003

Funding sources for essential drugs and medicines policy activities continue to be very diverse. In 2002–2003, in addition to regular budget funds—which accounted for 17% of funds available for the Department of Essential Drugs and Medicines Policy at WHO Headquarters—important extrabudgetary contributions were received from a number of governments (Australia, Denmark, Germany, Italy, Japan, Luxembourg, the Netherlands, Norway, Sweden, the United Kingdom and the USA). Extrabudgetary contributions also came from the Regional Government of Lombardy (Italy), UNAIDS, the European Medicines Evaluation Agency, and the Nippon and Rockefeller Foundations. Income was received too from fees paid by pharmaceutical manufacturers for the assigning of International Nonproprietary Names (US$ 723,000). For 2004–2005, significant support is also anticipated from the European Commission, and the Bill and Melinda Gates Foundation.

Other human and financial support was leveraged by arranging co-sponsoring of technical meetings, including workshops and training seminars, contribution of technical expertise to specific projects, and co-funding of technical publications.

Areas of experience

For the 2002–2003 biennium, the budget for essential drugs and medicines policy activities at WHO Headquarters was US$ 34.9 million. Funds transferred from WHO Headquarters to supplement funding for medicines activities in countries and regions amounted to US$ 5.8 million. Funds were spent in line with the objectives and targets of the WHO Medicines Strategy 2000–2003. The largest share of the funding supported objectives relating to development, implementation and monitoring of national medicines policies, safe use of medicines, and medicines regulation and quality assurance.

Into the future

Diversity of funding and in-kind support will be maintained. Indeed, it is absolutely crucial given the volatility of distribution of funds for health, and increased competition for those funds. Loss of a source of funding could have a heavily negative impact on the direction and implementation of the WHO Medicines Strategy for 2004–2007.

Funding is still a concern, however. Growing country requirements for pharmaceutical technical support—particularly following extended efforts to increase access to medicines for HIV/AIDS, malaria and tuberculosis—mean that funds available do not match need. Thus at the end of 2003, the shortfall for the 2004–2005 biennium was calculated at US$ 9.1 million for WHO Headquarters and US$ 6.8 million for WHO regions and countries. Should this shortfall not be covered, a number of activities would have to be reduced in scope, delayed or cancelled.

Needless to say, given the need to maximize funds for health, increased efforts are being made to ensure timely liaison with donors, and careful matching of WHO and donor priorities and policies within the wider development context. Greater priority is also being given to monitoring and evaluation of medicines activities at country level, to help ensure that resources are applied where most needed and where they can be used to optimal effect.

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“People don’t want to hear how many meetings WHO has held. They want to know what difference it has made. Have medicine prices gone down? Has availability gone up? Are fewer unnecessary injections being given? Is generic substitution possible? Is drug promotion being monitored? Are safety mechanisms in place? Is quality improving?”

Dr Jonathan Quick is direct and forthright. Now, after seven years as head of the Department of Essential Drugs and Medicines Policy at WHO Headquarters, he is returning to the USA-based Management Sciences for Health (MSH) — scene of his first-ever student research project.

Dr Quick leaves a legacy: the WHO Medicines Strategy, which won the endorsement of all WHO Member States; the successful merger of the former Action Programme on Essential Drugs and the Division of Drug Management and Policies; the prequalification project; and the establishment of the Global Medicines Council.

“I am happy to have had the opportunity to define a single WHO strategy for medicines activities. It provides a framework, with the core aims of affordability, accessibility, quality and safety and rational use. In addition, it incorporates a practical monitoring programme, with each aim underpinned by specific and measurable progress indicators,” says Dr Quick.

Analysing finance and public-private roles in medicines supply, he has encouraged WHO medicines activities to focus on the balance between knowledge creation and implementation. He has also supported a modernizing approach to the WHO Model List of Essential Medicines, and believes that the Doha Declaration on the World Trade Organization’s TRIPS Agreement and Public Health has moved in the right direction, affirming most of the points WHO tried to make in the controversial discussions of 1998.

“Implementation of sensible pro-health policies in countries is not happening anywhere to the extent it should. If we get it wrong now, it’s not just wrong for us, but for our children, and our children’s children”, he adds.

Similar problems — diverse solutions

Dr Quick’s career began in Boston, USA. As a young medical student in 1978 — with majors in sociology and psychology — he embarked on an essential medicines research thesis. It became an eight-month global survey for MSH and WHO — whose Model List of Essential Medicines was still in its infancy — and led to the definitive Managing Drug Supply, published in 1981.

“The focus then was very much on the nuts and bolts of procurement, distribution and use. I went to Peru, which had one of the earliest generics and rational use programmes, Guatemala because they had good management, Costa Rica for their social health insurance, and Norway, because of its tough logistics. Tanzania was on my list, also Sri Lanka, Malaysia and Papua New Guinea. I had two weeks in each country,” says Dr Quick.

What struck me then — and still strikes me now — is how similar the problems are and how creatively diverse the solutions. I think one of the biggest barriers to progress is just not learning from what others have achieved.”

“Looking back, if you ask me where there has been significant and sustainable progress, it’s where there is both strong political commitment and sound technical support. Although it is ironic that many people from the political culture and the technical culture seem to miss the fact that they need each other to succeed,” he continues.

In terms of medicines, what will challenge WHO in the next decade? The loss of medical and pharmacy leadership in developing countries, unfair financing of medicines and failing management systems will all be critical issues according to Dr Quick.

Essentially qualified

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