EDITORIAL

Affordable prices, sustained financing, rational use and reliable health and supply systems are the inextricable links that underpin access to medicines. This issue of the Monitor highlights some recent activities to create or to strengthen these links.

Access to essential drugs continues to be high on the international agenda. The fears of developing countries and others concerning the impact of international trade agreements on drug prices and accessibility have been expressed in a series of recent statements in different international fora. These include most notably the special discussion on access to essential drugs in the World Trade Organization (WTO) Council for TRIPS in June, and the November meeting in Doha.

Concern has also been expressed about pressure on developing countries to enact patent legislation which goes beyond the WTO member requirements, “TRIPS plus”. The statement resulting from Doha (see page 4) has been warmly welcomed as an important step forward in the struggle for affordable medicines. The critical issue of how countries which have no national production facilities can make use of compulsory licences awaits resolution. This will be discussed in the TRIPS Council during the coming year.

Making life-saving medicines more affordable for developing countries was the core topic of a WHO/WTO workshop in April on differential pricing, reported on page 11. Participants shared much common thinking on two central points.

First that differential pricing can play an important role in ensuring access to essential drugs at affordable prices while allowing the patent system to play its role of providing incentives for research and development of new drugs. Second that while affordable prices are important, actually getting drugs to the people who need them in poor countries will require a major financing effort both to buy the drugs and to reinforce the health care supply systems. For that most of the additional financing will have to come from the international community.

Some interesting initiatives to promote the rational use of drugs, in very diverse parts of the world, are also reported in this issue. The Quality Circles, launched in Fribourg, Switzerland, and now spreading to other cantons, show that it is possible to influence health care from the local level up rather than top down, while drawing on the centralised information strengths of health insurance funds and professional societies. In Oman the Government recognises the need for national drug policy to focus not just on access to a supply of safe and appropriate drugs but also how they are actually used in practice. Its new Directorate of Rational Drug Use began work by undertaking baseline studies using the WHO core indicators for prescribing and dispensing. This will create a quantitative and qualitative knowledge base about current practices across the nation and enable the Government to establish priorities and target interventions. While on another continent – India – university students and NGOs are reinforcing the rational use message through street theatre, with both consumers and players learning much in the process.

Good procurement is also a lynchpin of access to quality and appropriate medicines. WHO, in partnership with UNICEF, UNFPA and the World Bank, has drawn on a common bank of extensive experience to produce Operational Principles for Good Pharmaceutical Procurement. Reproduced in full on pages 13–16, the guidelines should be a valuable summary tool and checklist for countries, development agencies and other organisations involved in drug supply.

In developed countries concern is growing about the widespread availability of prescription drugs through the Internet, as well as health and medicines information of dubious quality and biased source. Many such sites are simply disguised marketing ploys and web surfers need to beware. WHO’s guide to obtaining reliable, independent and comparable information on medical products on the World Wide Web is intended to help lead consumers through these relatively uncharted waters.

The global, organizational and professional diversity of all this work and advocacy is encouraging, as is the increasing recognition of the links in the chain of access. However, the deteriorating health situation in many developing countries and the unacceptable lack of access to essential drugs and care of so many millions highlights the urgency of action needed to bring more equity and rationality into a world we all share.
MALARIAS strategy that can meet these challenges. The success of African ITN initiatives, but affordable mosquito nets and insecticide. The programme does this by creating well-planned targeting, cross subsidisation, and cost recovery, an innovative programme in Malawi has increased protection of hundreds of thousands of people annually from this deadly disease.

Malariain this frequent cause of morbidity and mortality in Malawian children under five years of age, and is the cause of over 40% of deaths in children under two. Children under five suffer on average 9.7 malaria episodes per year, while adults suffer 6.1 such episodes. The human and economic costs are enormous. In addition to the expenses of consultation, treatment, hospitalisation and travel, malaria often leads to low productivity and lost income from days of work missed. The cost of malaria to the average Malawian household has been estimated at US$35 annually – or 7.2% of average household income.

Sleeping under ITN is a proven method of preventing malaria. Follow ing research trials in Africa in 1996, WHO reported that “the lives of some 500,000 African children might be saved each year from malaria if the nets treated with biodegradable pyrethroid insecticide, were widely and properly used.” More recently, the WHO Roll Back Mal aria (RBM) initiative called for a 30-fold increase in ITN use. Population Services International (PSI)/Malawi responded with an ITN social marketing initiative centered in Blantyre District, Malawi. In January 2000, this project expanded to become the first national ITN programme in Africa. PSI/Malawi is reducing malarial disease and death by increasing ownership and appropriate use of ITN. The programme does this by creating demand for and improving access to affordable mosquito nets and insecticide.

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**THE CHALLENGES**

- malaria transmission is highest in rural areas, where purchasing power is lowest;
- distribution outlets are sparse in rural areas;
- harvest-derived rural income is available only after the peak period of malaria transmission;
- young children and pregnant women, who are most vulnerable to the debilitating effects of malaria, do not have preferential access to ITN within the household.

**THE RESPONSES: PSI/MALAWI’S STRATEGIES**

### Segmenting the ITN market

Increasing access to ITN while maximising cost recovery has been achieved in the Malawi programme principally by segmenting the market – selling different products at different prices through different outlets to different target groups. PSI/Malawi supplies two types of branded Chiwetez Premium Net ("Protect Net" in the local language) mosquito nets, each packaged with an insecticide treatment kit. One is a blue conical net, the other a green rectangular net. Research showed that conical mosquito nets were most popular with urban dwellers sleeping predominantly on beds, while rectangular nets were most appropriate for rural dwellers sleeping on large mats. The blue conical net is sold to distributors for 20% above the direct product cost, and the green rectangular net for 35% below cost. After the addition of incentive margins for the distributors, the consumer prices of Chiwetez Net are equivalent to US$ 6.00 (blue conical) and US$ 2.10 (green rectangular). The insecticide treatment kit, branded M'Inweza Chiwetez ("Restore Protection"), is sold with a 60% subsidy.

The higher-priced blue conical nets are available to anyone and carried by all commercial outlet types throughout Malawi, including small shops, retail chain stores, and pharmacies. The lower-priced green rectangular nets are distributed in three trial districts through a total of 40 rural public sector clinics as part of an innovative collaboration between PSI, local District Health Management Teams (DHMTs), and the Malaria Control Programme under the central Ministry of Health and Population (MOHP).

**Targeting subsidies through rural public clinics**

Special strategies are needed to deliver subsidised ITN to vulnerable populations in rural areas where malaria and poverty are most severe. The lack of shops with sufficient capital to buy ITN is a major constraint to net ownership and use in rural areas. The few rural shops that are able to stock ITN serve the general population, rather than those most in need.

To increase access to ITN for the most important malaria risk groups, PSI/Malawi, in collaboration with three local DHMTs, sells green rectangular nets at a heavily subsidised price to pregnant women and parents of children under five years, who have registered at a participating clinic. PSI/Malawi trains clinic staff in ITN promotion and inventory management. Each clinic is then supplied with a stock of nets as seed “capital.” Nurses stamp the registration cards of pregnant women and children under five, thus limiting distribution to one net per eligible person. A team comprising one member of the local DHMT and PSI/Malawi visits each clinic every two weeks to restock nets (according to the number sold since the previous visit), collect cash (leaving behind an incentive margin for the nurses), monitor record keeping, and provide any other support required by the nursing staff.

By offering health workers the same profit margin as shopkeepers on each net sold, clinic staff are able to sell nets at rural sales outlet in rural areas. In Blantyre District, where the model has been in existence longest, 23,723 nets were sold through 18 public clinics in the first half of 2001, accounting for 40% of the total number of nets sold in the District for that period. Importantly, there has not been a loss of cash or nets at any of the 40 participating clinics in all three trial districts.

**Creating demand for ITN and promoting appropriate use**

Establishing the most appropriate net delivery system is just one component of the ITN programme in Malawi. Communications messages have been developed to address research findings on the primary reasons – both in terms of knowledge and attitude – for not purchasing ITN. In general, the nets are desired for their capacity to prevent mosquito bites, which is considered a relative luxury. It is less common for nets to be perceived as potential lifesaving devices. In addition, it is not well understood that malaria protection comes more from the insecticide than from the net. Therefore messages focus on the prevention benefits of insecticide treated nets, and the specific benefits of the insecticide component. Communications also highlight the health, financial, and emotional costs of malaria: the exclusive role of mosquitoes in transmitting malaria; the risk groups who suffer most (pregnant women and children under five); and the importance of using treated nets year-round.

PSI delivers messages through a variety of communications channels. A six-month nationwide radio campaign was carried out to improve knowledge and change attitudes toward malaria and malaria prevention in nine identified areas. The campaign combined radio drama, using characters from the popular soap opera Zimachitika, with the excitement of a competition, as well as a series of musical jingles by a local artist. The competition yielded 26,000 postal entries of which nearly 60% contained the correct answers to all nine questions relating to the key areas. A pre- and post-campaign
survey demonstrated an increase in knowledge in all nine areas and major improvements in four knowledge items: (1) only mosquitoes can transmit malaria, (2) malaria mosquitoes bite only late at night and (3) ITN are the best way to prevent malaria in the household. Because radio ownership is lower in rural areas, a drama group performs on market days in these regions, where crowds of up to 500 regularly attend. Also, PSI/Malawi holds mobile video shows using a large, portable screen, attracting crowds of several thousand.

**Promoting retreatment**

Low rates of net retreatment with insecticide are a problem for all ITN projects. PSI/Malawi convened a workshop to identify the major constraints to net retreatment, and to devise new marketing strategies to surmount them. Several notable constraints were identified:

- poor brand awareness and lack of visibility of M'bweza Chitetezo;
- perception that a net without insecticide provides sufficient protection;
- failure to remember that nets need retreatment;
- fatalistic attitude about contracting malaria;
- well-established response of purchasing drugs for treatment rather than means for prevention.

Addressing these constraints, PSI/Malawi launched an annual, three-month retreatment campaign to coincide with the start of the rainy season and the increase in the mosquito population. The slogan “Mosquitoes are back: it’s time to treat your net” was used in radio spots, on point-of-sales materials, and on billboards around Blantyre. Brand visibility was increased by placing branded stick- ers on public transport minibuses, by developing new wall paintings of the brand, and by painting the brand on the sides of the delivery trucks. Retail promotions encouraged shopkeepers to order more stock and make attractive, eye-catching displays. The winning shops received a bicycle, and runners-up reduced their prices. Today, imported white nets are still sold from the same outlet as M'bweza Chitetezo, but the average price of white nets (without a treatment free status, means that PSI/Malawi can provide malaria prevention services that they otherwise could not.

**The results: ITN programme successes**

**Increased informed demand**

Results from a population-based survey before the launch of Chitetezo Net showed that only 3% of respondents had ever heard of treating mosquito nets with insecticide. Two years later in a random sample reported having heard of insecticide treated mosquito nets, brand awareness for Chitetezo Net had reached 68% and 57% for the retreatment kit, M’bw era Chitetezo. The proportion of respondents who reported mosquito nets as the best way to prevent malaria rose from 1% to 50%. A user follow-up survey found that the percentage of children protected in net-owning households had risen from 5% to 88%, while the percentage of net owners using their nets every night had risen from 51% to 76%. The proportion of respondents who stated malaria transmission (as opposed to nuisance biting) as the principal threat from mosquitoes rose from 12% to 77%.

**Increased ITN use**

In two years, households owning at least one net in Blantyre District, where the ITN programme was launched in October 1998, rose from 13% to 44% in urban areas and from 5% to 15% in rural areas. By September 2001, a total of 340,000 ITN and 125,000 retreatment units had been sold nationwide.

**Improved private sector net supply**

Before the PSI/Malawi programme, only expensive white mosquito nets (averaging US$9 each) from Tanzania were available in Blantyre through a limited outlet as a national commercial distributor. PSI/Malawi introduced green rectangular nets to vulnerable populations through anti-malarial campaigns. Several bilateral and multilateral donors have committed to the scale-up, which is expected to begin in early 2002. The R BM partners expect that over 100,000 blue conical nets and 200,000 green rectangular nets will be delivered each year for the next five years, along with a total of one million retreatment kits.

**Scaling up**

Already, the more expensive Chite tezo Net is available in commercial outlets throughout Malawi, ensuring efficient delivery to those who can afford to pay a commercial price for a treated mosquito net. However, pregnant women and children now have access to affordable ITN in only three districts. The RBM partners in Malawi have developed a plan for scaling up the public sector delivery approach nationwide. With the coordination of MOHP’s Mal ari Control Programme, PSI/Malawi will partner with each DHMT in Malawi to replicate the public sector model of delivering heavily subsidised green rectangular nets to vulnerable populations through antimalarial clinics. Several bilateral and multilateral donors have committed to the scale-up, which is expected to begin in early 2002. The RBM partners expect that over 100,000 blue conical nets and 200,000 green rectangular nets will be delivered each year for the next five years, along with a total of one million retreatment kits.

**BITNET’s health and economic impact**

The health impact of ITN was established during four community-based trials organized by WHO. These estimates, together with local published figures on malaria endemicity in Malawi and on malaria-related costs, allow some programme cost-effectiveness indicators to be estimated.

PSI estimates that 365,000 treated nets and 140,000 retreatment kits will have been sold by October 2001 (three years after launch). These product sales will provide 944,438 person years of malaria protection (PYMP). This translates to 6.1 million malaria episodes averted and 1,935,193 child deaths averted. On top of this health impact on estimated US$7.8 million in malaria-related costs, including lost earnings, will be averted. The cost-effectiveness of the programme compares favourably with many other successful child health interventions:

![Teams of promoters perform lively skits in market areas to promote correct use of insecticide treated nets](image)

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**References**


**Historic ministerial declaration on public health and TRIPS**

The WTO is the international organization that sets the ground rules for international trade, and TRIPS is among its agreements with the greatest relevance for the health sector, covering trade and intellectual property rights issues in the pharmaceutical area (for more details see Articles No. 27 and 29). TRIPS’ provisions have proved controversial, and the Declaration has been warmly welcomed by those supporting the global campaign for a clearer definition of the safeguards that TRIPS offers to protect public health – particularly for the benefit of poorer nations.

In a statement issued at the beginning of the Conference, the Honourable Murasoli Murerwa, Minister of Industry and Foreign Affairs of the Republic of Zimbabwe, said “Availability and affordability of essential medicines is a universal human right. WTO should not deny that right. This Conference must send out a clear message to the world that nothing in the TRIPS Agreement should prevent governments from taking measures to protect public health. Accordingly, the TRIPS Agreement must be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and ensure access to medicines for all.”

**Declaration on the TRIPS Agreement and public health**

Adopted on 14 November 2001

1. We recognise the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, we reaffirm our commitment to the TRIPS Agreement, that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognise that these flexibilities include:
   (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles;
   (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted;
   (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency;
   (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the Most Favoured Nation and national treatment provisions of Articles 3 and 4.

6. We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceuticals, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

**A round up of reactions**

**WHO’s views**

In her statement on the Conference outcome, Dr Brundtland said, “Ministers of trade, economy, industry and foreign affairs gave a great deal of attention to the issue of access to essential medicines in Doha. This demonstrates the growing apprecia- tion of importance of international trade agreements for people’s lives and well-being. I am pleased to hear of the Ministers’ conclusion that the TRIPS Agreement ‘can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, promote access to medicines for all’.” WHO will continue to work with its Member States, with the WTO, and with other relevant organizations to help with implementation.”

**Industry comment**

Pharmaceutical Research and Manufacturers of America commented that the WTO Declaration explicitly states that “intellectual property protection is important for the development of new medicines” and member countries made an unequivocal point of “reiterating our commitment to the TRIPS Agreement.” Furthermore, the WTO members agreed to address the HIV/AIDS pandemic while “maintaining our
commitments in the TRIPS Agreement. The Declaration recognises that TRIPS and patents are part of the solution to better public health, not a barrier to access. Without altering the existing rights and obligations under TRIPS, the Declaration provides assurances that countries may take all measures consistent with the Agreement to protect the health of their citizens.”

**NGOs’ reactions**

**Arambe**

(Association pour la recherche de l’amélioration des conditions de vie au Bénin / Association for Research on the Improvement of Living Conditions in Benin)

“The Doha Declaration on TRIPS is a big step to access to drugs for poor countries. Now all African countries are waiting for its real application by our governments not only in terms of access to HIV drugs but in order to let their people have access to the other drugs chiefly those which will be discovered . . . The struggle for life and justice continues.”

**Consumer Project on Technology**

“The Doha Declaration on TRIPS is the strongest and most important international statement yet on the need to reframe national patent laws to protect public health interests. It is a road map for using the flexibility of the TRIPS to protect the public health, it sets a standard to measure any new bilateral or regional trade agreement. The Declaration is a political statement that did not modify in any way the TRIPS Agreement, and the decision to settle for a political statement was controversial in the negotiations. The developing countries had asked for legally binding interpretations of the Agreement, including a solution to the single most obvious problem with the TRIPS, the Article 31 limitations on exports of medicines manufactured under a compulsory licence. We were disappointed the European and American negotiators blocked agreement to use Article 30 of the TRIPS to export medicines to countries that do not have domestic capacity for manufacturing, but pleased this issue will be examined by the TRIPS Council in 2002. The negotiation over the export of medicines provisions in the TRIPS will be the next battleground in terms of trade policy.”

**Médecins Sans Frontières**

This Declaration is a major step forwards in the quest to ensure access to medicines for all. The text that has been agreed upon now was consistent six months, six weeks, even six days ago. It states clearly that there are serious conflicts between the obligations under the TRIPS Agreement and countries need to protect public health including providing access to medicines, it states that countries have the right to take measures to overcome patent barriers to public health and the statement outlines clearly how countries can do this. It is a missed opportunity that this ministerial conference did not offer a solution for countries without production capacity that want to make use of compulsory licensing. But we are confident that this issue will be resolved in the next year in the TRIPS Council. Countries can ensure access to medicines without fear of being dragged into a legal battle, importers need to use this power to bring down the cost of medicines and increase access to life-saving treatments.”

**Oxfam**

“Doha is a big step forward in the battle for affordable medicines. The huge profile given to the issue changes the political climate, building on the victories in the South Africa and Brazil cases. It will now be much harder . . . to build on TRIPS over their patent policies. We would have liked to see a stronger Declaration but there is a clear political statement that the Agreement must be implemented in a way that promotes access to medicines. The next step is to ensure that next year’s scheduled review of the TRIPS Agreement takes a hard look at the length and scope of pharmaceutical patents in developing countries, which remains the heart of the problem.”

**Third World Network**

“The Declaration (as it stands) is a good first step. The developed countries, in agreeing to the Declaration, have committed themselves to this process. We want to see a commitment on their part, and their pharmaceutical lobbies, to stop pressures on developing countries. The developing countries can get down to the work of implementing and enacting domestic measures with the guarantee that there will not be pressures or legal threats.”

Further information on the Articles of the TRIPS Agreement can be found in Globalization, TRIPS and Access to Pharmaceuticals, WHO Policy Perspectives on Medicines, WHO/EDM/2001.2. Also available on the Web at: www.who.int/medicals/organization/odf/trips_med.shtml

**WHO launches GMP training modules**

A n international committee of experts has concluded that for many years some tobacco companies deliberately subverted WHO’s efforts to control tobacco use. With the release of previously confidential documents, the report’s authors state that “What is now clear is the scale and intensity of their often deceptive strategies and tactics”. The documents show that companies sought to: divert attention from the public health issues; reduce budgets for scientific and policy activities carried out by WHO; discredit WHO as an institution and to pit other UN agencies against it; persuade developing countries that WHO had a “First World” agenda that was contrary to that of the developing world; and distort the results of important scientific studies on tobacco.

In their campaign against WHO, the documents show that tobacco companies often hid behind a variety of ostensibly independent, quasi-academic, public policy and business organizations whose tobacco industry funding was not disclosed. Tobacco company strategies to undermine WHO relied heavily on international and scientific experts with hidden ties to the industry, it was revealed.

**Protecting WHO’s integrity**

The Committee of Experts believes that there are important lessons to be learned from this experience. They conclude that WHO should strengthen its policies on conflict of interest, with all staff, consultants, temporary advisers and members of expert committees having to declare personal financial interests. There should be clear and well enforced penalties for anyone breaking the rules. No one with financial ties to the tobacco industry should be able to work for WHO, and the Organization should educate scientists and collaborators about the need for vigilance when dealing with the tobacco industry, the experts concluded.

**Experts say industry subverted WHO tobacco strategy**

A s part of its cost containment measures, the Belgian Government has decided to limit pharmaceutical representatives’ visits to doctors to two per year. The aim is to reduce representatives’ pressure on doctors to prescribe, and so keep pharmaceutical costs in check. The Ministry of Health has also announced its intention to limit the number of drug samples that can be handed out. In further moves, from 1 April 2000 all products which have been on the market for 15 years will have a 12% price cut, and to boost the use of generics the Government has implemented a 16% cut in the patient co-payment for generic prescriptions. A number of new companies are entering the Belgian market launching generic products at discounts of 40–50%, compared with around 10–15% previously.

Source: Scrip No. 2522, 15 March 2000

**Belgian Government set to cut representatives’ visits**

Looking out to what kind of future? WHO is overcoming many obstacles in its determination to stop people, like this woman in the Dominican Republic, damaging their health by smoking.

Reference

Getting to grips with gender inequality

Gender discrimination remains pervasive in many dimensions of life – worldwide. This is so despite considerable advances in gender equality in recent decades. The nature and extent of discrimination vary considerably across countries and regions. But the patterns are striking. In no region of the developing world are women equal to men in legal, social and economic rights. Gender gaps are widespread in access to and control of resources, in economic opportunities, in power and political voice. Women and girls bear the largest and most direct costs of being regarded as second-class citizens – but the costs are more broadly across society, ultimately harming everyone.

Engendering Development, a new World Bank Policy Research Report, asserts that promoting gender equality is therefore a crucial part of a development strategy that seeks to enable women and men alike to escape poverty and improve their standard of living. The Report focuses on the broad economic and social implications of gender issues in developing and transitional countries. It examines the conceptual and empirical links between gender, public policy and development outcomes, and demonstrates the value of applying a gender perspective to policy design.

High price of discrimination

The evidence presented shows that societies that discriminate by gender pay a high price in terms of their ability to develop, and to reduce poverty. To promote gender equality, the report proposes a three-part strategy emphasizing institutional reforms, based on a foundation of equal rights for women and men; policies for sustained economic development; and active measures to redress persistent gender disparities. Engendering Development, which presents new data and analyses and reviews an extensive development literature, is intended for policy-makers, development specialists, and anyone involved in promoting, designing and implementing effective and sustainable development strategies.

Engendering Development is available from the World Bank, P.O. Box 960, Herndon, VA 20172-0960, USA. Fax: + 1 703 661 150, on the Web: http://publications.worldbank.org/acomenca/catalog/ or from the network of World Bank distribution partners worldwide. Price: US$35 plus postage and handling.

Developments in combination therapy for malaria

Malaria parasites are becoming increasingly resistant to first-line medications, and combination therapy is being advocated to delay the development of resistance and play a significant role in “rolling back malaria.” A blister package containing one dose of sulfadoxine/pyrimethamine and three doses of artesunate is being developed by the WHO Special Programme for Research and Training in Tropical Diseases (TDR), Médecins Sans Frontières (MSF) and the International Dispensary Association (IDA) to meet the need for high quality, affordable, effective and safe malaria treatments. The product will be produced entirely under Good Manufacturing Practice guidelines. The final price of the product will be significantly lower than generally anticipated for drug combinations.

The approach followed is to consider this medication as a “public good”, and to address the proprietary rights issue upfront. In this respect, investments are being made for the process to produce both raw material and formulated product belonging to the public sector. As a result, the cost of development will not be included in the final price of the drug, and the process can be sub-licensed to third parties as needed. The choice of development partner was made through a tendered process and IDA, a non-profit making pharmaceutical organization, was selected. TDR will oversee development of the drug.

MSF is funding most of the development work with money received from the Nobel peace prize awarded in 1999, and TDR is also contributing funds. To ensure that drug dosing is optimal, easy to administer in the field, and based on sound scientific data, a study was conducted with the US Centers for Disease Control. In this study, mostly African anthropometric data rather than US population-based data were used (the current CDC/WHO National Center for Health Statistics standard is based on a healthy US population). Weight-for-age data from 137,000 persons from disease-endemic areas, primarily in Africa, were used to ensure that as many people as possible receive an optimal dose of each drug (not an under- or over-dosage).

Following completion of large randomized controlled trials of artesunate-containing combinations, work is in progress on the feasibility of fixed-dose combinations of artesunate with other companion drugs, such as amodiaquine and mefloquine.


New resource centre manual from Healthlink Worldwide

Health workers in Nicaragua are celebrating an updated and expanded version of their popular reference book, Buscando Remedio. This edition, the fourth, had an official launch on 12 June 2001, and should again prove to be an invaluable tool for health centre and pharmacy staffs, those supervising them, and for those in training.

Well-illustrated and user friendly, the publication is in three parts. The first contains basic information about essential drugs, their management and rational use, while the second section gives treatment guidelines and prevention advice for the most frequent conditions presenting at local health centres. The book concludes with details of 50 essential drugs, covering indications, dosage and storage requirements. New departures for this edition are the inclusion of information on domestic violence, contraception, breast-feeding, pesticide poisoning and snakebites. Care has been taken to use non-sexist language. A bigger and better Buscando Remedio

Health Action International and Réseau Médicaments et Développement have published a French-language version of Andrew Cheethy’s book Problem Drugs. The French version, updated with information on medicines use in francophone Africa, is intended as an education and advocacy tool for policy-makers, health workers, pharmacists, medical students, consumers and media.

The majority of original chapters have new annexes providing additional information and francophone perspectives to the challenges of problem drugs. English brand names of drugs have been changed to the names commonly used in France and French-speaking Africa.

In his analysis the author covers a wide range of the most overused and misused medicines, including anti-infectives, antibiotics, analgesics, growth stimulants, cough and cold remedies, vitamin supplements, drugs in pregnancy and contraceptives. The book contains special sections on children, women and the elderly. It discusses unethical marketing of drugs and how problems with medicines often begin with the prescriber and consumers. The former may prescribe more drugs than are needed or prescribe drugs for dangerous combinations, and consumers may mistakenly insist on certain drugs or drug combinations in order to feel as though they have been treated.

Each chapter includes clear recommendations for action, with positive steps to reduce the misuse and overuse of drugs.


Problem Drugs now available in French
Back ing for medicines strategy at historic Assembly

After eight days of intense deliberations the 54th World Health Assembly closed its business in Geneva on 22 May 2001. The biggest event in the annual calendar for WHO, the Assembly charts the course for the Organization and its 191 Members States in dealing with major public health threats. For the first time in WHO’s history, the United Nations Secretary-General addressed the Assembly. In his AIDS-focused speech, Mr Kofi Annan outlined the structure of a multi-billion dollar Global AIDS and Health Fund to fight HIV/AIDS and “other infectious diseases that blight the prospects for many developing countries – starting with TB and malaria”.

In a resolution on the global response to HIV/AIDS, Member States called on WHO’s Director-General to “take an active part, together with other international actors, in the development and establishment of a global HIV/AIDS and health fund and to maintain close collaboration with the international community and the private sector with the aim of providing the availability of medicines for HIV/AIDS, including antiretroviral therapy.” The resolution urges Member States to scale up their responses to HIV/AIDS, with particular emphasis on building up partnerships across sectors. It also addresses the issue of access to medicines, calling on the international community to “cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and development of domestic industries consistent with international law.”

Another very important resolution linked to access to drugs was that on the WHO medicines strategy. High-lighting the number of people still without access to essential drugs, the resolution urges Member States to promote equitable access to medicines. It requests the Director-General to stimulate the development of drugs for diseases which mainly occur in developing countries, and to increase efforts to report on health implications of international trade agreements. Monitoring and reporting on global drug prices were also requested as part of the efforts to increase equity in access to essential drugs (see box).

As part of Resolution WHA54.11 on WHO’s Medicines Strategy, the 54th World Health Assembly requested the Director-General:

1) jointly with Member States, nongovernmental organizations and other partners involved in public health, to keep under review the effectiveness of the current strategy for essential drugs, and to stimulate the development of drugs for diseases whose burden lies predominantly in poor countries;

2) to explore the feasibility and effectiveness of implementing, in collaboration with nongovernmental organizations and other concerned partners, systems for voluntary monitoring of drug prices and reporting of global drug prices with a view to improving equity in access to essential drugs in health systems, and to provide support to Member States in that regard;

3) to provide support for implementation of drug monitoring systems in order to better to identify development of resistance, adverse reactions and misuse of drugs within health systems, thus promoting rational use of drugs;

4) to continue and to enhance efforts to study and report on existing and future health implications of international trade agreements in close cooperation with appropriate intergovernmental organizations;

5) to provide enhanced support to Member States that need and request it for achieving the priorities set out in the WHO medicines strategy;

6) to provide support to Member States to set up efficient national regulatory mechanisms for quality assurance that will help ensure compliance with good manufacturing practices, bioavailability and bioequivalence;

7) to continue WHO’s work in the field of traditional medicines;

8) to report to the Fifty-fifth World Health Assembly on the progress of initiatives taken, globally or regionally, to expand access to essential drugs.”

Management of drug supply

The International Dispensary Association (IDA), of the Netherlands, and Management Sciences for Health, of the USA, are again joining forces to run a two-week course on Managing Drug Supply for Primary Health Care. The aim is to expose participants to modern management principles of drug supply systems, and train them how to apply these in their own situations.

The approach will be highly participatory to facilitate an exchange of views and experiences between senior level staff. Major topics will include: national drug policy; selection and quantification of drugs; procurement methods and strategies; quality assurance; kilogram distribution; financing drug supply; store management; inventory control; distribution strategies; rational drug use; drug supply management information systems; and indicator-based assessments.

The course will take place in September 2002 in the Netherlands. It is intended for physicians, pharmacists, senior health system managers, and technical assistance professionals from ministries of health, NGOs and donor agencies.

For further information contact: Suzanne Hill, WHO Collaborating Centre for Training in Pharmacotherapy and Rational Drug Use, University of Newcastle, Australia. Email: hsiu89@mail.newcastle.edu.au.

Pharmacoeconomics course

The 3rd international short course on the use of pharmacoeconomics in drug selection, will be held in India from 6–16 February 2002. It has been developed by an international consortium, including departments of clinical pharmacology and public health at the Universities of Newcastle and Sydney, Australia and Birmingham, UK.

The course gives participants an understanding of the principles and techniques of pharmacoeconomics, and how these tools can be used in making decisions about selecting and purchasing pharmaceuticals. Applicants should be working in some part of the academic or public health sector and have some responsibility for drug selection, essential drugs lists or hospital formularies. A basic understanding of the principles of assessing and evaluating data for drug selection are also required.

For further information contact: Suzanne Hill, WHO Collaborating Centre for Training in Pharmacotherapy and Rational Drug Use, University of Newcastle, Australia. Email: hsiu89@mail.newcastle.edu.au.

Launch of GDF web sites

The Stop TB Partnership Secretariat is pleased to announce the launch of two new websites: the Global TB Drug Facility (GDF) site http://www.stopbph.org/GDF/, and the GDF/UN-WEBUY site www.stopbph.unwebbuy.org, hosted by the Inter-Agency Procurement Services Office (IAPSO) www.iapso.org. Visit the Stop TB website for the latest information online of all Stop TB Partnership activities at www.stopbph.org

More to see on EDM’s web site

The Department of Essential Drugs and Medicines Policy’s web site continues to expand. As well as introducing the essential drugs concept, national drug policies and the work of WHO and EDM, more of the Department’s documents can be viewed and downloaded in all language versions. Check us out at: www.who.int/medicines/
Useful web sites and electronic discussion groups on pharmaceutical issues

E-DISCussion Groups

AFRO-NETS African Networks for Health Research and Development
For exchange of information between networks active in health research for development in eastern and southern Africa. To subscribe contact: majordomo@usa.healthnet.org. Leave the subject line blank and write “subscribe afro-nets” in the text space.

E-Drug
An easy way to obtain and discuss current information on essential drugs, national drug policies and standard treatment guidelines. It is also a good source of information on upcoming conferences, guidelines, new publications, recent articles, and broader political (e.g. trade, patents, pricing) aspects of drug access. To view: http://www.who.int/programs/edrug.html. To subscribe contact: Leave the subject line blank and write “subscribe e-drug” in the text space.

For the French language E-Drug, write “subscribe e-med” and for the Spanish “subscribe e-farmacos”.

EVMED
Provides a new electronic forum in Spanish for those wanting to discuss new ideas, research, education or practice of evidence-based health care. To subscribe contact: RafaBravo@bitmailer.com

HIF-net at WHO
An e-mail discussion list for people who want to improve access to reliable information for health workers in developing and transition countries. To subscribe contact: INASP_Health@compuserve.com

INDICES: International Network for Drug Information Centres
An electronic forum for discussion of issues related to drug information. To subscribe contact: majordomo@usa.healthnet.org. In text of message put: Subscribe indices

IP-Health
Very comprehensive and super-rapid discussions of intellectual property and health care issues, including pharmaceutical policies, particularly in relation to access to medicines, pricing, global campaigns. A digest option is available. To subscribe contact: ip-health@lists.essential.org and to set the digest option go to: http://lists.essential.org/mailman/listinfo/ip-health

No Free Lunch
Serves as a forum for the exchange of ideas and information on evidence based treatment and industry promotional activities. To subscribe contact: nofrelunchserve@parillist.net

On the web at: http://www.pairlist.net/mailman/listinfo/nofrelunch

SAPCO (SIDA en Afrique du Centre et de l’Ouest)
Network set up to encourage discussion (in French) and the electronic exchange of information on issues related to HIV or AIDS in francophone Africa. To subscribe contact: safco@hivnet.ch

Useful web sites and electronic discussion groups on pharmaceutical issues

Web sites

NGOs
Alliance for the Prudent Use of Antibiotics, APUA:
http://www.healthsci.tufts.edu/apua/apua.html
Cochrane Collaboration:
http://www.cochrane.org
Consumers International:
http://www.consumersinternational.org
Health Action International:
http://www.haiweb.org
Healthlink Worldwide:
ttp://www.healthlink.org.uk
Healthy Skepticism (formerly the Medical Lobby for Appropriate Marketing):
http://www.healthy skepticism.org/
International Clinical Epidemiology Network, INCLEN:
http://www.inclen.org
International Network for Rational Use of Drugs, INRUD (includes the journal INRUD News):
http://www.msh.org/inrud
Management Sciences for Health:
http://www.msh.org
The International Drug Price Indicator Guide is available on Management Sciences for Health Manager’s Electronic Resource Centre web site at: http://erc.msh.org
 Médecins Sans Frontieres:
http://www.msf.org
MSF’s access to medicines campaign:
http://www.accessmed-msf.org
Public Citizen Health Research Group:
http://www.citizen.org/hrg
Wemos Foundation, Dutch NGO concerned with international health issues, including a campaign to improve drug donations:
http://www.wemos.nl

Media (professional and mass)
A sample of what is available
Australian Prescriber:
http://www.australianprescriber.com
British Medical Journal:
http://www.bmj.com/bmj
International Society of Drug Bulletins:
http://prn.usm.my/isdb.html
Lancet:
http://www.thelancet.com
Lancet’s experimental electronic research archive in international health:
http://www.thelancet.com/newlancet/eprint
Pharma Kritik, Swiss drug bulletin:
http://www.informed.org

Tools
Biomain is a new search tool which period-odically does a user-customized Medline search and sends articles to the user’s e-mail address:
http://biomain.sourceforge.net/biomain/

SATELLITE free information services to health professionals. More details at:
http://www.healthnet.org

National, regional and governmental
Australia. A database on quality use of medicines activities in Australia:
http://www.qum.health.gov.au
Dutch Medicines Evaluation Agency (includes all its evaluation reports on drugs newly registered in the Netherlands):
http://www.cbg.msh.nl
European Evaluation Agency:
http://www.eudra.org/emea.html
Food and Drug Administration, USA:
http://www.fda.gov
LANIC Latin American Network Information Center (includes Drug Bulletin):
http://lanic.utexas.edu/farmacos
Scottish Intercollegiate Guidelines Network, SIGN (supports development of evidence-based clinical guidelines for the UK National Health Service):
http://www.sign.ac.uk/index.html
South Africa. Key documents on South Africa’s national drug policy and essential drugs programme:
http://www.healthlink.org.za under “Info. Resources”
Also on line press cuttings on health issues at:
United States Pharmacopeia:
http://usp.org
WHO
ICUIM. Presentations from the International Conference on Improving Rational Use of Medicines, in Chiang Mai, Thailand in April 1997. Reviews interventions to promote rational use of drugs, developing policy guidelines and identifies areas for future research:
http://www.who.int/dap-icium
International Digest of Health Legislation database:
http://www.who.int/dhd
WHO. Information on WHO programmes, diseases, publications, press releases and much more. Links to WHO Regional Offices:
http://www.who.int
WHO Department of Essential Drugs and Medicines Policy:
http://www.who.int/medicines/
WHO’s Antimicrobial Resistance Information Bank (AR InfoBank) at:
http://oms2.35e.jussieu.fr/arinfobank/
WHO Regional Office for the Americas:
http://www.paho.org/
WHO Regional Office for Europe Pharmaceticals Programme:
http://www.who.dk/ch/pha
The Programme’s Special Project for the NIS:
http://www.dk/ch/pha/NIS
WHO Regional Office for South-East Asia:
http://www.who.int/searo/health/for/med.htm
WHO Regional Office for the Western Pacific:
http://www.who.org.ph/technical/programme/std.htm
WHO priced publications on pharmaceuticals:
http://www.who.int/dsa/car98/pha8.htm

Web sites on trade-related issues and access to medicines

The Consumer Project on Technology web site is an extensive source of information (articles and data) on regional trade agreement and TRIPS, patents and drugs, compulsory licensing, parallel imports, health registration data and generic competition:
http://www.cptech.org/ip/health
The South Centre is an intergovernmental body which works for the benefit of developing countries of the South. Its web site provides interesting bibliographical references and papers, some covering pharmaceuticals and trade issues:
http://www.southcentre.org/
The Third World Network is an independent non-profit international network of organizations and individuals involved in development issues. Its web site offers articles and position papers on a variety of subjects related to developing countries, including trade, health, biotechnology and biosafety:
http://www.twinside.org.uk
The World Intellectual Property Organization provides information related to intellectual property and patents in general, and to the international intellectual property treaties it manages:
The World Trade Organization has a very comprehensive web site, including a page on the TRIPS Agreement:
http://www.wto.org

Drug access campaign web sites

Various activist organizations are involved in treatment access campaigns, including some internationally-coordinated work, for example:
Global Treatment Access Campaign:
www.globaltreatmentaccess.org
South Africa’s Treatment Action Campaign:
http://www.tac.co.za
Save the Children Fund:
http://www.savethechildren.org.uk
Oxfam:
http://www.oxfam.org.uk
VSO:
http://www.vso.org.uk
ACT UP: chapters in New York, Paris and Philadelphia:
http://www.actup.org
See also MSF access campaign, address listed under NGOs.
Global harmonization and the ICH

Global harmonization of various elements of drug regulatory activities has taken place in the last decade and has involved intergovernmental initiatives at both the regional and international levels. The driving force behind the harmonization effort is the need to improve availability of pharmaceutical products and to respond to the forces of international trade with adequate standardized technical regulations on safety, quality, and efficacy. By reducing unnecessary duplication of regulatory requirements, it is proposed that therapeutic advances will be made more rapidly and at a lower developmental cost.

A prerequisite to any harmonized approach to international drug regulation is the existence in each of the participating countries of a functional drug regulatory system. This is understood as full drug registration processes, pharmaceutical inspection services, and certified compliance with good manufacturing practice.

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 by the drug regulatory authorities and research-based pharmaceutical industries of the European Union, Japan, and the USA to focus on new drug development and subsequent regulation. ICH is a tripartite venture of 17 high-income countries. To date, it has produced over 45 guidelines containing technical requirements related to specific components of the drug registration process drawn up by groups of specialists from drug regulatory authorities and the pharmaceutical industry of the ICH countries. The scientific level of each guideline is high and reflects state-of-the-art technology. The cost related to full implementation of the guidelines may in some cases be considerable but, it is argued, this is offset by more rapid registration of new drugs in the ICH countries.

The ICH initiative was established to harmonize the documentation needed for drug development and subsequent regulatory evaluation of products containing new chemical entities or products obtained by biotechnology. WHO is accorded observer status within the ICH Steering Committee but is not directly involved in the process of drafting or developing ICH guidelines and has no control over their approval.

History of ICH

The International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) was established in 1990 as a tripartite regulatory/research-based industry venture. The major aim of the ICH is to provide a forum for constructive discussion on the real and perceived differences in technical requirements for the registration of new chemical entities. Other objectives are to achieve greater harmonization in the interpretation and application of technical guidelines for the registration of new chemical entities or products obtained by biotechnology by its members, to improve the efficiency of global drug development, and to reduce redundant studies.

The co-sponsors of ICH comprise the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA); the Japanese Ministry of Health and Welfare (JMHW) and the Japanese Pharmaceutical Manufacturers Association (JPMA); and the US Food and Drug Administration (FDA) and the Pharmaceutical Research and Manufacturers of America (PhRMA). These are co-sponsors represent the voting members of the ICH Steering Committee.

The ICH thus represents 17 countries comprising 15% of the world’s population and accounting for 90% of the US$ 200 billion annual sales made by the multinational research-based pharmaceutical industry. ICH regulatory authorities are among the first to evaluate new chemical entities and new products obtained from biotechnology. The Secretariat is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), WHO, Health Canada and the European Free Trade Association (EFTA) hold observer status in the ICH Steering Committee.

ICH Guideline on Implantable Medical Devices (Q3A)

The Network, Pakistan

Q3A has been put forward by the ICs as a means of harmonizing regulatory approaches to implantable medical devices. The approach to guidance development is discussed in this article.

ICH Guidelines

ICH guidelines are developed by the ICH members, some countries and nongovernmental organizations excluded from the process have become vocal about perceived shortcomings of the ICH. The composition of the ICH has been a cause for concern from a range of interested parties, including patients and consumer groups. For example, the ICH has produced Guidelines on Good Clinical Practice which include reference to ethics committees and to informed consent. Some consumer groups have argued that while these are central to consumer protection, there has been little consultation with patient or consumer groups in the development of these guidelines. It has also been pointed out that while many clinical trials are conducted in developing countries, there has been no consultation between ICH and key officials from these countries.

While it is fair to assume that the partners within ICH are satisfied with the infrastructure and process, commentators outside have questioned the appropriateness of having the IFPMA coordinate the process and provide the Secretariat. Some critics have stated that this structure has led to an industry driven agenda, with the regulators tending to accept this as the status quo. Similar comments have been made about a perceived lack of sufficient consultation with academics, scientists and the medical profession. While these concerns may be theoretical, specific examples given below tend to support this view.

Over the years, ICH has grown to rely more on advanced pharmaceutical technology in its standard setting on the assumption that this technology will lead to increased safety of new drugs. An example is the ICH Guidelines for Impurities in New Drug Substances (Q3A). The additional safety benefits from these rigorous standards have not yet been demonstrated but the costs incurred by manufacturers in meeting these requirements are significant. Setting such norms allows only the well-resourced pharmaceutical companies to achieve the necessary standards. This will become a concern if the guidelines are intended for global application. Smaller pharmaceutical companies, generic companies and many larger companies responsible for essential drugs in developing countries may be effectively squeezed out of the drug manufacturing picture if ICH guidelines start to be interpreted as the only global standard. For example, the application of the ICH Guideline on Impurities – Residual Solvents (Q3C) was developed for new products but is being extended to cover all products registered in the European Union. Another example is the ICH Guideline on Stability Testing (Q1) which covers only stability requirements in Climatic Zones I and II (temperate climates), and does not yet cover Climatic Zones III and IV (stability requirements for hot/dry and hot/humid climates).

The public health implications of the application of these guidelines in developing countries may be far-reaching. In many countries, essential drugs required for the prevention and treatment of locally endemic conditions are not...
supplied by the major multinationals, but by local industry or by generic manufacturers. If they are unable to meet what may be unsubstantiated quality standards, the adverse impact of the withdrawal of these drugs on the health of the population would be far more dramatic than that of any hypothetical risk by failing to achieve the ICH standards.

Another element of some ICH guidelines is that they describe high safety requirements as appropriate for drugs which are marketed in the high-income countries but many of these products are intended to improve the quality of life of the population. Since the ICH guidelines do not address specific requirements for any category of products they do not contribute to neglected diseases, including debilitating tropical diseases.

It might be argued that the above scenarios are irrelevant, since the initial aim of the ICH was to set global standards for drug development and evaluation. Further, ICH has no legal mandate from the international community on which to base such an assumption. However, recent developments concerning the ICH Global Cooperation Group would suggest that ICH activities are set to gain wider international acceptance. During the initial phase of ICH activities, it was made clear that the intentions of the ICH had relevance only to the co-sponsors, to the extent that approaches from other individual countries seeking membership were refused by the Steering Committee as unnecessary and a potential cause of confusion. It should, however, be stressed that ICH advocacy seminars have already been held in different regions of the world and participating countries look on the ICH guidelines as the international “norm”.

This interpretation of the ICH process is a particular challenge for WHO as reflected in the recommendation of the Ninth International Conference of Drug Regulatory Authorities (ICDRA) held inFreiburg in 1999 that WHO should take into account the full implications for non-ICH countries when participating as an observer in the ICH process.

Benefits of the ICH process
The establishment of ICH 10 years ago reflected a need felt by the research-based industry and certain governments to streamline the approval process for the registration of new drugs. The tendency in different regions of the world, and participating countries look on the ICH guidelines as the international “norm”.

This interpretation of the ICH process is a particular challenge for WHO as reflected in the recommendation of the Ninth International Conference of Drug Regulatory Authorities (ICDRA) held in Freiburg in 1999 that WHO should take into account the full implications for non-ICH countries when participating as an observer in the ICH process.

Challenges for WHO
Recommendations about the future role of WHO with respect to ICH must take into account both the current high status achieved by ICH internationally, the applicability of ICH products in non-ICH countries, and the possibility of involving the ICH working groups responsible for developing the different guidelines have contributed to the high calibre of technical and scientific content in the recommendations. They argue that while recognizing serious omissions in some of the guidelines, this should not detract from the quality of the content of those already approved.

While the structure of the ICH was clearly exclusive from the outset, this position continues to be defended by its supporters as an appropriate partnership to achieve ICH aims and objectives. The omission of other participants, such as the generics industry, was not seen as a barrier to ICH work, as the original aim was not to harmonize the approval of generic drugs. Similarly, the ICH partners would argue that before countries implement the guidelines, regulatory authorities are able to involve consumer groups, who can give comments. Additionally, in all the countries represented within ICH, there are appropriate mechanisms which allow public comment on the guidelines before they are finally adopted.

One of the most important criticisms of the ICH process is that its guidelines have been increasingly perceived as the “gold standard” for international harmonization. The ICH has never claimed to have formal international authority to produce global standards and it further indicates that it is in no position to compel national drug regulatory authorities to adopt these standards. Nevertheless, many countries consider adoption of the guidelines as a necessary move. ICH proponents argue further that the intention of involving WHO as an observer in ICH was to ensure that international concerns about the protection of public health interests are met.

Recommendations to WHO
The ICH has made clear that it is committed to ensuring that the status quo to achieve full effectiveness of the ICH process. However, other groups have influenced the ICH to change some of its procedures. Although it is considered unlikely that the ICH would accept a significant change in either the membership of its Steering Committee or current guideline modification or development, WHO should be encouraged to find ways to work more closely with ICH to engage and seek input from other countries.

The ICH guidelines have been proposed for implementation by WHO. They are dependent on resources being made available for implementation.

WHO should continue to play an observer role within the ICH Steering Committee.

The Review Team proposes that observer status takes on a more critical role within the ICH. This could take the form of proposals of topics for guideline development and opinions on the potential public health implications of some guidelines.

WHO accepts observer status within the ICH Global Cooperation Group.

Further, measures should be taken for this not to be considered as an endorsement of ICH guidelines or procedures by WHO Member States.

WHO establishes a mechanism to review and accept ICH guidelines as WHO international guidelines for drug regulatory activities, as relevant.

Within this mechanism, a series of consultations and meetings should be convened to review the existing ICH guidelines. These meetings should include national representatives, selected experts and academics other than those involved in ICH, as well as senior policy staff and scientific advisers from ICH and non-ICH countries encompassing all levels of regulatory activity.

As part of the process, endorsement could be achieved through WHO governing bodies or similar mechanisms.

WHO should include the recommendations of the review group as topics for discussion at the Tenth ICDRA to be held in Hong Kong in November 2001.

The Review Team also considered that a more active involvement of WHO as a full partner to the ICH process would be beneficial in allowing development of guidelines which would take public health issues fully into account. However, this would represent a significant structural change for the ICH.
Making life-saving medicines more affordable for poor countries is vital, and finding ways to achieve this is now firmly at the top of the international agenda. A high-level WHO/WTO workshop held in Høsbjør, Norway, in April 2001 has moved this agenda forward.

More than 80 experts from 21 industrialised and developing countries and a wide range of professional backgrounds met for a 3-day exchange of views on how to respond to the current crisis. Below we reproduce the executive summary from the Workshop Report.

"The workshop brought experts together to explore the often complex questions involved in ensuring access to existing essential drugs and in developing affordable in poor countries and adequate financing for this purpose, while providing adequate incentives for research and development (R&D) into new drugs. In addition to individual academic, legal and consultancy experts, the perspectives of governments, manufacturers from both the research-based and generic industry, international governmental organizations concerned with health, and intergovernmental organizations, were heard in presentations and discussions. The principal focus at the workshop was on two main topics: differential pricing and financing of essential drugs.

While it was not the purpose of the workshop to seek agreed conclusions, there seemed to be a large measure of common thinking among participants on two central points:

➤ First, that differential pricing could, and should, play an important role in ensuring access to existing essential drugs at affordable prices, especially in poor countries, while allowing the patent system to continue to play its role of providing incentives for research and development into new drugs.

➤ Second, that while affordable prices are important, actually getting drugs, whether patented or generic, to the people who need them in poor countries will require a major financing effort, both to buy the drugs and to reinforce health care supply systems, and that for these countries most of the additional financing will have to come from the international community.

Access to essential drugs

There was recognition of the wide range of obstacles to adequate access to essential drugs in poor countries, including issues of financing, pricing, supply, selection and distribution. The price of drugs alone does not determine who gets access to health care. Nevertheless, it was noted that the health expenditure of the world's poor is largely devoted to buying drugs, often through private outlets. So the price of essential drugs matters to poor people and to poor countries. However, it was also noted that low-priced drugs, or even those made available free of charge, are often not being sufficiently used. Locally available health services, adequately staffed, equipped, managed and financed, and oriented to local needs and priorities, as well as efficient distribution systems and tariff and tax-free treatment for drugs are some of the other factors that play an important role in enabling access on the basis of medical need.

Participants assigned different importance to the individual factors influencing access to care, but all recognised the complexity of the access puzzle, and its variability from one setting to another.

Financing of health care and essential drugs

The point was made that, even with low prices, substantially expanding access to essential medicines will require additional domestic and international financing for the purchase of essential drugs as well as for building effective health and supply systems. This is important not only for newer drugs, such as the anti-retrovirals, but also for essential generic drugs such as many of those for treating tuberculosis, malaria, diarrhoeal disease and respiratory infections. Mobilisation of domestic resources in middle-income developing countries is an important way of improving access, but in poor countries financing needs will have to be primarily met by the international community. It was not the purpose of the workshop to estimate what these needs were or to explore the most suitable modalities for meeting them, but there was a common view that there was a need for a massive upward shift in the level of international health aid.

Differential pricing is necessary and feasible

By differential pricing is meant the setting of prices charged by the seller to the purchasing power of govern-ments and households in different countries. The workshop heard that more widespread and sustainable differential pricing can be feasible provided the right legal, technical and political environment can be secured.

Economic feasibility – It was explained that differential pricing can be feasible where there are substantial fixed costs, and variable or marginal costs of production are relatively low. While there is perhaps greater scope where patented products are concerned, because of the high level of sunk R&D costs, differential pricing can also be feasible for non-patented products. Some leading economists explained how differential pricing can be in the interests of both consumers in poor countries and manufacturers, while not adversely affecting consumers in richer countries, provided markets can be effectively segmented.

This entails prevention of diversion of low-priced products into high-income markets (a technical issue) and a readiness on the part of consumers in such markets to accept sustained price differences (a political issue). They also showed how differential pricing can have a beneficial effect on the twin objectives of affordability of existing essential drugs and providing incentives for research and development into new drugs, by support for R&D costs being shared according to ability to pay.

Differential pricing is already practice, but in a limited manner – Several manufacturers already, independently of each other, offer heavily discounted prices and donations to certain poor countries for selected drugs. Experience with vaccines, contraceptives and drugs for tuberculosis presented at the workshop shows that low prices can be made available for poor countries, both for patented and non-patented products. Reductions of 90 per cent or more below developed country prices have been achieved through bulk purchasing, competitive tenders and skilful negotiation. The point was made that generic competition has also been shown to bring prices down.

Ways of giving effect to differential pricing – A variety of options was put forward and discussed to carry forward the concept of differential pricing. These included creating the right conditions and leaving it to the market, the bilateral negotiation of price discounts between companies and governments, the use of regional or global bulk purchasing, the impact of moral suasion, the role of voluntary and, where necessary, compulsory licensing, and the establishment of a flexible, global differential pricing system. The role of donations was also considered. There was discussion of the respective pros and cons of these approaches. Some argued that a global mechanism could be difficult to manage and have undesirable, unintended consequences while some others took the view that it would not be sufficient to rely on individual initiatives focusing on a limited number of drugs and countries. Some felt there is need for greater international cooperation to support differential pricing.

While differing views were expressed, there seemed to be a wide view that more than one of the modalities mentioned above may need to be used, depending on the circumstances. Among the issues discussed were the role of competition in reducing prices, for example through voluntary licensing, and the relation of this to intellectual property regimes, the scope for incentives by developed countries for differential pricing and donations, and the constraints that competition law in many countries places on arrangements that involve concerted action among companies on how they compete with each other.

Achieving favourable prices – While there was wide support for the notion that essential drugs should be made available to poor countries at the most favourable price, which was variously referred to as a marginal cost or not-for-profit price, differing views were expressed as to how such a price should be determined. This question was considered important not only by developing country buyers but also by developed country donors who were concerned that, if large amounts of development funding were to be allocated for financing the purchase of essential drugs, the products would be bought at the lowest possible price. Approaches suggested included negotiation, perhaps aided by local cost of production calculations and large volume purchases; increased competition through voluntary licensing or eventually compulsory licensing or its possibility; and the development of target prices related to...
Experts debate... cont’d from pg. 11

therapeutic value through economic analysis. Maintaining separate markets and preventing diversion – Participants ac-
ccepting that markets for differentially priced drugs need to be tightly segmented to prevent leakage of differentially priced drugs to higher-income markets. A range of mechanisms that can be used for this purpose was discussed, including market-
ing strategies by manufacturers relating to the use of different trademarks and the presentation of products, stricter supply chain management by purchasing entities, the role of the drug regulatory authorities in high-income countries and export controls in poor countries and in-
tellectual property-based rights to prevent parallel imports into the high-income countries. While these issues will require further study, there was a view that the available techniques, used in combina-
tion with each other with responsibility shared between the low-income and high-income ends, could ensure the de-
gree of market separation necessary for differential pricing to be feasible.

Political feasibility – There appeared to be a common view that preferential prices in developing countries should not be a factor in pricing in developed coun-
tries. Some proposals hinged critically on the political acceptability of lower prices in poor countries. It was suggested that, in a climate of increasing international scrutiny of prices and growing direct and indirect reference pricing schemes, the industrialised countries may need to make undertakings not to use differential prices meant only for poor countries as benchmarks for their own price regulation systems or policies. A more difficult point was how to forestall differential pricing being used in the po-
litical process in these countries. Some felt that this required political leadership, advocacy efforts and public education. Part of this will be the need to reassure public opinion that lower prices in poor countries do not mean higher prices in rich ones or a greater burden on national health budgets. Also, consideration must be given to whether differentially priced products may be seen as a form of unfair competition by local industries in devel-
opling countries and possibly subject to recourse to anti-dumping relief.

Wider use of middle-income countries and well-to-do populations in poor coun-
tries? – Discussion recognised, but did not resolve, the questions of middle-income countries paying prices proportionate to their levels of possible pro-
hibition of parallel trade between low-
and middle-income countries. The further question of whether the eligibility of the well-to-do segments in poor countries for differential prices would significantly affect its likelihood and, if so, whether it would be feasible to separate their mar-
kets from those of the poor in those countries was also raised. Some propose-
d that differential prices not be restricted to the public sector, but cover also not-for-profit providers and large employers.

The role of intellectual property rights

The point was made that differential pricing of essential drugs is fully com-
patible with the TRIPS Agreement and should not require countries to forego any flexibility they have under it. The need to find an appropriate balance in intel-
lectual property rights systems between providing incentives for the development of new drugs and facilitating access to existing ones was also widely stressed. In this connection, many emphasised the importance of respecting the balance found in the negotiation of the TRIPS Agreement and the rights of developing countries to use the flexibility in it, in-
cluding in regard to compulsory licensing and parallel imports, to respond to health concerns. It was noted that there was as yet relatively little experience with the use of these safeguard mechanisms. Concern was expressed about external pressure on countries to limit the use of these options. Some important reassur-
ances were repeated in this connection. It was also noted that the TRIPS Agree-
ment does not prohibit countries from aiding market segmentation through the prohibition of parallel imports, for exam-
ple from poor countries to high-income countries. There seemed to be a wide acceptance of the view that the patent system, while a necessary condition for much research and development, was not a sufficient one to secure adequate research and development into the neglected diseases of the poor; and that additional measures of support for such research and development are necessary. Some participants warned of the possi-
ble negative effects on local and global innovation of excessive resort to TRIPS safeguard provisions.

Wider use of differential pricing and greater inter-
national funding: issues requiring further work

While the workshop contributed im-
portantly to a better understanding of a number of key issues, many points were ac-
nowledged to require further in-depth analysis and discussion. These included:

➤ The international funding required for ensuring effective access to essential medicines in poor countries and the most appropriate mechanisms for the mobilisation and distribution of such funds.

➤ The most appropriate ways in which differential pricing can be given ef-
flect. Linked with this are questions of how the differential price at which products will be sold in poor coun-
tries can be determined, including how negotiation and competition should contribute, in ways compatible with international agreements, to achieving the most favourable prices, what constraints are imposed by competition law, and how to develop incentives for differential pricing.

➤ How to insulate in political terms pricing in developed countries from differential pricing in poor countries, including in regard to the use of ref-
erence pricing systems. Also, the best ways of securing effective separa-
tion of markets and preventing trade diversion, while taking into account international trade rules.

➤ How to treat middle-income deve-
loping countries and well-to-do populations in poor countries under differential pricing.

Highlights of WHO Director-General, Gro Harlem Brundtland’s, closing speech

...The problems we are discussing are urgent. Reaching the targets set by both the leaders of developed and developing countries, for reducing the burden of disease caused by HIV/AIDS, malaria, TB and the other health conditions that create and perpetuate poverty will not be easy. I am convinced that it will not be possible without a massive increase in the scale of the national and international response. And access to essential drugs is a critical component of that response.

What have we learnt?

We have heard quite clearly that the price of drugs matters – it matters to poor people, and it matters to poor countries. But little progress will be possible without a significant investment in building effective health systems. And even with lower prices – particularly in the case of antiretrovirals – additional finance will be essential.

We have heard that the protection of intellectual property is a necessary factor in stimulating the innovation needed to produce new drugs, vaccines and diagnostics. It is equally clear, as we have heard this morning, that effective protection of intellectual property needs to be combined with incentives that will drive research and development in the direction of the health conditions that disproportionately affect the poor.

The present regime of international trade agreements has been designed to strike a balance between the rights of patent holders and the rights of patients. The TRIPS Agreement contains important public health safeguards. It has been argued here that we do not yet have sufficient experience to judge their real effectiveness. But we have also heard at this meeting some important reassurances that countries’ rights to exercise these safeguards must be respected.

When it comes to increasing access to drugs through lower prices, we cannot rely on one single solution. As one presenter put it: we need a mix of mutually supportive strategies, geared to the circumstances of individual countries.

We have focused particularly at this meeting on differential pricing. The presentations we heard today show that differential pricing is feasible. It can result in prices that are between 1% and 10% of those charged in high income markets. This has happened through a combination of high volume purchasing by governments and international agencies, adequate and reliable levels of finance, advocacy, corporate responsibility and market forces.

For differential pricing to work on a large scale, I think we can all agree that there must be watertight ways of preventing lower-priced drugs from finding their way back into rich country markets...

There were other important lessons that were reinforced. Just making drugs avail-
able – even at no cost – does not guarantee that they will be used. All the other pieces of the picture have to be in place as well: the distribution systems; the partnerships between public and private providers; the agreements between governments and development agencies; and – as several of you stressed – clear and explicit goals and objectives...

New international health fund

The need for significant increases in international financial assistance has been a recurrent theme. We in WHO believe there is a strong case for the estab-
lishment of a new international health fund. It will give political prominence to priority health issues including HIV/AIDS – and it is a tangible response to earlier commitments on the part of the international community to mobilise more money. It offers the opportunity to capture resources from new partners, particularly those who do not have a strong country presence. It is also a means of ensuring more resources to those countries without a strong donor presence.

The issue... is not just that we need an absolute increase in the level of resources, but that we need to think carefully about how these resources are provided. We need mechanisms that transfer money rapidly to countries. We need to combine speed with transparency and accountability. We need mechanisms that ensure that decision making and priority setting remains, where it belongs, at national level. Moreover, if funds are to be used to procure commodities, we need to build on what exists – both nationally and internationally. No reinvention of wheels, and most important, no undermining of existing capacities and systems. The full report of the Workshop is avail-
able at: http://www.who.int/medicines/
library/edm_general/who-wto-hsbiyj- wholeraportheejorworkshop.fin.pdf
Drug procurement – the principles for getting it right

Some countries routinely pay 150% to 250% of world market prices for essential drugs, while others complain of unreliable suppliers and poor quality drugs. Improper procurement practices lead not only to high prices and poor quality, but can also result in shortages of life-saving drugs. Now the Interagency Pharmaceutical Coordination Group has produced Operational Principles for Good Pharmaceutical Procurement, to assist all involved in procurement to obtain lower prices, better quality and more reliable delivery of essential drugs.

The Group, consisting of the pharmaceutical advisers of WHO, the United Nations Children’s Fund, the United Nations Population Fund and the World Bank*, is especially well placed to advise on procurement issues. And the need for improvement is great, as experience shows that the process can go badly wrong. The number of different agencies involved in procuring drugs – including ministries of health, manufacturers and donor agencies – can render the process highly complex and vulnerable to inefficiency and waste. Other problems, such as corruption and lack of transparency, lead to lack of competition, with fewer choices, higher prices and poorer quality. At the same time, irregular and limited funding can greatly hinder efforts to secure timely delivery of drugs, although external funding from international agencies or bilateral donors sometimes helps. Outdated local regulations and supply procedures, unsuitable for the special requirements of buying pharmaceuticals, can further complicate matters.

The Operational Principles, reproduced below, tackle these problems by providing a solid basis to help ministries of health, donor agencies and others to harmonise their drug procurement practices. They can be reviewed and adapted by individual governments and public or private organizations in the process of developing their own internal procurement procedures.

Although in many respects applicable to all procurement settings and for most types of procurement situations, the primary target is pharmaceutical procurement for public sector health systems. It is recognised that public sector procurement may be managed in a variety of ways, ranging from total in-house systems, through various sector procurement to total privatisation. These principles are applicable to each of those variations.

Grouped into four categories, the 12 principles cover: (i) transparent management, (ii) selection and quantification, (iii) financing and competition, and (iv) supplier selection and quality assurance.

Even without appropriate policies and procedures, lack of properly trained personnel can doom a procurement system to failure. So, as well as advising on best procurement practices, the Operational Principles are intended for use in staff training programmes.

Coordination and collaboration among technical development agencies is another major issue. It is hoped that the operational principles will foster cooperation and standard approaches among national governments and donors actively attempting to improve public health and drug management around the world.

Four strategic objectives of pharmaceutical procurement

1. Procure the most cost-effective drugs in the right quantities
2. Select reliable suppliers of high-quality products
3. Ensure timely delivery
4. Achieve the lowest possible total cost

Operational principles for good pharmaceutical procurement

Efficient and Transparent Management

1. Different procurement functions and responsibilities (selection, quantification, product specification, pre-selection of suppliers and adjudication of tenders) should be divided among different offices, committees and individuals, each with the appropriate expertise and resources for the specific function.

Justification and explanation

Senior managers responsible for procurement must ensure that pharmaceutical procurement is carried out effectively, efficiently and in accordance with the country’s policies, laws and regulations. The health system’s procurement office, under various names, is normally responsible for actually managing the procurement function. The procurement office should be responsible for coordinating inputs to achieve the desired result. But in most public sector contexts the reality is that all functions of the drug procurement process are entirely in the hands of one office or official.

Without appropriate separation of function and authority the procurement process is much more susceptible to influence by special interests. In that case, procurement personnel may be able to bias drug selection, manipulate orders to increase the quantities of certain drugs, prejudice supplier qualification decisions, manipulate the final award of tender, and slant product specifications to limit competition. Separation of key functions contributes to professionalism, accountability and an efficient procurement system.

Practical aspects

A number of key procurement functions typically require different expertise and should be separated. Examples include:

Drug selection, which should be done by a national formulary or essential drugs list (EDL) committee. Where such a committee does not exist an ad hoc committee should be set up for this purpose.

Quantification of drug requirements, which should have inputs from the medical stores and/or from district or health facility managers in decentralised systems. However, the procurement office should draw up the final procurement list.

Product specifications, which should be prepared by a standing committee or an ad hoc technical committee.

Pre-selection of suppliers, which should be done by a broad-based procurement committee composed of managers and technical staff, including quality assurance experts.

Adjudication of tenders, which should be reserved for the procurement committee or tenders board. Procurement office staff can make technical recommendations but should not have a vote in the contract decision.

Pharmaceutical procurement is a specialised professional activity that requires a combination of knowledge, skills and experience. Too often drug supply agencies are staffed by individuals with little or no specific training in pharmaceutical procurement. It is essential, therefore, that staff in key procurement and distribution positions be well trained and highly motivated, with the capability to manage the procurement process effectively. The procurement office should have at least one pharmacist as part of its senior staff, in addition to having pharmacists’ expertise all along the pharmaceutical procurement chain.

2. Procurement procedures should be transparent, following formal written procedures throughout the process and using explicit criteria to award contracts.

Justification and explanation

Fairness and the perception of fairness are essential to attract the best suppliers and achieve the best prices. When the pharmaceutical tender process is less transparent and even secretive, it tends to be perceived as corrupt or unfair. There may be accusations of unfair influence. Whether true or not, such charges are damaging and suppliers, health care providers and the public lose confidence in the system. Unsuccessful suppliers may feel that they have no chance of winning and consequently withdraw from future tenders. As the pool of potential suppliers decreases to a small set, price competition decreases and procurement prices become much higher than necessary.

Practical aspects

The tender procedures should be transparent. Formal written procedures should be developed and followed throughout the tender, and explicit criteria should be used to make procurement decisions. Broad-based committees should have the sole authority to make contract awards. Tender adjudication should be done properly and the award of contracts and issuing of orders should be completed within the shortest period of time possible. Information on the tender process and results should be public, to the extent permitted by law. At the very least, both bidders and health personnel should have access to information on the successful suppliers and the prices for all winning contracts.

...cont’d on page 14 ➠
3. Procurement should be planned properly and procurement performance should be monitored regularly; monitoring should include an annual external audit.

Justification and explanation
In order to ensure that drugs are available where and when they are needed, drug procurement must be carefully planned. Planners should consider factors such as accessibility and availability and the number of levels in the logistics system, constraints of time and resources affecting procurement functions such as drug selection, quantification, tendering and contracting; the lead times at various levels of the system; import procedures; customs clearance; and access to transport.

Practical aspects
A reliable management information system (MIS) is one of the most important elements in planning and managing procurement. Lack of a functioning MIS or the inability to use it appropriately is a key cause of programme failure. The MIS should track the status of each order and payment, and compile the information required for supplier monitoring, as discussed in Operational Principle 11. It is important that the MIS also tracks the number of orders placed, payments made, quantities actually purchased compared with estimates, purchases from all contract suppliers, and drug purchases from non-contract suppliers. In all but the smallest procurement systems, the procurement information system should be computerised in such a way as to facilitate tracking and reporting on performance by suppliers and by the health system.

The procurement office should be required to report regularly on key procurement performance indicators, selected by senior managers. Some standard indicators include the planned versus actual items and quantities purchased; prices obtained versus average international prices; average supplier lead time and service level; percentage of key drugs in stock at various levels of the supply system; and report on stock-outs. At least once a year the procurement unit should undergo an audit, either internal or external, to verify procurement office accounting records. The auditor should issue a statutory audit report in accordance with the legal regulations of the jurisdiction and in addition should issue a detailed Letter of Comment to the management of the organization and to the appropriate public supervisory body.

Drug Selection and Quantification
4. Public sector procurement should be limited to an essential drugs list or national/local formulary list.

Justification and explanation
No public or private health care system in the world can afford to purchase all drugs circulating in the market within its given budget. Resources are limited and choices have to be made. A limited list of drugs for procurement, based on an essential drugs list or drug formulary, defines which drugs will be regularly purchased and is one of the most effective ways to control drug expenditure.

A nationally developed formulary or selection based on the essential drugs concept has been used in both industrialised and developing countries’ health systems for more than 20 years. This allows the health system to concentrate resources on the most cost-effective and affordable drugs to treat prevailing health problems. The selection of drugs based on a national formulary or national list allows for concentrating on a limited number of products. Larger quantities may encourage competition and lead to more competitive drug prices. Reducing the number of items also simplifies other supply management activities and reduces inventory-carrying costs.

Practical aspects
Some public and private health systems strictly limit procurement to drugs listed on an essential drugs list. However, in most cases some mechanism exists to address special needs, allowing the occasional procurement of non-list drugs after approval by senior officials.

5. Procurement and tender documents should list drugs by their International Nonproprietary Name (INN), or generic name.

Justification and explanation
The INN is widely accepted as the standard for describing drugs on a procurement list or tender request. Although this is most obviously applicable when purchasing drugs which are available from multiple sources, generic description should also be used when purchasing single source products. When purchasing products which present potential problems with pharmaceutical equivalence or bio-equivalence the procurement request should specify the quality standards but not mention specific brands.

Practical aspects
This does not mean that brand-name suppliers should be barred from tender participation; they may offer the most cost-effective product, and in fact may offer more competitive prices for certain branded drugs than generic competitors. However, all drugs supplied to the public health system should be properly labelled in accordance with standards laid down by law (or in accordance with labelling instructions), including the INN featured prominently in addition to the brand name that may be on the label.

6. Order quantities should be based on a reliable estimate of actual need.

Justification and explanation
An accurate quantification of procurement requirements is needed to avoid stock-outs of some drugs and overstocks of others. In addition, if suppliers believe the estimated procurement quantities are accurate, they are more willing to offer the lowest competitive price on an estimated-quantity supply contract.

Practical aspects
Past consumption is the most reliable way to predict and quantify future demand, providing that the supply pipeline has been consistently full and that consumption records are reasonably accurate. Such consumption data must be adjusted in the light of known or expected changes in morbidity patterns, seasonal factors, service levels, prescribing patterns and patient attendance. The downside of basing quantification only on past consumption is that any existing patterns of irrational drug use will be perpetuated.

In many countries consumption data is incomplete or do not reflect real demand because a supply pipeline has not always been full and drug use has not always been rational. In such cases the morbidity-based and extrapolated consumption techniques may be used to estimate procurement requirements. These techniques, particularly the morbidity-based method, should also be used periodically to check on the rationality of past consumption, by comparing actual consumption with the estimated need to treat common diseases based on standard treatment protocols and epidemiological data.

When funds are not available to purchase all drugs in the quantities which were required, it is necessary to prioritise the procurement list to match available financial resources. Various techniques such as VEN (vital, essential and non essential) Analysis, Therapeutic Category Analysis and ABC analysis can be used to select priorities and reduce the quantities of less cost-effective drugs. A VEN priority list should be defined in advance of any decision on drug procurement. These tools are discussed in detail elsewhere.

Financing and Competition
7. Mechanisms should be put in place to ensure reliable financing for procurement. Good financial management procedures should be followed to maximise the use of financial resources.

Justification and explanation
Potential sources of funds for pharmaceutical procurement include government financing, user fees, health insurance, community co-financing and donor financing. These options vary in terms of their efficiency, equity and sustainability. The most important considerations for procurement are total funds available, adequate access to foreign exchange and the regularity with which funds are available. It is the responsibility of governments and senior managers to establish appropriate and reliable funding for public drug procurement as a high priority, and to implement mechanisms which provide adequate funding on time to support public sector procurement.

Efficient financial management systems are especially important if funds are limited and procurement priorities must be set. Being able to order drugs when needed and to pay for them on delivery has a very positive effect on reducing both prices and stock-outs and on increasing supplier confidence in the procurement system. Prompt, reliable payment can have as great an influence on bringing down drug prices as bulk discounts.

Practical aspects
Financial mechanisms such as decentralised drug purchasing accounts may help the procurement cycle to operate independently of the treasury cycle. Revolving drug funds can help achieve this separation by establishing their own bank accounts and their own working capital. An aspect of financing which is sometimes overlooked is funding for the procurement process itself. Procurement services may be part of the warehouse and distribution operation or set up as a separate office. In either case, salaries and operational costs of the procurement office must be covered by the users. Options include:

➤ support through the government budget; pay periodic payment from users at the beginning of the procurement cycle, based on the projected value of the total procurement, or at the end of the cycle, based on the actual value of total shipments;
➤ regular payment from suppliers, based on a percentage of the invoiced value; this method may be contrary to some countries’ procurement integrity regulations;
➤ payment from users in the form of a flat annual fee, based on total expenses divided by the total number of areas and independent institutions served.
There is some risk in tying a procurement office’s reimbursement to the value of purchases by user facilities, as this may create an incentive for the procurement office to increase, rather than decrease, prices and purchases. Therefore, if this sort of approach is used, checks and balances should be put in place, such as a requirement that all major procurement decisions be made by user representatives.

8. Procurement should be effected in the largest possible quantities in order to achieve economies of scale; this applies to both centralised and decentralised systems.

**Justification and explanation**

Larger procurement volume makes favourable prices and contract terms more likely, by increasing suppliers’ interest in bidding and by providing them with an incentive to offer a competitive price.

**Practical aspects**

A higher volume for single items may be achieved through pooling of procurement volume from many facilities or from several States or countries, by restriction of the drug list or by elimination of duplication within therapeutic categories. A large contract awarded to one supplier by no means implies that the entire volume must be shipped at once. Many procurement services specify, as part of contract terms, divided deliveries over the period of the contract or to multiple delivery points. Some supply systems use estimated orders and tenderers, with orders placed throughout the contract period as needed. In decentralised procurement programmes, one way to sustain procurement volume is to negotiate prices centrally for a list of essential drugs and allow provinces, districts or health facilities to order the drugs as needed from the contract supplier. These strategies allow for optimal use of available storage and transport capacity, facilitate inventory management and ease cash flow constraints.

9. Procurement in the public health sector should be based on competitive procurement methods, except for very small or emergency orders.

**Justification and explanation**

There are four main methods for purchases through pooling. Three of them are competitive: restricted tenders, open tenders and competitive negotiations. The fourth method is direct negotiation with a single supplier. Since inducing supplier competition is a primary key to obtaining favourable prices, public sector should use competitive methods for all but very small or emergency purchases. This assumes, of course, that there are multiple suppliers for the items needed. As discussed in Operational Principle 5, drugs that are available from multiple sources should be competitively purchased under their generic (INN) name.

**Practical aspects**

As long as drug quality and service reliability are assured, competition should be increased to the point at which drug prices are as low as possible. The “rule-of-five” for pharmaceutical pricing holds that generic prices generally reach their minimum when there are at least five generic pharmaceutical tenderers, with orders placed throughout the contract period as needed. In decentralised procurement programmes, one way to sustain procurement volume is to negotiate prices centrally for a list of essential drugs and allow provinces, districts or health facilities to order the drugs as needed from the contract supplier. These strategies allow for optimal use of available storage and transport capacity, facilitate inventory management and ease cash flow constraints.

10. Members of the purchasing groups should purchase all contracted items from the supplier(s) which hold(s) the contract.

**Justification and explanation**

Except in those systems where each health facility negotiates prices and purchases drugs individually, public pharmaceutical procurement systems are seen as purchasing groups. Normally, group purchasing achieves lower prices than would be available to the same group of health facilities if they purchased individually. These discounts are based on the fact that facilities which are part of the purchasing group will purchase contract items only from the selected contract supplier, as long as that supplier is able to perform. This is called sole-source commitment. If group members do not free to make separate deals for contract items with other suppliers at will, the suppliers who participate in tendering will be able to offer the best possible discounts to the purchasing group.

**Practical aspects**

Sole-source commitment must be monitored and enforced. Monitoring is particularly important in systems where prices are negotiated centrally and ordering is done by individual health facilities. Suppliers that do not win contracts in a competitive tender may offer more competitive prices or negotiate direct supplies in an attempt to split the purchasing group. If group members do not resist such price dumping, the prices at subsequent tenders will rise to previous unfavourable high levels.

**Supplier Selection and Quality Assurance**

11. Prospective suppliers should be pre-qualified, and selected suppliers identified through a process which considers product quality, service reliability, delivery time and financial viability.

**Justification and explanation**

Pre- and post-qualification procedures help to eliminate substandard suppliers, if properly managed. Pre-qualification is the procedure of evaluating supplier capacity and reputation before bids are solicited for specific products. This is the preferred procedure, especially for ongoing drug procurement systems. Although substantial time is required to establish an initial list of pre-qualified suppliers, this has been done once and the pre-qualified tenderer for each product is deemed to be qualified, which expedites adjudication and contract award. Post-qualification evaluates the suppliers after bids have been received. This is the preferred procedure, especially for ongoing drug procurement systems, since it is non-disruptive and allows for tendering the lowest pre-qualified tenderer for each product. Post-qualification also allows for the identification of potential problems with poor product quality, ideally using pre-printed, simple reporting forms. All reports should be carefully assessed to establish the need for laboratory testing and appropriate follow-up action must be taken, including product recall if warranted. The reporter should be informed about the results and the action taken, even if products are not defective, in order to encourage continued participation in the reporting programme. Product defect reports and results should be recorded as part of the supplier monitoring system.

**Practical aspects**

Most established procurement systems use some form of restricted tender with pre-qualification, soliciting bids only from suppliers that have been pre-qualified. Procurement systems using restricted tenders with pre-qualification should make continuous efforts to seek out potential new suppliers in order to maintain competitive pressure on established suppliers. Since this has been done once and the pre-qualified tenderer for each product is deemed to be qualified, this expedites adjudication and contract award.

The process for evaluating new suppliers can include formal registration, formal inspection, reference checks with past clients and international agencies, test purchases in small quantities and informal local information-gathering. All countries that operate regulatory agencies and drug quality control laboratories must make vigorous efforts to check references of new suppliers and should buy only from those suppliers that are known to provide quality products. One important aspect of quality assurance is the concept of “traceability.” The supplier must be able to trace the product to the finished product manufacturer, and be able to identify the ingredients to their producers, all in a transparent manner.

In addition to using pre- and post-qualification procedures, successful procurement offices ensure continued good supplier performance through a formal monitoring system which tracks lead time, compliance with contract terms, partial shipments, quality of drugs and their shelf-life, compliance with packaging and labelling instructions, etc. A cumulative file for each supplier should have copies of registration papers, references, special correspondence, complaints and other anecdotal supplier information. The information system should track chronologically the number and value of tender contracts awarded, and the value of total purchases from the supplier by year and performance for each tender.

12. Procurement procedures/systems should include all assurances that the drugs purchased are of high quality, according to international standards.

**Justification and explanation**

Four components make up an effective quality assurance system:

- selecting reliable suppliers of quality drugs;
- using existing mechanisms, such as the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, which encourages health workers to report potential problems with poor product quality, ideally using pre-printed, simple reporting forms. All reports should be carefully assessed to establish the need for laboratory testing and appropriate follow-up action must be taken, including product recall if warranted. The reporter should be informed about the results and the action taken, even if products are not defective, in order to encourage continued participation in the reporting programme. Product defect reports and results should be recorded as part of the supplier monitoring system.
- establishing a programme of product defect reporting;
- performing targeted quality control testing.

The selection of suppliers that are known to provide high-quality products as discussed in Operational Principle 11 is the primary key to ensuring drug product quality. When using new suppliers whose products are not familiar in the country, the procurement system must be particularly alert to product quality issues.

**Practical aspects**

Some products vary substantially in formulation and bioavailability from supplier to supplier. When this difference is therapeutically significant, purchasing offices should be cautious about making changes in supplier from year to year, and particularly about accepting unknown suppliers. Even when new products are completely equivalent in content and effect, changes in dosage form can be problematic, requiring patient and provider re-education. For drugs used in chronic diseases there should be a significant cost benefit before changes are made. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is a way of exchanging information on the supplier between the regulatory authorities of the exporting country and those of the importing country. It does not constitute an absolute assurance of product quality but does provide a mechanism for ascertaining that a drug product comes from a reputable source. The certificate is as independent and reliable as the regulatory authority that issues it. All shipments from suppliers should be physically checked on receipt. A formal system should be established which encourages health workers to report potential problems with poor product quality, ideally using pre-printed, simple reporting forms. All reports should be carefully assessed to establish the need for laboratory testing and appropriate follow-up action must be taken, including product recall if warranted. The reporter should be informed about the results and the action taken, even if products are not defective, in order to encourage continued participation in the reporting programme. Product defect reports and results should be recorded as part of the supplier monitoring system.

If supplier selection is managed effectively it is not necessary to carry out quality control testing on every batch of every drug received. Many procurement agencies limit routine testing to new suppliers and to sensitive products. In all public drug supply systems there should be access to quality control laboratories to test suspect drug products. Unfortunately, not all governments have been able to sustain their own drug-testing laboratories. In some countries a college of pharmacy or an independent laboratory may have the required testing facilities. Also, quality control laboratories in industrialised countries will provide drug analyses against payment. If analyses must be performed by foreign laboratories, foreign exchange problems...
Drug procurement... cont’d from pg. 15

may be reduced by requiring the suppliers of suspect prod-
ucts to pay the laboratory directly, with the arrangement
clearly described in the purchase contract. Financing for
quality control testing is a difficult problem in many coun-
tries, and governments and donors should collaborate to
find viable solutions.

Practical implementation issues

The 12 operational principles for good pharmaceutical
procurement practices aim to improve pharmaceutical pro-
curement by ministries of health, supply agencies, NGOs
and other organizations involved in drug supply. When in-
troducing and using these principles, the following should
be kept in mind.

The operational principles should be used to
develop standard operational procedures

These 12 principles constitute the minimum conditions
for a reliable and cost-effective drug procurement system.
They should be used as the basis for developing a set of
more detailed standard operational procedures, taking
into account the specific institutional circumstances and
market conditions under which the system must operate.

Standard operational procedures must be
actively implemented and monitored

The operational principles and the standard operational
procedures must be supported by the national drug policy,
regulations and legislation. International agencies and other
terms between the government and the contractor; and
reliable financing and accounting systems.

The right purchasing and inventory control
model should be chosen

Procurement can be done through a single annual ten-
der, through a schedule of periodic tenders throughout the
year, through a perpetual inventory system in which pro-
curement is initiated as soon as stocks fall below a certain
level, or through a combination of such systems. The choice
depends on a variety of factors, including the type of drugs
used (expensive drugs, short shelf-life, high or low con-
sumption rate), the geographical situation, local production
capacity, total requirements and combiners. The geography
is important since more isolated areas tend to purchase
less frequently. Local production capacity allows greater
flexibility and more frequent deliveries. High-volume
items may be purchased more frequently throughout the
year. The choice of purchasing and inventory model
affects the direct cost of the drug, staff requirements
(frequent purchases need more staff time) and inventory
costs (less frequent procurement requires more warehousing
space).

At a certain stage, an effective computerised system
should be introduced to manage inventory control. This
should probably be done in phases, with the system devel-
oped or backed up by a local company. A well-functioning
manual inventory control system can be converted into a
computerised one.

Legislation and regulations may need to be adapted

National legislation and regulations provide the neces-
sary legal foundation for procurement procedures, contract
enforcement, financial authority, staff accountability and
other critical aspects of procurement. Existing legislation
and regulations may be fully consistent with the 12
core principles. Often, however, legislative or regulatory
changes will be needed.

A common problem is that the general rules for drug
procurement by the public sector do not take account of
the specialised procurement requirements of buying phar-
maceuticals. The challenge may be not only to identify the
changes that are needed, but also to convince the relevant
legal and financial authorities that pharmaceutical pro-
curement does in fact require a different approach. Some
examples of specific requirements are: separation of the
key procurement functions, the need for financial audit,
mandatory use of generic names, the need for product
registration (which should also apply to the public sector
but is often ignored) and formal supplier qualification.
Other related issues are pricing policies and ethical
criteria for drug promotion.

Capacity needs to be built

Pharmaceutical procurement is a specialised profes-
sional activity, which requires a combination of knowledge,
skills and experience. Too often drug supply agencies are
staffed by individuals with little or no specific training in
pharmaceutical procurement. It is essential, therefore, that
staff in key procurement positions be well trained and
highly motivated. Training may be organized through na-
tional or international courses, through apprenticeships
with international supply agencies or supply agencies in
other countries, or by enlisting experienced short-term or
long-term support from external technical advisers.

International and bilateral agencies should
support the national procurement system

Development assistance through loans, grants and other
financial mechanisms is intended to contribute to long-term
health sector development. External technical assistance
is intended to build local capacity and to develop sustain-
able systems, and should therefore be consistent with the
policies of the country.

It is essential that development assistance reinforces
good pharmaceutical procurement practices and aims at
sustainability, rather than undermining or delaying the na-
tional development of such practices. From a development
point of view, investing in strengthening procurement prac-
tices may be more important than just procuring the drugs.
Thus international, multilateral and bilateral agencies
may need to review their own procedures, requirements and
technical advice in the light of the present document.

In the same vein, WHO’s Guidelines for Drug Donations
or their national adaptations should be respected by
external agencies.

Procurement in decentralised systems

needs special arrangements

Health system functions are increasingly being de-
centralised to provincial, district or local health services.
In the pharmaceutical sector experiences with decentrali-
sation have been mixed. Proper drug selection, price
reductions from bulk purchasing, quality assurance and
accountability may all be threatened in decentralised
procurement.

In principle, the 12 core principles for good pro-
curement apply in decentralised systems as well, but they
may need to be adapted in practice. For example, separa-
tion of key functions may be difficult with limited local
staff. Bulk procurement may be possible only if districts
and major health units pool their requirements and negoti-
ate one contract. Under a system of direct delivery, drugs
are then delivered to and paid for by the district or health
unit. Finally, it may be difficult for local authorities
to verify the quality of the drugs. Some decentralised systems
rely on a list of qualified suppliers provided by national
authorities.

To achieve good drug procurement practices in decen-
tralised systems the role of the central government should
be made clear. It would usually be its responsibility to
guarantee the safety and efficacy of all drugs circulating
in the market and in the health system, and to monitor the
performance of the decentralised procurement system. In
addition, the central government may tender for the prices
of the drugs, for direct delivery systems.

Other operational issues

In addition to the above, there are other possibilities for
improving procurement performance, which should be
considered. These include:

▶ the use of international drug supply agencies, such as
  the Equipment for Charity Hospitals Overseas (ECHO)
  organization, the International Dispensary
  Association (IDA) and the United Nations Children’s
  Fund (UNICEF). Their services can especially be ben-
  eficial when small quantities of a product need to be
  procured;
▶ access to information on prices and supply sources.
  Comparative price information is currently available
  to countries through the International Drug Price
  Indicator Guide (Management Sciences for Health and
  World Health Organization);
▶ primary and secondary systems for pre-registration
  and post-registration of suppliers;
▶ managing mixed systems of procured and donated
  drugs, especially in countries where donations form a
  large part of drug supplies. In such countries an active
  donor policy, clear indications of drug needs to poten-
  tial donors and early announcement and registration of
  drug donations in the pipeline are extremely important
  in order to derive the maximum benefit from the dona-
  tions and prevent overlapping donation requests and
  drug orders.

Operational Principles for Good Pharmaceutical Procure-
ment is available, free of charge, in English, French and
Spanish, from: Department of Essential Drugs and Medi-
cines Policy, World Health Organization, 1211 Geneva 27,
Switzerland. It is also available on the Web at: www.who.
int/medicines/.

References

1. MS/H/WHO. Managing drug supply. 2nd ed. J.D. Quick, J. Rankin, R. Laing,
  R. DeCramer, H.V. Hagstrom, M.N.G. Dukas and A. Gassert, editors.
  Health Organization, 1984. WHO/SSM.00.2.

* UNAIDS has since joined the Group.
Research update

Antibiotic use in infants hospitalised with HIV-related pneumonia

I. Chitsike, Department of Paediatrics and Child Health, Medical School, University of Zimbabwe, Harare.

The aim of the study was to describe the clinical features of infants admitted with HIV-related pneumonia, and to describe antibiotic use in relation to recommended treatment guidelines. Researchers conducted a cross-sectional analysis of records from the paediatric wards of two university teaching hospitals in the capital, Parirenyatwa and Harare Central, to determine mortality and antibiotic use.

The records of 100 infants admitted for 48 hours or more with features of HIV-related pneumonia were analysed for clinical features and antibiotic use. The study showed that the peak age of children admitted was two months and overall mortality was 27%. The odds ratio of dying at Harare Central Hospital was three times that of Parirenyatwa. Increased mortality was associated with use of ampicillin, whereas decreased mortality was associated with use of benzyl penicillin, which is the recommended drug in the treatment guidelines.

The study concludes that there is an urgent need to address rational prescribing in the face of changing pattern of disease as result of the HIV epidemic.

Teaching mothers to provide home treatment of malaria in Tigray, Ethiopia: a randomised trial

G. Kidane, R.H. Morrow

No satisfactory strategy for reducing high child mortality from malaria has yet been established in tropical Africa. The authors compared the effect on under-5 mortality of teaching mothers to provide antimalarials promptly to their sick children at home, with the present community health worker approach. Of 37 tabias (clusters of villages) in two districts with hyperendemic to holoendemic malaria, tabias reported to have the highest malaria morbidity were selected. A census was done which included a maternity history to determine under-5 mortality. Tabias were paired according to under-5 mortality rates. One tabia from each pair was allocated by random number to an intervention group and the other was allocated to the control group.

In the intervention villages, mother coordinators were trained to teach other local mothers to recognise symptoms of malaria in their children, and to promptly give chloroquine. Villages in the control group continued to use the community health worker/facility-based approach for antimalarial treatment. Under-5 mortality was reduced by 40% in the intervention tabias, compared with 366 of 7294 (50.2 per 1000) in the control tabias. Under-5 mortality was reduced by 40% in the intervention villages.

The authors conclude that a major reduction in under-5 mortality can be achieved in holoendemic malaria areas through training local mother coordinators to teach other mothers to give children service delivery, and used mother coordinators for surveillance. In both intervention and control tabias, all births and deaths of under-5s were recorded monthly.


Framework for design and evaluation of complex interventions to improve health


Randomised controlled trials are widely accepted as the most reliable method of determining effectiveness, but most trials have evaluated the effects of a single intervention such as a drug. Recognition is increasing that other, non-pharmacological interventions should also be rigorously evaluated. This paper examines the design and execution of research required to address the additional problems resulting from evaluation of complex interventions – that is, those “made up of various interconnecting parts.” The issues dealt with are discussed in a longer Medical Research Council paper (www.mrc.ac.uk/complex_packages.html). The authors focus on randomised trials but believe that this approach could be adapted to other designs when they are more appropriate.

Details of these and other recent articles can be found in INRUD News, March 2001, available on the Web at: http://www.msh.org/inrud/

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The study concludes that there is an urgent need to address rational prescribing in the face of changing pattern of disease as result of the HIV epidemic.

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From January to December 1997, 190 of 6383 (29.8 per 1000) children under-5 died in the intervention tabias compared with 366 of 7294 (50.2 per 1000) in the control tabias. Under-5 mortality was reduced by 40% in the intervention villages.

For further information contact: Ministry of Health and Social Services, Division of Pharmaceutical Services, Private Bag 13 198, Windhoek, Namibia.

References

Medical products and the Internet: WHO’s guide to safe surfing

As sales of pharmaceuticals and the supply of medical information on the Internet have increased substantially, so too have reports of suspected illegal advertising and other complaints from consumers. How safe is it to seek medical advice or buy pharmaceutical products online? How can the Internet user know if the information offered is reliable? Is there any guarantee that medical products bought online will be safe or effective? And what sanctions exist to prevent improper use of the Internet?

To guide consumers through these relatively uncharted waters, WHO has produced a guide to obtaining reliable, independent and comparable information on medical products on the World-Wide-Web.¹

The guide – Medical Products and the Internet – has been developed in consultation with drug regulatory authorities, drug information experts, consumer organizations and the pharmaceutical industry. An edited version of the guide appears below.

Box 1
Key points
◆ If used properly, the Internet allows quick and easy access to health information. It provides useful information on topics such as diseases, therapies, medical products, and health-related organizations (see Point I).
◆ Information obtained from the Internet can be helpful when consulting a doctor or other health care provider. But this guidance should complement, not replace, a consultation with a health care provider (see Point II).
◆ Although often difficult to determine, it is essential to verify the source of information available on the Internet (see Point III).
◆ If information sounds too good to be true, it usually is. The information should be verified and carefully assessed (see Point III).
◆ The sale or purchase of medical products via the Internet is illegal in some countries and users are strongly advised to obtain medical products through legitimate distribution channels such as pharmacies (see Point IV).
◆ Patients should consult a doctor or other health care professional before embarking on self-treatment (see Point V).

POINT I
The Internet is a valuable source of information – provided the source is known and trusted

The Internet is a valuable source of information on topics such as diseases, conditions, therapies, medical products, and health and medical organizations. When used properly, it allows quick and easy access to such information from on-line medical libraries, universities, health associations and government agencies. However, the quality of health and medical product information on the Internet varies, and it is often difficult for the Internet user to identify the true source of the information, and to determine whether it is reliable, complete and up-to-date.

Box 2
Looking at a web site? Check the following:
◆ Is there clear indication of the name and contact address of the web site owner?
◆ Is it clear which organization(s) contribute funding, services or other support to the web site?
◆ If advertising or sponsorship is a source of funding, is this clearly stated?
◆ Is this a site for consumers, health professionals or some other audience?
◆ When was the information displayed last updated?

Health authorities and organizations in each country can provide a list of sites with links to reliable sources of health and medical information. In addition, several private organizations are investigating ways of assuring the quality of information on the Internet. They include Health on the Net Foundation (<http://www.hon.ch>) and Internet Healthcare Coalition (<http://www.ihealthcoalition.org>). National authorities should identify and list additional organizations and reliable web sites known to them. The Internet also offers information on medical products. However, not all product information may be truthful. If information sounds too good to be true, it probably is. Warning signs include:
◆ Advertisements or information that use phrases such as “scientific breakthrough”, “miraculous cure”, “exclusive product”, “secret formula”, “ancient ingredient”, “without risk”, “anti-ageing”, “improve sexual performance” and “all natural”;
◆ Case histories from “cured” customers claiming amazing results;
◆ A list of symptoms and diseases it is claimed the product cures – for example, claims that one product can cure or treat HIV/AIDS or cancer, arthritis, Alzheimer’s disease, wrinkles, weight problems, or memory loss;
◆ Advertisements for the latest fashionable product featured in the media;
◆ Claims that a product is available from one source only and for a limited time;
◆ Testimonials from “famous” medical experts;
◆ Claims of “no risk” or failure to include information about risk. No product or treatment is completely risk-free; and
◆ Claims that a product is “scientifically proven”.

Since products with the same name may contain different ingredients in different countries, it is essential to look at the International Nonproprietary Name (INN) of the active ingredients and not just the product name (brand name, trade name). Product information should be as complete as possible, and include at least the elements outlined in Box 3.

Box 3
Product information: what to look for
A reliable web site provides the following information:
◆ product name
◆ active ingredient(s)
◆ name of other ingredients known to cause problems to some people
◆ location and address of the manufacturer
◆ when not to use the product (for example, in pregnancy, allergies, interactions with other medicines or foods)
◆ how to store the product
◆ possible undesired effects
◆ how to report the product
◆ manufacturer’s name and contact information
◆ latest update of the information.
3. Quality may not be assured
When medical products are bought through the appropriate channels, such as a pharmacy, the product can usually be relied on to meet manufacturing requirements and to be of good quality. The product is likely to contain the right active ingredients and to have been manufactured, packaged, transported and properly stored prior to purchase. However, buying medical products through the Internet may deny consumers the quality assurance offered by authorised channels of medical product manufacturing, distribution and sales.

4. Products may circumvent regulatory protection
Medical products sold through the Internet may circumvent the regulatory protection provided by health authorities and governments. And it may be impossible to obtain compensation from the manufacturer or distributor for any damage resulting from the use of these products. The identity and location of the source of products may be disguised – a common ploy in the case of fraudulent medical products.

5. Products may be fraudulent and harmful to health
Products promoted and offered for sale on the Internet may be fraudulent if they do not meet the standards required for approval in the country where they are being purchased and if they are not sold by licensed or authorised health organizations. The use of such products for self-treatment may be harmful to health or provide no benefit at all – both of which can be dangerous. In the meantime, the opportunity to be properly treated by health care professionals may be lost.

6. Reimbursement may not be possible
In many countries, health insurance programmes may not agree to reimburse the cost of medical products bought through the Internet. Before buying medical products in this way, it is advisable to find out whether the cost is reimbursable and whether the Internet medical product provider is recognised by the health insurance programme.

7. Products may waste valuable resources
Seeking medical treatment through the Internet instead of through a health care professional could involve a waste of valuable resources. Money may be wasted on useless products and time lost in obtaining proper treatment.

8. Products bought across borders may be prohibited in some countries
Countries have different laws about what medical products can be sold and shipped across national borders. Products that have been identified as a hazard to public health or which are not approved for sale in a particular country may not be allowed in if they are identified at entry. And if the product has already been paid for, it may be impossible to get reimbursement. An additional constraint on the import of medical products is the prescription status of medical products, which varies from one country to another. Products that may be sold without prescription, or are even unregulated, in one country may only be available on prescription in another.

9. Products with the same name may be different in different countries
Internet users need to be aware that products with the same name may contain different ingredients in different countries. As a result, the wrong medical product may be selected. In addition, countries may have different standards for the quality of medical products and their manufacture. Products purchased across borders might not be exactly the same product or quality as in the Internet user’s own country.

10. Personal information may not remain confidential
Many web sites require the disclosure of personal medical data. However, there is no guarantee that this information will be kept confidential. To avoid this risk, medical products should be purchased through conventional, legitimate distribution channels.

POINT V Consult a health care professional before embarking on self-treatment or changing medication

Even after finding reliable health or medical information on the Internet, it is important to consult a health care provider to discuss the specific disease or condition and the information found on the Internet before embarking on self-treatment. This is important because:

- Not all diseases and symptoms need medical treatment. Medicines or medical products may be used unnecessarily – exposing the individual to unnecessary risk.
- Many medications or other medical products may cause harm if used improperly. It is important to be under the care of a health care professional when using such products.
- Not every medication is appropriate for everyone. For example, some individuals may be allergic to certain medications. A health care professional can help in determining the best medicine or treatment tailored to individual needs.
- A health care professional can provide guidance on the safe use of medication. For example, the effectiveness of some medications may be influenced by other products, such as other medicines, alcohol or certain foods. Mixing medication with these other products could strengthen or weaken the effect of the medication or cause an adverse reaction. This could be dangerous to health or delay recovery.
- Patients such as pregnant or breastfeeding women, the elderly and children, have special requirements when taking medication or using medical products. For example, some medications can harm an unborn child and pregnant women are advised to consult a health care professional before self-treatment.

> When a patient takes medication or uses a medical product, it is important to inform a health care professional of any side-effects experienced. In this way, the health care professional is better prepared to offer advice or change the treatment in the event of an adverse reaction.
> By ordering medical products through the Internet patients may deprive themselves of the opportunity for personal, professional care and advice from a doctor, pharmacist or other health care professional.

Medical products and the Internet: a guide to finding reliable information is available at http://www.who.int/medicines/library/ qsm/who-edm-qsm.99.4.medicines-on-internetguide.html
In Portuguese: http://www.cvs.saude.sp.gov.br/medical.html
In Italian: http://www.edifolini.com/farmaci_int.html
For those without web access a limited number of hard copies of the booklet in English are available from: Department of Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland. Reference: WHO/EDM/GSM/99.4.

We want to hear from you
WHO is working with national health authorities to address the illegal advertising and sale of medical products through the Internet. In addition to reporting suspected illegal activities and problem cases to their national health authorities, the Monitor would like readers to inform us of their experiences.

WHO would also be grateful to receive any comments or experiences gained from the practical use of the guide, which would help in developing it further.

Contact: Department of Essential Drugs and Medicines Policy World Health Organization 1211 Geneva 27, Switzerland email: reggp@who.int
Breakthrough on developing countries’ access to journals

WHO and the world’s six largest medical journal publishers have announced an initiative which will enable many developing countries to gain access to vital scientific information that otherwise they could not afford. This major breakthrough was announced in London in July 2001, with the signing of a Statement of Intent by the publishers’ senior executives. It allows over 1,000 of the world’s leading medical and scientific journals to become available through the Internet to medical schools and research institutions in developing countries free of charge or at greatly reduced rates. Access to the journals will be exactly the same as for other subscribers.

Until now, biomedical journal subscriptions, both electronic and print, have been priced uniformly for medical schools and research centres and similar institutions, irrespective of geographical location. Annual subscription prices are on average several hundred dollars per title, with many key titles costing over $1,500 per year. This has made it all but impossible for the large majority of health and research institutions in the poorest countries to access critical scientific information.

At the signing ceremony in London, Dr Gro Harlem Brundtland, Director-General of WHO, said that the initiative “is perhaps the biggest step ever taken towards reducing the health information gap between rich and poor countries.” WHO spearheaded the project, together with the British Medical Journal and the Open Society Institute of the Soros Foundation network. The outcome is a tiered-pricing model that will affect institutions in the 100 poorest countries. Countries with a Gross National Product per capita of less than US$ 1,000 are candidates for free access from four publishers (the majority of the offered journals) and minimal prices from two publishers. Those with Gross National Product per capita between US$ 1,000 and US$ 3,000 will be offered greatly discounted prices.

Scheduled to start in January 2002, the initiative is expected to last for at least three years while being monitored for progress. It will benefit bona fide academic and research institutions, which depend on timely access to biomedical journals. Between now and the end of 2001, these institutions will be identified individually, and the process put in place so that they can receive and use access authentication. This will be a learning experience for the publishers and the participating institutions. Decisions about how to proceed after the initiative will grow from the precedents it sets, and will be informed by the working relationships which have developed among the partners.

While celebration was the order of the day at the initiative’s launch, Richard Smith, Editor of the British Medical Journal, acknowledged that there is more to do. “Other publishers must be persuaded to join the venture.” Those in the poor world need help with being connected to the Internet and trained to use it. WHO and George Soros are helping here. We need to improve the flow from poor to rich, and within the poor world. Publishers can help here too by exporting not only content but also their skills.”

The new arrangement is an important step in establishing the Health InterNetwork, a project introduced by United Nations’ Secretary-General, Kofi Annan, at the UN Millennium Summit last year. Led by WHO, the Health InterNetwork aims to strengthen public health services by providing health workers, researchers and policy-makers access to high-quality, relevant and timely health information through an Internet portal. It also aims to improve communication and networking. The project will provide training as well as information and communication technology applications for public health.

For further information contact: Barbara Aronson at the World Health Organization, 1211 Geneva 27, Switzerland. E-mail: aronsonb@who.int

WHO hosts meeting in Bangkok on traditional medicine

Traditional knowledge – particularly the knowledge of traditional medicine and medicinal plants – is increasingly used in developed and developing countries, and plays a vital role in health care. As a result more WHO Member States are concerned with the need to protect such knowledge, and to secure equitable sharing of any benefits derived from it. Some governments, academics and NGOs have voiced the need to protect traditional medicine under existing or new forms of intellectual property rights protection, as a means to recognise and compensate the creators and possessors of such knowledge. Others object to such proposals on economic or other grounds. However, there is general consensus on both the need to enhance access to medicines that are essential to millions of people and to oppose unauthorised appropriation of traditional knowledge and biological materials under intellectual property systems.

Against this background of current debate, in December 2000 WHO organized an inter-regional workshop in Bangkok, Thailand, in cooperation with the WHO Regional Offices for the Eastern Mediterranean, South-East Asia, and the Western Pacific. Forty-eight participants from 21 countries met to share information and review strategies on national laws covering traditional medicines, and policies and possible mechanisms to protect traditional medicine knowledge.

After intense and wide-ranging discussions participants made numerous recommendations including:

- Countries should have a national policy on traditional medicine as part of their national health policy, and should develop and use traditional medicine as an integral part of the national health care system.
- The organizational infrastructure of traditional medicine should be developed and/or strengthened and given official recognition.
- More technical cooperation among countries is needed to increase innovation. Indigenous and local communities should be involved in this.
- Traditional knowledge that is in the public domain needs to be documented in the context of traditional knowledge digital libraries in the respective countries.
- Traditional knowledge should be recognised in the form and concepts of countries’ traditional medicine systems, and not necessarily on a western model.
- Efforts should be made to use the flexibility provided under the TRIPS Agreement to promote easy access to traditional medicine for the health care needs of developing countries.

Regional meetings explore TRIPS

**Discussing strategy in Africa**

Fifty-two participants from 15 countries met in August for a workshop on TRIPS and TRIPS safeguards in relation to pharmaceuticals. They were drawn from ministries of health, justice, finance and trade/commerce. Representatives from the African Regional Industrial Property Organisation, Consumer Project on Technology and Médecins Sans Frontières also attended, and they were joined by faculty and experts from the World Health Organization (WHO), in collaboration with EMM.

Participants spend an evening assessing the implications of the TRIPS Agreement in a convivial atmosphere.

Regional Industrial Property Organisation, Consumer Project on Technology and Médecins Sans Frontières also attended, and they were joined by faculty and experts from the World Health Organization (WHO), in collaboration with EMM.

**Meeting on impact of TRIPS for European countries**

It was the turn of eastern European countries to focus on the TRIPS Agreement and its impact on access and prices of pharmaceuticals, at a high-level meeting in Warsaw, Poland, in September 2001. Once again raising awareness of the Agreement’s technical content and implications for public health, the meeting included presentations by representatives from each country on their experiences in implementing the TRIPS Agreement. Participants responded to the possibility of a “TRIPS and AIDS Medicines” declaration being made in Qatar by calling for coordination between ministries of health, justice, economic affairs and trade and patent offices, in order to present unified national positions (see p.4).

At one session prospective EU countries reviewed how trade and access related problems can be tackled within the framework of EU accession, and the implications of harmonizing legislation in the field of pharmaceuticals and trade.

Concluding the meeting Dr Tronczyński stressed that despite their political, economic and social differences, eastern European countries have common problems relating to access to essential medicines. And that – while TRIPS does not preclude WTO members formulating and implementing their own health policies and measures to protect public health, participants reviewed their options under the Agreement to import or produce drugs at reduced prices. Delegates heard that several governments have already sought to reduce the issue of access to HIV-AIDS medicines by stimulating parallel imports and low-cost production, and by negotiating lower prices with manufacturers.

**Coordination vital**

Welcoming international initiatives to monitor the implications of international trade agreements on access to medicines, delegates looked ahead to the 4th WTO Ministerial Conference, to be held in Qatar, in November 2001, urging that public health issues should be debated. Participants responded to the possibility of a “TRIPS and AIDS Medicines” declaration being made in Qatar by calling for coordination between ministries of health, justice, economic affairs and trade and patent offices, in order to present unified national positions (see p.4).

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Swiss Quality Circles: improving health care, reducing costs

One of the challenges faced by health professionals of all disciplines is to work together to improve quality of care while reducing its cost to society. With this in mind, in 1997 the Medical and Pharmacists’ Association in Fribourg, Switzerland, launched a pilot project called ´Physicians and Pharmacists Quality Circles for Drug Prescription´. Two years later, the Project’s founders presented their first assessment, showing encouraging results in human, professional and economic terms – and showing why others have much to learn from the Swiss experience.

Ambitious objectives, modest means

When the Quality Circles team launched its Project, with the backing of four health insurance funds, its objectives were clear. It wanted to: improve the quality of care; improve the relationship between local physicians and pharmacists; evaluate a method of interdisciplinary, locally run continuing education; and make the savings expected by political authorities and health insurance funds without sacrificing quality of care.

The Project’s initiators organized themselves into a Professional Interest Group, which coordinated the Circles’ work. They then negotiated with the Swiss Pharmaceutical Society’s Quality and Development Department to provide the Project’s documentation service. The Department does research and selection of current evaluated and comparative clinical and therapeutic data, economic data and international recommendations.

The Group also entered into a collaborative agreement with the Swiss Insurance Companies and Sickness Funds Billing Office, to obtain the statistics needed for drawing up a prescriber profile of each participating physician. This means the Group can monitor the Circles’ work and evaluate their impact.

The Office sells the data if confidentiality is guaranteed. All participating prescribers have the opportunity to update and expand their own knowledge before passing the information on to the doctors.

In their enthusiasm for the initiative, physicians and pharmacists met regularly. At exhaustive 2–3 hour sessions, they compared the risk/benefit of drugs in one or several classes and discussed drug prescribing patterns. Participants tried to agree a set of treatment options based on fixed objectives: first of all improving care quality, and secondly finding the most economical solutions. Once back in their surgeries, prescribers tried to put into practice the strategies that had been chosen collectively – the fruit of their hard work.

The Circles’ two first years reflect these health professionals’ commitment to working together, achieving the initial objective of improving relations between physicians and pharmacists. The Swiss General Practitioners’ Association now recommends that doctors take part in Quality Circles, counting this work as part of in-service training.

Impact

The Circles’ economic impact has been analysed by the Swiss Pharmaceutical Society. The Society used data from the Swiss Insurance Companies and Sickness Funds Billing Office to calculate the cost of drug prescriptions (corresponding to the topics addressed in the Circles) for the first seven months of 1997, and for the same period in 1998. These costs were compared to those of reference groups, drawn randomly from a list of doctors with practices comparable to those of physicians in the Circles.

Findings included that the overall cost of antibiotic and hypertensive drug prescriptions was higher in 1998 than in 1997, but less so in Circle prescribers than reference groups. The overall cost of painkillers, anti-inflammatory drugs and drugs to treat rheumatism fell by almost 4% between 1997 and 1998 in the Circles, while increasing in the reference groups. And there was a significantly higher increase in generic prescribing among the Circles than the other groups. For example, in 1998, the change in the proportion of generic drugs to treat hypertension was +11.7% among the Circles compared with +1.8% among the reference groups.

A thought-provoking example

The Swiss Physician-Pharmacist Quality Circles in Fribourg have demonstrated that health professionals are capable of launching a movement to reorganize health care at local level, without waiting for solutions “from above”. Circle members believe that the initiative could be extended to other parts of Switzerland or beyond, provided that all the partners involved in organizing care, and particularly insurers, participate.

Even if there is no guarantee that the community’s overall health costs will be lower, there is every reason to believe that health professionals are collectively capable of offering means of improving patients’ care. The Swiss experience is a source of fresh inspiration for health professionals in other countries.


For further information contact: O. Bugnon, Swiss Association of Pharmacists, Stationstrasse 12, CH-3097, Bern-Liesbefeld, Switzerland. Fax: + 41 31 978 58 39.

References


Box 1

The Project studied medical attitudes to:

■ Prescribing antibiotics for common infections in out-patient treatment;
■ Hypertension, heart failure, angina pectoris and postinfarction;
■ Rheumatism, muscle pain and prevention of the undesirable effects of non steroidal anti-inflammatory drugs;
■ Blood lipid disorders and prevention of cardiovascular disease;
■ Depressive and/or anxious patients;
■ Sleep disorders;
■ Generic substitution;
■ Therapeutic innovations;
■ Drug interactions.

While the Professional Interest Group ensured coordination of the Circles’ work, the pharmacists were responsible for the links between the Group and the Circle to which they belonged. The pharmacists held monthly meetings with the Swiss Pharmaceutical Society’s Quality and Development Department, to obtain current scientific and economic data on the topics the Circles studied. This gave them the opportunity to update and expand their own knowledge before passing the information on to the doctors.

Physicians-Pharmacists Quality Circles

Generic substitution between 1997–1999

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Graph: Q. Bugnon, Swiss Association of Pharmacists.
Street theatre reinforces rational use message in Delhi

Extravaganza among the office blocks of central Delhi can be found a true mix of communities, from slum dwellers to middle income households, and this was the area chosen recently for an interesting experiment in promoting rational drug use. University students and NGOs joined with the Delhi Society for Promotion of Rational Use of Drugs to celebrate “Health” Month in August 2001 – designated the Year of Women’s Empowerment – by performing street theatre to convey key messages on medicines use.

Before the performances, a survey of 100 households in central Delhi set out to discover what women in the locality knew about using drugs correctly. Results showed that 50% of women administered prescription drugs without prescription, 19% were unaware of expiry dates and only 50% knew of oral rehydration solution to treat diarrhoea. Consulting neighbours or unlicensed “doctors” or resorting to self-medication of prescription-type drugs for serious health problems were common practices. Spurred on by the survey results, the Delhi Society for Promotion of Rational Use of Drugs collaborated with Delhi University’s Women’s Studies and Development Centre to design a series of street play performances to be given at nine locations in the city.

Laughter and tears

The production teams responded with great creative enthusiasm. For example Indrapratha College produced a series of stark and powerful vignettes, exposing the links between drug dealers and unethical (unscrupulous?) doctors. Gargi College used comic satire by having “Santo Tai”, a traditional matronly figure, as the central character. Delving into her bag of “home remedies” she innocently and foolishly causes sickness and harm, never admitting that “a little knowledge is a dangerous thing”. The NGO group Mohak adopted a sombre note in showing the death of a child because of “A Small Mistake”, as the play was called, depicting the tragedy brought to a family by wrongly prescribed and wrongly bought medicines.

Good response

So what impact did this innovative approach have? In the poorest area, where the original survey took place, 500 people came to watch the play. Each performance, whether in educational institutions, in communities or gardens, drew its own range of audience. The teachers overseeing the Women’s Development Centres carefully warned rational drug use messages into the plots. The college students who wrote the scripts and directed the productions said that they too were now more aware of the correct use of antibiotics.

For further information contact: Delhi Society for Promotion of Rational Use of Drugs, National Institute of Immunology, Aruna Asaf Ali Marg, New Delhi – 110 067, India. Fax: 9111 616 2125, e-mail: dsprud@satayam.net.in

Humanitarian agency’s essential drugs policy

An endorsement of the essential drugs concept, the International Federation of Red Cross and Red Crescent Societies’ General Assembly has adopted a comprehensive essential drugs policy. The Agency noted that despite the “ever increasing production and distribution of pharmaceuticals, acute shortages and irrational use of essential drugs are prevalent in most parts of the world. Moreover, the emerging and re-emerging diseases, epidemiological transition and increasing resistance to drugs have compounded the problem.”

The policy forms the basis of guidelines geared to ensuring provision of good quality essential drugs. It outlines responsibilities within emergency response operations and long-term development programmes. It also underscores the links between pharmaceutical and other primary health care activities.

The Federation’s policy statement commits to:

- implementing an essential drugs programme as part of broader health policy, with national societies involved in implementing essential drugs programmes where necessary and feasible;
- basing selection of drugs and medical supplies primarily on the national list of essential drugs, or if unavailable or incomplete on the WHO Model List of Essential Drugs;
- using generic names in drug selection and procurement;
- adopting a procurement strategy that ensures the availability of drugs of good quality, safety and efficacy at the lowest possible price without undermining financial sustainability;
- applying the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and other quality assurance methods in the procurement process;
- organizing storage and distribution systems which promote efficiency and ensure drug quality;
- requesting donors to provide essential drugs with an acceptable length of shelf-life and adopting the interagency Guidelines for Drug Donations;
- promoting the rational procurement, distribution, prescription, dispensing and consumption of pharmaceuticals at all levels. In order to achieve these, organizing educational activities for health workers and consumers in collaboration with national and international organizations, and formulating guidelines on sound supply and management systems;
- undertaking activities at country level to support relevant ministries in the development of national drug policies and legislation promoting the essential drugs concept and participating in its implementation.

At the same time as updating its drugs policy, the International Federation of Red Cross and Red Crescent Societies has issued a policy statement providing principles and guidelines for the implementation of quality procedures in blood programmes. The Federation either provides or assists in the provision of at least one-third of the world’s blood supply.

Modernising patient treatment in Nepal

Nepal’s 4,000 health posts and sub-health posts – where 80% of the population obtain basic health services – have received eagerly awaited copies of their new standard treatment guidelines. Published by the Department of Drug Administration and Management Sciences for Health, the 3rd edition of the Guidelines for Drug Administration and Management Sciences for Health, the 3rd edition of the National Institute of Immunology, Aruna Asaf Ali Marg, New Delhi – 110 067, India. Fax: 9111 616 2125, e-mail: dsprud@satayam.net.in

A dramatic moment in one of the street theatre performances

A village health worker and his young patient in Nepal. All health workers are benefiting from the updated standard treatment guidelines.

This is the second revised edition of a pocket-sized guide to the rapid diagnosis and management of severe P. falciparum malaria. In view of the complexities of management, the need for speed, and the severe consequences, it guides the selection of new drugs in a didactic approach. It offers an at-a-glance reference to the signs to look for, the tests to perform, the actions to take immediately and later, and the nursing care required. Special problems addressed throughout the book include the tendency of malaria to mimic many other diseases, the difficulty of diagnosis in cases of self-medications, the spread of parasite resistance to chloroquine and other drugs, and the need for special precautions in areas where blood may be contaminated with the human immunodeficiency virus (HIV).

Addressed to doctors and other medical staff, the book is designed to facilitate rapid decisions and immediate action. Fold-out flaps on the inside and back covers guide the correct selection, dosage, and administration of antimalarial drugs, provide a map showing the global status of chloroquine resistance, and summarise the immediate steps to take when faced with the many complications. Coloured tab dividers make it possible to flip to the appropriate section containing full details on the clinical features and management of a given complication, the general principles of management and nursing care that apply to all patients, and the special protocols to follow when treating children and pregnant women.


This is a list of common stems for international nonproprietary names (INNs) for pharmaceutical substances for which chemical or pharmacological categories have been established. These stems and their definitions are intended to guide the selection of new INNs (generic names) for substances that belong to an established series of related compounds. The list aims to encourage consistency in the designation of generic drug names while also protecting the principle that INNs are public property.

In two main parts, the publication first gives common stems and their definitions for 23 categories of drugs, the second part provides an alphabetical list of recommended stems and the corresponding family of INN. The publication is intended for manufactur- ers engaged in research and development, trademark officers and national regulatory authorities, and teachers of medicinal chemistry and pharmacology.


WHO Model Prescribing Information provides up-to-date, independent clinical information on essential drugs, including details of dosages, uses, contraindications and adverse effects. It is intended as source material for adaptation by national authorities, in particular in developing countries, that wish to produce drug formularies, data sheets and teaching materials.

Although many communicable disease and effective contained, bacteri- al infections remain a major cause of morbidity and mortality, particularly in de- veloping countries. This new volume of Model Prescribing Information includes drugs for the treating respira- tory, gastrointestinal, urinary, personal, dental and cardiovascular infections. It also covers sepsis, endocarditis and infections of the skin, soft tissues, bones and joints, sexually transmitted diseases and other commonly encountered infections. As the increasing prevalence of strains of com- mon pathogenic bacteria resistant to widely available, affordable antimicrobials is, in many cases, dangerously eroding their effectiveness, general principles of anti- microbial prescribing are discussed.


This report of a situation analysis on drug availability and drug quality in the West Bank and Gaza Strip concludes that both are generally satisfactory, with major disruptions of sup- ply only occurring as a result of political turbulence. The document provides demographic, socioeconomic and epidemiological background, followed by an overview of the health care system. It then focuses on pharmaceutical issues, with a series of recommendations on improving drug policy.

Available, free of charge, from: Department of Essential Drugs and Medicines, World Health Organization, 1211 Geneva 27, Switzerland.

Important

The Department of Essential Drugs and Medicines Policy cannot supply the publications reviewed on these pages unless stated otherwise. Please write to the address given at the end of each item.

Published Lately

Management of the Child with a Serious Infection or Severe Malnutrition, Guidelines for Care at the First-referral Level in Developing Countries, World Health Organization, 2000, 162 p.

Intended for doctors and senior nurses in small hospitals, the manual aims to provide all the practical and technical guidance needed to facilitate quick decisions and life-saving interventions. Although advice on outpatient care is included, the manual concentrates on the inpatient management of children known to be the major killers of chil- dren in the developing world. Conditions covered range from pneumonia, diarrhoea, and severe malnutrition to meningitis and measles.

The manual follows a logical, sequen- tial approach to management that relies on a limited number of drugs, laboratory investigations and practical procedures. Recommended lines of action combine the latest clinical knowledge with extensive practical experience concerning what works best when resources, drugs, and equipment are limited. Throughout, charts, tables, model forms, alerts to common errors and step-by-step instructions enhance the manual’s value as a practical tool.


The book contains a comprehensive list of names for radicals and groups used in the WHO system for assigning international nonproprietary names (INNs) for pharmaceutical substances. Names for radicals and groups arise from the need to provide modified names for the salts or esters of substances already identified by an INN. In view of the complex compo- sition of many radicals and groups, use of the chemical nomenclature is inconvenient and shorter nonproprietary names are therefore selected. The list also includes reference to two- word INN, and to British, Japanese and United States Accepted Names for the radicals, groups, and additives published or accepted for use by the national nomenclature committees.


This case history describes the develop- ment of the Bhutan Essential Drugs Programme – one of the best in the region – from 1984 to 1998. The approaches taken and lessons learnt during this period are described in detail for areas such as drug selection and rational use, store management, inventory management, drug procurement and quality assurance.

Available, free of charge, from: Department of Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland.

This comprehensive book documents the traditional knowledge and use of African medicinal plants. In total more than 5,400 plants from the sub-Saharan region are listed, together with over 16,300 medicinal applications, giving the plant part used, preparation method and dose.

Plants are arranged alphabetically by their scientific names. A supplement to the book gives an alphabetical list of diseases and ailments, with a numbered search system for the relevant plants. The publication is primarily intended for scientists looking for medicinally active plants for further research, and will also be of interest to botanists, biologists and ethnologists.


Health programmes in which patients pay fees for services generate much-needed revenue but also raise important concerns. For example, do user fees limit access to health services by the poor? How can people receive the health services they need even if they cannot pay for them? Some countries have developed mechanisms to protect the poor from the negative effects of user charges; do these protection mechanisms work?

This book examines user fee systems in five countries: Ecuador, Guinea, Indonesia, Kenya and Tanzania, to answer these questions and to make recommendations for policy experts and decision-makers. In many instances, user fees have reduced the access of the poor to health services, often because exemption mechanisms are poorly designed or implemented. In other cases, fees have resulted in improved access to and quality of services. The book synthesises lessons from these five countries and other studies, and the authors identify issues that must be addressed to protect the poor, and provide guidelines for designing and managing user fee systems.


Declining government resources for health and increasing demand have led many countries to seek funding for health services by charging users. Although these user fee systems usually incorporate mechanisms to protect the poor, the mechanisms often do not work well. This guide offers suggestions for making new or existing user fee systems more equitable. It helps policy-makers and programme managers decide what information they need before introducing fees, and advises on the types of mechanisms available to protect the poor, their effectiveness and cost.

Available from: Management Sciences for Health, 165 Allandale Road, Boston, MA 02130, USA. Tel: +1-617-524-7799, Fax: +1-617-524-2825, e-mail: books@msh.org
Publications are free of charge to people in Africa, Asia and Latin America. Contact MSH for details of prices elsewhere.


WHO has developed these general guidelines to respond to the question of what types of academic research approaches and methods can be used to evaluate the safety and efficacy of traditional medicine. The guidelines consist of sections on herbal medicines, on traditional procedure-based therapies, on clinical research, and related issues including ethics, education and training, and sustainability of systems.

The specific objectives of the guidelines are to: harmonise the use of certain accepted and important terms in traditional medicine; summarise key issues for developing methodologies for research and evaluation of traditional medicine; improve the quality and value of research in traditional medicine; and provide appropriate evaluation methods to facilitate the development of regulation and registration in traditional medicine.

Available free of charge, from: Department of Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland.


This document presents information on new national regulatory decisions and on voluntary withdrawal of products by manufacturers on grounds of safety, that were reported to WHO up to December 2000. Products are listed alphabetically within sections, with international nonproprietary names used wherever possible. Each product entry includes, where available, the product’s country of origin; the approval, registration, and synonyms including other generic names and chemical name; the effective date on which the restriction came into force; a summary of regulatory measures taken by governments; brief explanatory comments where necessary; and legal and bibliographic references. While the information given is not exhaustive, either in terms of products or regulatory measures, the document covers regulatory actions taken by a total of 41 governments on 76 products

This is the second update to the Sixth Issue of the United Nations Consolidated List of Products whose Consumption and/or Sale have been Banned, Severely Restricted or Not Approved by Governments – Pharmaceuticals. It is intended for drug regulatory health authorities and health professionals interested in assessing and rational use of drugs.

Available, free of charge, from: Department of Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland.


One in four people in the world will be affected by mental or neurological disorders at some point in their lives. Around 450 million people currently live with such conditions, placing mental disorders among the leading causes of ill-health around the world. Worldwide, treatments are available, but nearly two-thirds of people with a known mental disorder never seek help from a health professional. Stigma, discrimination and neglect prevent care and treatment from reaching people with mental disorders, says WHO’s World Health Report 2001.

With the Report WHO seeks to break this vicious cycle and urges governments to find solutions for mental health that are already available and affordable. Policy-makers should move away from large mental institutions and towards community health care, integrating mental health care into primary health care and the general health care system, the Report states.

The Report invites governments to make strategic decisions and choices in order to bring about positive change in the acceptance and treatment of mental disorders. It states that some mental disorders can be prevented; most mental and behavioural disorders can be successfully treated; and that much of this prevention, cure and treatment is affordable. Over 80% of people with schizophrenia can be free of relapses at the end of one year of treatment with antipsychotic drugs combined with family intervention. Up to 60% of people with depression can recover with a proper combination of antidepressant drugs and psychotherapy. Up to 70% of people with epilepsy can be seizure free when treated with simple, inexpensive anticonvulsants. According to the Report the responsibility for action lies with governments. Currently, more than 33% of countries allocate less than 1% of their total health budgets to mental health, while another 33% spending just 1% of their budgets on it. A limited range of medicines is sufficient to treat the majority of mental disorders. But about 25% of countries do not have the three most commonly prescribed drugs used to treat schizophrenia, depression and epilepsy at the primary health care level.

The poor often bear the greater burden of mental disorders, both in terms of the risk in having a mental disorder and the lack of access to treatment. Constant exposure to stressful events, dangerous living conditions, exploitation, and general ill health all contribute to greater vulnerability. Lack of access to affordable treatments accelerates the course of the illness more severe and debilitating, leading to a vicious circle of poverty and mental health deterioration.

WHO’s message in the Report is that every country, no matter what its resource constraints, can do something to improve the mental health of its people. It requires is the courage and the commitment to take the necessary steps.


World Health Organization is the agency designated for the evaluation of the medical, scientific and public health aspects of psychoactive substances under the Single Convention on Narcotic Drugs, 1961 (amended by the 1972 Protocol), and the Convention on Psychotropic Substances, 1971. An assessment procedure has been developed following resolutions of the World Health Assembly and the United Nations Commission on Narcotic Drugs. This document sets out guidelines dealing with the underlying principles of the review procedure, working arrangements within the WHO Secretariat and with external bodies, and the nature of the documentation to be prepared. The guidelines cover WHO’s responsibilities on whether or not to recommend international control of substance, as well as the assessment of exempted preparations.

Available, free of charge, from: Department of Essential Drugs and Medicines Policy, World Health Organization, 1211 Geneva 27, Switzerland.
Attention Deficit/Hyperactivity Disorders: Their Diagnosis and treatment in Developing Countries. Drug Trafficking in Drugs (Pompidou Group), Council of Europe, 2000, 113 p.

The rise in the number of stimulants being prescribed to treat attention deficit/hyperactivity disorders has led to increasing debate over the use of drugs to treat child sufferers. In December 1999 the Pompidou Group (an intergovernmental body) and WHO organized a meeting to exchange information on the situation in Europe. This report of the meeting focuses on two European studies presented to participants: one on social and cultural factors, and the second on diagnosis and treatment practices in Europe. It also includes the meeting’s recommendations on improving the availability of proven medication and the quality of service delivery, whilst avoiding stimulant abuse and diversion of drugs to the illicit market.

Available, in English and French, from: Centre of Europe Publishing, F-67075 Strasbourg Cedex, France. Tel: +33 (0) 3 88 41 25 81, fax: +33 (0) 3 88 41 39 10, e-mail: publishing@coe.int Web site: http://book.coe.fr Price: Frs 85/US $ 21.


This paper provides some reflections on the review of the TRIPS Agreement required under Article 71.1, noting the need for a full review of the Agreement from a development standpoint. This is in line with the decision of WTO Members at the General Council Meeting of 7 February 2000, which provides that “the General Council also agreed that mandated reviews should address the impact of the agreements concerned on the trade and development prospects of developing countries.” The paper suggests that the review should carefully examine the impact of implementing the Agreement will have on developing countries and the options available to them.

In the second section, the document discusses the scope of the review, while part three explores a number of issues that developing countries have identified as relevant. It begins by examining the TRIPS Agreement’s objectives and principles, including the need to maintain a balance of rights and obligations. The authors then look at what it is important for WTO Members to gain understanding of the potential impacts of implementing the Agreement on the transfer of technology, and on developing countries and the options available to them.


This paper builds on the analysis of non-violation complaints included in Occasional Papers No. 3 in this series that examined the Article 71 review of the TRIPS Agreement (see above). It explores in more detail the concerns raised by non-violation complaints, and concludes that WTO Members should not apply these complaints to TRIPS. As a step towards this goal, it recommends that WTO Members extend the moratorium on the application of the non-violation remedy until further experience is gained with the Agreement’s implementation.


From the developing country perspective, protection of plant varieties raises fundamental political, economic, social, biodiversity and other questions. The rights of plant breeders to be protected include authorising the use of their varieties as well as their propagating material. This affects access to propagating material (seeds) by local or rural communities that in developing countries make up to 90% of the population, who meet their agricultural, food and financial needs from (subistence) farming.

The author argues that farming communities have a well established practice of saving, sharing and replanting seed (farmers’ rights) which may be threatened if plant breeders’ rights are protected in a way that restricts or even destroys this practice. As well as equity concerns, the issue of food security is also involved. Plus, over the years these communities have identified, selected and bred plant varieties of food or medicinal value, conserving and sustaining this genetic diversity. WTO Members should be aware of their capacity to maintain a balance of rights and obligations by establishing exceptions to the rights of, and applying obligations to, title-holders.

Diagnosis and Treatment – A Training Manual for Primary Health Care Workers, K. Birrell, G. Birrell, 2000, 272 p.

This manual teaches primary health care workers how to diagnose and treat the most common illnesses that present at rural and urban health centres, prescribe rationally and in line with WHO and national guidelines; and deliver good patient care with scarce resources.

Lesson plans are based on successful training courses developed by VSO (Voluntary Service Overseas) doctors, national doctors and health workers. The manual also incorporates information from over 30 health experts and practitioners worldwide.

It can be used as a self-study guide and as a reference manual. Twenty-three appendices give more detailed practical information about diagnosis, treatment and procedures, and include reference charts, a glossary, progress checklists for trainers and students, and a list of medicines and their uses.


A new publication from the British Columbia’s Centre for Health Services and Policy Research points to what it sees as some disquieting realities in the modern pharmaceutical sector. Tales from the Other Drug Wars is assembled from papers presented at the 12th Annual Health Policy Conference in Vancouver. Its contributors examine what they view as pharmaceutical manufacturers’ successful infiltration and “skewing” of the research and drug approval process, to improve not patient health but profit. The authors argue that a coherent industry strategy is emerging, aiming to pressure or co-opt researchers, regulators, providers and consumers.

The publication notes that critical voices in research have been singled out for oppressive silencing tactics in Canada and internationally. It concludes that the aim is to leave industry-sympathetic research free to develop drugs which often only provide minor therapeutic advantage, but which can be aggrandized into major marketing promotions for the “management” of industry-defined “conditions”.

Available from: Centre for Health Services and Policy Research, University of British Columbia, 429-2394 Health Services Mall, Vancouver, BC, V6T 1Z3, Canada. Price: Canadian $10 plus postage and handling. Also available on the Web at: www.chspr.ubc.ca

Gesundheit für Alle oder nur für die Pharmaindustrie? (Health For All or Only For the Pharmaceutical Industry), BUKO Pharma-Kampagne, 2000, 28 p.

This series of articles expresses the authors’ concern that a new law they believe is currently problems created by the pharmaceutical industry. The major issues covered include: direct consumer advertising, with examples from Germany and India, the dangers of drugs being sold on the Internet, and difficulties which can arise from public-private partnerships and inappropriate drug donations.

Available, in German only, from: BUKO Pharma-Kampagne, August-Bebel Str. 62, 33602 Bielefeld, Germany. Fax: +49 521 67396, e-mail: bukopharmakampagne@compuserve.com Price: DM14, including postage.

Updates on new formulations, treatment guidelines, essential drugs lists, drug bulletins and newsletters

The Department of Essential Drugs and Medicines Policy produces a global index of formularies, therapeutic guides and essential drugs lists, which is available free of charge. (Please note that we are unable to supply copies of the publications themselves. Requests should be addressed direct to the countries concerned.) Some recent additions are:

- India. Himachal Pradesh State: Standard Treatment Guidelines 2000. Department of Health and Family Welfare. The conditions included are based on the morbidity pattern and on consensus between a committee of experts and the many end users consulted.
- Malaysia. National University Hospital of Malaysia: Drug Formulary 2000. Drug Information Centre of the Pharmacy Department, National University Hospital. Includes advice on prescription writing.

Drug bulletins and newsletters

Action Against Infection is a WHO newsletter which provides a forum for discussion and communication among all those committed to taking action against infectious diseases. Full of news and reviews on projects and meetings, it is available monthly, free of charge, in English, French and Spanish. To be put on the mailing list contact: CDS Information Resource Centre, World Health Organization, 1211 Geneva 27, Switzerland.

Pharma-Link is the recently launched Russian-language newsletter of the Ecumenical Pharmaceutical Network. Intended for readers in the Newly Independent States, the first issue contains articles on antiretroviral prices, access to essential drug information, and the World Bank and pharmaceuticals. For further information contact De Natalia Cebotarenco, Director, DrugInfo Moldova, 11/22 Moscovska St, Chisinau, Moldova. E-mail: natalie@drugs.mldnet.com or epn_nis@yahoo.com

APUA Newsletter (Alliance for the Prudent Use of Antibiotics) is now available in Russian. The contact address is the same as for Pharma-Link above.
E S S E N T I A L   D R U G S   M O N I T O R

Issue No. 30, 2001

Research and Development for MSF: Access to medicines

NGOs campaign for treatment access

Some recent publications

MSF: Access to medicines campaign
www.accessmeds-msf.org

Fatal Imbalance


This is the first in a series of papers that will analyse the human development impact of transnational corporations. It reviews the role of GlaxoSmithKline, a UK-based pharmaceutical company, and outlines what Oxfam views as the three critical challenges facing this and other global pharmaceutical companies wishing to increase access to medicines. The paper states that in order to ensure that changes in global intellectual property protection do not increase the price of medicines in developing countries, secondly, companies must meet the acute need for research and development into diseases associated with poverty. Finally, the paper highlights the need to curb corporate marketing and lobbying activities when they run “counter to the public interest”. Oxfam be- lieves that if companies fail to meet these challenges they face the threat of more stringent government regulation and loss of public support.


The second in Oxfam’s Company Briefing Papers focuses on the world’s largest pharmaceutical firm, Pfizer. It calls on the company, which owns three important drugs for infectious diseases, to be more flexible on pricing and patent enforcement in poor countries.


Less than 5% of people living with HIV/AIDS in Thailand has access to the anti-retroviral medicines needed to combat the virus – mainly because of the high cost of drugs. Although some versions of HIV/AIDS medicines exist, mostly patients depend on expensive brand-name products from multinational pharmaceutical companies. Oxfam says. According to this paper, these either have their market protected by patent or through market exclusivity rights, which result in effective monopolies over medicines. Oxfam explains the way in which key external actors have secured these conditions through what the Organization views as the threat of trade reprisals and other forms of pressure, and illustrates what terms “the devastating impact” this has had. The paper argues that this situation has been contributed to by the effects of TRIPS Agreement in the pharmaceutical sector.


The document argues that with millions already unable to afford essential medicines, and public health threatened by new diseases and drug-resistant variants of old killers, WTO patent rules will further reduce access to modern medicines for the poor. The paper sets out Oxfam’s concerns about the way management of the international trading sys- tem puts corporate interests before poverty reduction. It describes the health crisis in developing countries, before examining what Oxfam believes are the likely adverse effects of WTO patent rules on drug prices and on local pharmaceutical industries. The authors discuss governments’ role in filling the gaps in pharmaceutical research and increasing health sector support. The document con- cludes with a series of recommendations, focusing on TRIPS reform, and on the need for rich countries and transnational companies to stop pressuring developing countries on patent issues.


This paper Oxfam argues that by re- stricting the right of governments to allow parallel imports of generic medicines, WTO rules will restrict competi- tion, increase prices and further reduce the limited access of developing countries to vital medicines. The paper states that the implementation of WTO patent rules is tak- ing place against the backdrop of a sustained campaign led by the pharmaceutical indus- try. Oxfam believes this campaign may well erode the public health protection offered by safeguard provisions in patent legislation, such as compulsory licensing and parallel imports. The document looks at the role of public-private initiatives in making medi- cines more widely available. It argues that the main problem with them is that drugs are often offered in limited quantities, and at prices which compare unfavourably with ge- neric-equivalent products. Oxfam makes eight recommendations for immediate action to improve access to medicines.

VSO: Treatment for life campaign
http://www.vso.org.uk/


As part of its campaign to increase drug access for people living with HIV/AIDS, VSO has produced a new report, based on their research in India, Kenya and Uganda. Street Price suggests that a new approach to equity pricing is necessary, moving away from what the authors view as the current ad hoc initia- tives. They advocate a global approach that takes into account, amongst other things, minimum prices, the range of products being offered, equity between developing countries and the sustainability of price re- ductions. VSO has developed a set of criteria that it believes must be met if any solution to the problem of drug prices for developing countries is to be found.

VSO proposes that the international com- munity must set up a new, equitable pricing framework, based on the needs of de- veloping countries. It advocates a simple framework which delineates global “essential regulation”, which expands and systematizes elements of existing initiatives and which operates under the remit of an existing UN organization.

Within the framework VSO proposes that each pharmaceutical company, both generic and research-based, should offer a price at or approaching marginal cost for each of their HIV/AIDS drugs (including those for pa- tient care and opportunistic diseases) to eligible developing country purchasers. Street Price states that companies’ low levels of access for rich countries is to be found. VSO proposes that the international com- munity must set up a new, equitable pricing framework, based on the needs of de- veloping countries. It advocates a simple framework which delineates global “essential regulation”, which expands and systematizes elements of existing initiatives and which operates under the remit of an existing UN organization.

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A ny national drug policy should be concerned not only with the supply of safe, effective and appropriate drugs for the country but also with the way that they are prescribed and dispensed by health personnel. Patient demands and beliefs are other major factors influencing prescribing patterns. In recent years there has been growing concern in countries worldwide about the rising cost of health care, and of drug treatments in particular. The Sultanate of Oman is no exception, and policy makers firmly believed action had to be taken immediately to maximise the use of available health resources and to minimise waste. Oman took a bold new initiative by establishing a Directorate of Rational Drug Use, which came into being on 15 April 2000 as a result of a Ministerial Decree.

Oman’s population is 2.33 million (1999) in a country of about 312,000 sq km. Administratively, the country is split into 10 regions, with Muscat Region around the capital city the most densely populated. The Sultanate has a very progressive health system, which has grown dramatically over the past 30 years, and Oman recently had the distinction of receiving top ranking in the index of performance on the level of health in a WHO global review.1 Health services in the public sector are free, with patients paying only a minimum fee of 1 Rial (approximately US$ 2.59) for annual registration and 200 baisa (the equivalent of 52 cents) for each subsequent visit.

The Directorate reports to the Office of the Undersecretary for Health Affairs, and has been given the prime responsibility to research all aspects of irrational prescribing, dispensing and drug use (see figure 1). It is staffed full time by an Omani Director who is a clinical pharmacologist, a Senior Medical Officer, a Specialist Clinical Pharmacist and a Secretary. It is currently recruiting more staff.

Profiling prescribing practices

The Directorate began by undertaking baseline studies using the WHO core indicators for prescribing and dispensing.2 This is resulting in the creation of a quantitative and qualitative knowledge base about current practices across the nation (see figures 2 and 3). In addition to these core indicators, prescriptions are examined during the study process. Any prescription which appears to be irrational is put aside for review and patients’ case notes are examined where necessary. Finally these prescriptions are grouped and catalogued according to any specific problems found. As a result, a profile of prescribing practices is rapidly accumulating.

To date most of the studies have been conducted in and around the capital, Muscat, at three levels of care, with data gathered from three major hospitals, one psychiatric hospital and three large health centres or poly-clinics. Now the Directorate plans to extend these studies to all regions of the country. Preliminary site visits to some regions have revealed similar problems but also many unique issues need to be examined. It is hoped that the whole country will have been covered by the end of 2001. Once this has happened a group from the Directorate and key officials in the Ministry of Health will meet to discuss priorities and possible interventions. Further studies will be carried out to measure outcomes and the impact of such interventions.

Irrational drug use has many facets, and the Directorate is tackling the problems on a variety of fronts. High priority has been given to training and further education. Collaborative projects with the Medical School at Sultan Qaboos University and the Oman Institute for Assistant Pharmacists have been set up so that the principles of rational prescribing and drug use are included in the teaching. Lectures will be given by Directorate staff at each of the institutions on a variety of topics, including writing a legal and rational prescription, rational pharmacotherapy, the concept of (personal)-drugs’, therapeutic objectives, the importance of generic prescribing, and public education and counselling.

Oman is not yet self-sufficient in the supply of health care professionals, and recruitment of physicians takes place from many countries around the region and from the Asian subcontinent. These physicians come with a wide range of backgrounds, experiences and practices. As a part of a new initiative the Directorate is actively involved in the interview process and sets a separate examination paper as part of the overall recruitment examination. In addition it has been decided that the Directorate will begin an induction workshop for each batch of new physicians starting employment at the primary care level in the Sultanate. In this way new doctors will be introduced to the use of standard treatment guidelines and protocols, the Oman National Formulary and the Health Centre Formulary, as well as the major principles mentioned above.

Public education is another important sphere of activity for the Directorate. One of the physicians recruited to the Directorate already has a background of research into communication and promotional strategies for public education in rational drug use. It is hoped to extend these studies in a number of areas. One advantage is that Oman has a good infrastructure in place and there is widespread access to mass media. A knowledge, attitudes and practices (KAP) survey is planned for the near future.

Encouraging dialogue

Another area of influence for the Directorate is in the facilitation and monitoring of hospital or regional drug and therapeutics committees. It is anticipated that if these committees are well structured and meet regularly then much useful groundwork on rational prescribing, dispensing and drug use can be achieved. The committees’ structure is designed to allow maximum dialogue between pharmacists and prescribers and to allow for problem-solving and new initiatives to be generated, for example, the establishment of a local formulary.

Directorate staff have been actively involved in these committees centrally and regionally, and uniformly find great enthusiasm amongst the participants. The Directorate plays a high profile role in workshops, seminars and conferences regionally and nationally. These gatherings provide the opportunity to present on key topics, and to raise awareness of the Directorate’s work.

In summary, Oman has been very proactive and forward-thinking in establishing the Directorate of Rational Drug Use. By giving responsibility to a single body it should be easier to study problems of irrational use and to make interventions as quickly as possible. It is now up to the Directorate to produce results. It is certain that many countries will be interested to learn the outcomes of the work carried out in Oman.


References