**EDITORIAL**

Essential medicines: prices and people

This issue of the Monitor features a special supplement on the measurement of medicine prices, and highlights the work of some of the many individuals in the essential medicines field. We carry interviews with the WHO Assistant Director-General responsible for Health Technology and Pharmaceuticals, Dr Vladimir Lepakhin, and with Dr Jonathan Quick, the outgoing Director of the Essential Drugs and Medicines Policy Department. We also introduce WHO’s National Medicines Advisers in Africa, who tell us about themselves and their work on improving access to essential medicines in their countries.

We hope that both types of article will show the “human face” of essential medicines.

A major part of this Monitor is devoted to the price of medicines. We know that in poor countries most people have to pay for their medicines out-of-pocket, while in richer countries there are often mechanisms such as insurance schemes or government provision of medicines. This means that many people living in poor countries frequently face a choice between buying medicines or buying food or other necessities. So medicine prices do matter! But when people have tried to investigate the reasons for high prices, or to compare prices between sectors in a country, it has been difficult to do so.

For many years NGOs have worked on this area and the issue was raised at the WHO Public Interest NGO Pharmaceutical Roundtable in 1998. A working group was formed and began developing a simple but robust method to measure drug prices. Groups in nine countries then used the new methodology in field tests. The last Monitor included some results from South Africa and in this issue we report on more field tests in other countries. The manual published by WHO and Health Action International, *Medicine Prices: a new approach to measurement*, is a working draft for field-testing and revision, and a final version will probably be issued later this year. Many useful comments have already been received, and a meeting was held recently in London with Patricia Danzon, an American expert, to discuss methodological issues. But your comments are also needed! Please use the manual and send your suggestions to the authors.

This issue also includes an article about the very successful long-term ivermectin donation programme for the control of onchocerciasis. The programme predated the Interagency Guidelines for Drug Donations but fulfills all of the 12 components of these guidelines. The Chief Executive Officer of Merck, who made the decision to provide the ivermectin for as long as necessary, was an unusual and far-sighted individual.

We also include two articles on utilising electronic methods to improve medicines use. One is about using text messaging to remind patients to take their TB medicines and the other is on linking together prescribers in Bosnia, Indonesia, New Zealand, the UK and US to learn how to improve diabetes management. An article about pharmaceutical policy in Balkan countries brings information about this frequently neglected area of the world. As usual we have book reviews, news of events and, sadly, in this issue an obituary for Dr Molly Thomas, one of the many individuals who contributed to the world of essential medicines changes. As always we welcome your comments and feedback.
WHO’s country medicines advisers: making a difference to medicines work in Africa

Gilles Forte, Jean-Marie Trapsida, Helen Tata, Moses Chisale

In March 2002, WHO’s newly appointed national medicines advisers for the African Region met in Pretoria, South Africa, to set priorities and define strategies to contribute to improving access to quality medicines in countries and the Region, in line with the global WHO medicines strategy. Medicines advisers have been recruited in 11 African countries. These countries expressed an interest in having a medicines adviser and fulfilled specified criteria related to burden of diseases, commitment to improving access to quality medicines, existence of core health systems and pharmaceutical technical expertise.

Medicines advisers are national professional officers (NPOs) with specialised national and regional expertise in pharmaceuticals and medicines issues. As can be seen from their personal profiles, they bring a wide range of experience to the crucial task of providing practical support to governments and stakeholders on key pharmaceutical issues. They work closely with the ministry of health and other stakeholders, such as academics and civil society to improve access to quality medicines, including those for priority diseases. Medicines advisers also facilitate and coordinate WHO technical input in: national medicines policy implementation and monitoring; affordability of medicines and globalization; drug financing mechanisms; quality and safety; rational use of medicines; traditional medicine; and other critical areas of medicines work.

Support to their respective ministries of health to carry out a baseline survey of the pharmaceutical situation marked one of the first major contributions of the 11 medicines advisers. These surveys have provided policy-makers and stakeholders with needed evidence, and helped identify priority areas of interventions for improving national medicines policies.

Each medicines adviser’s work is based on a plan of action developed with the ministry of health and reflecting country needs. This work is regularly monitored and evaluated. Once a year, the medicines advisers come together for a planning and evaluation meeting, and the most recent took place in Dakar in April 2003. The medicines advisers are an important network of country-based experts communicating on key issues, exchanging information, and sharing innovative solutions to common problems. They receive regular training and participate in regional and international events along with their country counterparts. Located in WHO country offices, they work closely, sometimes on joint projects, with WHO advisers dedicated to HIV/AIDS, malaria, health systems, primary health care and other issues important to medicines work. They also receive administrative and technical support from WHO Representatives, the Regional Office and Headquarters on a daily basis.

The medicines advisers’ network is a significant step towards accelerating implementation of sound medicines policies in countries in Africa, where improving access to quality medicines remains a major challenge. The establishment of the medicines advisers network in Africa is a key long-term support mechanism for sustainable pharmaceutical development and has been possible thanks to the support of major partners such as DFID and the World Bank (for example, the latter funds WHO support to the Ministry of Health, Directorate for Pharmacy, Medicines and Laboratories in Chad). The project has an estimated life of six years and we are hopeful that more partners will join in to ensure that the network continues to thrive and is able to expand to more countries and regions.

Gilles Forte is AFRO Focal Point, in EDM’s Drug Action Programme (DAP). Jean-Marie Trapsida is EDM/AFRO Coordinator, Regional Office for Africa, WHO, Cite du Djeou, P.O. Box 06 Brazzaville, Congo, Helen Tata is a Technical Officer, DAP/EDM, and Moses Chisale is Regional Adviser on Pharmaceuticals, Regional Office.

SENEGAL
Mamadou Ngom

I’m a pharmacist, who previously worked as the Chief Inspector in the Division for Administrative Control of Medicines. My work as an NPO is to facilitate the collaboration on essential medicines issues between the Ministry of Health and WHO Headquarters/Regional Office and the many partners in the pharmaceutical sector in Senegal. Providing the necessary technical support in improving access to essential medicines, particularly for priority diseases, such as HIV/AIDS, malaria and TB, is a major part of my work, as is monitoring the pharmaceutical sector to identify gaps and make proposals on the technical assistance necessary to address these gaps.

I help to coordinate the technical assistance that WHO can offer, with the Ministry of Health and other partners, in the areas of pharmaceuticals and traditional medicine, not only in Senegal but at subregional and regional levels too. Another important element of my job is to help identify existing expertise and projects in Senegal that need support – working to strengthen health institutions and develop human resources.

My ambition is to do everything necessary for the whole population of Senegal to have access to essential medicines. I have two daughters and two sons, and I relax by watching football.

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GHANA
Edith Andrews

I have an MPH and MSc in pharmacy, with 10 years’ experience of hospital pharmacy and four years in district health administration.

I have been an NPO since the beginning of September 2003. My work involves intensive collaboration with all stakeholders in the pharmaceutical sector, and particularly with the Ministry of Health. My previous employment with the Ministry makes such cooperation easier. I think that there is room for greater collaboration with NGOs and Ghana’s universities, and we need closer links with professional bodies and industry through the Food and Drugs Board.

I’m married, with three children, two girls and a boy. My secret ambition is to learn to play the guitar.

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CAMEROON
Rose Ngone Mbulla

I’m an industrial pharmacist, who has worked for UNAIDS’ Access to Care Initiative – ([Observatory of Prices of HIV/AIDS Drugs for Africa] in the Country and Regional Support Department from July to December 2002. Between 2000 and 2002, I was a consultant and temporary adviser to the WHO/AFRO Essential Drugs Programme. I spent the three previous years as Team Leader of the Cameroon Strategy for Standardization in the Ministry of Trade, and was Director of Pharmacy and Medicines in Cameroon’s Ministry of Health from 1995–1998.

One highlight for me is that this year I’m involved in many vertical health programmes promoting rational use of drugs, good procurement and distribution practices, and improving access to drugs.

I am proud to be EDM focal point in the WHO Country Office.

On the personal side I’m a widow, and mother of five children: Karen (13), Antoine (12), Marina (9), Ricky (5) and Lucreace (2). The most sensational and dangerous thing I have done in my life was to cross the Sahara desert by car, from Algeria to Niger with 2 friends, when I was only 19 years old. I used to be a basketball player in secondary school.

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MALI
Arama Ené Augustin

I’m a pharmacist who was previously the health inspector responsible for the enforcement of laws and regulations in public and private health facilities. I act as the interface between WHO and the Ministry of Health and partners in the medicines sector, providing technical support to the MOH, together with the rest of the WHO Office team. I am particularly happy to be able to contribute to health education, for example, at the Faculty of Medicine and Pharmacy, and the School for Health.

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NIGERIA
Ogori Taylor

I’m a pharmacist, and my previous job was Senior Lecturer in the Department of Clinical Pharmacy and Biopharmacy, part of the College of Medicine, at the University of Lagos. I have also been active in INRUD Nigeria. Work as an NPO is exciting. It offers a huge opportunity to contribute towards improving the quality of pharmaceutical services provided in the country. I’m married to Emmanuel, and blessed with three children.

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UGANDA
Joseph Serutoke (Jr)

My training as a pharmacist and in health systems management has resulted in very broad work experience. I have been employed in hospital pharmacy, district health services, university teaching, the pharmaceutical industry, national medicines procurement and supply systems, pharmacy profession legislation and administration, and health sector reforms in Uganda. Being an NPO is exciting and challenging work, involving innovative approaches and strategies, implemented to contribute to the achievement of WHO’s mission in essential drugs and medicines policy. I’m married to a pharmacist, Christine, and have two children Calvin (6) and Jean (3). My first job before enrolling for pharmacy was in a bank. These days in my spare time I act as a Team Nurse during the football season of the Kampala Kids League, where my son plays in the Junior League.

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KENYA
Charles Kandie

Trained as a pharmacist, my previous work was as Coordinator for the Revolving Drug Fund Project in Nyamira District, Kenya, from February 2001 to December 2002. Before that I worked at Kenya Medical Supplies Agency as the Pharmacist-In-Charge, from April 1995 to January 2001. I have been integrated well into the WHO Country Office Team and provided with the office space and equipment I need. I have begun initiating EDM activities according to the country plan of action. I have also sensitised my counterparts at the Ministry of Health on my new role as the NPO, and my involvement in WHO support for the pharmaceutical sector.

I’m married and blessed with two children.

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ETHIOPIA
Bekele Tefera Jembere

I’m a pharmacist with professional management training, and was previously Head of the Drug Evaluation and Registration Department in Ethiopia’s Drug Administration and Control Authority. My work is challenging but interesting. It calls for initiative coupled with sound technical know-how. Good communication skills and interpersonal relationships are also needed for professional success.

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CHAD
Daniel Boysinda

I’m a pharmacist by profession, and formerly I was responsible for technical work at the Central Pharmaceutical Purchasing Agency. I also have experience of the commercial sector. My role as NPO is to give technical support to the Ministry of Health in analysing the pharmaceutical situation, and addressing identified gaps in the medicines supply system and the use of essential medicines in health facilities. One highlight for me is that as NPO I can collaborate in coordinating the activities of multilateral and bilateral partners and NGOs in my country.

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RWANDA
Stella Tuyisinge

My previous experience was as an office manager, and a health centre administrator. I have also been an adviser to the Office of the Minister of Health and manager of a national pharmaceutical store. In my capacity as NPO I have a strong obligation towards my fellow Rwandans and WHO, which gives me the impetus to work well. The potential offered by this post gives me job satisfaction.

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UNITED REPUBLIC OF TANZANIA
Rose Shija

I am a pharmacist, and before joining WHO I was responsible for the Management Information System for drugs and medical supplies in the Ministry of Health. I have experience in health sector reforms, medicines regulation, national pharmaceutical supply systems and promotion of rational medicines use. I have been an editor of a drug information bulletin, as well as at other Ministry of Health documents. These include the National Formulary and the National Package of Essential Health Interventions in Tanzania, among others. Work as an NPO is challenging, and I am grateful for all the support I receive from WHO HQ, AFRO, and the WHO Country Office as well as from officials in the Ministry of Health. I enjoy my work greatly and I am looking forward to translating WHO-EDM policy perspectives into successful country adaptations to improve the pharmaceutical sector in Tanzania.

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Talking essential medicines

A s Jonathan Quick, Director of EDM, he who speaks to Monitor Editor, Richard Laing, about his career to date and his plans for the future.

RL: Thank you for meeting with us. I think it is a great opportunity for us to have you review your career in essential medicines, so that readers get to know you in a rather different way. To begin, can you tell us who and what were the major influences in getting you here today, as nobody in essential drugs has come through a conventional career path?

JQ: That’s true. There were several influences. On my mother’s side of the family, there are several generations of medical people and on my father’s side business/management people, and so that sort of laid the foundation. A number of people were important but that come to mind, one was the head of preventive medicine in Rochester, USA. He was a professor who, when I needed to do a thesis for a masters degree and wanted to do it overseas, was wildly supportive and that gave me the early support to get involved in international health. That led me to the second person who is Ron O’Connor, founder and head of Management Sciences for Health (MSH) in the UK. He was a health carelessness to send a third-year medical student around the world in 1978 with absolutely no demonstrated research capabilities to look at four different countries. His willingness to do that was what led to the book Managing Drug Supply* and basically got me hooked into that area. The more recent influence in my transition to WHO was David Nabarro when I joined the UN Development Programme. So it was that string of individual influences. I think the other thing is that as a child I spent a lot of time watching adventure movies set in Africa, the Middle-East and Asia, and when I think back that really developed my interest in the rest of the world.

RL: What meetings or other events do you see as either informative or very significant?

JQ: Back in the late 1980’s there was a meeting at Harvard that the founding director of WHO’s Essential Drugs Programme, Ernst Lauridsen, had and I think Lauridsen has had an indirect effect by influencing the people who have worked with me. In those days, there were several different initiatives and I think my thinking, there was a big national drugs policy meeting, in Australia in 1995, which was arranged in a very interactive way, and I think it was a real lesson in getting people cross-linked in that region.

RL: Can you talk a little bit more about the countries you visited for Management Sciences for Health, and how that experience got you into essential medicines?

JQ: I had to do a thesis and I looked around for a way to do it overseas. I decided to work with Management Sciences for Health, which had just got a small grant from WHO to look at essential medicines. I had an interest in pharmacology, and had spent a summer working in Washington for Senator Edward Kennedy’s health sub-committee and had some contact with the US Food and Drug Administration through that. At that time, January 1978, WHO had recently completed the first Model List of Essential Medicines, which had been published in Boston (MSH headquarters) to start work on the thesis and was given a stack of papers, not even half a metre high, which represented pretty much everything that had been written on essential medicines up to that point – no kind of conceptual framework or idea of what the pieces were. My job for eight months was to plan a trip around the world to look at this and to basically do essential drugs management research. One of the things that struck me was that people had a good, well-developed concept person there. Costa Rica because they had a good programme of social health insurance and Norway, because it was a small country with tough logistics and so very educational in that respect. Tanzania was on the list because they were one of the leading, then on pharmacy education, with pharmacy technician training. The leading programme of the 1970s was Sri Lanka so it made sense to visit there and they could show some good work. Malaysia had had a strong tradition of pharmacy and good public sector management, so I went there.

In each country I had roughly two weeks to figure out what there was to learn. The last country was Papua New Guinea and again it was one of the unsung successes of essential drugs. They’d had what we would now call an essential drugs programme in place since 1945, and that was the first program I got to teach. People all gave very different pictures of the current state of things and then that actually led to the overall framework which we used for Managing Drug Supply.* Each country visit was written up but nobody was much interested. WHO was not sure if there was all this going to go, so the whole thing slept for two years while I went off to be a family medicine resident.

RL: And then you wrote the first edition of Managing Drug Supply?

JQ: It was really interesting because we basically sat with Ron O’Connor around October 1981 and on October 1st we finalised the book. When I finished the book in October 1981 had the book done and out to approximately 120 countries. It was the first international and reference book on drug writing experience I ever had ever.

RL: You have talked about those eight countries, and since then, you have had the opportunity to visit many others. What are the things that have been really significant for you?

JQ: The thing that struck me then and still strikes me now is how similar the problems are from country to country and how creatively diverse are the responses in the solutions. I think one of the biggest barriers to progress is just not learning from what others have achieved.

The man who made General Electric the biggest company in the world, said that for his first 10 years he fought what he called the NIH reflex – Not Invented Here. People would react against anything that they hadn’t discovered themselves. What he said was, take the ideas, plagiarise the ideas, learn whatever works. And we tried to make Managing Drug Supply* an ideas book. The other thing I am struck by, looking back, is if you ask if there has been significant progress and sustainable progress, it’s been where there has been both strong political commitment and technical support. We can look at Norway in the 1960s, Sri Lanka in 1970s, the Philippines 1980s, South Africa 1990s and Brazil coming into this decade with its ADS Programme. It’s been where those two ingredients (political commitment and technical support) come together. Whatever works. And we tried in 1998, and actually confirmed back, is if you ask if there has been significant progress and sustainable progress, it’s been where there has been both strong political commitment and technical support. We can look at Norway in the 1960s, Sri Lanka in 1970s, the Philippines 1980s, South Africa 1990s and Brazil coming into this decade with its ADS Programme. It’s been where those two ingredients (political commitment and technical support) come together. Whatever works. And we tried in 1998, and actually confirmed back, is if you ask if there has been significant progress and sustainable progress, it’s been where there has been both strong political commitment and technical support. Whatever works. And we tried in 1998, and actually confirmed back, is if you ask if there has been significant progress and sustainable progress.

RL: That brings us to the next question. What do you think your major achievement as Director of EDM, would managing that merger be one of them?

JQ: I think part of the merging process, and one of the things I am happiest about, was to step back and to define a single WHO Medicine and Drug Programme** that was sensible for countries on the ground, and that was in the end endorsed by all WHO Members. The debate was whether we should have a single work for all of WHO’s medicines work, with the core aims of affordability, accessibility, quality and safety; and rational use. To add to that, if you had a monitoring programme to assess WHO performance in country progress. So each of our aims is underpinned by some specific and measurable progress indicators. People don’t want to hear how many meetings WHO has held, they want to know what it has done – have 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? I think a third area is traditional medicine, where we have been doing a lot of individual activities but we haven’t had an overall strategy. What we tried to do is bridge the gap between the two so that one of the things we worked on was a comprehensive programme to assess performance in country progress. Our aims is underpinned by some specific and measurable progress indicators. People don’t want to hear how many meetings WHO has held, they want to know what it has done – have 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? I think a third area is traditional medicine, where we have been doing a lot of individual activities but we haven’t had an overall strategy.

RL: Even before you became Director you were involved in writing a number of publications, on finance and public/private roles, for example, yet there seems to be a continual demand for those sorts of review and analysis. How do you think those would have been on your list of achievements?

JQ: I haven’t got there yet. On the whole, I have been so busy with the work that we were so focused that we were putting so much energy into just helping individual countries, which is absolutely a priority, but we weren’t really spending much time thinking about where things were going. I think it’s necessary to try to strike the balance between knowledge creation and knowledge...
implementation. So yes, I think the work on the public/private issues was important, and I have been supporting people in the department who are modernising the approach to the Model List of Essential Medicines. We still spend a lot of time talking on pricing – getting people to think about where there are major gaps and addressing those in a practical way.

RL: Are there any other things on your list?

JQ: I’m happy to see the evolution of the Global Medicines Council – the four headquarters-based team leaders and six regional advisers on medicines issues. Eight years ago, there was a lot of tension among UN agencies. Now there is still tension occasionally. But we can get on the phone and debate it through.

RL: Disappointments? What didn’t you achieve that you had hoped for?

JQ: I think I have learned a lot, certainly looking back on what I know now, there are things I would have done differently. But I don’t have any regrets per se. I think faster implementation would have been good. Improving quality would have been helped by being more decisive sooner on some of the tough issues. You also need more accountability in a programme, so in the last two years there has been much more attention to that. We were looking backward and forward at the same time thinking. For me, writing is actually a helpful way of thinking through tough problems. Time is write about your observations and principles for drug promotion that were set out by civil society or the private sector. We need an even greater impact in the future. But I don’t have any regrets per se.

RL: With the changes in the last few years related to AIDS/TB-malaria, how do you think the programme could have adapted to the implications of the tremendous interest and funding available for those diseases, while still balancing the ongoing needs of countries and programmes?

JQ: I think in most respects, certainly in the AIDS area, if you look at most of the key pieces that ought to have come from a medicines council, most of those were started in the last three years: the process of selection and getting the right antiretrovirals, starting to track prices and sources, looking at quality, and regular prequalification lists. The first level framework and support structures are in place, so we are now moving to look at how to get the drugs distributed in countries. We have actually looked at where the problem is needing to be in place and what was missing. What is now coming with the 3 by 5 strategy is a unique opportunity that bridges the medicines area with the financing, with the prevention and health systems programme – all that was missing and now that’s coming together. What we are seeing now is the need for a kind of new medicines coordination group that looks across all of the components that links together the development of the public health data and evidence. A community of practice says this is something that ought to be using, with the identification of producers, with the development of quality standards, with the development of markets and the growing group. For some of the diseases we have most of those pieces but for others we haven’t and we are catching up.

RL: What about advice for your successor, whoever that person might be?

JQ: The first thing is to keep the basic mission and the centre of things. Setting priorities is probably the single hardest thing. We have a clear mission, which is saving lives and reducing suffering by being sure that people have the medicines they need, when they need them, of good quality and that the medicines are used well. People can disagree with your specific policies and actions but if this mission is in the centre of things it’s hard to disagree with your direction. I think the second thing is to really trust the support staff that are working here. There is a world class group of essential medicines staff at headquarters, in each of the regions and in many countries, so set the direction, prioritise and then support, support, support. The third thing is to do the analysis of the tough issues that come up, avoid political correctness reflexes, avoid rejections, avoid stereotyping – but don’t avoid the core issues. Whenever we have made it through tough issues like the revision of our approach to the Model List of Essential Medicines, prequalification of antiretrovirals, WTO agreements, we need to ground it because good analysis. What are the issues? What’s at stake? What are the options? What makes sense as a health point of view? If you ground the debate in good analysis you have hope of getting sensible, defensible outcomes. I think those are the really main things.

RL: What do you think the priorities over the next five to 10 years should be, if we are looking back over the last 15 years, what would be the big differences?

JQ: Human resources, numbers of people and the sort of training. The greatest perverts of globalization is that the low-income countries are actively subsidising high-income countries with pharmacists, with nurses and with medical doctors. Developing countries are losing their medical and pharmacy leadership. So I think we have to look pragmatically and realistically and take a practical approach on human resources. The second is medicines financing. The single biggest problem in access to medicines is financial – unfair financing, the fact that in poor countries it is poor house-holds that pay the biggest bill for medicines. Unfair financing can be addressed in a variety of ways through health financing, insurers, employers and through good use of international assistance. Also the financing lever is perhaps the most effective lever in fixing some of the other problems in the system, in promoting rational drug use policies and in ensuring a reliable supply system. The third thing is realistic thinking about how we can get support. The WHO has a massive outlay on good governance in many countries, so it is relatively expensive to get support. But we have to look pragmatically and realistically at ways of avoiding the biggest problems.

RL: One thing you have always done though is write about your observations in a pretty systematic way. Do you think that’s been an important part of your work?

JQ: I think people don’t spend enough time thinking. For me, writing is actually a way of thinking and it has been extremely useful.

RL: As an author who has written widely on stress in the workplace, what techniques do you use to stay calm in a high pressure environment like this?

JQ: One of them is trying to run in the mornings as often as I can. It burns off frustrations, reduces anxiety and helps in thinking through tougher problems. Time spent on exercising is almost always repaid by better concentration and productivity. The second thing is, to focus positively on the future. Looking back on the last 15 years of experience is to keep a good balance between work and family and friends, and I consider myself a recovering workaholic.

RL: So we have talked about how you relax, what about your family? Do you have time to read other, non-technical, materials?

JQ: Yes, I try to read periodicals from both ends of the political spectrum, so the Economist and the New Internationalist are two of my favourites. I like reading biographies, management books, books from contemporary Christian writers.

RL: And your goals for the future, after WHO?

JQ: Clearly a goal is to support my wife and three daughters in being as happy and successful as they can be. I am going on to head Management Sciences for Health. MSF deals with the building blocks of health care financing, people and medicines, and the management glue that make health systems work. MSF has a long history of helping countries to make practical improvements and a real commitment to hope to help MSF build on this success to have an even greater impact in the future. In my 70’s maybe I’ll spend more time drumming. I still play the drums.

RL: Have any of your family followed in your footsteps professionally?

JQ: I’m a little bit young for them to have followed yet, but I have one daughter who is interested in becoming a paediatrician. My great-grandfather who at age 60 went through psychoanaly- sis and became a child psychiatrist. He finally retired at age 85 and died at 105. So I suppose I like to think I might be close to his trajectory.

RL: Last question – if you hadn’t followed this career path, what do you think you’d have liked to have done?

JQ: Good question. In high school I thought I might want to be a chemistry professor or run a pizzeria, because I used to make pizza on Sundays. I think if I was to do something different, it might be journalism or broadcast media, something that brings ideas together, or just more time writing, but I have been really happy with this mix of medicine and management.

RL: Thank you.

Dr Jonathan Quick has worked in the Department of Essential Drugs and Medicines Policy for the last nine years, six of those as Director. He originally joined in January 2004 to become Chief Executive Officer of Management Sciences for Health.


When did you become involved with WHO?
VL: In October 1974 in the WHO Scientific Group on Guidelines for Regulation and Evaluation of New Drugs for Use in Man was the youngest member, along with 33, and all the others were well-known professors from many other countries. WHO wanted somebody from an Eastern Block, socialist country, not only for geographical representation but because we had a different system with its own advantages and disadvantages. WHO sent an invitation to the USSR Ministry of Health and the Ministry nominated me because I had some experience of working in the area of drug evaluation. I am proud to say that this Scientific Group and the technical report it produced laid the foundations for Good Clinical Practice.
RL: Let’s jump forward a little bit to ask, if you can, what would you have done?
VL: Who knows? I was interested in pharmacology and at that time space discovery was very popular. The first space launch – Yuri Gagarin’s trip was in 1962 so I was already at medical school, but before that I could probably have worked on developing spurtks or satellites and such things. I prefer research, when you are looking for something, when you are exploring something, scientific work is much more interesting for me.
RL: In many ways your experience has been in academia, policy-making, research and administration at different times. When we look at the medical and pharmacy education system, I wonder what your thoughts are about how it should be changed to help new graduates meet today’s needs?
VL: Well, I think that there should be more practice in the curriculum, and so-called problem-solving education, which has now been introduced in many countries, is very useful. Knowing about drug-related problems, I must say that there is a need for far more education on the rational use of drugs, and the importance of clinical pharmacology in the curriculum. In the majority of countries, it is not studied enough, and often the system is for students to study pharmacology before they know clinical medicine. For example, they start pharmacology during their second or third year and they study psychotropic drugs, but they only do psychiatry in the fifth year. So it is theoretical study, just to pass the exam and then forget pharmacology shouldn’t be taught as a theoretical discipline, it is applied. Many more hours are given to pharmacology than to clinical pharmacology in the majority of countries. It is so important to know more about the rational use of drugs, to know the different models, but as they are not going to be veterinarians to treat animals, medical students have to know how to treat patients and how to deal with people. I am sure that there is a need for far more hours on clinical pharmacology connected to different disciplines. And what I introduced in my University, together with the Ministry of the Medical Faculty, was that four professors of different disciplines presented lectures to students on one subject (for example, stomach ulcers), one topic after another, beginning with the professor of pathological physiology. Students were given information on diseases, the pathogenesis of diseases, the description of pathology then spoke about diagnosis, about developments and finally, or my colleagues, as clinical pharmacologists, talked to them about drugs and how to treat.
RL: That seems such a logical approach.
VL: Well, previously we had not known and we started this as an experiment and students liked it, in spite of having to sit for four hours.
RL: Can we take you to the next phase. You lived in interesting times, with the change in the Soviet system and the change in the pharmaceutical system that went along with that. I wonder what your insights are about those major changes and particularly what were some of the good things, and the lessons that may have been lost or forgotten in this transformation?
VL: When people say it was an interesting period, I mean particularly when the Soviet Union, I would answer – and the majority of Russian people would probably agree – that for us it was not interesting, it was a very difficult time because people had not been prepared to live in that system. The most respected people were scientists, doctors, teachers and people did not care too much about money. Then when, overnight, this dramatic change happened, people were not prepared to struggle for their lives, and those people who were most respected before – because the Soviet society was paying salary. Can you imagine having to live several months without salary, or several years? And science suffered a lot. Many capable scientists left the country, especially those from theoretical science where there is nothing to sell immediately. For many people there are a lot of goods in the shops – in Moscow you can find anything – but the majority of the population cannot afford them.
RL: And that includes medicines?
VL: Yes, medicines became very expensive. People didn’t care about the price of medicines in the former times because sometimes the prices were just symbolic. We had tablets for coughs that cost 1 kopeck, 1 kopeck is almost nothing. Everything was subsidised by the State and treatment in hospitals was free of charge. Now, if somebody needs an operation and there is no money, unless it is an emergency it is a problem. Fortunately, the economic situation of the country is improving, so people’s lives are easier.
RL: That and includes medicines?
VL: Yes, medicines became very expensive. People didn’t care about the price of medicines in the former times because sometimes the prices were just symbolic. We had tablets for coughs that cost 1 kopeck, 1 kopeck is almost nothing. Everything was subsidised by the State and treatment in hospitals was free of charge. Now, if somebody needs an operation and there is no money, unless it is an emergency it is a problem. Fortunately, the economic situation of the country is improving, so people’s lives are easier.
RL: Can you tell us about your priorities for the Health Technology and Pharmaceuticals Cluster, and, of course, you are responsible not just for essential medicines but essential equipment. What do you see over the next five to 10 years for your cluster?
VL: Well it is very difficult to choose priorities because the Cluster and the departments it controls are so diversified. What I would like to mention is the new strategy of the Essential Health Technologies Department, which is very country oriented, and focused on countries’ needs. The Department has developed a special basic operational framework, with tables showing the needs of countries and their priorities on one side and on the other side what WHO has and what it doesn’t have to meet these priorities. So we invite countries to participate in choosing their priorities, not to say that it is the priorities of WHO Headquarters, but the priorities of countries.
RL: Equipment has been somewhat neglected compared to essential medicines. Essential medicines have gone forward very rapidly.
VL: Yes indeed, and when I came to this job I realised that I had to concentrate first on the development of the Blood Safety and Clinical Technology Cluster, which I renamed it Essential Health Technologies because it should provide essential technology, basic appropriate technologies, especially to developing countries. We are drawing on some experiences from EDM’s work, for example, we are going to create a list of essential equipment.
RL: What about your family? Do you have children who are following in your footsteps?
VL: Well, my wife is also a medical doctor, we studied together, and she helps me at WHO. We are both dedicated to working on drug-related problems and very well known in Russia and other CIS countries as Dr Arantxa Lepakhin at the Institute for Adverse Drug Reactions in the Soviet Union, and then when the system was destroyed, I worked for many years as a consultant to the new centre in Russia – the Centre for the Control of Drug Safety and Drug Monitoring. For some years after the dissolution of the Soviet Union, the Russian Ministry of Health had no centre for pharmacovigilance, and in practical terms my wife was responsible for re-establishing one. Also, in 1994, she started to publish the Bulletin on Drug Safety on her own, and now she is Chief Editor.
My wife has always provided me with valuable information on drug-related problems and drug safety. She helped me a great deal in evaluating products by drawing my attention to the negative side of drugs, or of their use. When people have a lot of information on the efficacy of a product, they tend to focus only on the positive side. Every company, the television and the other mass media speak about how effective these drugs can be, how they can cure everything. We are both dedicated to working on drug safety issues, and I am very grateful to my wife for her constant support in my work. We have one daughter who is also a doctor.
RL: How do you relax?
VL: When I was younger, I liked sport very much, swimming, skating, playing tennis, I played volleyball, but not now of course. Now I try to go to the swimming pool. I was a member of the swimming
WHO pledges massive effort to increase ARV treatment

O n World AIDS Day, 1 December 2003, WHO and UNAIDS released a detailed plan to reach the “3 by 5” target of providing antiretroviral (ARV) treatment to millions of people living with HIV/AIDS in developing countries and those in transition by the end of 2005. This is a vital step towards the ultimate goal of providing universal access to ARV treatment to all those who need it. In the words of WHO’s Director-General, Dr Lee Jong-wook, “Preventing and treating AIDS may be the toughest health assignment the world has ever faced, but it is also the most urgent… The lives of millions of people are at stake, and this strategy demands massive and unconventional efforts to make sure they stay alive.”

In November 2003, UNAIDS announced that 40 million people around the world are infected with HIV, and that the global AIDS epidemic shows no signs of abating. During that year 8000 people died from HIV every day. WHO estimates that six million people worldwide are in immediate need of AIDS treatment, and the new strategy outlines the steps needed to deliver treatment to half of them within two years. After 20 years of fighting the epidemic, it is now clear that a comprehensive approach to HIV/AIDS must include prevention, treatment, patient care and community. Evidence and experience shows that rapidly increasing access to ARV treatment in line with 3 by 5 targets will make it easier to deliver quality-assured “fixed-dose combinations” of ARV, which are equally effective. The selection of an individual regimen for a patient will be based on a combination of individual needs, together with the availability and suitability of a particular regimen in a country. The strategy also recommends the use of quality-assured “fixed-dose combination” (FDC) therapy, so that ARV medicines become available to all. The strategy also recognizes that manufacturers, products, procurement agencies and laboratories meet international quality, safety and efficacy standards.

Urgent training needs
Training of health workers is an urgent need in all countries involved. Many of the countries with the highest numbers of people living with HIV/AIDS have trained doctors or other trained health staff. Many health workers have died as a result of untreated AIDS. Other AIDS doctors have moved to seek better pay and job security in wealthier countries. The strategy acknowledges that the involvement of communities and community workers is essential to the success of this initiative. Significant evidence and experience address the fact that strong community support can make the difference between life and death. Countries are expected to take action to ensure that all have access to new knowledge and effective treatment. An intensive training programme will enable these health workers to evaluate and monitor patients, and make sure that they receive and are taking their medicines.

Funding
Substantial new funding of around US$5.5 billion is needed over the next two years. “We know what to do but what we urgently need now are the resources to do it,” said Dr Lee. “This is the time to stop leaving the building strong alliances immediately to implement this strategy. Three million people are counting on it.”

For further information contact: World Health Organization, Department of HIV/AIDS, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland. Tel: +41 22 791 4530 / 791 1497, fax +41 22 791 4834, email: whoaids@who.int Web site: http://www.who.int/3by5/en/
**South Africa: a novel approach to improving adherence to TB treatment**

**T**uberculosis is an increasing public health problem in Cape Town. Poor adherence to treatment regimens results in a low cure rate and an increasing incidence of multi-drug resistant tuberculosis. Current usual care is to directly observe patients for all or most of their doses in the short course regimen. Direct observation has been shown to be no better than self-supervised care. Further, in a Cochrane review it has not been shown to improve outcomes of care.

Directly observed treatment (DOT) plays a relevant role in health centre staff. During 2001 there were a total of 3,559 and 3,432 TB cases requiring treatment in Cape Town’s Khayelitsha and Nyanga districts respectively. On average, cases require 6.5 months of treatment. This equates to 1,928 and 1,859 patients respectively receiving directly observed TB treatment everyday in those districts. Adherence interventions, other than direct observation, are required that improve adherence and decrease the workload of the staff at health centres.

Now with a relatively simple, but innovative idea, a Cape Town doctor, David Green, has dramatically helped the fight against TB. He has introduced a Short Messaging Service (SMS) – a text message service that enables short messages of up to 160 characters to be transmitted between cell phones – to remind patients to take their medicines. Dr Green has called this system Cell Phone Prompted Self Administered Therapy (PSAT). It is a system whereby selected patients are released from the requirement of direct observation and are prompted by the text message service of the GSM (Global System for Mobile Communications) standard to take their medication daily. This relieves patient loads for DOTs employees whilst not decreasing the cure rates currently achieved by DOTs. The decreased workload will allow staff to focus attention on patients who are poorly compliant, thereby increasing the likelihood of improving compliance amongst all TB patients (not only those on PSAT).

Pilot studies at the Chapel Street Clinic in Cape Town have shown cell phone usage amongst 71% of the target population. Further, wide-scale patient and staff acceptability of this intervention have been shown. The local health authority is paying the R11.80 (US$1.3, approximately) per patient per month to run the SMS reminder service.

The system is simple, affordable and flexible – Dr Green enters the names of TB patients onto a database. Every half hour his computerserver reads the database and sends personalised messages to the patients, reminding them to take their medication. The technology that he uses is extremely low-cost – a freely available open source software operating system, web server, mail transport agent, applications and a database. When patients complained that their messages were boring, Dr Green sent them a variety of alerts, including jokes and lifestyle tips, with the result that he now has as database of over 800 messages that he changes on a daily basis. Of the 300+ patients involved in the pilot there were only five treatment failures, and WHO has singled out the scheme as an example of best practice.

The initiative not only uses technology to address a real need effectively, but it does this in a simple, affordable and flexible way.

Dr David Green, The Compliance Service, Cape Town, South Africa. Email: david@on-cue.co.za, web site: http://www.compliance.za.net

This article is based on the text “Using cell phones to boost TB compliance” published in the EDrug Electronic Discussion Group.

**References**


ICUIM 2004: the Second International Conference on Improving Use of Medicines

DEAN SOSS-DENZAN

F
t hundred leading researchers and policy-makers from the international health community will meet in Chiang Mai, Thailand, at the end of March 2004, to discuss and plan interventions to improve use of medicines in resource-poor settings (see Monitor 32). The Second International Conference on Improving Use of Medicines (ICUIM 2004) comes seven years after the first, which produced the first state of the art consensus on interventions to improve drug use in non-industrialised countries. It also defined evidence-based recommendations for programme implementation and a global research agenda to fill gaps in knowledge. This research agenda was conceptualised as a five-year plan. Based on that plan, the partner organizations have supported 31 interventions and policy analyses under the auspices of the Joint Research Initiative on Improving Use of Medicines. These studies will form a core of presentations at ICUIM 2004.

Since 1997, the area of essential medicines has advanced considerably, but has also encountered several difficult new challenges. Under pressure from international banks and facing spiralling health care costs, many governments have reconsidered the financial viability of centrally-organized, publicly-delivered health services, including the provision of affordable medicines. The period has been marked by various innovations in health reform, decentralisation, and a rapidly expanding private health sector. New financing schemes to support access to essential medicines have been explored in many settings. At the same time, spurred on by the development of new global initiatives to address the catastrophic epidemics of HIV, TB and malaria, the issues of access to and appropriate use of antimicrobials have taken on new prominence in global public health thinking. An increased global flow of antimicrobials brings with it, however, the twin threats of growing rates of antimicrobial resistance and rising prices for alternative antimicrobials to treat resistant infection. In developing countries, where resources are often scarce, these mounting threats can be daunting.

Building consensus

ICUIM 2004 aims to build an up-to-date international consensus on strategies for implementing effective and innovative interventions for improving medicine use; and to define a new global research agenda relevant to current conditions and unfolding developments in international health. Conference products will include:

- a review of previous and current initiatives to improve medicine use, producing materials to be disseminated widely through electronic media and print publication;
- an expert consensus on which interventions are successful in various settings and strategies for implementation;
- a defined, prioritised global research agenda within each of the Conference topic areas to fill gaps in knowledge of what works and barriers to improvement;
- a strategy for implementing this research agenda and disseminating its findings.

The Conference will concentrate on six major focal areas, each of which will be discussed during half-day sessions (see Figure 1). In addition, there will be opening and closing half-day sessions to introduce the major themes of the Conference and to summarise the discussions within the six focus areas respectively.

A one-hour plenary session will open each half-day focal area. In each plenary, two or three speakers will present on key issues of medicines use, relevant to the half-day focus area. Guest speakers include leaders within WHOs international academic institutions, and ministries of health. For example, one key plenary session will focus on the perspectives of country health ministers on use of medicines issues.

ICUIM 2004 will allow for “meetings within a meeting” of groups of researchers and policy-makers who share common interests in specific topics in the use of medicines. These groups, referred to as topic tracks, are organized around an illness (malaria, HIV/AIDS, tuberculosis), a population group (children, adults with chronic illness), and/or a policy area (antimicrobial resistance, access to essential medicines).

After the plenary presentations, participants will break into topic-specific groups. Each breakout session will last for two hours. The first hour will generally consist of four or five brief oral presentations (accepted or invited abstracts) or an alternative presentation (for example, a roundtable discussion) to develop the issues to be covered in the session. During the second hour of each session, Conference rapporteurs working with track coordinators will summarise discussions in the session according to a defined set of criteria (key lessons learned, recommendations for action, research needs). These topic-specific summaries will be fed systematically into an overall conference summary.

Archive of presentations

ICUIM 2004 will have three major outputs: an archive of state of the art research; consensus recommendations for programme implementation and research; and a summary conference report and journal publication.

One innovation of the 1997 International Conference on Improving Use of Medicines was the creation of a permanent archive of all conference presentations. Participants were requested to prepare all presentations (including oral presentations) as posters using a standardised size and format, and these presentations were scanned and captured in electronic form. This archive, widely used for teaching and research, is available on the WHO web site (http://www.who.int/medicines/organization/pat/icium/icium.shtml) and is distributed in teaching courses of the International Network for Rational Use of Drugs.

ICUIM 2004 will again capture all Conference presentations in electronic form. Presentations that are submitted prior to the Conference will be burned on CDs and distributed to all participants so that they can have them as a permanent record.

Recommendations and research agenda

The first ICUIM Conference was most successful in developing a coherent summary of the state of the art and an agenda for post-conference research. ICUIM 2004 will duplicate this successful process using a structured web-based reporting system. A rapporteur will summarise each session using a structured reporting format. In the final session of the conference, a broad summary of lessons, recommendations, and key questions will be given. The edited collection of the daily summaries will form the basis for the overall conference recommendations and global research agenda.


Following ICUIM 2004, WHO will again prepare special coverage in the Monitor. To extend thinking about improving use of medicines beyond the traditional audience, ICUIM 2004 will also seek to publish its key presentations, recommendations, and research agenda more widely in scientific journals.

Figure 1

<table>
<thead>
<tr>
<th>Structure of ICUIM 2004</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Focus Areas</strong></td>
</tr>
<tr>
<td><strong>Tuesday March 30</strong></td>
</tr>
<tr>
<td>Morning</td>
</tr>
<tr>
<td>Opening</td>
</tr>
<tr>
<td>1 International policies and systems</td>
</tr>
<tr>
<td>Access, pricing, and use of medicines; including HIV/AIDS</td>
</tr>
<tr>
<td>Within each focal area, a plenary session will open the discussion, followed by group discussions in each of the following parallel topic tracks:</td>
</tr>
<tr>
<td>Access, pricing, and use of medicines; including HIV/AIDS</td>
</tr>
<tr>
<td>Closing, with synthesis of issues across focal areas and tracks</td>
</tr>
</tbody>
</table>
Promoting rational use activities in Iran: a successful trend

M. Cheraghali, F. Solaymani, G. Shalviri

The Islamic Republic of Iran’s Ministry of Health has a mission to provide access to sufficient quantities of safe, effective and high quality medicines that are affordable for the entire population of 65 million. Since the 1979 revolution, Iran has adopted a full generic-based National Drug Policy (NDP), with local production of essential drugs and vaccines as one of the main goals. Currently 55 pharmaceutical companies produce more than 96% (quantitatively) of medicines on the market. Although over 85% of the population use an insurance system to reimburse their drug expenses, the government subsidises pharmaceutical production in order to increase affordability of medicines. Today, essential medicines are available and affordable for more than 85% of the population.1

Iran has adopted a national drugs list, compiled by the Iran Drug Selection Committee, comprising medical specialists, pharmacists, pharmacologists, and drug regulatory and national control authority members. The committee meets regularly and evaluates medicines, based on their efficacy, safety and cost-effectiveness. Iran’s drug list includes more than 1500 drugs, listed by generic name, and including different dosage forms. In order to improve affordability, drug procurement is centralized to one State-owned company that is responsible for procuring most of the imported drugs, and two semi-private companies. Iran has a highly regulated pharmaceutical market and all medicines including biologicals require registration before granting marketing authorisation. Both the national regulatory authority and national control laboratories in the Ministry of Health are well developed.

However, there are convincing data which show that excessive prescribing occurs. Evidence of irrational use of drugs, including a high number of drugs per prescription, and a high level of use of injectable drugs and antibiotics, convinced the Ministry of Health to set up a Centre for Promoting Rational Use of Drugs (RUD) and coordinating all related activities. Founded in 1995, the Centre has three main functions, collecting data through a unique prescribing auditing system, disseminating drug and poison information, and coordinating the country’s Adverse Drug Reaction Centres. The RUD Centre now has branches in all the major provinces, and has trained many health professionals. It publishes regular updates of the Iran Drug List and distributes it among health professionals, especially doctors. The first and second editions of the National Formulary of Iran (NFI) were published in 1998 and 2000 respectively, and the third edition will be published in late 2003.

As one of the active centres of Iran’s RUD network, The Tehran Medical Science University hosted the first international training course on RUD to take place in WHO’s Eastern Mediterranean Region (EMRO), in May 2001. Held jointly with WHO/EMRO the course attracted 29 participants from 12 countries, both within EMRO and in other regions. “Tehran proved to be an excellent venue for this type of training activity, with motivated staff and several examples of successful local rational drug use interventions that have already taken place (including a prescription database system for medical auditing).”2 Building on this success, the University hosted the second international course in June 2002, attended by 31 participants from 13 countries.

Drug and Poison Information Centres

The impact of drug use on the health of a population not only depends on availability, affordability or accessibility, but more importantly on the rational use of drugs at clinic level. Drug and Poison Information Centres have a significant role in educating medical groups and the public. The main objective of Iran’s Centres is answering patient-oriented questions from medical professionals (passive dissemination) and also updating medical staff about drugs (active dissemination). The Centres promote and educate on rational use of medicines to prevent unwanted/toxic effects. As more Centres are opened around the country, their beneficial effects will increase.3 For further information on Drug and Poison Information Centres in Iran see Monitor No.28/29.4

National Prescribing Auditing Committee

Prompted by the high number of drugs per prescription, unjustified use of parenteral drugs, antibiotics and Clinical Nurse Specialist (CNS) medications, the National Committee of Prescriptions Auditing was created in 1996 and later developed its national network, with 40 sub-committees across the country. The Committee collects prescription data from different provinces and analyses them, based on the drugs prescribed, the most used drugs/dosage forms, the most prescribed drug categories, etc. using Rx Analyst software. Data analysis provides information on:

- a physician’s prescribing pattern in comparison to that of other physicians in the same area or in the country;
- prescribing patterns of a group of physicians or a medical specialty in comparison to other physicians or medical specialties in the same area or the country;
- frequency of prescribing a certain drug; a certain class of drug; and a certain drug dosage form in a specific place, part of a city, a whole city, province, and finally in the country as a whole;
- average number of items per prescription;
- potential drug interactions in three categories: severe, moderate and mild.

The Committee analyses the prescription pattern of every general practitioner at least once a year and not only informs doctors about their patterns of prescribing, including their weakness and strengths, but provides training seminars and workshops on RUD for medical doctors and pharmacists. So far the Committee has trained more than 5000 medical professionals in three-day RUD workshops. The National Committee is served by three sub-committees: policy and legislation, computer and data analysis, and medical science advisory. Depending on their focus the sub-committees consist of officials and experts from the Ministry of Health, the Iranian Medical Council, universities and health insurance providers.

The National Committee’s responsibilities towards local committees include policy-making, standard-setting for qualitative analysis of RUD in doctors’ daily practice; providing software, hardware and technical support for local data collection and analysis; annual budgeting; and cooperation in organizing seminars, workshops, and continuing education courses on RUD. Local committees consist of an advisory sub-committee of medical experts and an executive sub-committee for prescription data collection, analysis and other local activities.

Box 1

The functions of local and national committees

- encouraging cooperation between doctors and pharmacists to improve medical services, particularly in terms of RUD. One example is correcting patients’ irrational beliefs on drug therapy, such as injections being better than oral forms of medicine;
- computer analysis of all physicians’ prescriptions and informing them periodically about their daily practice, with particular attention to RUD-related problems;
- appraising physicians who employ RUD in their daily practice. Appraisal is done by ministry officials and health insurance providers;
- organizing seminars, workshops, and continuing education courses on RUD, with special emphasis on the risks of drugs prescribed irrationally;
- preparing and distributing pamphlets about RUD to medical professionals;
- advertising locally and nationally via radio, television and newspapers to correct the irrational use of drugs and its health and economic impact.
Local committees send a copy of computerised data to the National Committee for national analysis, plus a seasonal report of all of their activities for review and feedback.

Figures 1 and 2 show that all of these efforts are having an effect, but more needs to be done. Although the average number of drugs per prescription and use of injectables have declined they are still very high, and the percentage of patients receiving antibiotics continues to rise. More work and new interventions must be considered. However, the availability of such information will be helpful to several sections of the MOH and other government and private organizations, in the following ways:

- predicting and ensuring correct programming for the annual importation, production and distribution of pharmaceuticals in different parts of the country, according to their real needs;
- estimating the annual budget for the pharmaceutical needs of the Iranian population by the Ministry of Health and health insurance providers;
- changing medical schools’ curricula to ensure students are properly educated to practice RUD, with emphasis on the frequent problems caused by irrational therapy;
- discovering local or endemic diseases in certain parts of the country and taking all the necessary steps to find and possibly eradicate the reasons for them, treat the patients correctly and prevent the expansion of communicable diseases. Seminars, workshops, and continuing education courses on RUD programmed according to the problems and needs of each region.

**Box 2**

**Local committee procedures for analysing physician prescribing patterns**

- prescriptions received from health insurance providers;
- data keyed in by computer operators under supervision of pharmacist(s);
- data analysed by pharmacist(s) using the software provided by the National Committee;
- report prepared for review by the medical advisers;
- decision made on physician’s practice regarding rational or irrational use of medicines;
- reports prepared containing the results and the decision of the advisory subcommittee;
- reports sent directly to physicians whose prescriptions have been analysed;
- a copy of the profiles of those physicians whose prescribing practices continued (after being informed at least twice) to pose major RUD problem sent to the local medical council and health insurance providers for appropriate action. In some cases health insurance providers might decide to discontinue their collaboration with the doctor.

**Figure 1**

**Average number of medicines per prescription**

<table>
<thead>
<tr>
<th>Year</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average</td>
<td>4.3</td>
<td>4.2</td>
<td>3.9</td>
<td>3.7</td>
</tr>
</tbody>
</table>

**Figure 2**

**Percentage of patients receiving injectable drugs or antibiotics**

- Antibiotic
- Injection

<table>
<thead>
<tr>
<th>Year</th>
<th>1999</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>70%</td>
<td>60%</td>
<td>50%</td>
<td>40%</td>
</tr>
</tbody>
</table>

**Figure 3**

**Number of adverse drug reaction reports sent to the National Centre 1998–2002**

<table>
<thead>
<tr>
<th>Year</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases</td>
<td>1163</td>
<td>1710</td>
<td>1675</td>
</tr>
</tbody>
</table>

**Box 3**

**Activities of the Adverse Drug Reaction Centre**

- collecting, analysing and recording reported ADRs (see Figure 3);
- screening recorded ADRs to find new signals on ADRs;
- publishing “Safety Alerts” to inform all health professionals of new safety information;
- conducting seminars at university teaching hospitals;
- sending ADR reports to WHO’s Uppsala Monitoring Centre;
- contributing to the Centre’s annual meeting for WHO members;
- organizing training courses for health professionals;
- lecturing at continuing education seminars;
- providing feedback information for ADR reporters, to promote reporting;
- communicating with other national ADR centres.

**Coming up…**

There are plans to publish a national ADR bulletin, to have on-line reporting of ADRs and to provide an ADR database. It is also intended to do intensive hospital monitoring of ADRs by training staff in university teaching hospitals, and to monitor adverse events induced by vaccines and herbal medicines. For further information contact: Ministry of Health, Food and Drug Department, Promoting Rational Use of Drugs Centre, 2nd Fl., Fakhr-e-Razi St., Enghelab Avenue, Tehran-I.R. Iran. Tel: (+9821) 6404223/6405569; Fax: (+9821) 6417252.

**References**

RATIONAL USE

WHO’s database on rational use of medicines

Kathleen Holloway, Verika Ivanovska

T...ial Use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time, and at the lowest cost to them and their community. Unfortunately irrational use of medicines is widespread throughout the world. Problems include the unnecessary prescription of drugs, particularly antimicrobials and injections. This is harmful in terms of economic loss, unnecessary adverse drug events, antimicrobial resistance and the spread of hepatitis B and C and HIV through unsterile needles.

Much has been done in the past 15 years to improve the use of medicines. The International Network for the Rational Use of Drugs (INRUD) was formed in 1989 with the objective of undertaking multidisciplinary intervention research to promote more rational use of drugs in developing countries. INRUD was instrumental in developing the WHO indicators of drug use and a rapid appraisal method for investigating drug use. In 1997 the first international conference for rational use of medicines (ICIUM) was held in Chiang Mai, Thailand, where 272 participants from 46 countries met to review experience and define future directions, particularly for developing countries.

In April 2004 the second International Conference For Rational Use of Drugs will be held, again in Chiang Mai. Here progress made since the first conference will be assessed, and remaining gaps and future directions discussed. A new WHO database containing quantitative drug use data is being constructed in order to provide a general overview of drug use patterns in primary health care settings in developing countries over the past decade. Specifically, the database will tell us whether there has been any improvement in drug use over the period, what interventions have been done and where, and their impact and what serious gaps remain. The results will be presented in the conference and used to help define a future global agenda and also as an advocacy tool for promotion of rational use of medicines in the developing world.

Relevant studies on rational use of medicines for the period 1990–2003 are being identified using the latest INRUD bibliography and WHO/EDM country’s archives including articles, research proposals, theses, and reports on the subject studied. The database is based on standard WHO/INRUD indicators and some additionally developed indicators that describe drug use patterns more completely. Details concerning methodology and interventions are being entered into the database so that the impact of interventions can be assessed. The database will also be linked to other WHO databases, in order to obtain more comprehensive picture of drug use practices again in the way they are affected by health system factors.

The world of essential medicines loses a pioneer

Dr Molly Thomas, former Professor and Head of Pharmacology and Clinical Pharmacology at the Christian Medical College, Vellore, India, died on 22 March 2003. As Head of the Christian Medical Association of India’s Working Group on Rational Drug Use she was a true champion for the cause of rational therapy. Dr Thomas edited the Rational Drugs News Letter, and was an active member of the All India Drug Action Network. Her abiding belief was that rational medicines use would bring health care within the reach of the poor by reducing costs.

Dr Thomas travelled tirelessly across the country conducting training workshops for mission hospitals, developing their policy on rational drug use, undertaking prescription audits and coordinating drug reaction reporting. In 1983 she set up the first adverse drug reaction monitoring centre, in Vellore.

An excellent teacher, who went beyond the class room to care for her students, Dr Thomas was made a Fellow of the Royal College of Physicians of Edinburgh, UK.

By September 2003, 2739 articles from the INRUD bibliography for 1993–2002 had been screened, 187 relevant articles identified and 249 survey results entered into the database. Table 1 shows more detail of where surveys and interventions have been conducted.

Figure 1 shows some initial findings for one indicator of drug use – the percentage of patients treated in accordance with clinical guidelines. These initial results should be treated with caution as a complete analysis has not yet been done, and the database does not yet contain many of the unpublished surveys held within the WHO archives. Thus the final results may be quite different and will be accompanied by other details such as disease and prescriber type and impact of interventions implemented. Nevertheless, initial data show that there continues a great need to improve prescribing habits, as more than half of all patients have not been treated in accordance with guidelines. Also it is clear that relatively few studies have been done.

In summary, this database will be presented at the second ICIUM and used to help to identify progress and gaps and a future agenda for achieving global rational use of drugs in the developing world.

Table 1

Drug use surveys and interventions conducted in WHO regions 1993–2002

<table>
<thead>
<tr>
<th>WHO region</th>
<th>AFRO</th>
<th>EURO</th>
<th>EMRO</th>
<th>SEARO</th>
<th>WPRO</th>
<th>PAHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of surveys</td>
<td>103</td>
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WHO Regional Offices for Africa (AFRO), Europe (EURO), Eastern Mediterranean (EMRO), South-East Asia (SEARO), Western Pacific (WPRO), the Americas (PAHO)

Figure 1

Primary health care patients treated according to guidelines

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<td>2000/1</td>
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In 1994/5 1996/7 1998/9 Year

Africa/Asia

No. of countries | 5/5 |
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Africa | Asia

No. of patients treated

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K. Holloway

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Issue No. 33, 2003
Shedding light on medicine prices

ANDREW CREESE

Every day millions of people throughout the world go without treatment because they cannot afford the medicines they need. People in industrialised countries generally have insurance or subsidies that cover most of the price of their medicines. But those in poorer countries with less well developed health systems, typically pay the full cost of almost all of their medicines themselves. These are the people who know that medicine prices are a problem. Although prices may vary quite a bit within a country, people usually do not have the information about what prices are, or where to find the best prices. The same is often true of government authorities dealing with medicines.

Enough to give you an ulcer? If someone actually has a peptic ulcer and requires a month’s treatment, the brand version of ranitadine will cost the equivalent of:

- 13 day’s wages in the Philippines’ private sector;
- nearly 19 day’s wages in Armenia;
- and 50.5 day’s pay in Cameroon – almost two month’s pay for one month’s treatment.

It’s easy to see how a family’s whole income can easily be consumed by the medicines bill. Of course, people might be able to get their ulcer medicine at lower prices, if they can find generic equivalents from public sector sources. But in two of the three countries mentioned above (Armenia, Cameroon) the generic was not found. In the Philippines ulcer treatment costs are 12 day’s pay – one day less than for the brand drug from the public sector.

There are dozens of medicines and hundreds of prices. The same medicine may have different prices, in its originator brand or generic form, in public, charitable agency or private pharmacies, in urban and rural areas. This makes it impossible for the public to know what a “best buy” and where they can get it.

Medicine Prices – a new approach to measurement is an important step towards making price information for key medicines more widely available and more easily understood. The manual and the accompanying software and database also help to clarify what makes up today’s prices. Reliable information on what prices are and how they are made up is a first step to better negotiation, management and policy to make medicines more affordable by bringing prices down.

The launch of the WHO/HAI Medicine Prices manual at the World Health Assembly 2003

Measuring medicine prices and availability

KIRSTEN MYHR

The prices of medicines vary according to a number of factors, including:

- The sector in which they are purchased: the price is often higher in the private for-profit sector.
- The type of procurement agent: for example, different prices may be paid for the same product by a public sector purchaser, such as the Ministry of Health, the health facility that supplies the medicine to the patient, and the individual who purchases the medicine.
- The distribution route: a patient who purchases a medicine at a public hospital pharmacy may have to pay more if the hospital pharmacy purchased the product from a local wholesaler than if it has been purchased by tender and supplied through the public health sector distribution system.
- The patent status: the price of patented medicines is often higher than that of their generic equivalent, at least while the patent is in force.

It has been quite a challenge for WHO and HAI to develop a methodology that enables you to draw a sample on which to make recommendations and conclusions that make sense in different parts of the world. We cannot be sure yet that we have succeeded, but we think we have taken a large step towards that objective. The methodology’s success requires everyone to follow the guidance in the manual. Pharmaceutical prices are complicated and only by collecting data in a systematic way can you ensure that the findings are representative of your country or of the region in which the survey is being conducted.

Here, we briefly explain the key components – which medicines to look at, and where to look for their prices and availability.

Core and supplementary medicines lists

Many different medicines are registered and available worldwide. For many diseases or conditions, there are one or several therapeutically equivalent medicines available, and different countries may show substantial variation in what they have chosen. In order to make the survey manageable, a short “core” list of 30 medicines has been selected as the basis for data collection and analysis. The great variation in therapy tradition between countries makes it quite a challenge to pick the 30. We recommend that you make up a supplementary list of medicines that you find are important in your country.

The core list is a list of essential medicines with very widespread use, which makes them needed in most countries. Because they are widely used, we can collect prices from different countries and so make international price comparisons. The supplementary list is to be made up locally and includes prescription medicines that are either widely used in your country or used for important diseases, necessitating price monitoring. You may also select medicines for this list which are therapeutically equivalent to the ones on the core list, in particular if the ones we have chosen are not the therapeutic alternatives you use. Because the medicines on this list may vary between countries, they are to be used for national comparison only, for example, to measure prices between sectors and between originator brands and generics.

Originator brands and generics

Most of the medicines on the list are no longer patented, but we have also included a few which may still be patented in countries that observe patent laws. On your supplementary list you may choose to include more expensive medicines.

When medicines are not patented, there may be several products with the same active ingredient on the market. One may be the former patented product, we have called that the originator brand. The others will be generic products (generic equivalents) and they may...
have a brand name (“branded generic”) or have the generic name followed by the manufacturer’s name. Generics are usually much cheaper than the originator (sometimes known as innovator) brand. We have therefore asked for the price of the originator brand as well as the most-sold generic equivalent and, in the local facility that you visit, the cheapest generic copy. We think it is important to document if there is a price difference between not only the originator brands and most sold generic equivalents, but also between the most sold generic and the lowest-price generic. If there is a difference in price also between generics, then more money could be saved if there was a policy to use the lowest-price one.

You will most certainly notice another big difference in the number of products in each sector. Not only will the public sector have a limited number of substances, but also often only one product containing each substance. That is likely to be a generic product as it will be less expensive, but it could also be that the country has negotiated a good price on the originator brand product.

For each medicine, the core list contains one dosage form, one strength and one recommended pack size, to facilitate standardisation and to ensure as few sources of error as possible. Some countries have substances of products on the market so there may be significant differences in quality. You should only include products approved by your regulatory authority.

### Sampling method

Most countries, if not all, have at least two different parts to the health sector, a public part and a private-for-profit part. The private sector may consist of not only private retail pharmacies but also dispensing doctors and private hospitals. Often other groups such as the private not-for-profit sector exist, and may comprise NGOs such as a church mission sector and other aid organizations, or insurance companies etc. All these sectors will probably deliver or sell medicines, possibly at different prices.

The public sector normally purchases on tender and so there will be a net tender price, but that is not always what the patient pays. They may pay nothing, or a fixed fee which could be less than the purchase price, or they may pay more if a mark-up is charged. In the public sector we therefore examine both procurement prices and the prices patients pay to be recorded separately.

So, prices may vary between all these sectors. And they may also vary between different parts of the country, e.g. between urban and rural areas.

The manual describes a methodology which tries to take all this into consideration. It means measuring prices in different health facilities as well as in different pharmacies and in four different geographical areas, one being the capital or largest city. To ensure as accurate prices as possible, more than one facility or pharmacy in each sector and area are visited (see Figure 1, sampling diagram).

### International reference prices

You may find the way we express prices confusing. Instead of how much or actual prices found, they are compared with an international reference price, to facilitate national and international comparisons. The local price converted into US$ then compared to a reference price. The ratio between the local price and the international reference price is then used for comparison.

Our objective was to use reference prices that are widely available in the public domain (on the Internet). Not many such price lists are available and we therefore chose Management Sciences for Health Drug Price Indicator Guide supplier prices and use the median price for each medicine. MSP prices are net prices from not-for-profit wholesalers to developing countries, and you may find it strange to compare private sector prices with them, because wholesale and retail mark-ups are found in that sector.

But once you get used to this way of analysing, there should be no difficulties. One of the problems in choosing the MSP price list as reference, was that prices of patented medicines cannot be found there. However, our method allows you to choose a different list of reference prices if, for example, you want a choice, or to include on your supplementary list medicines that are still patented. One example of such a list is the public price list in Australia. These are the prices that have been negotiated with the industry for medicines that are reimbursed in Australia (see: http://www.health.gov.au/phs/).

### Affordability

While one issue is the price of medicines, another is whether people can afford them regardless of how expensive they are. One good method to find this out is to compare the cost of treatment with peoples’ income. We have chosen this method, and list the daily wage of the lowest-paid unskilled government worker for comparison.

In the Workbook you will find 10 conditions and suggested treatment courses representing both acute and chronic illnesses. In addition, you may enter more treatment schedules based on local/national treatment guidelines if they differ from the one in the manual. For the treatment courses we have selected, and using data which you will enter, the Workbook will automatically calculate the number of days an unskilled government worker will have to work in order to afford the cost of a defined course of treatment for these conditions.

When you look at the figures and remember that in many developing countries a large part of the population earns even less than the lowest paid government worker, you will find that this exercise is very illustrative and probably easier to understand, at least for the consumer, than the price ratios!

### Price components

We are attempting to find out how retail prices are made up. The final cost of a medicine whether paid by a government facility, a health insurer or the patient reflects the manufacturer’s selling price (MSP), plus all intervening price additions. Such additions may vary widely between countries and also between sectors in a country. Common add-ons are import duties, taxes, mark-ups for importers, wholesalers and retailers, distribution costs, dispensing fees and VAT (see p. 20). The manufacturer’s price is usually not disclosed by the government and/or the manufacturer.

Manufacturers often argue that they are wrongly blamed for high prices that are caused by high national taxes and mark-ups. When developing countries, such add-ons are controlled, in others the wholesalers and retailers may charge whatever mark-ups they want or as much as the market will bear.

### Basic information about the pharmaceutical sector

Finally, in order to help understand the medicines market in your country, we have developed a questionnaire for collecting basic information about the pharmaceutical sector, such as the procurement method, extent of aid programmes, reimbursement and exemptions, the size of the sector and distribution of pharmacies.

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**Key elements of the survey methodology**

- **Standard list of medicines**
- **Standard strength, dosage form and preferred pack size**
- **Standardised sampling of facilities**
- **Standardised calculation of prices and affordability**
- **Computerised Workbook**
Basic results that the WHO/HAI survey offers country-level investigators

The field survey process in brief

Until recently local investigators decide to undertake a WHO/HAI medicine prices survey, the bulk of their work revolves around the collection of price data from medicine outlets. A selection of outlets is visited in different health "sectors". For example, in most studies the study team will look at prices to patients at twenty or more government-sponsored clinics and also at twenty or more private for-profit pharmacy shops.

Often another important sector exists that should be included in their study, such as charitable or mission facilities or parastatal cooperatives, or health facilities created for employees of a major industry. The survey manual provides guidance on choosing sectors and then identifying the sample of outlets to be visited.

The WHO/HAI survey targets a set of 30 specific essential medicines, such as cotrimoxazole syrup and diazepam tablets. Study teams are encouraged to add other medicines of local interest to this core list. Data collectors on the local study team visit the medicine outlets and ask to see each of the medicines in three precisely-defined versions. First is the innovator or originator brand version of the medicine. Next is the generic version of that medicine that is most commonly sold or in stock. In some outlets, this generic may be the same as the nationally "most sold" generic. It may have a brand name. But it is never the innovator product. In large for-profit pharmacies, there could be many different products that are the same substance and strength. So, surveys of the for-profit sector frequently find a different product fitting each of the three versions. However, in public facilities there is often just one simple generic version of a medicine. If the innovator or most sold version is not found at an outlet, the corresponding spaces on the data collection forms are left blank.

Prices gathered on paper data collection forms in the field are checked for mistakes and then entered into a computer spreadsheet. There is a Microsoft Excel Workbook of spreadsheets that has been created for this purpose by the WHO/HAI survey. The Workbook provides a clear structure for entering all the field data. Data are entered twice, to ensure good quality. After data entry, several key analyses are produced automatically and immediately.

Analysis of results for specific medicines

Table 1 shows a small portion of the Excel Workbook, after some data have been entered. These data are from the 2001 Kenya medicine prices survey. Normally, the header and the first nine columns of this section would appear with a blue background. These columns identify the surveyed products and present some automated analyses. The last two columns (headed “1” and “2”) would have a white background, and this is where field data are entered by the local study team. The numbers below the header in the last two columns are prices for one unit of medicine, in the local currency. Thus, in the first outlet surveyed, a 1 gm vial of innovator brand ceftriaxone cost 2100 Kenyan shillings (KShs). The price in the second facility was considerably lower (1890 KShs). The generic forms of ceftriaxone were cheaper still in the first facility (both were 1400 KShs), but were not available in the second facility. A total of 26 for-profit facilities were surveyed in Kenya and all their data were entered in this spreadsheet page, but the remaining columns have not been shown here.

Once data are entered, the column headers “Medicine name” “Medicine type” “Medicine %ile” “MPR” “%ile med.” instantly presents results on medicine availability. We can see that half of the surveyed shops had the innovator brand of ceftriaxone in stock. The generic forms were less often found – about 19% of shops had the leading generic ciprofloxacin product in retail shops. As for the maximum price ratio, while the innovator brand ceftriaxone was about 20 times the international bulk generic price, the minimum price ratio seen for innovator brand ceftriaxone was 16.24 (shown in Column 7). The remaining price ratios were of course between the maximum and minimum. The Workbook also calculates the 25th and 75th percentile of the price ratios, which together mark off a more "usual" or central range. Finally, the median price ratio (or MPR, Column 4) is the result which is most representative among all the shops visited.

Generic versions of surveyed medicines are almost always less expensive than the innovators. We can see this pattern in Kenya’s results in Table 1. Prices for the leading generic competitor to innovator brand ceftriaxone are typically only two-thirds as high (MPR 12.03 versus 18.56). Finally, the presence of additional generics on the market results in much lower price for generic ceftriaxone that is less than half of the median for the innovator brand (MPR, 8.59).

For ciprofloxacin tablets, the contrast between innovator brand prices and generic prices is even sharper. The "lowest price" generic version in retail shops costs about 11 times the international reference price, while the innovator brand costs about 123 times the reference. (There were too few observations of the leading generic ciprofloxacin product in this survey, so summary statistics were not automatically calculated).

In another section of the Workbook (not shown), and again in an automatic analysis of field data, MPR results from different sectors are compared, product by product. In the case of Kenya, we learn that in the NGO sector, patient prices for the innovator’s ceftriaxone were somewhat lower than at private for-profit outlets (MPR 23.33 versus 18.56), but innovator brand ciprofloxacin tablets were slightly cheaper in the NGO sector (MPR 117.79 versus 122.98).

Summary results for many medicines within a sector

The WHO/HAI medicine prices survey can produce a fairly accurate picture of prices in an entire sector by summarising results for all the medicines targeted in the survey. Again, the main measures used are ratios of local prices to international reference prices. Table 2 shows a portion of the Workbook that automatically presents summary analyses for a sector. In this instance, it is the private-for-profit sector in the Philippines. The energetic Philippines study team collected data from 77 retail outlets. They found ample price data there for 21 innovator brand products, 9 nationally “most sold” generic products, and 15 “lowest-priced” generic products.

The simplest way to make an overall comparison between, say, innovators and generics would be to take the median of the MPFs for all the innovator products, and compare that to the median of MPFs for all the “lowest priced” products. The Workbook does compute and display these two results. However, it is not wise to use this raw comparison. Differences in the availability of innovator and generic products usually result in different sets of products being sold. (Clearly, if there are 21 innovators and only 15 generics, then there are at least 6 additional medicines in the innovator group that were not found in the generic group.) In place of the unusual comparison, the Workbook offers the analysis shown in Table 2.

There are three pairs of boxed columns in Table 2. In each pair of columns, summary price ratios for pairs of equivalent products are compared, for the private for-profit sector only. There were just nine surveyed medicines that were included in both their innovator brand and their nationally most sold generic version. Statistics for these two types of medicines appear side by side in the first two boxed columns of Table 2. The median of the nine MPFRs for the innovator versions of the medicines was 18.28. The median of the nine "most sold generic" MPFRs was 16.21. So we...

...cont’d on page 16 ➤
can say that in the Philippines private sector, innovator brand medicines are estimated to cost about 13% more than their most popular generic equivalents. In the first “lowest category of lowest priced products,” for example, 14 medicines were found to be widely available in both categories. The survey found that innovator brand medicines in the Philippines for-profit sector cost, overall, about twice as much as equivalent lowest-price-in-shop generics (median of MPDR 15.37 versus 7.69). Finally, in columns 5 and 6 (headed Most Sold and Lowest Price) a comparison is made between paired generic products. For these nine pairs the most sold generics were more than twice the price of the lowest price generics (16.1 versus 6.77). The implication of this finding is that in the Philippines at least, choosing between generics is very important.

### Comparing summary results among different sectors

The Workbook also makes comparisons among different sectors, based on information summarised for many medicines. On the left side of Figure 1 is a view of some tables in the Workbook which present instant cross-sector analyses. On the right side of Figure 1, portions of these analyses have been presented graphically for the purpose of this article. (At present, there is no graphical capacity in the WHO/HAI Workbook. However, graphs such as those in Figure 1 can be produced quickly and easily in Excel or local facilities).

In a manner like that described earlier (for many medicines within a single sector), the cross-sector analyses shown in Figure 1 compare only similar groups of products. These data are from the 2002 survey in Peru. Medicine prices for patients were collected in the public sector, the private for-profit sector, and an NGO sector. Innovator brand versions of the surveyed medicines were available only in the for-profit sector, so no cross-sector analyses could be produced for innovator brands. Only a few of the nationally most sold generic medicines were found outside the private sector, so it is preferable to compare “most sold generics” among sectors on a medicine-by-medicine basis. (Black and white product examples are not sufficient for drawing solid conclusions about whole sectors. However, the Peru study produced plentiful and interesting results in terms of the category of lowest priced generics found at surveyed outlets. In the first “lowest price” row on the left side of Figure 1, we see a summary comparison of public sector and NGO sector prices for lowest-priced generics. Thirteen surveyed medicines were found in generic versions in both sectors. (If there were several generic versions of a substance available in a single outlet, then the lowest price among these was recorded as “lowest price”). The median of the MPDRs for the 13 medicines in the public sector was 3.7. That is to say, in general in the public sector, patients pay a little more than three times the international reference price for essential medicines. For the same medicines in the NGO sector, patients pay a little more than double the international reference price (median MPDR 2.18). Therefore, for matching groups of equivalent medicines, the Peru study found that the NGO sector was less expensive for patients than the public sector. The Workbook also automatically expresses this comparison as a ratio of NGO sector prices to public sector prices: 64.8%. On the right side of Figure 1, this cross-sector analysis has been graphically presented.

The second “lowest price” row on the left of Figure 1 presents a cross-sector comparison of the public sector to the private for-profit sector. There were 14 medicines widely available in generic form in both sectors. Because the group of medicines used in this comparison is different and slightly larger than in the first cross-sector comparison, the median of MPDRs for the public sector has changed slightly, to 3.66. For the same 14 generic substances in the for-profit sector, the median of MPDRs was 7.92. Thus, generics in Peru’s for-profit sector cost more than twice as much as they do in the public sector. (Or, in other words, retail medicine prices are estimated to be 216.3% of government prices). Again, this contrast is shown graphically on the right.

Finally, along the bottom of Figure 1, we find a comparison of generic medicine prices for the private-for-profit sector versus the NGO sector. For this analysis, there were 15 surveyed substances that were widely available in both sectors. Again the median MPDRs shift slightly from the earlier analyses, because there are more data included, but the overall results are consistent. The private sector has the most expensive generics, followed by the public sector. The least expensive medicines in Peru are apparently offered in the NGO sector.

### Other automated analyses in WHO/HAI medicine price surveys

In addition to patient price data collected in the field at health facilities and pharmacies, the WHO/HAI survey aims to collect procurement price data at the central level. Procurement prices are usually obtained from large recent government orders. These are entered into the survey Workbook in the same way as field outlet prices. Subsequently, procurement prices are automatically compared to international reference prices (as above, in the form of price ratios). This is an important tool for evaluating the efficiency of public bidding processes for medicines. Other interesting analyses of procurement prices include medicine-to-medicine comparisons, innovator brands versus generics, and examinations of how much variation there is among prices found for the same substance (e.g., from one order to the next). Procurement prices (which are at the start of the supply chain) can also be compared to patient prices (at the end), to quickly estimate the size of price mark-ups.

#### Data subsetting is a useful tool for all types of price data entered into the survey Workbook. Before using any automated analysis, the local investigator can decide whether to include data from all the outlets (or procurement orders) in a sector, or whether to select a limited subset. Subsetting is done by using a simple “subsetting” tool appearing in the Workbook above each facility ID. For example, within a private-for-profit sector, medicine prices to patients are often collected from different types of private pharmacies. An investigator may wish to compare results for these two different types of private facilities. To do so, the investigator first selects the hospitals, and selects the remaining outlets, which are the pharmacy shops. The second set of results is printed, or copied into the separate spreadsheet. Finally, the two sets of results are compared, either manually or with the help of a spreadsheet. This sort of subsetting is also useful for comparing results among different provinces, for rural facilities versus urban facilities, or for simply focusing on specific outlet types.

Having the data collected, analysed and produced in a standard manner allows policy-makers and programme managers to ask the questions that can lead to improved prices. For example, based on the three country examples in this article, Kenyan policy-makers can ask “Why should brand name products be so much more expensive than generic products? Are the taxes, duties or mark-ups different?” For the Philippines a key issue would appear to be the high price of the most sold generics, which are closer to brand name prices than to the lowest price generics. For Peru, the question could be why the NGO sector is selling the lowest price generics cheaper than the public sector. All of the analyses are designed to provide decision-makers with information that they can use to intervene and make essential medicines more accessible by reducing their price.
Availability of essential medicines: an example from Rajasthan, India

by Jeanne Madden and Anita Kopwani

The most recent WHO/HAI medicine prices survey was conducted in Rajasthan, India, by the Delhi Society for the Promotion of Rational Use of Drugs, and their survey used the revised methods for looking at availability. The Rajasthan team surveyed three different sectors – public facilities, private pharmacies, and an NGO sector of limited-profit cooperative outlets. They looked at 20 outlets or locations in each sector, and gathered data on 36 different substances. These included 27 substances on the current WHO/HAI core medicines list, and nine locally-selected substances. The other three substances on the core list were not looked for in the field because these substances (or strengths) were known to be unavailable in the region. As usual, for each substance, price and availability data were gathered on the originator/innovator brand, on the most popular generic version in the region, and on whatever brand, on the most popular generic version in the outlet.

Results are shown in Figures 1–3 and for each product category they have been grouped into four levels of availability. Some products were never found in the sector; some products were hard to find in the sector (50% of outlets); some were seen in most places (50% of outlets), had the product in stock, but (50% or more of surveyed outlets).

It is fascinating to compare across sectors and types of products. Only in the private sector could all 36 medicines be found in a generic version in at least some outlets (Figure 1). In other words, there were no medicines that were found in none of the private sector outlets. Most of the medicines (25 out of 36) were found in at least 90% of surveyed private pharmacies. In contrast, in the public sector, there were seven generic medicines that could not be found in any public outlet.

Availability of generics appears to have been highest in the private sector, lowest in the public sector, and in-between in the NGO cooperative facilities.

The drugs that were unavailable in the private sector were captopril, fluphenazine injection, hydrochlorothiazide, indinavir, losartan, lovastatin and nevirapine. The survey team reports that HIV/AIDS medicines and lipid-lowering medicines are not on the current Rajasthan Essential Drugs List, and therefore do not appear in local facilities. HIV/AIDS medicines are, however, approved for distribution to poor patients at the main public teaching hospital in the capital, Jaipur. It should be noted that in any WHO/HAI price survey, it is possible that some drugs that appear to have been unavailable were actually available in strengths other than the standard one sought.

When the Rajasthan surveyors looked for specific named products (the originator brand and the most popular generic version), similar patterns were found among sectors. Availability results in Figures 2 and 3 show that availability was consistently highest in the private sector, and somewhat lower for the NGO sector. The public sector, on the other hand, never provided the originator brand version of any of these 36 essential medicines (Figure 3). There were just two products (beclomethasone inhaler and salbutamol inhaler) whose most-sold generic version was found in the public sector, and then only in a handful of outlets (Figure 3). The remaining 34 most-sold generic medicines never appeared in the public sector.

The figures also illustrate the strength of the generics market in India. In both the private and NGO sectors, consumers are much more likely to encounter generic products, including the single most-sold version, than they are to find originator brand products for these essential medicines. In both sectors, half of the medicines (18 out of 36) were never available in the originator brand name. With a couple of exceptions, these were the same set of medicines in the two sectors.

What is a median price ratio?

Jeanne Madden

Results on medicine prices gathered by the WHO/HAI survey are usually expressed as “median price ratios” or MPRs. The MPR is a ratio of the local price, in US dollars, over an international reference price (also in US dollars). The reference price serves as “median price ratios” or MPRs. The MPR is a ratio of the local price, in US dollars, over an international reference price (also in US dollars). The reference price serves as a benchmark for local prices, and therefore to compare local prices with the MPR results in the WHO/HAI pilot surveys are based on reference prices taken from the 2001 Management Sciences for Health (MSH) International Drug Price Indicator Guide (http://erc.msh.org/). The prices for the current set of 30 core drugs taken from the 2002 Price Indicator Guide are available on the HAI web site: (http://www.haiweb.org/medicinesprices/manual/intrefprices.html). The MSH Guide pulls together information from recent price lists of large, non-profit generic medicine suppliers. These suppliers typically do not sell to individual private pharmacies. Rather, they sell in large quantities to governments and NGOs, and accordingly, prices in the MSH Guide tend to be low. But they offer a very useful standard against which locally available products can be compared in any country.

To obtain an MPR for a local medicine, investigators carry out a price survey in a sample of medicine outlets or health facilities – at least 20 outlets per sector. (Sectors may include the private pharmacy sector, the public primary care sector, mission hospital sector, etc.) The Excel Workbook that is part of the WHO/HAI survey method calculates the median among all the prices gathered during the field survey for one medicine in a sector. This is the “typical” local price charged to patients in that sector. The Workbook converts this typical local price into US dollars, and then divides that amount by the reference price for the same medicine. The resulting MPR tells the investigator how many times higher or lower the local price is compared to the external international standard price.
Components of patient prices: examples from Sri Lanka and Kenya

The WHO/HAI price survey methodology not only collects field data on actual prices to consumers – it also examines the structure underlying those prices. Through interviews with experts in local pharmacy systems and review of government policies, investigators try to separate the component parts of prices to the consumer.

For imported medicines, the price structure starts with the “CIF” price (Cost, Insurance, Freight), which is whatever the manufacturer charges for the medicine itself, plus extra charges to bring a shipment of medicine into a country’s port. Typically, after CIF, there are additional payments that must be made to the national government and to agents for getting medicines through the port. There may also be import taxes, and/or fees charged by importing companies. Once inside the country, there are usually additional mark-ups for each step in the distribution chain. And there may be additional taxes levied along the way. Consequently the final price to the consumer is considerably higher than the simple CIF price.

The typical mark-ups from CIF price to consumer price vary from country to country. This is partly because of differences in government policies with respect to entry procedures, taxes and allowable mark-ups. Also, countries differ in how their private markets are structured – for example, how many links there are in the distribution chain, whether there is meaningful competition, the size of profits sought and obtained by various businesses, and other factors. If it is believed that a country’s medicine prices to consumers are too high or have other problem patterns, the first step towards possible intervention must be to describe the structure that lies beneath prices.

International comparisons are useful in evaluating price structure. Figure 1 shows findings from the WHO/HAI pilot surveys in Sri Lanka and Kenya. These were the maximum price mark-ups typically seen within these two countries’ private sectors. Significantly, however, in Kenya, retailer mark-ups were occasionally found to be far higher than depicted here, particularly for the cheapest generic drugs. (Retailers told the study team that they must mark these up higher, because their customers believe that drugs that are “too cheap” cannot be effective).

The mark-up amounts in Figure 1 have been presented as a percentage of the CIF price. Because mark-ups are normally added in a sequence or chain, the mark-ups are somewhat larger here than they would appear when presented as the percentage added to the price one step earlier. For example, in Sri Lanka, private retailers add 16% to the price that they pay for medicines, but because retailers are at the very end of the distribution chain, and the price of medicines has already been marked up about 42% over the CIF price before the retail stage, the retailer’s mark-up is about 23% of the CIF price.

When results for Sri Lanka and Kenya are compared, one obvious difference is that there is a large importer mark-up in Sri Lanka that is not seen in Kenya. The importer is a government agency that purchases all imported drugs and then distributes to both the government’s own health sector and to private wholesalers. This arrangement was not seen in other pilot survey countries. Except for the unusual importer mark-up in Sri Lanka, all mark-up amounts in Kenya were found to be much larger than those in Sri Lanka. Neither Kenya nor Sri Lanka had a Value Added Tax (VAT) on medicines. However, in some of the other WHO/HAI pilot surveys, VATs as high as 18% were found at the point of retail sale.

If the typical price mark-ups are known for a country, we can work backwards from the consumer price to estimate the CIF price. In Sri Lanka, mark-up amounts in the private sector are fairly well-known and stable. Thus, we can presume that when a median price of 990 rupees was found for a treatment course of 21 amoxicillin tablets (250mg each) in the private pharmacies’ surveys, the original CIF price was about 602 rupees.

Affordability of medicines in Malaysia – consumer perceptions

Promoting affordability is a major component of Malaysia’s National Drug Policy, and is linked to access – a key policy objective. Within 25 years of independence the Government has been successful in providing health services for all.

Availability of medicines at negligible cost in Government hospitals and clinics is a key success indicator of the health care system.

Drug price regulation does not exist in Malaysia, and the Government has no control over the prices of medicines. The Malaysian Drug Control Authority, a regulatory body for pharmaceuticals, is not concerned with the prices. Its primary objective is to ensure the safety and quality of pharmaceuticals. Under such a system, market forces are expected to stabilise drug prices.

In Malaysia, medicines are available to the public almost free of charge. But regardless of this, many patients get their medicines from private clinics, hospitals, retail pharmacies and supermarkets or through dispensing doctors. It is also an established fact that leaving the financing and supply of drugs entirely to market forces may fail to achieve public health objectives. So it is very important to know the public out-of-pocket expenditure on medicines in this price-deregulated system. To research this, a study was carried out to investigate consumer attitudes about the affordability of medicines, and to compare the drug prices from different retail pharmacies with the international reference prices (IRP).

For this purpose, 13 innovator/brand drugs were selected (the majority from the WHO’s core list of essential medicines). Retail pharmacy prices were obtained from private retail outlets (n=6) in Kuala Lumpur (Federal Territory). It should be noted that there is no value added tax for medicines in Malaysia.

Consumer attitudes

To assess consumers’ perceptions, 230 questionnaires were distributed to the public randomly at major shopping centers at three different geographical locations (Kuala Lumpur, Penang and Perlak) across Malaysia. Prior to the actual study, a pilot study was conducted to test the accuracy and validity of the questionnaire.

A response rate of 86% was achieved within a period of two months. Among the respondents, 47.5% were males and 52.5% females.
Comparing pilot survey results from different countries

Jeanne Madden

When findings from WHO/HAI medicine prices surveys are compared from country to country, the results are often quite dramatic. New prices were involved in two rounds of pilot studies from 2001 to 2002. It is not possible to conduct all types of analyses for the pilots in a cross-national way, because of differences in country contexts or in the way data were collected as the methodology was under development. However, in Figures 1–3 we are able to show a number of valid comparisons.

The data presented in these graphs use the median price ratio (MPR) measure, which is explained in the box on page 17. The basic MPR is the median of the prices found for a single product category across a sample of outlets, converted to US dollars and then divided by an international reference price. For example, in Armenia, the price for a single tablet of the originator brand version of furosemide ranged from 12 to 16 drams in the shops surveyed. The most common price found was 16 drams, and this was also the median price (meaning that half of the prices found were lower than or equal to 16, and half of the prices were higher than or equal to 16). At the time of the survey, this median price was equivalent to US$0.0286. The international reference price (see box on p.17) for furosemide was US$0.0047. The median price ratio pulls all this information together. The MPR for brand furosemide was 6.1, meaning that, in general, brand furosemide in retail pharmacies was about six times as expensive as the international reference price.

To summarise MPR results for many medicines, we can take the median MPR for a group of them. There were 10 originator brand medicines found in the Armenian survey. The brand medicine with the lowest MPR – 2.2 – was the salbutamol inhaler. The highest MPR was for brand ciprofloxacin tablets, which was 95.5 times the international reference. Among all 10 of the originator brand drugs, the median MPR was 10.4.

When comparing the prices of the originator brands to the prices of generics for many substances, we can use the median MPR for the brands and the median MPR for the generics. However, it is important to drop any medicines where either the brand or the generic was not found. (This is done automatically in a section of the Excel Workbook that comes as part of the pricing survey methodology). Only eight medicines sought by the Armenian survey were widely sold in both their originator brand version and the leading national generic equivalent. We can think of these as matched pairs of equivalent medicines. The median

References
1. Balasubramaniam K. Health care - who cares? Towards affordable quality health care for all in Malaysia. Pri-


Table 1
Drug price variations – medians of private retail prices (expressed as ratio over international reference price)

<table>
<thead>
<tr>
<th>Generic name, dosage form, strength</th>
<th>Brand name(s)</th>
<th>Median Price Ratio (MPR)</th>
<th>Median Price Ratio (MPR) Min-Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>aciclovir tab 200 mg</td>
<td>Zovirax</td>
<td>15.3</td>
<td>11.5–16.0</td>
</tr>
<tr>
<td>atenolol tab 50 mg</td>
<td>Toprol</td>
<td>12.1</td>
<td>11.2–12.7</td>
</tr>
<tr>
<td>carbamazepine tab 200 mg</td>
<td>Tegretol</td>
<td>45.3</td>
<td>31.9–60.9</td>
</tr>
<tr>
<td>diclofenac tab 25 mg</td>
<td>Voltaran</td>
<td>31.6</td>
<td>29.2–40.4</td>
</tr>
<tr>
<td>lovastatin tab 20 mg</td>
<td>Cooxol</td>
<td>26.9</td>
<td>21.3–37.4</td>
</tr>
<tr>
<td>meftomin tab 500 mg</td>
<td>MevacoX</td>
<td>8.41</td>
<td>3.27–9.10</td>
</tr>
<tr>
<td>naproxenine Retard tab 20 mg</td>
<td>Glucophase</td>
<td>4.21</td>
<td>3.06–21.4</td>
</tr>
<tr>
<td>ramindine tab 150 mg</td>
<td>Adalot Retard</td>
<td>25.7</td>
<td>20.3–35.6</td>
</tr>
<tr>
<td>zidovudine caps 100 mg</td>
<td>Lexac</td>
<td>12.6</td>
<td>8.30–12.7</td>
</tr>
</tbody>
</table>

J. Madden

...cont’d on page 20...
Comparing results... conta’d from pg. 19

MPRs for the eight branded medicines and their eight leading generic equivalents are presented at the top of Figure 1. The median MPR for the brand version in the group of eight pairs was 10.4, whereas the median MPR for the generic versions of the same medicines was about 3.2. “Brand premium” usually refers to how much larger brand prices are compared to generics. For essential drugs in Armenia, a “typical brand premium” is about 330% (that is, 10.4 median MPR for brands divided by 3.2 for generics).

Figure 1 shows the median brand MPRs and median most-sold generic MPRs for eight of the pilot country studies. These results are for private sector pharmacies only. For each country, as with Armenia, the results shown are only for pairs of drugs where both the originator brand version and the most sold generic version were widely found. The specific medicines that make up these matched pairs are slightly different from country to country (and are listed in a table in the synthesis report of pilot survey findings on the HAI website at http://www.haiweb.org/medicineprices).

Nevertheless, because the median is the observation in the middle of all the observations, it is fairly representative of both the survey results as a whole and the private sectors in these countries taken as a whole. These were not unusual results, but rather the most typical results found.

High brand premiums can be seen in almost all of the pilot countries in Figure 1, (the darker brand bar tends to be much longer than the lighter generic bar). In cases where the two bars are similar in length (in Brazil and the Philippines, especially), brand medicines seem to be about as expensive as they are in other countries. The small brand premium in those two countries seems to be due to the fact that leading generics are also quite expensive – with median MPRs in the range of 15 to 25 times the international reference prices. Two other country cases that stand out as unusual are Peru and Sri Lanka. Peru’s generic prices tend to be high compared with other countries, while Peru’s brand prices are extremely high. A look at Peru’s median brand MPR indicates that innovator brand drugs typically sell at more than 61 times the international reference price. Meanwhile, Sri Lanka has the smallest MPRs in both the brand and the most sold generic categories – with 1.2 and 4.7 for median MPRs, respectively.

In public sector health systems, it is often unusual to find originator brand name drugs. Even the nationally most sold generic version may not be seen. Governments usually try to purchase the best medicine values, rather than the most popular or well-known products. For this reason, the price of the “lowest-priced generic available in the outlet” is often the most relevant measure. In the WHO/HAI pilot surveys, this was the category where the most data could be collected in the public sector. Figure 2 shows some results for four countries where prices to patients were collected from public health facilities. These median MPRs are for all the “lowest-priced generic products” that were sought and found in these countries’ public clinics. Again, these were not exactly the same groups of medicines in each country. However, only the median values are presented. Unusually high or low values that may exist for certain medicines have very little influence on the median MPR measure. Note the scaling in Figure 2 – the horizontal axis only goes up to an MPR of 10. Public sector “lowest-priced” generic prices found in these surveys tend to be lower than the “most-sold” generic prices in the retail sectors, as shown above.

Some pilot study countries collected procurement prices from the public sector. Examples of median MPRs for procurement of medicines in the “lowest priced generics” category are displayed in Figure 3 scaled for easy comparison to Figure 2. The procurement prices found in the three countries in Figure 3 appear to be generally lower than prices charged to patients in the four countries in Figure 2. We expect that there are mark-ups between procurement and sale in public sectors. However, none of the pilot countries has collected both public procurement prices and public patient prices, so we cannot yet make a direct comparison. Kenya stands out in Figure 3 for having high public procurement prices. In part, this is because the Kenya team obtained procurement data from three large public facilities that purchase medicines independently on the private market, whereas South Africa’s data come from a centralized procurement system, and Brazilian data are a mixture of procurement prices paid by several public agencies with responsibility for different classes of medicines and levels of care.

The hidden costs of essential medicines

Libby Levison and Richard Laing

An estimated one-third of the world’s population lacks access to essential medicines due in part to their cost.1 The cost of getting an essential medicine to a patient includes the manufacturer’s price as well as all costs for transportation, storage, import tariffs and taxes, wholesale and retail markups, staff salaries, stock losses and procurement practices. These latter costs – hidden costs – can more than double the manufacturer’s price.1 In order to reduce costs, participants in the health sector need to understand what the hidden cost components are and how they affect total cost. The hidden costs incurred in procuring essential medicines arise from two sources: government policies and procurement practices.

Hidden costs under government influence

Data were collected from publications and solicited through the on-line discussion forum E-Drug. The original query suggested several hidden costs to include, but encouraged respondents to list any...
that applied in their situation. In total, there was sufficient detail on nine countries to include in the analysis. The data are shown in Table 1. For the nine countries studied the hidden costs included: import tariffs; port charges; clearance fees; pre-shipment inspections; pharmacy board fee; importers’ marksups; value added tax (VAT); federal and state taxes; and wholesale and retail markups. While some of these rates are relatively low (for example, 1% for port charges), even 1% is significant on orders of US$5 million. And because the impact of hidden costs is compounded, each hidden cost has a “carry on” effect. On average, hidden costs increased cost by 68.6% in the surveyed countries. Blank cells in the table indicate that no data were reported (all reported zeros have been entered).

Comparing data among countries is illuminating. Despite an import tariff of 4%, Nepal has total hidden costs of 48%, due in part to no local taxes and low wholesale and retail markups.

In Armenia, on the other hand, there is no import tariff but charges 20% VAT and allows wholesale and retail markups of 25%, resulting in total hidden costs of 87.5%. All the hidden costs listed in Table 1 are government imposed or may be government regulated. Considering that ultimately a tariff increases the price of the essential medicine to the health system, one must ask why a government charges itself tariffs for public sector health goods. If the VAT alone were eliminated in Armenia, the hidden costs would decrease to 56.3%. On an average of US$1 million, this represents savings of US$312,000.

We know of other hidden costs for which data were too sparse to draw conclusions. Banking fees (fee to buy foreign exchange; the costs of letters of credit) of 1%–4% were reported (Sri Lanka, Kosovo and South Africa). Con- tingency fees added 10% in hidden costs in one South African country. These financial risks merit further attention.

Hidden costs of the procurement process

Many of the programming choices made in the procurement office affect cost. The implementation of product se- lection, quantification and tendering method, and programme overheads, also incur costs. Because of the small sample size we can only offer suggestions as to the impact of these hidden costs.

Product selection: By restricting procurement to medicines on the national essential medicines list and included in the standard treatment guidelines, and by removing therapeutic equivalents, procurement office see lower manufacturer’s prices from economies of scale. Inventory and stores management benefit from a reduction in the number of stock items to handle. Procuring generics rather than brand name products has similar advantages.

Tendering method: By restricting tenders to a limited number of prequalified suppliers, the procurement office works only with suppliers of high-quality products when selecting the lowest-priced goods. The tender award process is simplified, as there are fewer bids to evaluate, which brings savings in time and staffing.

Calculating these hidden costs is difficult. The Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) Special Purchase Committee in Delhi, India, has been using a form of prequalification since 1995 and has achieved savings of approximately 30–35% for drug purchases from an essential drugs list and through restricted procurement. Van der Veen and Fransen report that international purchasing agencies achieve lower prices for generic drugs than do ministries procuring with national procedures; they found that health ministries paid 3–6 times more for generic medications for sexually transmitted diseases.

Operating costs: The cost of running the procurement office is part of the procurement budget. Staff salaries, office space, and supplies are indirect costs that vary with the size of the procurement programme. Two non-profit suppliers, Mission for Essential Drugs and Supplies (MEDS) in Kenya and Joint Medical Stores (JMS) in Uganda, report operating costs as a percentage of gross expenditure on pharmaceuticals. Their operating costs, 15.5% and 9.5%, are indicative of these costs.

Carrying costs: There is a cost asso- ciated with keeping any stock in inventory. Adequate warehouse storage is needed, security must be provided, and inventory must be insured. In the field of supply management, a figure of 10–35% of the price of the inventory is allocated to carrying costs.

Stock loss: Inaccurate quantification can result in a surplus of medicines that expire; poor inventory control procedures (that do not enforce stock rotation) can also result in expiry. Expired or damaged medicines must be destroyed at an additional cost. Stock losses from theft also raise the hidden costs of the remaining inventory. Inventory lost to expiry, theft or damage result in hidden costs on the remaining stock.

More data needed

The data collected illustrate how hidden costs can more than double the price of essential medicines between manufac- turer and patient. Understanding these hidden costs is the first step towards reducing costs and increasing access. However, reducing hidden costs cannot be handled by the procurement office alone. It requires the establishment and implemen- tation of pharmaceutical policies at governmental level, the improvement of procurement practices, and the cooperation of medical professionals throughout the health care system.

Not all hidden costs can or should be removed – for example, quality control of medicines. Assurance quality should be the procurement division’s first priority. Bhutan estimates that over a 10-year period, the cost of quality control (predominantly sampling tests) was 0.39% of the total procurement cost. DSPRUD has spent 0.53% of its budget on quality assurance since the programme began in 1995 (including both Good Manufacturing Practice inspec- tions of bidding manufacturers as well as sample testing). Given the threat of sub-standard drugs, damage during shipping or packing mistakes, quality control is a highly cost-effective investment that all procurement offices should adopt.

The hidden cost data we have collected provide insights into various options for configuring national policies and procurement programmes to reduce the procurement costs of essential medicines. There is a role for both the government and the procurement divi- sion in the effort to reduce hidden costs. It is clear, however, that more data are needed – both on current hidden costs, and on strategies to reduce hidden costs. The new WHO/HAI pricing initiative will include a study on the component costs of medicine prices. Additional evi- dence from such projects will expand the available data on hidden costs and can be used to establish national policies and procurement procedures that reduce the cost of, and increase access to, essential medicines.
New medicine price database (but with a difference)

I

VESTIGATORS of medicine prices invariably ask the question – how do prices in my country compare with those of my neighbouring country? In the past, such international comparisons have been problematic, as prices are rarely publicly accessible (especially those of developing countries). And those that are on the web are not uniform in what they represent (for example, some are reimbursement prices with or without dispensing fees, others are wholesale prices or retail prices). To aid transparency and the ability to compare price information in different settings, HAI and EDM have published a database of results submitted by those who have undertaken price surveys using the new methodology. The database is freely accessible on HAI’s web site at http://www.haiweb.org/medicineprices

Figure 1 shows the three sections.

Undertaking a survey

Survey managers will find here all the information needed to undertake a price survey. The manual and computerised workbook can be downloaded and, importantly, updates to the manual are published here (including the latest MSH reference prices see page 17). In addition there are some FAQs and information is given on how to get help (if needed). New information is continually being added.

Survey results

National survey data are lodged here in a standard format. By comparing individual survey results, international comparisons can be made of:

➤ the price ratios of individual originator brand or generic medicines, from each sector, on the core list
➤ the affordability of selected courses of treatment, measured against each country’s public sector minimum wage
➤ the composition of the retail price of a medicine in different countries.

Contact details of survey managers are given for (any queries), plus any supporting documents, for example, the completed national pharmaceutical sector form (to contextualise price data), any training material used to train data collectors, the survey report and briefing papers.

Database

The ‘query the database’ section of the website is proving popular – which is not surprising as it allows for speedy comparisons of data. Currently you can carry out a query according to price or to affordability.

To query prices you can choose between:

(i) one medicine, many surveys
Here you can compare price ratios for an individual medicine, by sector, in all countries where data were collected. It is a simple 3-step process:

Select the medicine:
from a list of all medicines in the database.

Select the sector:
either procurement, public sector patient prices, private sector retail pharmacy prices or the ‘other’ sector patient prices.

Select the survey:
select either the national survey[s] of interest or all surveys that included that medicine.

On the screen you will then see the median price ratios for the originator brand, most sold generic and lowest-price generic of that medicine (along with the 25th and 75th percentile price ratios). To illustrate this, Figure 2 shows the outcome of a query for fluconazole 200 mg tablets, private sector retail pharmacy prices and all surveys.

(ii) one survey, many conditions
Select the country survey you are interested in. You will be given affordability data on all the conditions that were involved in the selected survey. See figure 4.

Database sections

The database sections are:

Survey results

On screen you will see data for all surveys that involved the selected condition and medicine. Figure 3 shows the number of day’s wages needed to pay for a month’s ulcer treatment with ranitidine 150 mg tablets in South Africa, Sri Lanka and Armenia.

Figure 3. No. of day’s wages needed to treat an ulcer with ranitidine in South Africa, Sri Lanka and Armenia.
Sound price data – sound price policies

Margaret Ewen

A recent workshop in the Netherlands, a Ministry of Health official from a developing country stated that medicines were unaffordable in her country, and she asked what could be done about it. She voiced what data from most pilot surveys using the WHO/HAI methodology showed, and what people in her country will have known all their lives: medicines are generally unaffordable in developing countries and that price matters. Thankfully for the millions of people in the world dying because they lack drugs, governments have many options to lower prices.

Before deciding on what price policy options to take, it is essential to gather evidence to identify the principal causes of high prices. The WHO/HAI survey (working draft) can be used to systematize reliably and regularly monitor what people have to pay for medicines. It has been designed to answer the following important questions:

➤ what price do people pay for a selection of key medicines?
➤ how affordable are these medicines for ordinary people?
➤ do the prices, availability and affordability of the same medicines vary in different sectors and in different parts of the country?
➤ what are the difference in prices of originator brands and generics?
➤ how do procurement prices compare with international reference prices and with local retail prices?
➤ what taxes and duties are levied on medicines, and what is the level of various mark-ups which contribute to their retail prices?
➤ how do prices, affordability and ‘add-on’ costs compare internationally?

Once these questions are answered, it becomes clearer what mix of policies are needed to make medicines affordable.

In developing the methodology, nine pilot surveys were conducted. Prices of medicines in various sectors – government, NGO and private – showed the value of linking price and use.

Increase the availability and use of generics

The pilot studies showed some staggering brand premiums, that is, the difference between the originator brand and lowest price generic equivalent. Brand premiums in Kenyan retail pharmacies were found to be as high as 40 for furosemide (i.e. the originator brand was 40 times more expensive than the lowest price generic equivalent). 8.6 for diclofenac, 8.5 for ibuprofen, 7 for amitriptyline and 5.6 for co-trimoxazole suspension. In Sri Lanka, the difference in prices of ranitidine between originator brand omeprazole to generic ranitidine would reduce the number of days the lowest paid government worker had to work to pay for a month’s therapy from 8.6 days to 4.7 days. This example illustrates the value of linking price and affordability data, policy permitting generic substitution and the use of standard treatment guidelines. Education would be key in implementation.

Remove all taxes on essential medicines

Governments in some countries are taxing the sick by applying high import duties and taxes, and adding ‘value-added’ or ‘goods and services’ taxes e.g. in Peru import duties of 12% are applied as well as 18% value added tax (VAT); in Armenia 20% VAT is added. If governments are serious about making medicines more affordable for their citizens, they must remove all taxes on essential medicines.

Monitor prices and price components – including prices in other countries

The data shows vastly different prices can be paid for the same product in different countries e.g. the retail price for generic ranitidine (Lanox®) in Kenya was 29 times the Sri Lankan price. This illustrates the need for careful evaluation of the manufacturer’s price. But ‘add-on’ costs, as the product goes through the distribution chain, also need close attention. In the pilot surveys, most of the add-on costs were applied as percentage mark-ups (some unregulated).

On top of already high manufacturers’ prices, this results in even higher prices for patients. Governments need to monitor both the manufacturers’ prices and price components then decide the best way to deal with excessive charging at any stage – either by promoting competition or regulation.

Further studies planned

While the survey will provide data, it does not identify the causes. During late 2003 and 2004, HAI and WHO will be conducting a number of national in-depth studies to determine the local causes of high prices and unexplained price variations, and to identify and prepare suitable lines of response. In-depth studies under consideration include:

➤ a multi-country assessment of price components and manufacturers’ prices (brand/generic, patent/off patent);
➤ monitoring medicine prices in a sentinel group of Sri Lankan pharmacies following pharmaceutical market deregulation;
➤ focused studies of HIV/AIDS medication – not only monitoring price and availability of medicines in this therapeutic group but also the impact of local programmes (Global Fund, Accelerated Access Initiative, differential pricing programmes etc.) on the prices people pay for medicines;
➤ assessing how sensitive people are to price i.e. household behaviour in response to medicine prices and availability;
➤ assessing the impact of negotiations and pooled procurement on prices. Results will indicate potential savings by better practice by drug purchasing agencies.

In addition to these studies, WHO and HAI will conduct studies to validate the survey method. We intend looking in greater detail at issues such as sample size, price fluctuations, market share, the effect of choice of generic on price, pack size etc.

Regional workshops

To assist investigators, workshops on using the survey tool are planned for Asia/Pacific (early April 2004 in Bangkok), Africa (Francophone and Anglophone), Latin America and Central/Eastern Europe and Newly Independent States (funding permitting). Dates and venues will be posted on E-drug, the electronic discussion group.

The first workshop was held in Cairo in mid-October 2003 with participants from 12 countries in the region and from various sectors – government, NGO and academia. All felt that the workshop was worthwhile in understanding the survey method. In the coming months we expect a number of surveys to be conducted in the region. The data will be published on HAI’s web site.

As the project continues in 2003 and 2004, experiences using the survey tool will be shared and it is expected a revised edition of the manual will be published in late 2004.

Please contact Margaret Ewen at HAI Europe (marg@haiweb.org) or Andrew Creese at WHO DM (creese@who.int) if you wish to conduct a medicine price survey.
First regional training workshop on medicine prices

Participants judged the first in a series of regional training workshops on the WHO/HAI pricing methodology a great success. Held in Cairo from 20–22 October 2003, the event was opened by Dr Zuhair Hallaj, WHO Representative in Egypt, who delivered a message to participants from Dr Hussein Gezairy, Regional Director of WHO Eastern Mediterranean Region. Dr Gezairy emphasised the continuing challenge of medicine prices and noted the Ministry of Health purchases imported drugs by a centralised tender process undertaken jointly with Gulf Cooperation Council countries. Retail prices are controlled by Government, and comparisons are made with other countries before prices in Oman are set. Health care is free of charge. A number of methodological issues were raised, for example how to deal with prices under insurance systems with reimbursement, and with subsidy elements in public sector prices. Clearer guidance will be given in the revised version of the manual, due out by the end of 2004.

Technical focus

WHO and HAI representatives discussed the pricing project’s background and the technical focus of the methodology. They were followed by Dr Anita Kotwani, who gave details of the price survey recently completed in Rajasthan, State, India. Following preparatory briefings on the data collection forms and computerised workbook, and an exercise with data entry, five working groups of participants made visits to nine pharmacies in the Cairo area. A shortened version of the Medicine Price Data Collection Form was used on these visits, which were arranged by the Egyptian Ministry of Health.

Following the data collection exercise, working groups exchanged their data for entry into the Workbook by another group, all the results were consolidated and were presented back to the plenary for discussion. Results were illustrative as the clinics were selected for their convenience and were not identified using the recommended sampling methodology. The database of results from previous studies on the WHO and HAI staff present responded that the manual and database could not answer all of the challenging questions involved, but that it offered a step towards greater clarity and transparency about local and international price differences. Sound information, produced in a standard format, offers a necessary base for better understanding and policy action on medicine prices.

Participants briefly identified some price issues in their own country, and considered how a medicine price survey might assist them in their work. For example, in Egypt the pricing system was felt to be relatively simple and acceptable for generic drugs, and the level of access to these is also acceptable. How to price innovative medicines remains problematic. In Jordan, median prices in other countries (sometimes in a drug’s country of origin, but particularly in neighbouring countries) are used systematically for reference purposes. As in Egypt and some other countries in the region, retail prices are fixed and monitored throughout the country. Lebanon has also undertaken recent international price comparisons of key medicines, and is currently implementing regulation to give pharmacists the right to substitute generic medicines for originator brands. Several countries acknowledged that official prices and actual prices in the retail market place may differ, because of discounts or ineffective price regulation.

Syria imports only about 10% of its drug requirements and has a price setting and regulating policy in place. Yemen, on the other hand, imports over 90% of requirements and has a free market for pricing. Some of its prices are the same as those paid in higher-income neighbouring countries but particularly in the country of origin, but particularly in the Gulf Cooperation Council countries. Retail prices are fixed and monitored throughout the country. Lebanon has also undertaken recent international price comparisons of key medicines, and is currently implementing regulation to give pharmacists the right to substitute generic medicines for originator brands. Several countries acknowledged that official prices and actual prices in the retail market may differ, because of discounts or ineffective price regulation.

The Rajasthan study entailed long distance travel for the principal investigator and so it was more expensive than the average, but the budget was only US$3,000.

Planning surveys

Participants from the countries attending the workshop then looked at organizing their own surveys, discussing feasibility and details of when, where and by whom these could be done. Any such surveys may receive support from EMRO and from the WHO-HAI project. Facilitators at the workshop indicated their willingness to exchange ideas and suggestions with participants in the early stage of their thinking about a price survey. A post-survey workshop, to help participants with a completed study through the data analysis and interpretation, was outlined. Its timing, location and participants will depend on the timing of results from previous studies develop over the coming months.

Acknowledgements

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The manual can be downloaded from the WHO and HAI web sites, and hard copies are available from: Department of Essential Drugs and Medicines Policy, WHO, 1211 Geneva 27, Switzerland
Access to essential medicines as a human right

HANS HOFERZIEL

The promotion of human rights is one of the principal objectives of the United Nations (UN), and in 1997 the Secretary General placed human rights among the Organization’s core activities. However, in 1946 WHO’s Constitution preceded the Universal Declaration of Human Rights with the following opening text: “The States parties to this Declaration declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, health and well-being of man.” Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. 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.

All human rights are interrelated, so that the right to health is related to the exercise of other relevant human rights, such as the right to education, information, privacy, association, equality and participation. All human rights are underpinned by health, since they need to function smoothly, which puts a particular emphasis on vulnerable groups. Human rights primarily concern the relationship between the state and the individual – they generate state obligations and individual entitlements. As governments also have prime responsibility for public health, they need to combine sound public health practice with fulfilling their obligations on human rights. The realisation of the right to health may be pursued through numerous approaches, which can be used simultaneously, and include formulating health policies, implementing health programmes, or adopting specific legal instruments. The human right to health is recognised in numerous international instruments. Article 25.1 of the Universal Declaration of Human Rights states (1948): “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.” It is also recognised in many other international (1,2,3) and regional (4,5) instruments. But in particular the International Covenant on Economic, Social and Cultural Rights, signed and ratified by over 160 countries, which provides the most comprehensive article on the right to health.

The International Covenant on Economic, Social and Cultural Rights

By the time countries were prepared to turn the provision of the 1948 Declaration into binding law, the Cold War had polarised human rights. The West argued that civil and political rights had priority, and that economic and social rights were mere aspirations, while the Eastern bloc said that rights to food, health and education were paramount, and civil and political rights secondary. So two separate treaties were created in 1966, the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights (ICESCR). In article 12.1 of the ICESCR, States parties recognise the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” and article 12.2, by way of illustration, cites a number of steps to be taken by States parties to achieve the full realisation of this right. These include obligations in relation to: maternal, child and reproductive health; healthy natural and workplace environments; prevention, treatment and control of disease; health facilities, goods and services. Essential medicines as part of the right to health

The implementation of the ICESCR is monitored by the Committee on Economic, Social and Cultural Rights and at regular intervals the Covenant is supplemented by authoritative comments. In one, General Comment no.14 of May 2000,1 the Committee interprets the right to health, as defined in article 12.1 of the Covenant, as an inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health. These determinants include access to safe water and sanitation, food, nutrition and housing, a healthy environment, and health education and information. Several sections of the report are particularly relevant to essential medicines. The Committee states that the right to prevention, treatment and control of diseases in article 12.2.c includes the creation of a system of urgent medical care in cases of accidents, epidemics and similar public health emergencies and the provision of disaster relief and humanitarian assistance in emergency situations. The right to health facilities, goods and services in article 12.2.d includes appropriate treatment of prevalent diseases, preferably at community level; and the provision of essential drugs.2 The Committee further specifies the following interrelated and essential components for the fulfilment of the right to health in all its forms, at all levels: Availability: functioning public health and health care facilities, goods and services. The precise nature of the services depends on many factors (see below) but will include water and sanitation, hospitals and clinics, trained professional staff, who are medically competent, facilities, and “essential drugs as defined by the WHO Action Programme on Essential Drugs” (since incorporated into the WHO Action Programme on Essential Drugs and Medicines Policy). Accessibility: Accessibility to facilities, goods and services has four components: non-discrimination, physical accessibility, affordability and access to information. Acceptability: Health facilities, goods and services must be respectful of medical ethics, and culturally appropriate and sensitive to gender- and life-cycle requirements. Quality: Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

Obligations to respect, protect, fulfil

The right to health, like all human rights, imposes three levels of obligations on States parties: Obligation to respect: to refrain from interfering directly or indirectly with the enjoyment of the right to health. This includes the obligation to refrain from denying equal access for all persons to preventive, curative or palliative care. Obligation to protect: to take measures to prevent third parties from interfering with guarantees of Article 12. This includes the obligation to ensure equal access to health care provided by third parties, and, for example, to ensure that privatisation of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services. Obligation to fulfil: This in turn contains obligations to facilitate, provide and promote. It requires states to adopt appropriate legislative, administrative, budgetary, judiciary and promotional measures towards the full realisation of the right to health. International obligations

To comply with international obligations in relation to Article 12, States parties have also to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating that right in other countries. States should facilitate access to essential facilities, goods and services in other countries, and provide the necessary aid when required.3 They include their obligations as members of international bodies, such as the International Monetary Fund and the World Bank. States should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment.

Progressive realisation

It is important to note that the right to health cannot be secured immediately because States may not have the means to do so. This is called “progressive realisation” and acknowledges the limits of available resources. However, the Covenant also imposes on States parties various obligations which have to take effect immediately.

Immediate obligations

States parties have an immediate obligation to guarantee that the right will be exercised without discrimination of any kind (art. 2.2) and to take steps (art. 2.1) towards the full realisation of Article 12. Such steps must be deliberate, concrete, and directed towards the full realisation of the right to health.4 There is a strong presumption that retrogressive measures taken in relation to the right to health are not permissible.5

Core obligations under Article 12

In General Comment no.3 the Committee confirms that States parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, including essential primary care as described in the Alma-Ata Declaration. According to the Committee in General Comment no.14, these core obligations include at least the right to: access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups; minimum essential food; basic housing, water and sanitation; essential drugs as defined by the WHO Action Programme on Essential Drugs; equitable distribution of health services, goods and services; a national public health strategy and plan of action, addressing the health concerns of the whole population with respect to health indicators and particular attention to all vulnerable or marginalised groups.

Violations of the right to health

In determining which actions or omissions amount to a violation of the right to health, it is important to distinguish between the “inability” and the unwillingness of a State party to comply with its obligations under Article 12. However, a State party cannot, under any circumstances whatsoever, justify indulgence in...
its non-compliance with the core obligations mentioned above, which are non-dielegible (i.e. they cannot be suspended or taken away, even in extreme emergencies). Violations can also occur through the failure of States to take all necessary steps to ensure the progressive realisation of the right to health. Examples include: the failure to adopt or implement a national policy designed to progressively ensure the right to health for everyone, insufficient expenditure or misallocation of public resources; failure to monitor the realisation of the right to health at a national level; and failure to take measures to reduce the inequitable distribution of health facilities, goods and services.

Practical implications of health as a human right

There are several practical implications of the health-related process of development cooperation, for WHO and for national policies and programmes.

1. **Use the Human Rights Approach in policies and programmes**

This implies a number of principles in policy and programme development, and international cooperation. Using the Human Rights Approach as a framework for development implies that the human rights implications of any policy or programme are being considered as part of the planning phase and prior to implementation. More specifically, this implies that the policy or programme should focus on marginalised and vulnerable groups (at least the impact on these groups should be considered) and on equity (e.g., by ensuring that health services are available to all). The programme should also include a gender perspective (e.g. by presenting disaggregated statistics) and free and meaningful participation by beneficiaries, and should promote the right to education and to information. The programme should be transparent, using clear indicators and benchmarks. And finally, there should be a system of safeguards and redress (patients and consumers should have the possibility of lodging complaints and appeals).

2. **A minimum list of essential medicines**?

A concrete implication of Art. 12.2(d) on the provision of essential medicines is the need for a list of priority diseases to describe the minimum essential level of primary care, and a cost-effective treatment for each. This can then be translated into a core list of essential medicines. The logical question is then: can the WHO model list of essential medicines be used as a tool for public pressure and international cooperation? Using the model list of essential medicines can better describe the minimum essential level of the right to health, and to health facilities, goods and services. The programme should then ensure the progressive realisation of the right to health will be exercised without discrimination, and to take deliberate and concrete steps towards its full realisation, with emphasis on vulnerable and marginalised groups.

In practice, the Human Rights Approach should be incorporated in all national medicine policies and programmes, the selection of medicines for essential public health functions should be further refined, States parties’ international reporting obligations on access to essential medicines should be strengthened, and national NGOs should be empowered to put pressure on governments to fulfil their commitments and obligations under the international and national human rights instruments they have signed and ratified.

Dr Hans Hogerzeil is Team Coordinator, Policy Access, Rational Use, Department of Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland.

**Conclusion**

Health is a human right. The right to health includes the right to emergency care and the right to health facilities, goods and services. The right to health facilities, goods and services specifically includes the provision of essential medicines as defined by WHO. States parties are under immediate obligation to guarantee that the right to health will be exercised without discrimination, and to take deliberate and concrete steps towards its full realisation, with emphasis on vulnerable and marginalised groups.

By the end of 2002, 142 States parties had signed and ratified the International Covenant, 109 countries have the right to health incorporated in the constitution, and 83 countries have ratified one or more regional treaties which include aspects of the fundamental right to health. The world’s countries are bound by one or more of these instruments. These commitments can be used as a tool for public pressure on national governments by nationals or national NGOs. As a first step, a schedule of which country has signed and ratified the various treaties is available from the Office of the UN High Commissioner for Human Rights and may be helpful. In addition, WHO is working on the identification and publication of a list of successful national court cases in which individuals or NGOs have successfully secured or improved access to essential medicines on the basis of human rights instruments. Additionally, the simple standardised monitoring tools for access and prices of essential medicines can be made suitable and available for use by NGOs as well.

**References**


**Box 1**

**Essential drugs as a human right: summary**

Article 25.1 of the Universal Declaration of Human Rights states “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.”

In article 12.1 of the International Covenant on Economic, Social and Cultural Rights, States parties recognise “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” Article 12.2 enumerates a number of steps to be taken by States parties to achieve the full realisation of this right, which include the right to prevention, treatment and control of disease, and the right to health facilities, goods and services.

Article 12.2 of the Covenant is further interpreted and defined in General Comment no.14 by the Committee on Economic, Social and Cultural Rights. The right to prevention, treatment and control of diseases includes the creation of a system of urgent medical care and the provision of disaster relief and humanitarian assistance in emergency situations. The right to health facilities, goods and services in article 12.2(d) includes appropriate treatment of prevalent diseases, preferably at community level, and the provision of essential drugs.

While the Covenant provides for progressive realisation and acknowledges the limits of available resources, States parties have an immediate obligation to guarantee that the right to health will be exercised without discrimination of any kind (art. 2.2) and to take deliberate and concrete steps (art 2.1) towards the full realisation of article 12. In General Comment no.3 the Committee confirms that States parties have core obligations, which are non-dielegible, to ensure the satisfaction of minimum essential levels of each of the rights enunciated in the Covenant, including essential primary care as described in the Alma-Ata Declaration. These core obligations are further specified in General Comment no.14, and specifically include the provision of essential drugs as defined under the WHO Action Programme on Essential Drugs, and a national public health strategy and plan of action with particular attention to vulnerable or marginalised groups.
The discovery of Mectizan provided a powerful new tool for addressing this disease. With the closure of OCP and the spraying programme in 2002, Mectizan is now the primary tool for treating onchocerciasis worldwide.

**A successful coalition**

While Merck awaited formal regulatory approval of Mectizan, its management began to think about how to make the drug widely available. Those who needed it lived in poor, remote areas. Many of the countries hardest hit by onchocerciasis had inadequate health infrastructures. There were few if any medical personnel or conventional health systems to manage the drug’s distribution and administration. There were also the challenges of drug importation regulations and customs duties. So simply giving the drug away was not a solution—yet abandoning it was inconceivable. A reliable, effective distribution system that would ensure Mectizan reached affected patients in 35 countries for more than 15 years was needed. In 1987, recognising that Mectizan was a very effective medication for onchocerciasis and that those afflicted could not afford such a therapy at any price, Merck decided to donate an unlimited supply of the drug for as long as necessary and to help create a reliable network for distributing the drug to those in need.

Faced with the enormous challenge of drug distribution, in 1988 Merck established the Mectizan Expert Committee (MEC) – a Merck-funded but independent committee of seven internationally respected scientists. The MEC was charged with evaluating requests to use Mectizan in community-based treatment programmes, and ensuring the widest possible availability of the drug while ensuring good medical practices were followed. MEC requirements for supplying the drug included a treatment plan approved by the ministry of health; an ability to maintain required medical records and to report adverse reactions; sufficient resources to sustain the treatment programmes for a minimum of 5 years; and agreement to integrate Mectizan into the existing health system wherever possible.

In the early years of the programme, NGOs working in the area of blindness prevention in Africa acted as a catalyst for Mectizan distribution. Mobile teams served as a primary mechanism for drug distribution. As the programme progressed, field-level partnerships between national governments, NGOs, local WHO offices and the community were formed. In addition, a strategy known as Community-Directed Treatment with Ivermectin (CDTI) was championed by WHO and piloted in the delivery of Mectizan. Experience showed that communities, once fully informed, were capable of organizing, directing and managing their own treatment. The community exercises authority over decisions; it decides who should distribute Mectizan, how the drug should be distributed (for example, at a central place, house-to-house, at clinics) and when the drug is distributed. Today, more than 60,000 communities have responsibility and ownership for Mectizan treatment, thereby enhancing the programme’s sustainability.

Working in close collaboration, Merck, the MEC, multilateral agencies, ministries of health, local and international NGOs, financial donors and affected communities have made the effort against river blindness a resounding success.

### Lessons learned

The Mectizan Donation Programme has taught us many lessons about how to mobilise resources in public-private partnerships to address significant health problems. Among the major lessons learned are:

- First and foremost, the MDP demonstrates that a drug donation must be appropriate, needed and accepted by recipients. While the MDP was established long before WHO published the Interagency Guidelines for Drug Donations, the donation of Mectizan is entirely consistent with the Guidelines. The lessons learned from the Mectizan experience have also helped to inform the Partnership for Quality Medical Donations (PQMD) and, more recently, the Partnership for Disease Control Initiatives (PDCI). PQMD is a coalition of pharmaceutical company and medical supply manufacturers and NGOs dedicated to raising the standards for donating drugs globally (website: http://www.pqmd.org). PDCI brings together pharmaceutical company donors and...
New initiative to develop drugs for neglected diseases

Jaya Banerji

The Drugs for Neglected Diseases Initiative (DNDi) was launched on 3 July 2003 in Geneva, Switzerland. This new research organization is comprised of a group of prestigious health and research institutes from Brazil, France, India, Kenya and Malaysia, as well as the medical aid organization Médecins Sans Frontières. DNDi will work in collaboration with the United Nations Development Programme, the World Bank and WHO’s Special Programme for Research and Training in Tropical Diseases (TDR) to achieve its goals.

DNDi, a not-for-profit organization, aims to harness cutting edge science to research and develop drugs for patients suffering from neglected tropical diseases. These diseases, such as sleeping sickness, leishmaniasis and Chagas disease, affect the poorest parts of the world. In 12 years the organization aims to develop six or seven drugs for these killer infectious diseases that together threaten around 350–500 million people every year. In addition to this output DNDi also hopes to have several new medicines in the development pipeline. To increase the chances of short- and middle-term success, the organization will develop drugs from existing compounds. It will also fund and coordinate research to identify new chemical entities and develop them into drugs. DNDi has proactively identified a number of promising drug development projects. With TDR’s help, it is in the process of selecting promising candidates from the response to a call for letters of interest to the scientific community. Once the projects are selected DNDi will provide the support and the structure to implement them.

DNDi will be the first not-for-profit organization to focus exclusively on the world’s most neglected diseases. Moving away from the traditional public-private partnership structure, it intends to take drug development out of the market-place by encouraging the public sector to take more responsibility for health. DNDi’s success will depend not only on government and private donations but also on the contribution of pharmaceutical companies, for example, in the form of access to compound libraries, expertise, and research and development facilities.

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The Balkans: critical times for pharmaceutical sector reform

During decentralisation and a move to market-driven economies have been at the heart of changes to the pharmaceutical sector in the Balkan countries. Although reorganisation started from different points, the critical steps taken for successful transition and long-term sustainability in the pharmaceutical sector have been very similar in the different countries. Recent analyses focus on the similarities and critical periods in the transition process in five neighbouring Balkan countries – Bulgaria, Bosnia Herzegovina, the former Yugoslav Republic of Macedonia, Romania and the Federal Republic of Yugoslavia*. The countries are different in population size, but all have low or negative growth, low GNP per capita and fluctuating inflation (see Table 1). Life expectancy is high, and in the future pressure on the health sector will increase because of the growth in the elderly population.

There has been a rapid increase in the number of medicines licensed for sale (Table 2) – in Bulgaria and Romania this has doubled during the last 10 years. The countries reimburse between one- and two-thirds of the registered International Nonproprietary Name (INN) drugs, and so need to be careful to maintain health insurance funds, because all of them are publicly funded and compulsory for the population.

Population expenditures finance most patient needs in terms of medicines in Romania and Bosnia Herzegovina, while in Bulgaria and Macedonia health insurance funds and government or regional budgets cover 60% of the pharmaceutical market. Only Yugoslavia finances medicines needs mainly through health insurance funds (Figure 1). Lack of funds for pharmaceuticals is a problem in countries with newly developed health insurance systems – Romania and Bosnia and Herzegovina. Administrative capacity is a problem in Bulgaria and Macedonia, while Yugoslavia’s pharmaceutical sector suffers from both problems. These factors make the affordability of the drugs questionable.

In line with market dynamics, the pharmaceutical sector is developing rapidly and the number of pharmaceutical facilities – mainly newly licensed private pharmacies – increases constantly, leading to a shortage of pharmacists. In Bosnia the situation is even worse, with the number of pharmaceutical facilities greater than the number of pharmacists, resulting from a lack of central control during the war there (Figure 2). Regulatory authorities in the countries should be greatly concerned that in the future lack of professionalism and responsible pharmaceutical care may be the main problems rather than lack of funds.

To keep pace with rapid economic changes and market pressures, pharmaceutical legislation is in a constant development process, but countries seem to lack the strategic vision to achieve a balance between the private and public sectors. For example, national medicines policy documents have been developed and officially approved only in Romania and Macedonia, while in Bulgaria a draft paper is circulating for discussion. Bulgaria and Romania have recently approved pharmaceutical laws to harmonise national laws with European legislation. Macedonia’s drug law is not supported by regulations, and Yugoslavia’s has not been updated since 1993. In Bosnia both entities (Republika Srpska and Federacija Bosna and Herzegovina) have different laws. Further efforts should be devoted to creating legislation that adequately reflects the economic situation in Bosnia and Herzegovina, Macedonia and Yugoslavia.

Three critical factors affect the legislation development process. The first is pharmacy ownership and licensing procedures. The ministry of health issues licences for pharmacies in all countries except Bosnia Herzegovina, where regional federal authorities can still grant a licence. Licences are given after presentation of the required documents, but if inspection capacity is low, as is the case in all the countries, the licence cannot guarantee strict compliance with the relevant legislation. Pharmacy ownership is either unclearly stated in the legislation or is outside regulatory control. In Bulgaria the licence is granted to the pharmacist as manager of the pharmacy, but the question of ownership is not covered by pharmaceutical legislation. As a result, chains of private pharmacies have grown up and some of them belong to the joint stock companies that include pharmaceutical manufacturers and wholesalers, which is against the drug law in Bulgaria. There is a similar situation in Romania where anyone can open a pharmacy. In Macedonia, Yugoslavia and Bosnia Herzegovina there are two types of pharmacies – governmental (51% or more belongs to the government) pharmaceutical companies possessing a warehouse and chain of pharmacies, as well as independent private pharmacies with a pharmacist manager and unclear ownership. The two types of pharmacies set different standards and performance in practice.

The second critical question is public sector procurement of pharmaceuticals. Four countries (all except Yugoslavia) require tenders for drug supply in hospitals or in the case of central procurement at national level for some medicines. Unfortunately in all these countries the tender system is based on laws valid for the whole public sector not just the health sector. The relevant pharmaceutical legislation does not have specific regulations for tendering for medicines. Consequently there are different procedures and unclear criteria for drug procurement in the public sector.

Pricing policy is the final factor to be considered. Bulgaria and Romania use regressive pricing scales with limited maximum wholesale and retail margins. Macedonia, Yugoslavia and Bosnia Herzegovina limit maximum wholesale and retail margins. Countries seem to rely on price decreases than on the establishment of effective price control...

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* G. Petrova

** Cont’d on page 30

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### Table 1: Socio-demographic characteristics

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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Population/million/</td>
<td>8,283,200</td>
<td>22,503,000</td>
<td>3,616,143</td>
<td>2,200,000</td>
<td>10,107,000</td>
</tr>
<tr>
<td>Average annual population growth (%)</td>
<td>-0.8</td>
<td>-1.5</td>
<td>6.8</td>
<td>1.05</td>
<td>-0.12</td>
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<tr>
<td>Life expectancy</td>
<td>70.5</td>
<td>69.2</td>
<td>70</td>
<td>70</td>
<td>68</td>
</tr>
<tr>
<td>GNP per capita (US$)</td>
<td>1,800</td>
<td>1,252</td>
<td>950</td>
<td>900</td>
<td>900</td>
</tr>
<tr>
<td>Inflation rate</td>
<td>4%</td>
<td>34%</td>
<td>14%</td>
<td>4.4%</td>
<td>24%</td>
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### Table 2: Registered drugs

<table>
<thead>
<tr>
<th>Number of drugs</th>
<th>Bulgaria</th>
<th>Romania</th>
<th>Bosnia Herzegovina</th>
<th>Macedonia</th>
<th>Yugoslavia</th>
</tr>
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<tbody>
<tr>
<td>Trade names</td>
<td>5990</td>
<td>6300</td>
<td>1630</td>
<td>1200</td>
<td>780</td>
</tr>
<tr>
<td>Dosage forms</td>
<td>7500</td>
<td>15000</td>
<td>2400</td>
<td>1900</td>
<td>1200</td>
</tr>
<tr>
<td>IMNs</td>
<td>1700</td>
<td>926</td>
<td>913</td>
<td>750</td>
<td>600</td>
</tr>
<tr>
<td>Positive drug lab/INN</td>
<td>324</td>
<td>350</td>
<td>250</td>
<td>450</td>
<td>560</td>
</tr>
</tbody>
</table>
There has been progress in privatization and opening up of the market, and that is a good basis for future development and increasing professional skills.

Guenko Petrova, is Associate Professor at the Medical University’s Faculty of Pharmacy, Sofia, Bulgaria.

* This article was written before February 2003 when the Federal Republic of Yugoslavia was renamed Serbia and Montenegro.

Shared agendas in traditional and complementary medicine

In May 2002, Dr Xiaorui Zhang, head of WHO’s global traditional medicine programme, witnessed the culmination of several years work in traditional medicine – the presentation of WHO’s Traditional Medicine Strategy to the World Health Assembly. The strategy was received enthusiastically by numerous countries and received wide coverage in the international press.

At the 2003 World Health Assembly, the strategy was endorsed and resolution WHA56/31 adopted – representing a major step forward for WHO’s work in this area. During the week of the Assembly, Dr Zhang attended the launch of Setting the Agenda for the Future, the new strategy of The Prince of Wales’ Foundation for Integrated Health. The Foundation aims to facilitate the development and delivery of integrated health care by encouraging conventional and complementary practitioners to work together to integrate their approaches.

The idea is that patients will then be able to meet their health needs by selecting from a wider range of health care.

The strategies of the two organizations share objectives relating to access, evaluation, regulation, and education and training. WHO and the Foundation are now working together to pool expertise and resources on a number of projects relating to training and regulation.

Talking with Dr Zhang, His Royal Highness the Prince of Wales expressed his belief that integration of conventional and complementary health care will depend very much on conventionally-trained doctors being given the opportunity to observe and experience the practice of traditional and complementary medicine.

Report provided by Rosalyn C. King, Director of the Pharmacies and Continuing Education (PACE) Center at Howard University Continuing Education, Silver Spring, Maryland, USA.

The Balkans... cont’d from pg. 29

measures. For reimbursement purposes all countries, except Macedonia, establish prices lower than the maximum retail price. Macedonia is organizing a tender with price volume agreements for the reimbursed quantities and prices. Because of the lack of resources and administrative capacity, the reimbursement drug lists change often and regular patient access to medicines is not guaranteed.

Resulting from the problems discussed here, what should we expect in the very near future? Driven by powerful economic forces, the pharmaceutical market will increase its sales both in units and financial volume. This will lead to an increase in the number of reimbursed drugs and an expanded role for health

insurance funds in drug financing and control of pharmaceutical expenditure, through changes in pricing and reimbursement policy. Particular attention should be paid to the tender process for drug procurement in hospitals and other public facilities – a process which should be based on transparent criteria and reliable methodologies.

To respond to market pressure, pharmacists should increase their knowledge of market intelligence, economic market strategies, patient education and patient care. Strong pharmaceutical associations are an essential element in ensuring a successful transition process. The pharmaceutical association is expected to develop a systematic continuous postgraduate education and to serve as a defender of professional performance and ethical market behaviour. Nevertheless

There has been progress in privatization and opening up of the market, and that is a good basis for future development and increasing professional skills.

Guenko Petrova, is Associate Professor at the Medical University’s Faculty of Pharmacy, Sofia, Bulgaria.

* This article was written before February 2003 when the Federal Republic of Yugoslavia was renamed Serbia and Montenegro.

Shared agendas in traditional and complementary medicine

In May 2002, Dr Xiaorui Zhang, head of WHO’s global traditional medicine programme, witnessed the culmination of several years work in traditional medicine – the presentation of WHO’s Traditional Medicine Strategy to the World Health Assembly. The strategy was received enthusiastically by numerous countries and received wide coverage in the international press.

At the 2003 World Health Assembly, the strategy was endorsed and resolution WHA56/31 adopted – representing a major step forward for WHO’s work in this area. During the week of the Assembly, Dr Zhang attended the launch of Setting the Agenda for the Future, the new strategy of The Prince of Wales’ Foundation for Integrated Health. The Foundation aims to facilitate the development and delivery of integrated health care by encouraging conventional and complementary practitioners to work together to integrate their approaches. The idea is that patients will then be able to meet their health needs by selecting from a wider range of health care.

The strategies of the two organizations share objectives relating to access, evaluation, regulation, and education and training. WHO and the Foundation are now working together to pool expertise and resources on a number of projects relating to training and regulation. Talking with Dr Zhang, His Royal Highness the Prince of Wales expressed his belief that integration of conventional and complementary health care will depend very much on conventionally-trained doctors being given the opportunity to observe and experience the practice of traditional and complementary medicine.

Report provided by Rosalyn C. King, Director of the Pharmacies and Continuing Education (PACE) Center at Howard University Continuing Education, Silver Spring, Maryland, USA.

The role of the pharmacist in Romania has been changing since the reform of the political system in 1989. As in many other countries pharmacists were educated with an emphasis on preparing and dispensing medicines. But when the health care system reformed to improve professional training as part of improving primary health care delivery and family planning, pharmacists were able to strengthen their role and expand the scope of their practice. The TrainPharm Project, begun in 1999, was initiated to enhance pharmacists’ skills in the areas of primary health care, reproductive health care and family planning. The project is a joint effort between the Howard University Continuing Education Pharmacists and Continuing Education (PACE) Center, in the USA, and the University of Medicine and Pharmacy (UMF-Chis) in Romania.

University-based, skills enhancement training workshops for practicing pharmacists were a core activity of the TrainPharm Project. A set of training manuals has been designed, produced and distributed to provide instructional content and training guidance for the Project. The set included a trainer’s and a participant’s manual, each divided into the following training modules:

➤ introduction and workshop overview
➤ the pharmacist providing reproductive health and family planning services
➤ contraceptive facts
➤ sexually transmitted disease/HIV/ AIDS treatment facts
➤ menopause and applicable treatment facts
➤ communications and counselling
➤ promoting the role of pharmacists in reproductive health
➤ administration and marketing of contraceptive products in the pharmacy

With 445 pages, the participant’s manual contains lecture and training material, handouts and space for note-taking. Along with the contents of the participant’s manual, the trainer’s manual includes step-by-step instructions for conducting the teaching, hands-on training aids, and an additional module on monitoring and evaluation, “Training Monitoring, Follow-up and Follow On”.

Each module begins with learning objectives to guide instruction according to each objective. The manuals incorporate a variety of learning approaches to accommodate different learning styles and to allow for a mixture of lecture, interaction and practice. The training approaches include:

➤ “lecturette”, which provide the content;
➤ discussions, which engage participants and allow them to tie what they are learning into their real-world responsibilities;
➤ exercises/games, which involve the participants and help them process what they are learning;
➤ case studies, which help participants put theory into practice;
➤ role plays, which allow participants to process and practice what they are learning.

The manuals offer a comprehensive approach to involving pharmacists. They can be easily adapted to specific country or programme training needs and content. The detail and structure of the manuals provide trainers with the strategies and resources to effectively reach and commmunicate with participants, creating a programme that is easy to conduct and evaluate. Participants are empowered also to develop contextual skills, a new perspective on their role and their clients’ concerns, and the knowledge to be effective resources for the community.
Out now – a new edition of WHO’s International Pharmacopoeia

To improve the quality and efficacy of medicines, facilitate control of counterfeit and substandard drugs and address problems of drug resistance, WHO has released a new edition of the International Pharmacopoeia. It provides specifications for the content, purity and quality of active ingredients and pharmaceutical products according to internationally approved standards. While the Pharmacopoeia is a practical tool for all settings, it is aimed especially at those countries where national regulatory authorities may not have enough funds or staff to function effectively.

The new edition will be particularly useful in identifying counterfeit and substandard medicines. Although countries do not always reveal data about these, those that do, demonstrate that on average 10-20% of medicines in developing country markets are substandard. Poor quality drugs may cause death, serious harm to health or, at best, have no therapeutic effect. Counterfeit and poor quality antimalarial medicines, for example, also contribute to the dramatic growth in resistance to anti-malarials, which has serious health and economic impacts. In its fifth volume, the Pharmacopoeia includes a special section on quality control of antimalarials. Also concerned with increasing access to effective treatment, the publication gives priority to medicines for illnesses affecting developing country populations disproportionately, such as HIV/AIDS, tuberculosis, malaria and diseases neglected by conventional pharmaceutical markets. However, the monographs contained in the publication can be used in any country or setting. They are designed to cater for both high-technology methods of testing or, when these are not available, for alternative methods that are less technically demanding.

In addition to monographs, WHO publishes basic tests for confirmation of the identity of active ingredients. These are especially useful when a fully equipped laboratory and analytical expertise are not available, and when rapid control is needed.

The International Pharmacopoeia Volume 5: Tests and General Requirements for Dosage Forms. Quality Specifications for Pharmaceutical Substances and Dosage Forms is available from: World Health Organization, Marketing and Dissemination, 1211 Geneva 27, Switzerland. Tel: +41 22 791 24 76, fax: +41 22 791 48 57, e-mail: bookorders@who.int

Price: Sw.fr.85, US$76.50, and in developing countries Sw.fr.59.50. WHO is offering a special 30% discount price for anyone wanting to buy all five volumes of the Pharmacopoeia: Sw.fr.212.80, US$191, and in developing countries Sw.fr.148.


The very rapid growth of expenditure on medicines is of particular concern and it has attracted considerable political attention. Over the years many Member States have approached WHO for advice or information on the feasibility of measures to control the growth of spending on pharmaceuticals. These calls for help resulted in a study being undertaken in 1983 and the study report was published as the 1st edition of Drugs and Money.

The latest edition provides policy-makers and regulators with a compact and practical review of the various approaches that have been developed and tested in an effort to contain the overall costs of pharmaceutical services and drug treatment. The book also addresses issues of the organization, standards and delivery of health care. Unlike earlier editions of Drugs and Money, this volume devotes considerable attention to the special problems of developing countries and those where the economy is in transition.

The book is structured in a way that provides the reader with a logical line of reasoning progressing from the scope and causes of the cost containment problem in Chapter 1, through the means which exist to examine and quantify it in Chapter 2 to an extensive consideration of the principal solutions which governments use to cope with the problem, and to measure the impact of whatever measures are taken in Chapters 3 and 4. Actual experience with the main methods used to date is considered in Chapters 6-13, while in the last two sections special attention is devoted to the situation in developing countries and those with economies in transition.


Drugs and Money

Practical guidelines on pharmaceutical procurement for countries with small procurement agencies, Manila, WHO, Regional Office for the Pacific, WHO/WPRO, 2002

Libby Levison

Procurement has become a standard procedure in the drug management cycle in most countries. This new publication from WHO argues for more systematic procurement procedures in order to improve essential medicine availability, reliability and quality. While written for small procurement agencies, this concise, easy-to-follow summary of pharmaceutical procurement process is a useful resource for any procurement office.

The manual discusses the different options available in term of tendering and the prequalification of suppliers. For procurement offices with limited staff and resources, one of the best ways to ensure pharmaceutical quality is to use a restricted tendering system and to prequalify suppliers. Issues in selecting suppliers discussed in the text and model questionnaires for prequalifying suppliers and a model tender invitation are provided in the appendix. This welcome publication is a useful document for all procurement offices.

The publication is available at: www.wpro.who.int/pdf/PHA/Practical_guidelines.pdf or contact: PHA, P.O. Box 2932, 1000 Manila, Philippines.

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This new book by D.C. Jayasuriya is intended to update a previous book by the same author, Regulation of Pharmaceutical Products Moving in International Commerce, published by WHO in 1985. Much has happened in the area of pharmacological law and regulation since 1985. Among other things, there have been many new regulations and revisions in the statutory law of developing countries, the acceptance of the essential medicines concept, and the development of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. This book is therefore intended as, in the author’s words, a “non-technical orientation to regulatory issues of concern to all those who are interested in regulating pharmaceuticals in developing countries.” It is designed to provide a “more in-depth and detailed analysis than that contained in the earlier book...” with more examples from selected national policies and laws.

The text is in three parts. Section I provides a good general background to legal principles. Section II summarises the scope and content of legal issues dealing with drug regulatory authorities, product registration, manufacturing, exports, imports, advertising and the like. Section III deals with specific issues such as intellectual property and clinical trials. This book is an excellent overview of the many legal issues facing drug regulatory agencies but the diffuse nature of its intended audience neither gives the book focus nor allows any critical review that might prove useful to policymakers working with attorneys who plan to craft new legislation. Indeed, lawyers might find the contents too superficial and pharmaceutical regulators might well question the lack of recommendations or guidance. Most significantly, one wishes for even more specific examples of “best practice”. Candidly, even if the author was ultimately wrong in making a specific recommendation, such statements would have stimulated some discussion and at the very least have provided a platform for future debate.

Some specific points will illustrate. There is a potentially useful discussion (p.54) of the structure of drug regulatory authorities and the text clearly delineates what governments should do to provide the legal framework to support these agencies. It would, however, have been far more interesting, useful, and important to compare what “should” be the case with what developing countries have actually done. Conflict of interest is an important subject (p.59) but there is only a single decade-old statutory example from Spain to illustrate the author’s point that a “small number of countries” have legislative mandates regarding conflicts of interest. If there are so few countries, why not list them in an Annex and try to provide “best practice” recommendations. The legal provisions for enforcement of pharmaceutical legislation for several developing countries are provided (p.128) and this is an excellent start but, again, particular examples or recommendations of “best practice” language would have been useful.

On rare occasions, the writing style can be cryptic and would have benefited from more editing. The author states (p.28) that, “Because of the very nature of medicinal products, additional regulatory regimes specific to them are essential, though not very common in most developing countries.” The non-expert might wonder what is this mysterious “nature of medicinal products”. It is left until later (p.45) to explain that “considerations of public health demand that [medicinal products]...” be subject to special regulatory regimes. The author (p.57) asserts that legal regulations must be specific and comply with principles of “natural justice” but this latter term, if it really adds to the discussion, is nowhere defined. It is even on rarer occasions that the book actually seems oddly outdated. For instance, this reviewer could find no list of web sites of any kind and they would have been useful. Direct to consumer advertising is allowed in both the United States (p.115) and New Zealand. A “very recent study” (p.112, footnote 110) was cited but the study was from 1993, already nearly a decade old. The author has succeeded in writing a non-technical orientation to regulatory issues but, in this reviewers’ opinion, has not provided the sort of in-depth analysis that could have broken new ground and been a major contribution to the field. The book can be recommended to students of law and public health and regulatory/pharmaceutical professionals looking for an introductory overview. Others will find the book disappointing. The book that critically reviews legislation and provides recommendations and “best practice” language still remains to be written.

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For further information contact Har-Anand Publications, F1211 Chittaranjan Park, New Delhi 110019 India.


Many opinions can be heard on the quality of medicines circulating in developing countries. The trouble is that up to now we were not sure whether these opinions were fact or fiction, but that has just changed. This outstanding collaborative study presents the results of quality tests on antimalarial medicines circulating in African countries. Samples were not only taken from various levels of the health systems in the seven participating countries, but also from distribution systems, private sector outlets and households. Significant problems of substandard products were found. They include percentage failures in ingredient content ranging from 20% to 67% for chloroquine tablets and 5% to 38% for sulphadoxine/pyrimethamine tablets. Dissolution failures ranged from 5% to 29% for chloroquine tablets and 75% to 100% for sulphadoxine/pyrimethamine tablets. These findings allow for a number of observations. First, that the quality of antimalarial products in African countries is not good enough. The amount of active substance in the products is often too low. However, what is probably equally important is that, in addition, there are serious dissolution problems for some medicines, especially sulphadoxine/pyrimethamine tablets. Whereas this problem was very much present with sulphadoxine/pyrimethamine, it was much less with chloroquine. According to the authors it is mainly the pyrimethamine component of the sulphadoxine/pyrimethamine combination that is to be blamed. Another interesting finding was that no clear relationship could be found between the quality of the product and the level of the distribution chain from which samples were taken.

What do these data mean? First, they mean that two of the most commonly used antimalarials in the world are often of poor quality and in some cases are almost useless. This, of course, has important implications for efforts to roll back malaria. Another conclusion is that while a poor therapeutic response to conventional antimalarial drugs may quickly be called “resistance”, in fact it is partly or wholly due to quality problems of the medicine in question. What this means for other medicines circulating in countries with less stringent regulatory agencies, I do not know, but it does not promise much good. As the authors explain, poor dissolution goes together with lower than expected blood levels, and hence, inadequate treatment levels. Of course this is not only the case for antimalarial medicines.

Finally, the finding that imported medicines failed tests just as much as locally produced ones is important, as it points to the need for strict quality assurance of all medicines to be procured – no matter where they are procured from. Good quality cannot be taken for granted. Buyer beware!

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Available, free of charge, from Department of Essential Drugs and Medicines Policy, WHO, 1211 Geneva 27, Switzerland.
Traditional medicine in Asia, Ranjit Roy Chaudhury, Uton Muchtar Rafei eds. New Delhi, WHO, Regional Office for South-East Asia, 2003

The success of a trip depends upon several factors, including the departure point, the personal background of the travellers, the final destination, good weather, the pictures taken on the way, and the subsequent tales to friends and neighbours. Rational use of drugs (RUD) promotion is also a trip — a trip that, to be successful, requires a deep knowledge of the departure point, an accurate map of the hills, the coves and the closed roads, a precise forecast of the highs and lows that will be encountered along the way, plus lots of pictures to analyse past and present situations, as well as the intervention results. Drug utilization studies supply the pictures necessary in RDU promotion. Drug utilization research (DUR) provides the tools to find out how drugs are used in a specific setting, to identify drug-use-related problems and to define interventions to overcome these problems. DUR tools also measure the impact of such interventions in order to gather the elements needed to re-adjust the route towards the common end-point: a better use of medicines.

The short manual, Introduction to Drug Utilization Research, recently published by several WHO Collaborating Centres is a great book. It describes the need for drug utilization research and defines its boundaries; it lists the different types of drug information and the sources DU researchers can look for it. Additionally, the manual includes an introduction to pharmacoeconomics, as well as a description of the drug classification systems and drug utilization matrix. The manual’s major strong points should be highlighted at once:

➢ It includes the definitions of basic DUR terms. This will be very useful both for the DUR newcomers and for advanced researchers, as it will help to unify criteria.

➢ It goes beyond the classical superficial drug use analysis (i.e., drug consumption data from drug sales), and sets the framework for a deeper drug utilization analysis — qualitative DUR. Qualitative drug utilization research helps to sensitize prescribers and clinicians, and facilitates changes of inappropriate drug prescription patterns.

➢ A general reading section encloses a list of related papers that allow a deeper insight of each topic.

➢ In addition to fully explained examples, every chapter includes several exercises that invite the reader not to be passive.

This new book on drug utilization research has the difficult virtue of being so short that it invites everybody to read it, and so deep as not to be overlooked as “just another book about drug use”. It will become an indispensable travel companion for those who undertake the intricate (and exciting) trip to get a more rational use of medicines.
**Study tour in Moldova**

In the years since the break-up of the Soviet Union, there have been considerable changes in the pharmaceutical situation in the Newly Independent States (NIS). New drugs have entered the market, while older drugs that were not selected on the basis of evidence remain. Health professionals in the NIS have inadequate and outdated information on the prescribing of drugs, a fact which directly impacts the population, who may receive inappropriate treatment. Irresponsible prescribing has serious economic repercussions for the region.

A study tour for drug information centre staff in the NIS provided an opportunity to discuss these issues and to try and find ways to improve public health in the Central Asian Region. Participants came from Kazakhstan, Tajikistan and Uzbekistan for the tour which took place in Moldova from 8–14 September 2002. The aim was to assist staff of newly established drug information centres to initiate rational drug use programmes, and to promote the creation and ensure the sustainability of drug information centres.

The tour was organized by ZdravPlus, and the Academy of Educational Development, which are USAID funded, in collaboration with DrugInfo Moldova. DrugInfo Moldova is the country focal point for a number of nongovernmental organizations: the Ecumenical Pharmaceutical Network, Health Action International, the Alliance for the Prudent Use of Antibiotics, KILEN, (a Swedish consumers’ group) and the International Society of Drug Bulletins. The tour provided a good opportunity for participants to learn more about the mission, objectives and main activities of these organizations.

During the study tour participants received information on:
- the essential drugs concept and rational drug use policy development;
- the role of the church in public health and how to establish collaboration with church-related medical institutions;
- how to involve the broad spectrum of volunteers – from students, physicans and nurses to teenagers and pensioners;
- the importance of adverse drug reaction reporting by consumers;
- how to establish collaboration between government and non-governmental organizations;
- the role of the mass-media in promoting public health, and how to work with journalists.

Practical skills were taught on:
- establishing drug and therapeutics committees;
- promoting good governance through the creation of boards, issuing independent drug bulletins;
- using different qualitative methods in public health surveys in hospitals, ambulatory care and in the work with patients and consumers;
- developing effective communication and facilitator skills through role play.

Visits were organized to Moldova’s Health Ministry, the National Institute of Pharmacy, the Repulbic Neurological Clinic, the Tuberculosis Hospital, and the Department of Pharmacy at the Medical and Pharmaceutical University of Moldova. Participants showed great interest in the innovative Children and Medicines project, promoted by DrugInfo Moldova with Management Sciences for Health and the US Pharmacopoeia. Lively discussions with the teenagers from the volunteer group proved a highlight of the tour, and set many of the visitors thinking about starting similar projects at home.

During a field visit to Edinet District, a rural area in northern Moldova, there was a chance to meet an official of a local hospital Drug and Therapeutics Committee, and also surveys on antibiotic use problems took place. Participants had developed five different questionnaires and used them in a variety of settings. One group did a survey among pharmacists in city pharmacies, the second with hospital patients, the third with family doctors, while the fourth organized a focus group discussion in an orphanage, asking children about their knowledge on antibiotics. The final group worked with teenage volunteers and did a street survey of young mothers.

Before the field visit the group had learned qualitative methods for receiving and incorporating such drug use information in their work. They learned about the importance of publicising this information in drug bulletins and at workshops and seminars. To capitalise on this, the last day of the tour was devoted to discussing ways to cooperate to produce drug bulletins and develop action plans for the next year. The group left Moldova, happy to have learnt so much, to have shared the common problems they experience and determined to create a network so that they continue to benefit from each others knowledge.

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The collaborative online learning (COL) course developed at Boston University offers these opportunities for professional education of healthcare providers, and for promoting rational and evidence-based medical care and medication use. Distance education methods for disseminating new protocols and guidelines from WHO and other organizations to improve the use of medications may be an important and neglected method of promoting adoption of new standards of care. To be successful, we believe that distance education must include opportunities for communication and discussion about the proposed changes to clinical practices. This type of learning should encourage reflection by the target audience on the complex processes of behavioural and organizational change implicit in the implementation of new guidelines and protocols. Properly designed online professional education programmes provide unique opportunities for these activities.

To date continuing medical education (CME) programmes have not taken advantage of the ability to communicate and collaborate online, however. Collaborative or “peer-to-peer” learning is an important principle, yet online CME programmes are generally created in a one-to-one relationship between the computer and the learner. This limits opportunities for reflective learning, and does not access the rich potential of interacting with peers. We believe that the Collaborative Online Learning (COL) course developed at Boston University offers these benefits and draws on an awareness that physicians, and other health care professionals, like to learn from each other in a collegial, non-threatening learning environment.

**A step-wise approach**

We ran a prototype online course designed to improve the skills of general practitioners (GPs) in the care of patients with type 2 diabetes. The course design reflects adult learning principles but, uniquely, applies them to online learning. The course has been taught twice, with the first enrolling 20 GPs from the UK, one based in Bosnia, and one in New Zealand. The second course had four GPs from Singapore, 13 from Indonesia, three from the UK and one from the USA. The course used BlackBoard(TM) software. Participants logged in twice weekly for seven weeks to study one of seven interactive modules on diabetes from evidence-based sources. The modules were designed with a step-wise approach to learning following the clinical progression of the chronic disease, starting with a module on screening and diagnosis, through lifestyle therapy, use of medications, and, in later weeks, screening for and management of complications of diabetes.

**Adapting to participants’ needs**

Participants’ feedback has been very positive. Many noted how well the course design and timing matched their learning styles and schedule constraints. One respondent felt the course would be a positive experience for other medical practitioners to organize additional educational needs, and quickly add corresponding content online. For example, when participants in the first course indicated a need for more information on the renal complications of diabetes, and how to prevent them, we were able to design and post online a module on this topic within two weeks. The 22 participants in the first course provided 340 postings, which included evidence of course effectiveness and documentation of application of course objectives and disease management strategies to change actual practice patterns. GPs reported changing screening protocols for diabetes; screening practices for diabetic renal disease; and organizing practice management systems to better track diabetic care. They also reported changing their prescribing of diabetic medications to emphasis medico-social choice for which there is best evidence for impact on complications of diabetes at lowest cost. Participants were given a written case online before and after the course, and were asked to write a management plan for it. Analysis of these documents demonstrated improvement in overall score and in many key areas of diabetes management.

After diagnosing and managing a new diabetic patient during the course, one participant from the UK wrote: “It was fantastic to feel that I am offering an up-to-date evidence-based approach in something that I am destined for.” There was similar feedback from the second course. Participants noted additional positive aspects of this method of professional development. In particular, the peer-to-peer learning from interaction with other participants was frequently mentioned as a major strength. A Singapore GP commented that the course “crosses international borders and allows participation of people I would have never met from other countries.” A GP from Indonesia commented on straightforwardness: “The modules are very clear, very simple and straightforward. There are many experienced participants in the discussion forum. It is free of charge...” Because the two participants from the UK were thoroughly schooled in the evidence-based approach to diabetes care, they could generate useful debate and counterpoints on some of the clinical practice guidelines promoted by medical associations in the UK, USA and Singapore.

Suggestions for improvement included requests for hard copies of materials, to reduce the need for downloading and printing material, which is prohibitively slow on the unreliable Internet connections in some countries. The need for more discussion of the psychosocial issues of the case patient, rather than emphasising the medical management, was mentioned. Several participants requested the course run longer than six weeks to give more time to learn new material. Most participants indicated they would enroll in future online courses using this collaborative method, on additional topics – the most requested of which were treatment and prevention of cardiovascular disease.

**Summary**

Our experience to date suggests that this teaching method provides exciting and rewarding opportunities for educators and learners for learning via links to additional resources. Subsequently, GPs engaged in two online discussion groups, in which learners could participate by posting messages at any time, without requiring the simultaneous presence of teachers. The course on the web site. These discussions were similar to an electronic discussion group rather than a chat room or Instant Messenger. They have been far more convenient than requiring adherence to a set schedule, so that participants could contribute when it suited them, and towards the end of the course, participants also read and responded to colleagues’ postings each week.

In a second discussion group, learners applied concepts from the modules to the collaborative management of a problem-based case of a patient with newly diagnosed diabetes. The patient was presented via an online medical chart and streaming videos. She returned each week of the course to mimic 18 months of care, with the problems and diabetic complications she presented at each week’s visit coordinated with the content of the learning modules. Learners used the material from each week’s module to develop a management plan for each virtual patient visit, which they posted to the discussion group. They collaborated by reading and responding to the postings with a goal of achieving consensus on the management of the patient. Faculty from Boston University, trained in online teaching, facilitated the discussion groups and provided feedback.

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**Further reading**


**Collaborative Online Learning (COL): a new distance education method**

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