Promoting science or sales?

In 1994, the Monitor focused on how medicines were being marketed and the potential impact provoking prescribing and treatment outcomes. Many of the concerns highlighted in that issue continue to be raised by health professions, consumer groups, scientific journals, academic researchers and meetings of WHO governing bodies. For this reason the Monitor returns to the subject — to challenge the prescription of drugs. Over the years, as new concerns have arisen, so too has the body of evidence linking promotion to the use of newer, more expensive but not necessarily more effective medicines (see page 18). One example is the study by Wazana reported on page 22, which involved a systematic review of evidence of how promotion affects doctors' behaviour. Recent research by the US National Institute for Health Care Management Research and Educational Foundation shows that direct-to-consumer advertising, a subject of great topical debate, may be inducing what it terms "significant, and potentially inappropriate, demand for prescription drugs". The Foundation reports that sales of the 50 most heavily advertised drugs in the USA rose an aggregate 32% from 1999 to 2000, compared to 13.6% for all other prescription drugs. Currently only two developed countries, the USA and New Zealand, permit such advertising, and a Lancet editorial (18 May 2002) concludes that experiences in these countries show potential for conflict of interest and biased research. The quote from a drug advertisement now in tablet form" makes chilling reading. In 1999 drug promotion was identified by the WHO/Public Interest NGO Pharmaceuticals Roundtable as a priority for technical collaboration, partly in recognition of the need for more evidence of the effects it has on public health. One outcome is the first comprehensive global database of studies and other material on drug promotion, which has been launched as part of this joint clinical trials database, complementing the Helsinki Declaration drawn up to protect trial subjects. Informed clinical decision-making, good prescribing practice and optimal treatment outcomes critically depend on an evidence base that is free from commercial bias, and access to comprehensive scientifically authenticated information. Many countries are increasingly basing their clinical guidelines and reimbursement decisions on a systematic review of all available evidence. Examples include the Scottish Intercollegiate Guidelines Network and the Pharmaceutical Benefits Scheme in Australia. On the other hand, promotion efforts also put considerable pressure on prescribers, and increasingly the general public. While informed and motivated prescribers can have access to unbiased information, this is much less the case for the public. Governments, regulatory agencies and professional organizations need to ensure that all information on medicines provided to prescribers and consumers, and the research on which it is based, contribute to better science and treatment outcomes rather than sales.
Editors act on clinical trial reporting

**CONFLICT OF INTEREST**

The editors have explained the background to this tougher policy in a statement issued simultaneously in their journals, the key elements of which we reproduce in the box. 

The full text of the editors’ statement is available on the web at: http://www.icmje.org/sponsor.htm.

---

"As editors of general medical journals, we recognise that the publication of clinical research findings in respected peer-reviewed journals is the ultimate basis for most treatment decision making. Public and private health-care policy are determined in large part by the scientific practice of medicine because it shapes treatment decisions made by physicians, and drives public and private health-care policy. We are concerned that the current intellectual environment in which some clinical research is conceived, studied, and published, undermines the capacity of the journal to maintain a fair and dispassionate view. This is due to the self-interest of the journal as the basis for editorial policy. As part of the reporting requirements, the journals will routinely demand that authors disclose details of their own and the sponsor’s role in the study. Many of the journals will ask the responsible author to sign a statement indicating that s/he accepts full responsibility for the conduct of the trial, had access to the data, and controlled the decision to publish.

The editors have explained the background to this tougher policy in a statement issued simultaneously in their journals, the key elements of which we reproduce in the box.

The editors assert their belief that authors submitting papers to them will be required to declare that they have the right to publish any and all of their data, whatever the sponsor’s views. Without that and other written assurances, articles will not be considered for publication.

Writing in the Journal of Neurology, Neurosurgery, and Psychiatry (2002; 72:143) the editors state that “Corporate sponsors must not be allowed to influence publication, or indeed to prevent it, especially when the data are not supportive of their product.” The 14 neurology journals, like others, already require authors to sign a statement of their financial arrangements with public, private, and industry sources of support. But the journals say that non-financial conflicts of interest between authors and corporate sponsors are of equal concern and require attention.

**Academic freedom**

The editors assert their belief that manuscripts submitted to their journals are the intellectual property of the authors, not the study sponsor. They argue that “academic freedom includes the right of authors to have access to all of the data obtained in their study, to review it, obtain statistical analyses independently, and to publish their data based on their own decisions and not those of the financial sponsor.”


---

More journal editors voice their concerns

Editors of 14 leading neurology journals have announced that authors submitting papers to them will be required to declare that they have the right to publish any and all of their data, whatever the sponsor’s views. Without that and other written assurances, articles will not be considered for publication.

Writing in the Journal of Neurology, Neurosurgery, and Psychiatry (2002; 72:143) the editors state that “Corporate sponsors must not be allowed to influence publication, or indeed to prevent it, especially when the data are not supportive of their product.” The 14 neurology journals, like others, already require authors to sign a statement of their financial arrangements with public, private, and industry sources of support. But the journals say that non-financial conflicts of interest between authors and corporate sponsors are of equal concern and require attention.

**Academic freedom**

The editors assert their belief that manuscripts submitted to their journals are the intellectual property of the authors, not the study sponsor. They argue that “academic freedom includes the right of authors to have access to all of the data obtained in their study, to review it, obtain statistical analyses independently, and to publish their data based on their own decisions and not those of the financial sponsor.”

Maintaining the integrity of the clinical evidence base

» JONATHAN QUICK

The integrity of clinical trials – essential for the development of new drugs – is increasingly under threat from commercial influence, resulting in an urgent need for rules and guidelines to safeguard the reliability of such trials. This is the argument put forward by Dr Jonathan Quick in his editorial for the Bulletin of the World Health Organization reproduced below.

“In this issue of the Bulletin Jose Esparza highlights the problem of modern clinical research in combating a major killer disease. During the last decade, at least 15 antiretroviral drugs have come onto the market, bringing longer life and vastly improved quality of life to AIDS patients. In recent months there has been vigorous debate about making these medicines affordable in the South, and about the procurement of ciprofloxacin for the treatment of anthrax in the North. The technical and moral challenge of both ensuring access to existing medicines today and providing incentives for the discovery of new ones for tomorrow has never been more immense.”

“Clinical trials form the basis of effective research and development, but their reliability is currently imperilled by three major flaws: conflicts of interest on the part of the investigators; inappropriate involvement of research sponsors in their design and management; and publication bias in disseminating their results.”

“On financial conflicts of interest, Bodenheimer has reviewed studies showing that authors who supported use of certain cardiovascular treatments were significantly more likely to have a financial relationship with the drug’s makers than those who did not; that studies funded by the manufacturer of a new therapy were more likely than others to find in favour of that therapy; and that independently funded pharmaco-economic studies of cancer drugs were seven times more likely than industry-sponsored studies to reach unfavourable conclusions about a product.”

“On inappropriate involvement, recent reviews have documented how industry sponsors influence clinical trials to produce desired results. Investigators may have little or no input into trial design, no access to the raw data, and limited participation in data interpretation. This may result in flawed design or invalid practices such as “data gerrymandering” (performing multiple post hoc analyses until some positive results show up).”

“A major cardiovascular trial used eight combinations of drug versus placebo, ensuring a 23% probability of at least one good outcome by chance alone. The share of contract research grew from 40% to 80% during the 1990s, making it easier for commercial sponsors to directly influence clinical trials.”

“Bias in publicising positive results and under-reporting negative ones is the third threat to the clinical evidence base”. One study of university-industry research centres found that 35% of signed agreements allowed the sponsor to delete information from publication, 53% allowed delay of publication, and 30% allowed both. A series of high profile cases have shown how investigators who publish or otherwise communicate results contrary to the wishes of the sponsor face intimidation, efforts to discredit them professionally, and threats of legal action to recover the value of ‘lost sales’.

“What can be done? Most clinical research is still conducted to highly exacting standards of objectivity. Yet concern over current trends led 13 editors of leading medical journals to publish a joint editorial about it in September 2001 (see page 2). Their statement is unequivocal: “[Research] contracts should give the researchers a substantial say in trial design, access to the raw data, responsibility for data analysis and interpretation, and the right to publish.” The former editor of the New England Journal of Medicine argues in a separate piece that the editors did not go far enough. “The entire system of clinical investigation is driven by profit,” he writes: “we are seeing the corruption of a system of research that used to have high ideals and be clearly in the public interest”. Lo and colleagues propose that university-based investigators and research staff should be prohibited from holding stock, stock options or decision-making positions in a company that may be affected by the results of their clinical research”. WHO is tightening its rules for staff and expert advisers on conflicts of interest, and has established procedures to maintain a “firewall” between commercial interests and normative, regulatory and research decisions.

“In a highly competitive world, the pressures may be simply too great for individual researchers, universities, medical journals or public agencies to stem the tide of commercial influence. Decades ago, when too many clinical trials were putting patients unacceptably at risk, the Helsinki Declaration was drawn up to protect trial subjects. Perhaps it is time for a similar declaration on the rights and obligations of clinical investigators and on how to manage the entire clinical trials evidence base.”

“In addition to the measures proposed by the editors in September, such a declaration could stipulate: certification by sponsors that specified rules have been kept to ensure the intellectual independence of investigators; inclusion of all details of all trials in a registry which is accessible to third parties such as the Cochrane Collaboration; prohibition of legal action by sponsors against investigators except in the case of fraud; and protection of “whistle-blowers” who report unethical or unorthodox research practices.”

“Investment always involves risk, and in clinical research unaflourable results are part of that risk. If clinical trials become a commercial venture in which self-interest overrules public interest and desire overrules science, then the social contract which allows research on human subjects in return for medical advances is broken. “In the last 50 years the world has seen a stunning output of new medicines and vaccines. Continued progress depends critically on the quality of clinical research.”

USA: growing reaction to drug representatives’ visits

No more free lunches and no gifts at the 20 clinics in the Indiana University Medical Group, as a ban on drug company sales representatives comes into force. The ban coincides with tightened policies on drug representatives throughout the Indiana University-affiliated medical system, including the medical school. The restrictions were prompted by concerns that sales representatives had become too intrusive, and make the Indiana practice part of a small but growing number of medical providers that are saying no to drug company salesmanship.

At the primary care practice, which treats some 135,000 patients, the ban replaces a loose policy that allowed drug company representatives into patient treatment areas and nurse stations. Here representatives promoted their companies’ products to doctors, handed out gifts bearing the company logo and often provided lunches for staff.

Announcing the move, the Group said that was ample evidence that pharmaceutical companies exert significant influence on provider behaviour, and that as faculty of a medical school the Group should set an example. There was concern that students would see a drug representative as a primary source of medical information. Under the new rules free drug samples are only accepted at a central pharmacy, where they are dispensed to patients. Representatives are no longer allowed to give them direct to doctors. Even though they can still mail or drop off information, invite staff to after-hours presentations and contact them at their offices.

The American Medical Association already has guidelines that prohibit member doctors from accepting gifts of “significant value” – such as travel with “strings” attached, such as a promise to prescribe a company’s drug. And in August 2001, the Association launched a US$1 million campaign to publicise its conflict of interest guidelines.

Study shows links between industry and clinical guide writers

On the first time a study has examined potential financial conflicts of interest for authors of clinical practice guidelines. These authors’ interactions with the pharmaceutical industry may be particularly relevant since such guidelines are designed to influence the decisions of large numbers of doctors. Eighty-seven percent of the 100 authors who responded to the survey of medical experts who participated in writing 44 clinical practice guidelines, covering conditions such as asthma, diabetes and pneumonia. Fifty-eight percent had received financial support to perform research and 38% had served as employees or consultants for a pharmaceutical company. On average, clinical practice guideline authors interacted with 10.5 different companies. Fifty-nine percent had relationships with companies whose drugs were considered in the guideline they authored, and of these authors 96% had relationships that predated the guideline creation process.

No formal process

Fifty-five percent of respondents indicated that there had been no formal procedure for declaring these relationships when they became involved in the guideline process. In published versions of the clinical practice guidelines, there were only two cases of specific declarations regarding the personal financial interactions of individual authors with the pharmaceutical industry. Only 7% of respondents thought that their own relationships with the pharmaceutical industry influenced the recommendations made, but 19% thought that their co-authors’ recommendations were influenced by their relationships.

Need for disclosure

Although the survey was small, the researchers conclude that there appears to be considerable interaction between clinical practice guideline authors and the pharmaceutical industry. They advocate appropriate disclosure of financial conflicts of interest for guideline authors, and a formal process for discussing these conflicts prior to guideline development.

Reference


Guidelines on financial conflicts of interest

The report recommends that academic institutions presume that any individual holding a significant financial interest in human subject research may not conduct that research, unless the researcher can demonstrate to a reviewing body that the circumstances are compelling. The report also recognises that each potential conflict of interest case must be closely examined on its merits, and the reviewers must respect the institutional, individual and scientific circumstances surrounding it. To achieve this, the Task Force recommends that academic institutions appoint a standing Conflicts of Interest Committee.

Further information is available on the web at: http://www.aamc.org/coif

Letter from the Editor

This space is usually occupied by letters from our readers. Exceptionally, in this issue, the letter comes from your Editor. After 14 years in which the Monitor has been one of the most rewarding parts of my professional responsibilities I am moving to new pastures and putting down the editorial pen. But I could not leave without saying farewell to you our 50,000 plus subscribers in five language editions and our even greater number of actual readers throughout the world. You work in health centres, hospitals, government ministries, universities and other training institutions, multilateral agencies and NGOs, and include a very wide range of professional disciplines.

It has been my great pleasure and privilege over the years to interact with you by letter, phone, and increasingly by e-mail, visits to WHO, and also very often in my professional travels and teaching. It has been stimulating and often moving to learn of the critical, frequently difficult work that you do to increase access to essential medicines and to ensure that they are used appropriately. It is not possible to publish all the articles, reports and letters we receive, but the information you send is never wasted. I have been delighted and sometimes surprised by where the Monitor is to be found. Quite often, visiting a centre or office in a remote part of the world I spot that familiar green border sticking out of a bookshelf or papers on a desk. And the supportive comments from so many of you about how you value the Monitor and the creative ways in which you use it, have been tremendously heartening to me and my colleagues in the editorial and distribution team. They have kept us going through sometimes tough times. Just one use that my colleagues and I regularly make of the Monitor is when teaching EDM courses on rational drug use where we have a session on use of the media.

In the 14 years that I have worked on essential drugs as a WHO staff member I have seen some positive changes in the global drug situation although not as many as I would have hoped. Steps forward include an increased commitment to national drug policies, and the adoption of essential drugs lists in developed and developing countries throughout the world. The rationale for such strategies is compelling as the article on page 23 makes clear. However adopting a policy does not necessarily lead to action. Policy implementation can be foiled in many ways: lack of funding, political change, opposition by vested interests, all of which can close a window of opportunity. The study of Souly Phanouvong and colleagues reported on page 26 highlights some of the national pitfalls in policy implementation.

Sometimes important national pharmaceutical policies are undermined internationally by actors that can include multilateral agencies or countries which feel that they have commercial interests at stake. There is insufficient public debate and documentation of such influences, particularly by official bodies, although the increased sharing of information on the Internet is changing this situation. Of personal concern to me over the years has been ‘behind the scenes’ pressure on developing countries not to take advantage of the safeguards in the TRIPS Agreement (see last Monitor). It is difficult for some countries to talk of this openly in public fora, although they will do so privately. We continue to live in a highly unequalitarian world, and nowhere more so than in access to treatment and medicines. Aid is all too frequently tied to trade, and international agreements tend to reflect voices of the powerful rather than the needy. I have to hope that this new century will bring change to a currently depressing scenario, and that the many committed people around the world struggling for such change will prevail.

Finally, I hope that you will continue to share your activities with EDM so that we can all learn from experience in different parts of the world. I send you my very best wishes for the continuation and success of your work. Goodbye and thank you for so many years of hugely rewarding interactions.

—Daphne Fresle
Editor, Essential Drugs Monitor (1988/2002)
Calls for stronger consumer voice at conference on medicines and media

David Finer*

The role and particular responsibilities of medical journalists came under scrutiny at a Conference entitled Medicines—People—Media, held in Stockholm on 16 October 2001. With the Swedish Medicines Agency as main organizer and Health Minister, Lars Engqvist, as opening speaker, 150 people heard presentations and discussions ranging over some of the contentious issues surrounding media reporting on medicines.

Keynote speaker was David Gilbert, Head of the Patient and Public Involvement Commission for Health Improvement in the UK. He made the case that the media essentially fail to represent the consumer interest, actively disregarding vital health aspects, such as preventive and palliative medicine. Media messages are too often polarized in positive (hope) and negative (fear) directions. As the power of both media and pharmaceutical industries increase, so too do the commercial pressures on journalism, he said.

Speaking about the research process, Gilbert argued that once again consumer influence is rare, with Alzheimer’s research an exception. He told the Conference that initial scientific scepticism has given way to enthusiasm for “real-life” patient input to the research process, generating new angles and safeguarding the relevance of the research. He urged that this experience should serve as an example for similar initiatives.

Another speaker addressed the issue of “critical medical journalism”, saying that it is about refusing to become a passive megaphone, and about helping the audience separate fact from fantasy – reporting accurately about things of relevance. The representative of the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden, focused on reporting drug safety issues. He spoke about the meaning of the Erice Declaration for drug safety (see Monitor No.25/26, page 26, for further details). He reminded the audience of the Declaration’s preamble which says that monitoring, evaluating and communicating drug safety must be governed by high scientific, ethical and professional standards as well as a moral code.

Media fail the consumer

Taking up a theme in the keynote speech, the Collaborating Centre representative summarised some current media failings, which he said include too little empowerment of both health care staff and patients as information receivers and too little analysis of their needs.

In conclusion, he raised the important but frequently overlooked question of how to inform the vast number of people in high- and low-income countries who have literacy problems.

The day resulted in a number of proposals, including the need to formulate special ethical rules for medical journalists, and for them to assume greater responsibility for potential consequences of their reporting. Participants also called for active exploration of new forms for consumer participation and influence over media content.

Regulating drug promotion in Europe: meeting debates way forward

Drug inspectors from ministries of health and drug regulatory agencies from 23 European countries were among those discussing drug promotion at a meeting in Bonn, organized by WHO’s Regional Office for Europe in December 2001. During initial discussions participants spoke about their main problems, such as the lack of information on practical aspects of monitoring and enforcement procedures. They also raised the lack of awareness health professionals and the public have about promotional strategies and their effects. Other concerns involved pharmaceutical industry lobbying, political pressures, the absence of clear definitions in legislation and lack of resources in regulatory authorities.

During discussions delegates were able to benefit from information provided by the recently completed survey of national systems to regulate drug promotion in Europe. Data for the survey, which involved 26 countries, were provided by the Netherlands Health Care Inspectorate and WHO’s Regional Office for Europe. The survey was done in response to growing concerns about the implications of medicinal drug promotion for rational drug use.

Reviewing European legislation, participants found that definitions of drug promotion and information varied by country, resulting in substantially different enforcement regimes. Most countries have different ways of regulating and controlling promotion and they also have different priorities. Many countries are hindered by a lack of resources to enforce existing laws on promotion and advertising. Considerable difficulties were reported in dealing with “hidden” advertising (such as disease symptom-oriented material and TV news programmes) and the targeting of certain diseases seen as “under-treated”. During a series of workshops there was more in-depth discussion, for example, on drug promotion on the Internet, and how to differentiate between information, promotion and advertising.

Collaboration vital

The meeting concluded that there is a need for increased networking, communication and information exchange among health authorities. Delegates said that ministries of health and health insurers must have an active policy on rational drug use and consumer information. Governments must also address gaps in legislation (setting boundaries, monitoring phase IV studies and the levels of inducements). They should collaborate with the mass media for the benefit of public health, and should raise awareness on the issue among the general public and health professionals. Participants also stressed the importance of governments monitoring the relationship between health professionals and the pharmaceutical industry, and how this can affect rational use of drugs.

Alliance protects rights to genetic resources

India, Brazil, India and nine other of the world’s most biodiverse countries signed an alliance on 18 February 2002 to fight what they call “piracy”, and press for rules protecting their people’s rights to genetic resources found on their land. The declaration they issued echoed long-standing complaints that wealthy nations are “prospecting” for species in order to patent or sell them without offering concessions or benefits for local people. Together, the 12 nations in the alliance, which contain 70% of the world’s biodiversity, said they would press for more equal trade rules on patenting and registering products based on plant and animal resources. Corporations that make medicines from naturally occurring plant derivatives or secure patents on genetic modifications of those species have raised fears that the people who first showed scientists where to find those plants could lose the right to use them or any profits from their use. “New rules should include, among other things, certifying the legal possession of biological materials and informed consent, and mutually agreeable terms for transferring it,” the countries’ joint declaration said.

Reprinted with permission of the Associated Press.

Russia acts to curb counterfeits

USSA’S Minister of Health, Yuriy Shevechenko, is to take personal control of efforts to prevent the spread of counterfeit drugs, as the country steps up its offensive against this serious problem. The Ministry of Health Board has urged its Department of State Control of Pharmaceuticals to speed up the introduction of amendments to existing laws, strengthening measures to fight counterfeit drugs. Other initiatives drafted by the Board include:

➤ amending the existing system for certification of pharmaceuticals to increase their safety;
➤ developing and launching test systems for screening pharmaceuticals to identify counterfeit drugs.

The Board also recommended that the regional health authorities improve local quality control of pharmaceuticals, raise efficiency of drug manufacturing licensing and certification, and better coordinate their efforts with local law enforcement bodies. In addition, local helplines should be set up for patients to ask about the safety of the drugs they are taking, and to report suspected counterfeit drugs.

ISDB defines genuinely innovative drugs

What makes a new drug a real therapeutic advance? The International Society of Drug Bulletins (ISDB) has become increasingly concerned by this question, and has issued a declaration clearly setting out its views. For the ISDB the crux of the problem is what it sees as pharmaceutical industry practices which deliberately blur the line between new drug and old. In its view, the few drugs that represent a real therapeutic advance and novel treatments extend the available options.

The ISDB is a forum for over 80 therapeutic journals which are all independent of the pharmaceutical industry. A number of ISDB bulletins critically appraise the evidence on all newly marketed drugs, and publish their conclusions on whether these new interventions extend the available options. Overall, no more than a few percent per year are judged to do so. Representatives from member journals directly concerned with assessing new drugs met with international experts in Paris in November 2001, to draw up a joint declaration on what features a new drug must have to be considered a real therapeutic advance.

The ISDB Declaration on Therapeutic Advance states that a new substance, or a new use of an existing drug, only represents a real advance when patients draw a supplementary benefit relative to previous treatments. A real therapeutic advance can be provided in three ways: improved efficacy, fewer adverse effects, or greater convenience to patients.

The Declaration makes a series of recommendations aimed at the following groups: policy-makers and regulators; governments and international organisations; and health professionals and the public.

For further information contact: ISDB Coordinating Office, P.O. Box 459, 75527 Paris Cedex 11, France. Tel: +33 1 47 00 33 20, fax +33 1 47 00 28 64, email: 106041.2744@compuserve.com

Reference

Drug companies employ many more staff for marketing than R&D

Brand-name drug makers in the United States employ 81% more people in their marketing departments than in their research and development (R&D) departments. And the “gap has been growing” over the past few years, according to a study by Boston University School of Public Health. Researchers found that drug companies employed 48,527 staff in their R&D departments in 2000, down from 49,409 in 1995, while employment in their marketing departments increased from 55,348 to 87,810 during the same period. According to the study, the additional 32,000 marketing department employees were “mainly” sales representatives who promote drugs to doctors and Health Maintenance Organizations.

In 2000, drug makers employed 39% of their staff in marketing, 22% in R&D, 26% in production and 11% in administration, the study found. Brand-name prescription drug makers say that they focus on discovering new cures, and that Americans must continue paying high prices to support research. Their employment priorities offer evidence that neither claim is true, the study concludes.

For further information contact: Boston University School of Public Health, World Consumer Rights Day Reform Programme, 715 Albany Street, Boston, MA 02118, USA.

Reference

World Consumer Rights Day

While policy-makers flock to hear the views of big business, the perspectives of those on the other end – consumers – are lost in the equation,” says Consumers International. “For this year’s World Consumer Rights Day, Consumers International is leading consumer organisations around the world in calling on governments to ensure that people have influence in the making of decisions that directly affect their lives.”

With this commitment to action, Consumers International launched a series of events worldwide to mark World Consumer Rights Day on 13 March 2002. “From Azerbaijan to Germany, Thailand to Uganda, consumers are standing up for their right to be heard”, Consumers International said, as conferences, street rallies and many other events were held to mark the day.

Successes, but more to do

At global level, consumer representatives at the international food standards body, recently took steps to ensure that consumers will soon have the right to know whether food is genetically modified. However, much remains to be done, and in its 13 March press release, Julian Edwards, Consumers International Director General singled out the World Trade Organization (WTO) for comment.

Concerned by the WTO’s failure to formally recognise the participation of consumer representatives in its work, Mr Edwards said “The WTO is a forum for decisions which affect consumers all over the world. It is not acceptable that it has no formal process for including civil society. We hope that Mike Moore will put this right before his term as Director General ends in September.”

Consumers International, the worldwide federation of over 250 consumer organisations in 115 countries, argues that consumer representation leads to more effective markets which also serve the interests of the broader economic community. It has issued a list, Voices for Change, which aims to advance consumer representation by outlining effective strategies for consumer groups and by examining the state of representation today.

For further information contact: Consumers International, Head Office, 24 Highbury Crescent, London N5 1RX, UK. Tel: +44 (0) 20 7226 6642, fax: +44 (0) 20 7314 0067, email: consin@consint.org, web site: www.consumersinternational.org

Reference

World Consumer Rights Day

While policy-makers flock to hear the views of big business, the perspectives of those on the other end — consumers — are lost in the equation,” says Consumers International. “For this year’s World Consumer Rights Day, Consumers International is leading consumer organizations around the world in calling on governments to ensure that people have influence in the making of decisions that directly affect their lives.” With this commitment to action, Consumers International launched a series of events worldwide to mark World Consumer Rights Day on 13 March 2002. “From Azerbaijan to Germany, Thailand to Uganda, consumers are standing up for their right to be heard,” Consumers International said, as conferences, street rallies and many other events were held to mark the day.

Successes, but more to do

At global level, consumer representatives at the international food standards body, recently took steps to ensure that consumers will soon have the right to know whether food is genetically modified. However, much remains to be done, and in its 13 March press release, Julian Edwards, Consumers International Director General singled out the World Trade Organization (WTO) for comment.

Concerned by the WTO’s failure to formally recognize the participation of consumer representatives in its work, Mr Edwards said “The WTO is a forum for decisions which affect consumers all over the world. It is not acceptable that it has no formal process for including civil society. We hope that Mike Moore will put this right before his term as Director General ends in September.”

Consumers International, the worldwide federation of over 250 consumer organizations in 115 countries, argues that consumer representation leads to more effective markets which also serve the interests of the broader economic community. It has issued a list, Voices for Change, which aims to advance consumer representation by outlining effective strategies for consumer groups and by examining the state of representation today.

For further information contact: Consumers International, Head Office, 24 Highbury Crescent, London N5 1RX, UK. Tel: +44 (0) 20 7226 6642, fax: +44 (0) 20 7314 0067, email: consin@consint.org, web site: www.consumersinternational.org

Reference

Drug companies employ many more staff for marketing than R&D

Brand-name drug makers in the United States employ 81% more people in their marketing departments than in their research and development (R&D) departments. And the “gap has been growing” over the past few years, according to a study by Boston University School of Public Health. Researchers found that drug companies employed 48,527 staff in their R&D departments in 2000, down from 49,409 in 1995, while employment in their marketing departments increased from 55,348 to 87,810 during the same period. According to the study, the additional 32,000 marketing department employees were “mainly” sales representatives who promote drugs to doctors and Health Maintenance Organizations.

In 2000, drug makers employed 39% of their staff in marketing, 22% in R&D, 26% in production and 11% in administration, the study found. Brand-name prescription drug makers say that they focus on discovering new cures, and that Americans must continue paying high prices to support research. Their employment priorities offer evidence that neither claim is true, the study concludes.

For further information contact: Boston University School of Public Health, World Consumer Rights Day Reform Programme, 715 Albany Street, Boston, MA 02118, USA.

Reference

World Consumer Rights Day

While policy-makers flock to hear the views of big business, the perspectives of those on the other end — consumers — are lost in the equation,” says Consumers International. “For this year’s World Consumer Rights Day, Consumers International is leading consumer organizations around the world in calling on governments to ensure that people have influence in the making of decisions that directly affect their lives.” With this commitment to action, Consumers International launched a series of events worldwide to mark World Consumer Rights Day on 13 March 2002. “From Azerbaijan to Germany, Thailand to Uganda, consumers are standing up for their right to be heard,” Consumers International said, as conferences, street rallies and many other events were held to mark the day.

Successes, but more to do

At global level, consumer representatives at the international food standards body, recently took steps to ensure that consumers will soon have the right to know whether food is genetically modified. However, much remains to be done, and in its 13 March press release, Julian Edwards, Consumers International Director General singled out the World Trade Organization (WTO) for comment.

Concerned by the WTO’s failure to formally recognize the participation of consumer representatives in its work, Mr Edwards said “The WTO is a forum for decisions which affect consumers all over the world. It is not acceptable that it has no formal process for including civil society. We hope that Mike Moore will put this right before his term as Director General ends in September.”

Consumers International, the worldwide federation of over 250 consumer organizations in 115 countries, argues that consumer representation leads to more effective markets which also serve the interests of the broader economic community. It has issued a list, Voices for Change, which aims to advance consumer representation by outlining effective strategies for consumer groups and by examining the state of representation today.

For further information contact: Consumers International, Head Office, 24 Highbury Crescent, London N5 1RX, UK. Tel: +44 (0) 20 7226 6642, fax: +44 (0) 20 7314 0067, email: consin@consint.org, web site: www.consumersinternational.org

Reference
US groups criticise magazine’s special issue on health

The controversy over direct-to-consumer (DTC) advertising by the pharmaceutical industry continues, with a recent issue of NewswEEK magazine fuelling the debate. Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the interests of large US pharmaceutical manufacturers, paid for all the advertising in a special issue of the magazine that contains only health-related articles. Concerned about the magazine’s collaboration with PhRMA, five US consumer groups have written an open letter to the journal. In this they claim that NewswEEK has “breached ethical standards in a virtually unprecedented manner” in its 10 September 2001 special issue.

Consumer Federation of America, Families USA, National Consumers League, Public Citizen and United Auto Workers point out that the issue contains numerous articles and advertisements extolling the virtues of recent and prospective drug developments. NewswEEK allowed the drug lobby to use a supposedly independent media outlet to further its public policy objectives, the letter states, and claims that the magazine has violated “the ethics of responsible journalism.”

The consumer groups contend that in recent years PhRMA has blocked legislative proposals designed to make pharmaceuticals more affordable, by arguing that such consumer-friendly legislation would damage the industry’s research and development capacity. The letter points out that “at a time when other media outlets and many in the medical community – including all of the major medical journals, the American Medical Association, and many medical schools – are questioning the ethical dangers of financial ties to the drug industry, it is astounding that NewswEEK developed an exclusive advertising relationship with the drug lobby that allowed it to promote its policy agenda.”

In particular the consumer groups stress that nowhere in the special edition is there any discussion about increasingly unaffordable drug prices. Nor, they say, is there any indication that generic drugs can save people money, and how some companies’ use of federal patent laws prevents such generic drugs from coming to market. The letter concludes that it is in this context that NewswEEK’s special issue must be seen, and why it does “a great disservice to the public.”

Responding to the criticisms NewswEEK Editor-in-Chief, Richard Smith, said that advertisers play no role in the magazine’s editorial process, and that NewswEEK had conceived the idea before going to advertisers. PhRMA commented that it did not see the issue “until it was produced, printed and given to us.”

Australia reports on a decade of quality use

In an effort to improve the use of medicines and further develop Australia’s National Medicines Policy, the Australian Government established the Australian Pharmaceutical Advisory Council and the Pharmaceutical Health and Rational Use of Medicines Advisory Committee in 1991. At the time it was recognised that there was considerable drug-related morbidity and mortality in Australia, much of which was preventable. However, there were very few strategies or structures in place to support improvements in medicines use. Research into successful ways to improve drug use was also limited, both within Australia and internationally. At the time resources and services such as a national formulary, national therapeutic guidelines, consumer medicines information, academic detailing and medication management services were dreams of what was necessary for achieving quality use of medicines.

Significant achievements

The recently published Quality Use of Medicines Report documents how over the last 10 years the Advisory Council and the Committee have taken these ideas and turned them into reality. It shows how through strategic research and policy development the two bodies have contributed to the realisation of successful national medicines programmes, which are integrated with other components of the health care system. For more details contact: Australian Department of Health and Ageing, GPO Box 9848, Canberra ACT 2601, Australia – http://www.health.gov.au/index.htm

Adverse reactions to drugs increase

The number of people who die in England and Wales after errors in drug prescribing or from an adverse drug reaction is showing a marked upward trend, the UK Audit Commission has warned. The Commission estimated that just under 11% of patients on hospital medical wards experience an adverse event, such as being given the wrong drug or having an adverse reaction to a drug. Such an event, although not fatal, can lead on average to an additional stay in hospital of 8.5 days, costing the National Health Service as much as £1.1 billion (US$1.5 billion), according to a report in the BMJ (5 January 2002).

It is difficult to establish the scale of the problem. Only one hospital had a comprehensive system of reporting errors. Among the mistakes made were giving patients with cancer temozolam instead of tamoxifen, giving a contraceptive steroid instead of an antidepressant injection, and prescribing an anticonvulsant medicine at 1000 times the correct dose. The Commission estimates that nearly half of these events were preventable.
UN initiative evaluates HIV medicines

A new effort to assess the quality of HIV medicines could make treatment services more accessible to poor countries. WHO has evaluated several HIV-related medicines, and on 20 March 2002 published the first list of products which were found to meet WHO recommended standards. The project’s initial phase includes 40 products from eight branded and generic manufacturers. Managed by WHO, the initiative also involves UNICEF, and the UNAIDS Secretariat, with support from the UN Population Fund and the World Bank.

D E T A I L S

**A dynamic process**

The pilot project evaluates pharmaceutical products according to WHO’s recommended standards of quality, and for this first international conference on facturing Practices. It is just the beginning of an ongoing process that will keep adding products and suppliers to its lists and when they are found to meet the set standards. The list is available on the WHO web site: http://www.who.int/medicines and on those of the collaborating agencies. So far eight companies have been evaluated, with another 13 suppliers and 100 products currently under review.

**Conference promotes regional collaboration in SAARC countries**

Drug regulatory harmonization was high on the agenda at the first international conference on pharmaceutical affairs for nations within the South Asian Association for Regional Cooperation (SAARC). The Association has seven member countries, and its primary objective is to accelerate economic and social development in Member States through collective action. Representatives from the SAARC nations of Bangladesh, Bhutan, India, Nepal and Sri Lanka, joined over 250 delegates and speakers from 11 countries in Kathmandu, Nepal, from 17-20 December 2001. Participants came from government agencies, pharmacy and medical practice, and the pharmaceuti cal industry, with presenters also from a wide range of organizations, including WHO.

Co-sponsored by the U.S. Pharmacopeia Drug Quality and Information Program and the Drug Information Association, local conference organizers were Nepal’s Department of Drug Administration of the Ministry of Health and the Graduate Pharmacists Association. Wide-ranging discussions were held on regional cooperation in drug registration procedures, regulatory information exchange, drug quality control, good manufacturing practices, and counterfeiting and substandard products. Drug stability issues in the South Asian region and drug information access and use were also debated.

**Future agenda**

The conference concluded with a panel discussion by the official representatives of the SAARC countries present. Panel members proposed promoting collaboration among drug regulatory authorities and other stakeholders by establishing a South Asian Network for Drug Regulatory Harmonization (SANDRHa). The Network’s mission would be to develop a framework of harmonized drug regulatory procedures, so improving access to good quality drugs at affordable prices, improving rational drug use and avoiding unnecessary expenditure. Registration, evaluation, compliance and enforcement procedures, regulation of herbal and traditional medicines, information exchange, and training and education programmes were the main topics considered in relation to harmonization. It was proposed that a steering committee for SANDRHa should be formed, comprised of the drug regulatory authorities of SAARC nations, with other key stakeholders, such as professional and industry organizations as observers. Working groups would tackle specific topics and steering committee meetings would rotate among member countries. It was agreed that the host country, Nepal, would formally present the recommendations and start activities. The recommendations have now been signed by Nepal’s Health Secretary and forwarded to the Ministry of Foreign Affairs. The Ministry will request the SAARC Secretariat and the Embassies of other SAARC countries based in Kathmandu to endorse them.

The new UN initiative on HIV medicines aims to make treatment more accessible for patients such as this at an AIDS reception centre in Brazil.

**Tackling antimicrobial resistance**

Europe’s Council of Ministers is taking steps to address the growing problem of resistance to antibiotics, and in November 2001 it adopted the Recommendation on the prudent use of antimicrobials in Europe. This is part of the European Commission’s strategy on resistance, which calls for antimicrobial use to be restricted to the treatment and prevention of infectious diseases, and an end to their unnecessary use.

**Running a dangerous risk**

Antimicrobial misuse will be a key public health issue in the future, particularly as the Commission begins to draft strategies to prepare for future events such as pandemics. Speaking at the European Conference on Antibiotic Use, Health Commissioner, David Byrne, said that while resistance is a multi-faceted problem, there was a clear relation between the quantities of agents used and the prevalence of drug-resistant microbes. “This problem can no longer be overcome by continuously developing new drugs, as the time needed may one day become too short”, Mr Byrne commented. “We cannot run the risk of someday finding ourselves one last-resort drug away from failure, largely due to overuse”, he argued. To avoid this scenario, an immediate reduction of unnecessary and inappropriate use of antimicrobials is essential.

**New surveillance system**

Four European Commission projects are already specifically addressing the resistance problem, and European Union Member States have been collecting data on resistance, although these tend to be scattered and unavailable to the public. The Commission has decided to create a new surveillance system on antibiotic consumption.

Among the proposals in the Council Recommendation is for Member States to establish a multiannual strategy for the in-vitro monitoring of antimicrobial resistance. Key areas of those strategies will be enforcing prescription-only rules for antibacterials, and monitoring resistance pathogens and antimicrobial consumption and prescribing practices. Other measures include preventing infections by immunisation and infection control standards, and controlling good market practice for antimicrobial agents.

**Study on research and development costs questioned**

A study claiming that the average cost of developing a new prescription drug is $802 million significantly overstates real research and development (R&D) costs, according to an analysis by Public Citizen, the US consumer group. The study, by the Tufts Center for the Study of Drug Development in Boston, was published in November 2001.

The Tufts Center study has two major flaws, Public Citizen argues. First, it is not representative of real drug industry R&D because none of the 68 drugs used in the study received any Government support. Many, if not most, drugs brought to market receive financial support from the Government at some stage in their discovery and development, Public Citizen states. The group claims that Tufts focuses on a skewed sample of the most expensive new drugs and so inflates the actual cost of R&D for the average drug.

The study also exaggerates the actual R&D expenditures for its sample of drugs, Public Citizen believes. Specifically, its estimate of US$802 million includes significant expenses that are tax deductible and theoretical costs that drug companies do not actually incur. For example, roughly half the author’s estimate (US$399 million) is the “opportunity cost of capital” – a theoretical calculation of what R&D funds might be worth if they were invested elsewhere. Actual out-of-pocket R&D costs for drugs in the study were calculated at US$403 million per new drug. Those out-of-pocket expenditures are pre-tax costs, however. Drug companies can and do deduct 34% of their R&D expenses under US Federal tax law. Therefore, the actual after-tax cash outlay for each drug in the new Tufts study is about US$240 million, according to Public Citizen. But the Group stresses that the average R&D cost for each new drug brought to market is significantly less than US$240 million because that figure applies only to the drugs used in the Tufts study.

For further information contact:

Public Citizen, 1600 20th St. NW, Washington, DC. 20009, USA. Tel: +202 888 1000, web details at: http://www.publiccitizen.org/press/releases/06/05/954


**Source**: Scrip, 21 November 2001.
WHO at work in Afghanistan

The World Health Organization (WHO) team conducting a preliminary assessment of Afghanistan’s pharmaceutical sector, in response to the humanitarian crisis, has found that the situation is deteriorating dramatically. Years of war have left the health infrastructure seriously weakened, with some buildings completely destroyed and many others badly damaged. The type of essential drugs is very common in public health facilities, and the expensive brand-name medicines available in private pharmacies remain unaffordable for most Afghans. In addition, there is widespread consumption of low-quality and ineffective medicines, including the drug-manufacturing plant, warehouses, and the quality control laboratory. Meetings took place with senior government officials, including the Minister of Public Health, and representatives of other UN agencies and NGOs involved in the pharmaceutical sector.

**Long-term commitment**

Major technical and financial assistance will be required to develop pharmaceutical systems that offer the level of services so urgently needed by the population. WHO has proposed a US$25 million budget to the international community for the first year. This would allow medical stores to be established at the central and provincial levels, supplying safe essential drugs to the Afghans in Kabul, in the provinces, and also in remote areas where the majority of the population lives.

Several specific activities have been identified for immediate implementation. There were four main criteria for selecting an activity: its importance as a basis for sustainable development of the sector; whether it could serve to bring together key players under the overall guidance of the Ministry of Public Health; whether it could be initiated immediately, moving from assessment to action without undue delay; and finally if it was financially viable. Areas identified for immediate action include:

- appointing an essential drugs focal point in the WHO Office in Kabul;
- developing national guidelines for drug donations;
- reviewing and updating the national list of essential drugs;
- training key staff;
- initiating the process of developing a national drug policy;
- establishing a mechanism for testing drug samples in the region.

Building up the pharmaceutical sector will take years, and will require long-term commitment from any partner involved in the country. WHO is committed to working closely with the Government of Afghanistan, and coordinating the efforts of other United Nations agencies and NGOs involved in developing the pharmaceutical sector.

**Advise on supply chain logistics**

Understanding supply chain logistics for health products in developing countries can help organizations and individuals to donate responsibly. The DELIVER project offers a number of free publications that address this topic. Publications explain the importance of estimating the demand for supplies, maintaining optimal inventory levels, and avoiding expiration and overstocks. One of these resources includes a large wall chart that outlines proper storage guidelines for health commodities. For further information, check out: http://www.deliver.jsi.com

**MSH launches electronic newsletter**

Focus on Pharmaceutical Management is a new e-mail-based publication from Management Sciences for Health, which will come out three times a year. It is intended for health care professionals interested in pharmaceutical management developments worldwide, and for donors and other concerned organizations. Each issue will focus on upcoming conferences, publications of interest, and recent developments and achievements in pharmaceutical programmes and projects. To subscribe contact: cpm@jsi.org

**New site on HIV/AIDS drugs**

The AIDS Treatment Activist Coalition (ATAC), launched in September 2001, has a web page for sharing information about companies making HIV/AIDS drugs and diagnostics: http://www.atacusa.org/Pharmatotes.html

**International Pharmaceutical Federation site**

The International Pharmaceutical Federation (FIP) is a world-wide federation of national pharmaceutical associations. Its web site provides links to online journals and discussion groups, as well as policy statements and guidelines for improving the profession and science of pharmacy. Learn more at: http://www.fip.nl

**Science on the Internet**

SciDev.Net is a free-access, Internet-based network devoted to reports and discussions on modern science and technology that are relevant to sustainable development, and particularly to developing countries’ social and economic needs. Launched in December 2001, SciDev.Net will be of interest to scientists, journalists, government decision makers, international aid agencies and NGOs. The web address is: http://www.sci-dev.net

**Intellectual property rights and developing countries**

The UK Government’s independent Commission on Intellectual Property Rights examines how intellectual property rights can work better for poorer people and developing countries. Its web site includes several useful papers on the issue: http://www.ipcommission.org/meetings/index.asp
Analysing drug advertisements in Russia

In Russia, drug advertisements that omit essential information and so could mislead consumers are illegal. However a recent study1 examining pharmaceutical advertisements in medical journals for their adequacy of information revealed that the law is frequently broken. The authors argue that if physicians had access to better information the value of opening up the regulatory environment to permit direct-to-consumer advertising would be enhanced. The study involved a survey of primary care physicians in Vancouver, British Columbia, from June to August 2000 and in Sacramento, California, from March to June 2001.

Patient-physician questionnaires, covering a single consultation, were used to determine the frequency of patients’ requests for prescriptions and of prescriptions resulting from these requests. Seventy-eight physicians and 1431 patients participated in the study. Drugs were classified as “advertised to consumers” if they were among the 50 drugs with the highest US advertising budgets, or were described as advertised to consumers in Canadian media reports in 1999–2000, or were among the 50 most advertised in medical journals.

The study concludes that patients’ requests for medicines influence prescribing decisions. In most cases physicians prescribed requested medicines but were often ambivalent about the choice of treatment. The authors argue that if physicians prescribe requested drugs despite personal reservations, sales may increase but appropriateness of prescribing may suffer. They contend that concerns about pharmaceutical promotion and the International Pharmaceutical Manufacturers Association code of pharmaceutical marketing practices are rarely achieved in Russia. And multinational companies’ internal guidelines are often not put into effect in fields of medicine and different types of publications, and evaluated all advertisements in all issues of the selected journals for 1998. Researchers counted the number of advertisements in medical journals for their adequacy of information. There were 397 placements of 207 distinct advertisements. Only 154 placements (40%) mentioned any indication, 42 (11%) mentioned safety warnings and contraindications, 25% warned about drug interactions, and just 8% (2%) provided references. The six companies responsible for the most advertisements on average provided less information than the other companies.

Reviewing these results the authors stress that the need for effective control over promotion is universal. Studies in Western Europe and North America have shown that even where objective sources of prescribing information are readily available physicians are still vulnerable to messages in promotional material. In countries like Russia, where access to scientifically-based information is severely limited, even in university and hospital libraries, the situation is even more dangerous, they say. Even the voluntary standards of the WHO criteria for ethical pharmaceutical promotion and the International Pharmaceutical Manufacturers Association code of pharmaceutical marketing practices are rarely achieved in Russia. And multinational companies’ internal guidelines are often not put into effect.

Effective regulatory systems imperative

The study concludes that few of the drug advertisements published in Russia provide the basic information required for appropriate prescribing and that pharmaceutical companies will not provide the information required for the appropriate use of their products unless forced to do so. The authors argue that clearly laws alone are insufficient. Effective regulatory systems are needed. They accuse some companies of appearing to be exploiting Russia’s lack of defences for short-term gain at the expense of health care in the country.

Canadian survey on direct-to-consumer advertising

A recent Canadian study1 was in part prompted by pharmaceutical industry campaigns to relax regulatory restrictions on direct-to-consumer advertising in Canada and the European Union (see page 14). The study examined the relation between direct-to-consumer advertising and patients’ requests for prescriptions, and the relation between patients’ requests and prescribing decisions. (Many Canadians view direct-to-consumer advertisements via the US television channels which they receive.) The research involved a survey of primary care patients in Vancouver, British Columbia, from June to August 2000 and in Sacramento, California, from March to June 2001.

Patient-physician questionnaires, covering a single consultation, were used to determine the frequency of patients’ requests for prescriptions and of prescriptions resulting from these requests. Seventy-eight physicians and 1431 patients participated in the study. Drugs were classified as “advertised to consumers” if they were among the 50 drugs with the highest US advertising budgets, or were described as advertised to consumers in Canadian media reports in 1999–2000, or both.

Patients requested prescriptions in 12% of surveyed consultations. Requesters received prescriptions in 79% of cases as against non-requesters who received them in 26% of cases. When requests were made to doctors they were for products advertised to consumers in 42% of cases. After controls for health and socioeconomic status, demographics, drug payment, and physicians’ sex, specialty and years of practice, researchers examined the influence of requests on the probability that a patient received a new prescription. Researchers asked physicians: “If you were treating another similar patient with the same condition, would you prescribe this drug?” An answer of “very likely” indicated confidence in choice and “possibly” or “unlikely” indicated some degree of ambivalence. Doctors were ambivalent about their prescribing in 50% of cases when patients requested advertised drugs, 39% when patients asked for non-advertised drugs and in 12% of cases when prescribing without request.

The study concludes that patients’ requests for medicines influence prescribing decisions. In most cases physicians prescribed requested medicines but were often ambivalent about the choice of treatment. The authors argue that if physicians prescribe requested drugs despite personal reservations, sales may increase but appropriateness of prescribing may suffer. They contend that concerns about the value of opening up the regulatory environment to permit direct-to-consumer advertising in Canada and the EU seem justified.

Reference


Issue No. 31, 2002
Research update

The effects of different kinds of user fee on prescribing costs in rural Nepal
K.A. Holloway, B.R. Gautam, B.C. Reeves

The study estimated the cost of irrational prescribing, and compared the effect of three different kinds of user fee on prescribing costs, in rural eastern Nepal between 1992–1995. A controlled before-after study was conducted in 33 government primary health care facilities. A fee per prescription (covering all drugs in whatever amounts) was regarded as the control against which two types of fee per drug item were compared. The average total cost to the patient for two drug items was the same in all fee systems. Total cost, expected cost (according to standard treatment guidelines) and wastage costs (total minus expected cost) per prescription were calculated from an average of 400 prescribing episodes per facility per year. The proportion of prescriptions conforming to standard treatment guidelines was calculated from 30 prescriptions per facility per year.

Researchers found that 20–52% of total drug costs were due to inappropriate prescribing. A fee per drug item, as compared with a fee per prescription, was associated with significantly: fewer drug items prescribed per patient; lower drug costs per prescription; lower wastage due to inappropriate drug prescription; and a significantly greater proportion of prescriptions conforming to standard treatment guidelines. The study concludes that the economic consequences of irrational prescribing are severe, particularly in association with charging a fee per prescription. Item fees in the public sector reduce irrational prescribing and associated costs.


Ten recommendations to improve use of medicines in developing countries
R. Loing, H.V. Hogerzeil, D. Ross-Degnan

Inappropriate prescribing reduces the quality of medical care and leads to a waste of resources. A variety of educational and administrative approaches have been tried to improve prescribing. This article reviews the experiences of the last decade in order to identify which interventions have been effective in developing countries, and it suggests a range of policy options for health planners and managers.

Considering the magnitude of resources that are wasted on unnecessarily used drugs, many promising interventions are relatively inexpensive. Simple methods are available to monitor drug use in a standardised way and to identify inefficiencies. Intervention approaches that have proved effective in some settings are: standard treatment guidelines; essential drugs lists; pharmacy and therapeutics committees; problem-based basic professional training; and targeted in-service training of health workers. Some other interventions, such as training of drug sellers and public education, need further testing, but should be supported. Several simplistic approaches have proven ineffective, such as disseminating prescribing information or clinical guidelines in written form only. Two issues that will require a long-term strategic approach are improving prescribing in the private sector and monitoring the impacts of health sector reform.

Sufficient evidence is now available to persuade policy-makers that it is possible to promote rational drug use. If such effective strategies are followed, the quality of health care can be improved and drug expenditures reduced.


Potentially inappropriate medication use in the community-dwelling elderly
C. Zhan, J. Sangl, A.S. Bierman, M.R. Miller, B. Friedman, S.W. Wickizer, G.S. Meyer

Inappropriate medication use is a major patient safety concern, especially for the elderly. Previous US studies found that 23.5% and 17.5% of the US community-dwelling elderly population used at least 1 of 20 potentially inappropriate medications in 1987 and 1992 respectively. This study was undertaken to determine the prevalence of potentially inappropriate medication use in community-dwelling elderly persons in 1996. Trends over 10 years could be assessed, inappropriate medication use categorised according to explicit criteria, and risk factors for inappropriate medication use examined.

Respondents were aged 65 years or older (n = 2455) from a nationally representative survey of the US non-institutionalised population. A seven-member expert panel was convened to categorise inappropriate medications. The main outcome measure was the prevalence of use of 33 potentially inappropriate medications.

The study showed that in 1996, 21.3% of community-dwelling elderly patients in the USA received at least 1 of 33 potentially inappropriate medications. Using the expert panel’s classifications, about 2.6% of elderly patients used at least one of the 11 medications that should always be avoided by elderly patients; 9.1% used at least one of the eight that would rarely be appropriate; and 13.3% used at least one of the 14 medicines that have some indications but are often misused. Use of some inappropriate medicines declined between 1987 and 1996. People with poor health and more prescriptions had a significantly higher risk of inappropriate medication use.

Researchers concluded that overall inappropriate medication use in elderly patients remains a serious problem. Specific criteria can be applied to population-based surveys to identify ways to improve quality of care and patient safety. Enhancement of existing data sources to include dosage, duration and indication may augment national efforts to improve monitoring and increase rational use of medicines among the elderly.


Drug supply systems of mission-ary organizations. Identifying factors affecting expansion and efficiency: case studies from Uganda and Kenya
E. Kawasaki, J. Patten

There are few detailed studies on the management of drug supply by mission organizations, despite their often large contribution to developing countries’ health systems. Some mission supply systems have become self-sustainable and have expanded their drug supply capacity to the public and private sectors. In order to identify the key factors for success and obstacles facing mission-run drug store systems, a detailed qualitative and quantitative study was done on the drug management of the Mission for Essential Drugs and Supplies in Kenya and the Joint Medical Store in Uganda. The study methods, using in-depth interviews and analysis of data given by the organizations, have produced a comprehensive overview of both, and have provided lessons regarding sustainability and expansion.

Both MEDS and JMS have grown progressively over the past five years, and are now self-sustaining. Their efficient management is reflected in low operational expenditures – only around 10% of total expenditure is on operational costs, with some 60% of this for staffing. The two organizations charge prices which are very competitive internationally, and their stock availability rates run at about 90%.

The study shows that JMS and MEDS use different approaches because of their different economic environments. Both provide reliable drug supply systems for their customers, and are beginning to supply significant amounts of medicines to organizations in neighbouring countries. The authors conclude that governments should consider exploring areas for linkages and using mission organization drug supply infrastructures. They argue that direct support from international donors in training and computerized operating systems could contribute to self-sustainability of other mission organizations.

Women and drug promotion: “the essence of womanhood is now in tablet form”

A woman boards a bus in Vancouver, Canada. A large billboard at the bus shelter shows a woman laughing and playing with her daughter: “Lose a little weight and you’ll feel better,” says the advertisement. “Ask your doctor about weight-loss options that are available now.” Inside the bus, another advertisement shows an attractive young woman with the caption: “A lesson in first impressions… Always leave something to the imagination. Be mysterious.” At the bottom of the advertisement is the name of a birth control pill, with the pill’s blister pack.

Each message has strong social content. The obesity drug publicity advises women to maintain their beauty as well as their health. The birth control advertisement tells women that in new relationships by taking the pill they can “be mysterious,” and avoid talking to their partner about birth control.

From a public health perspective, these messages leave much to be desired. Obesity can cause serious health problems, but so do eating disorders and anti-obesity drugs. Young women should protect themselves against pregnancy, but not by birth control. The obesity drug publicity advises women to “protect themselves against pregnancy, but not by birth control.”

In Canada, as in most other countries, advertising of prescription drugs to the public is illegal. However, legislation is often inadequately enforced, and many governments are under pressure from the pharmaceutical and advertising industries to change the law.

Does direct-to-consumer prescription drug advertising affect women differently from men? What about the effects of other forms of drug promotion, such as targeting physicians and other health professionals?

Why do national laws prohibit prescription drug advertising to the public?

The aim of drug promotion is to sell a product. Used judiciously, medicines can cure diseases, prevent complications, and provide much needed relief of pain, discomfort and other symptoms. However, even when used appropriately, medicines can cause harm as well as benefit. Any decision to prescribe or use a medicine is a balancing act, weighing the probability of benefit, given a person’s circumstances and health condition, against the possibility of harm.

A rational weighing of probabilities, however, is far from the experience of someone who is seriously ill or a mother caring for a child in distress. Illness, pain and fear of death or disability create a vulnerability that is very different from a decision to buy a loaf of bread or a new pair of shoes.

The toxicity of medicines and people’s vulnerability when they are ill distinguish pharmaceutical promotion from the advertising of other consumer products.

Many types of drug promotion

Drug promotion is defined as: “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce sales of medicines, supply, purchase and/or use of medicinal drugs” (1).

Direct-to-consumer advertising (DTCA) of prescription drugs has grown rapidly in the 1990’s in the USA and New Zealand, where it is allowed. US spending reached nearly $2.5 billion last year, up from less than $100 million per year in the early 1990’s. Spending is highly concentrated among new, expensive drugs for long-term use by broad target audiences, generally healthier people.

Many of the drugs most heavily advertised to the US public are used mainly by women, such as drugs for menopause, obesity, migraine, arthritis, depression and bladder control. A systematic review of 10 years of magazine advertising found that when there was sex-specific targeting, women were 2.6 times as likely to be targeted as men.

Most promotional spending everywhere, including in the USA, is on sales representatives (“drug detailers”), who make one-to-one visits to doctors. Companies also sponsor educational and scientific meetings, journal supplements, post-marketing research studies and media events, and advertise their products in medical journals and through direct mail.

There are other more subtle forms of drug promotion: a recent study in the Journal of the American Medical Association found that 90% of authors of clinical guidelines receive funding from or acted as consultants to drug companies (see p. 4).

Over-the-counter drugs are advertised directly to the public in a variety of media, including print, billboards, radio and television. In addition to DTCA, described above, companies use a variety of methods to advertise medicines to the public, including press campaigns and patient group sponsorship.

Ashley Wazana carried out a systematic review of 29 empirical studies on the influence of interactions with the pharmaceutical industry on physicians. Effects on physicians’ knowledge and practice were mostly negative, including: inability to identify inaccurate claims; formulary requests for medications without treatment advantages; irrational prescribing; increased prescribing rates; less generic prescribing; and prescribing of more expensive new medicines without treatment advantages (see p. 22).

A tension exists between judicious use of medicines only if and when they are needed, and manufacturers’ need to continually garner and expand market share. There are only so many ill people at any given time.

The medicalisation of menopause

If a healthy life stage experienced by half the population can be redefined as a medical event, the result is an enormous market opportunity.

Menopause marks the end of menstruation and in many ways mirrors the menarche, or beginning of menstruation. However, whereas menarche is seen as a young woman’s passage into adulthood, with mood swings accepted as normal, greatly between cultures. In population-based surveys in Thailand, 23% of menopausal women experienced hot flushes. In the UK, the proportion was 57% (5). Mayan women in rural Mexico experienced no hot flushes despite hormone levels similar to US menopausal women. Menopause may be seen as a positive event marking freedom from childbearing or purdah, as in Northern India, or as a sign of loss of social status, as in the west.

Hormone therapies provide symptomatic relief from hot flushes, night sweats and vaginal dryness. They are not effective against ageing. However, a best-selling estrogen was promoted to physicians as “a gift of time.” Advertisements often portray menopause negatively. In Bolivia one called menopause “a visible problem”; another in Peru called it a “daily impediment to the quality of life”, and a US advertisement suggested that women, “...Forget menopause.” It is hard to miss the suggestion that being female and of a certain age is a visible problem that needs forgetting.

Post-menopausal women and disease prevention

Short-term symptomatic treatment of large populations is lucrative. However,
Prevention of osteoporosis

Gradual bone loss occurs normally with age in both women and men, but osteoporosis progresses more rapidly in women than in men. An excellent example of a process Lyn Payer described as the ‘disinguishing’ of risk factors 18. In 2000, the manufacturer of a leading osteoporosis treatment published an article in women’s magazines in the USA saying, “See how beautiful 60 can look! See how invisible osteoporosis can be!” The advertisement cites a nearly 1 in 2 chance of having osteoporosis, ominously “no matter how healthy you look on the outside.” The company urged women to get their bone density tested, saying that osteoporosis can lead to broken bones and disfiguring dowager’s hump, which can be prevented if detected early enough.

Bone density does not accurately identify women on fracture at the age they are; many women are misclassified than are accurately classified 19. Age alone is a better predictor of the risk of hip fracture. Women over 80 with bone mineral densities more than one standard deviation above the mean experience more fractures than any group of women aged 70-79, irrespective of their bone mineral density 20. Bone density testing does predict use of drug therapy, however 21. For many women, benefits of treatment may not outweigh risks, age-related bone loss is common at age 60, but hip fractures are rare.

Cardio protection: an unfulfilled promise?

Hormone treatments have been widely promoted to prevent heart disease in post-menopausal women, based on changes in lipid levels 22, and less observed heart disease in hormone users than non-users 23. However, lipid changes do not necessarily reflect lower disease risk, and observational studies may reflect a systematic bias, since hormone users tend to be healthier and wealthier than their non-users 24.

The only way to know if hormones prevent heart disease is through well-designed randomized controlled trials. The first randomised controlled trial of hormones and heart disease prevention in post-menopausal women, the HERS trial, was published in 1998 25. This is the best available evidence, and hormone treatment did not prevent heart disease, shattering previous assumptions.

“The good news is that a woman’s risk of heart disease is increased dramatically after menopause, but can be significantly reduced by 35 to 50 per cent with hormone replacement therapy (HRT),” said a newspaper article in September 2000, over-exaggerating the trial 26. “Post-menopausal and not taking hormone replacement therapy (HRT) is the first ‘risk factor’ for heart disease.”

Isabelle Savoie and colleagues examined reports on women and heart disease in major US and Canadian women’s magazines in 1997 and 1998 27. They found over 100 articles and advertisements. Three themes predominated: heart disease is the number one killer of women; women must demand equal access to prevention and treatment; and lifestyle changes are likely to be inadequate, drug treatment is needed. A common theme was that, “one of the most compelling reasons to take replacement hormones is for your heart’s sake.”

Heart disease risks were frequently examined with messages that after menopause women’s risk ‘skyrockets’ or equals that of men, which is untrue at comparable ages. With no evidence of fracture or heart disease prevention, and with ongoing concerns about increased breast cancer risks, long-term hormone use may cause more harm than benefit. Drug promotion is not solely responsible, but it clearly contributes.

Overprescribing of psychotropic drugs: a pervasive problem

Women have long been targeted in psychotropic drug advertising, mainly those for benzodiazepine tranquilizers and sleeping pills in the 1970s and 1980s, and antidepressants today as well as health effects, and can affect women differently from men. There is little systematic research on the influence of drug promotion on women.

The risks may be to society as well as to the individual if research and development focuses on ‘lifestyle products’ for the healthy rather than needed medicines for untreated serious diseases. A largely unexamined risk to is women’s equality if individual drug treatment is the only solution offered to distressing life situations or to ill health caused by social inequality.

WHO’s Ethical Criteria for Medicinal Drug Promotion stress the principle that drug promotion should be in keeping with national health policies. National governments have been slow to integrate the regulation of drug promotion into broader health and drug policies, and to consider special measures to control promotion of certain classes of drugs or targeting of certain groups. Politically such a move may be difficult, as governments often balance health against economic priorities and face international pressures. Many countries lack adequate resources for effective regulation of drug promotion, and regional or international collaboration may be the answer.

In 2001, the US Government told manufacturers of AIDS drugs to stop showing unrealistic images of treatment success. This was after a San Francisco Public Health Department study had shown that young gay men who saw many drug advertisements were at higher risk for HIV infection, as they practiced more unsafe sex and tended to believe that HIV/AIDS was no longer a problem.

This is only one small step, but it shows that regulation of drug promotion can go beyond consistency with approved labelling and also reflect broader health policies.

References

11. Art for all your necks! Recent examples of unethical and misleading marketing. Health Action International Amsterdam 1996.
There has been a strong reaction against a proposed relaxation of the European Union ban on direct-to-consumer advertising of prescription medicines. The proposal from the European Commission will permit pharmaceutical companies to provide consumers, at their request, with promotional information on prescription-only medicines authorised to treat HIV/AIDS, asthma and diabetes. There is concern that this change, for a five-year trial period, could open the way for full-scale direct to consumer advertising in the European Union. This type of advertising is banned in every industrialised country in the world, except the USA and New Zealand.

**Negative effects**

At a meeting in Brussels in January 2002, researchers, consumers, patients, WHO and pharmaceutical industry representatives, drug regulators, health professionals, insurers and others met to discuss the issue. Everyone agreed that the public needs access to balanced comparative, relevant up-to-date, accurate and unbiased information on pharmaceuticals and non-pharmaceutical treatments. But consumer advocates and public health officials asserted that the Commission’s proposal would not result in this. Instead they argued that the likely outcome would be unnecessary and possibly unsafe use of medicines with spiralling health care spending, and irresponsible promotion of medicines. The Netherlands’ view voiced the fears of many at the meeting. Mr de Joncheere told participants that, based on the Ethical Criteria, “WHO

**The Netherlands’ view**

**A WHO view**

A WHO perspective was given by Mr Kees de Joncheere, Regional Adviser for Pharmaceuticals and Technology at the WHO Regional Office for Europe. The Office recently organized a meeting in Bonn for European health authorities responsible for regulating direct-to-consumer advertising (see page 5). Mr de Joncheere told delegates in Brussels that “Direct-to-consumer advertising raises concerns for WHO. At present, there are only two countries that officially allow this kind of advertising. Two other countries, South Africa and Australia, have considered it, but ultimately both decided against it. When we talk about advertising and drug information we have to remember their impact on people’s health. It is good to emphasise that a medication is actually the product plus the information plus the culture in which it is being used. If we want to reap the full benefits that drugs offer, we have to make sure they are being prescribed and used appropriately.”

Mr de Joncheere informed the meeting that at the 1988 World Health Assembly, WHO Member States had adopted the Ethical Criteria for Medicinal Drug Promotion. These define promotion as “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.” They go on to say: “advertisements to the general public...should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions, that can be treated only by qualified health practitioners...scheduled narcotic and psychotropic drugs should not be advertised to the general public.”

“Direct-to-consumer advertising implies that the consumer decides what drug to buy. In fact, it is the doctor who prescribes it and the bill is paid for by ‘society’. Here in Europe patients do not pay the pharmaceutical bill themselves. The basic question remains: is direct-to-consumer advertising really necessary to improve drug information for patients? Is it direct-to-consumer advertising or rather direct-to-consumer information that is actually the way forward?”

“The EU’s proposal raises some serious questions about the quality of the legislation being proposed and how it will be enforced. If access to information is the purpose, then new EU legislation is not necessary. If, on the other hand, permitting direct-to-consumer advertising is the purpose, then EU legislation is needed. Enforcement of the new legislation at both the EU and national levels is unclear. It seems difficult to start with three health conditions and stop there. Other groups affected by different health conditions could begin calling for it too.”

**Providing quality information**

“Consumers and patient organisations These groups have an important role to play in informing consumers about promotional activities by the pharmaceutical industry. These groups should also be involved in the formulation of codes of practice. They can provide information on practical experiences as well.”

“Industry’s role What role should industry play? Pharmaceutical companies can provide factual information about drugs on their web sites. However, there is a great need for more transparency about their data. We need better access to information about existing research data.”

“National governments Governments are responsible for legislation and enforcement. They should support a system of drug development, quality control and supply of information [in connection with market authorisations]. They may consider occasional information campaigns on specific health-related issues.”

**Should DTCA be permitted?: some conclusions**

“Promotion of rational drug use by the pharmaceutical industry remains unlikely. It is not their primary goal. Experience in the US has shown that increasing direct-to-consumer advertising leads to increasing drug use and higher health care costs. The US has also shown us that patients are easy to influence through direct-to-consumer advertising while they are not the ones who make buying decisions or ultimately pay most of the bill. They also may not know the risks involved in the prescription of medically unjustified therapy.”

“If the industry really wants to inform consumers, it should bring about greater transparency of its data. For all of these reasons and more, we need to say no to direct-to-consumer advertising.”

Mr. Léon Wever, Director, Pharmaceutical Affairs and Medical Technology, Ministry of Health, Welfare and Sport, The Netherlands.

**The Dutch experience**

“Although direct-to-consumer advertising is banned in The Netherlands [as in all of the Member States] the Dutch Ministry of Health has had to take action against a number of “disease-awareness” campaigns that crossed the line into advertising”.

“Information about a product can only be assessed in its context. Information that is used as a sales tool is advertising. There will always be a ‘grey area’ between information and promotion. This makes it hard to address in legislation. Instead, it has to be considered on a case-by-case basis. Does this say something about the EU Commission and the enormous workload the proposal will bring for national and EU level enforcement agencies?”

“New European legislation should reflect a number of key points. First, it must be in the interest of patients and health care services. That means it must ensure quality and safety, accessibility, and aid efficiency (cost containment). In addition, providing more information for patients implies more transparency on the part of the pharmaceutical industry; it must also improve the quality of legislation and law enforcement. We must remember that good health care is the goal. There is a need for more industry transparency. To protect health, we want information on all aspects of drugs, not just positive information.”

“Direct-to-consumer advertising implies that the consumer decides what drug to buy. In fact, it is the doctor who prescribes it and the bill is paid for by ‘society’. Here in Europe patients do not pay the pharmaceutical bill themselves. The basic question remains: is direct-to-consumer advertising really necessary to improve drug information for patients? Is it direct-to-consumer advertising or rather direct-to-consumer information that is actually the way forward?”

“If we examine the idea of increasing patients’ access to information about some prescription-only products, it seems clear that this information should be patient-oriented and controlled (approved) information. It should not be direct-to-consumer advertising. In addition, the EU should draw up a set of ‘good information practices’.”

“...In the proposed changes for Article 88, the Commission is trying to make it possible for industry to give information about certain illnesses directly to patients. But can the industry give objective information, or will it, in fact, be drug promotion? The Commission talks about allowing the changes in advertising as a ‘pilot phase.’ That is, for the next few years specific groups of long-term and chronic diseases related to AIDS, asthma and chronic bronchitis, and diabetes would be affected. The Commission says the change has been proposed on the basis of strong and specific patient demand for it. And that the effects will be monitored and assessed. Finally, in five years time the experiment will be reviewed. But we are not sure that DTCA is not the inevitable outcome of this pilot phase.”

“Promotion of rational drug use by the pharmaceutical industry: call to leave current situation intact”  E S S E N T I A L   D R U G S   M O N I T O R Issue No. 31, 2002
believe the European Union and any country must be cautious in changing legislation where there is considerable potential for harm and little if any documented evidence of benefit.”

How to optimise drug information

Looking to the future, the WHO representative discussed some of the conclusions of the Bonn meeting with European health authorities, and said that “There are a number of actions to be taken to improve drug information, including:

➤ operationalising definitions on promotion, advertising and information. There must be more clarity on what constitutes what;
➤ examining the role of the Internet as a medium for information. While some see the Internet as a problem or threat, it can also provide an opportunity;
➤ determining what information consumers need: about a disease, about a product, and about comparative information on treatment options. Different people have different needs. It is important for people to know about all of their available options, but we cannot expect companies to provide information on all of the treatment options;
➤ taking on a more pro-active role for health services in providing information to patients;
➤ finding ways to use the media as sources of health information.”

“National health authorities need to get the right information out to the public,” Mr de Joncheere continued, saying that, “This is often not happening. Problems are often related to the fact that they are not generating enough quality information about medicines or that they are prioritising other things.” In conclusion, he referred to discussions at the Bonn meeting on drug promotion, which had emphasised the need for ministries of health and health insurers to have an active policy on rational drug use and consumer information. Mr de Joncheere told delegates in Brussels that there had been calls for governments to address existing gaps in legislation, to collaborate with the mass media in a way that benefits public health, and to raise awareness on the issue among the public and health professionals. In addition, government monitoring of the relationship between health professionals and the industry, and its consequences for rational drug use were also advocated.

Drugs promotion

During the period March 2000/2001, after 10 years collecting data, the review Prescrire’s Representatives Monitoring Network has concluded that medical representatives in France continue to mislead prescribers about drug safety and efficacy. Numerous Government attempts to regulate representatives’ visits have done little to remedy the situation, the group says. The Network has involved hundreds of doctors and pharmacists throughout France in completing Prescrire’s questionnaires that analyse a representative’s visit for misleading information. (see Essential Drugs Monitor 17 and 24).

Continued vigilance needed

During the period March 2000/2001 the main trends reported by observers concerned more frequent promotion of off-label indications. In total only 68% of indications promoted conformed to the summary of product characteristics, compared to 79% in 1997. Warnings about risks were included in only 10% of cases against 17% the year before. Drug interactions were mentioned in 8% of visits, while in 6% they were denied, and adverse effects were stated in just 10% of cases and denied in 9% (up from 4% the previous year).

During the year representatives were less likely to offer documents on the drugs they were promoting – only 17% of cases. Just a few gave out copies of the statement from France’s Transparancy Commission that compares a drug with others in the same class. It is a legal requirement for medical representatives to supply this document, which uses a scoring system to assess a drug’s benefit and cost-effectiveness. The statement was only used in 2% of cases.

Prescrire’s Network believes the findings are particularly alarming given that drug manufacturers say visits by medical representatives remain the most effective way of persuading physicians to prescribe their products. Regulations, industrial ethical codes and international recommendations have had no significant effect so far, according to la revue Prescrire, which will continue to monitor the situation.


FDA reviews its direct-to-consumer advertising policy

Does direct-to-consumer pharmaceutical advertising confuse patients and does it adversely affect their relationship with their health care providers? These are among the questions that the US Food and Drug Administration is attempting to answer through a review of the effects of direct-to-consumer advertising, reports Scrip (4 April 2001). The review was provided for when the Administration first issued guidance on the subject in 1999, and will determine whether the guidance should be changed, rescinded or left as it is.

A growing phenomenon

There has been a great increase in direct-to-consumer advertising – in the first half of 2000 alone it rose by 43% – with the pharmaceutical industry claiming that it “empowers” consumers. But the Food and Drug Administration has criticised several TV advertisements for being misleading or lacking in fair balance. The Administration is conducting two telephone surveys, one of patients and the other of doctors, to obtain their views on both print and broadcasting advertising of medicines. The review is also going to include evaluating published research conducted by other organizations. The FDA is particularly keen to see if such advertising is leading to inappropriate prescribing and to patients getting drugs that they should not be, partly as a result of them pressuring doctors for particular medicines.
An innovative approach to educating medical students about pharmaceutical promotion

**Michael Wilkes, Jerome Hoffman**

**Pharmaceutical promotion exercise**

The educational exercise was designed to address the impact of pharmaceutical manufacturers on physicians’ behaviour. The faculty development session stressed the overall objectives of the exercise:

1. To understand the reasons for detailing pharmaceuticals to the medical profession;
2. To understand potential advantages and disadvantages of pharmaceutical – medical professional interactions;
3. To understand the impact of pharmaceutical promotion on health care costs;
4. To discuss possible reasons in support of and against accepting gifts intended to influence prescribing behaviours;
5. To understand the accuracy and honesty of information that is conveyed to physicians by pharmaceutical company details.

The exercise consisted of a presentation by University of California (UCLA) full-time pharmacists playing the role of a pharmaceutical representative before small groups. Each pharmacist gave the eight students and two faculty members in each group a 20-minute talk on the virtues of a non-sedating antihistamine. The students were unaware that these “drug reps” were actually UCLA pharmacists.

The students were told at the outset of the session that because they would be exposed to pharmaceutical representatives on a regular basis throughout their careers, one such encounter would be presented. They were told that the drug reps would have an opportunity to make a brief presentation to the group on behalf of a very popular and aggressively marketed medication, and would then be willing to answer questions. The drug reps brought handouts, supportive educational and promotional materials (including items such as pens and writing tablets), and a snack of bagels and cream cheese (actually provided by the manufacturer of the drug being “detailed.” The pharmacists had seen the current marketing approaches that had been used by the pharmaceutical representatives prior to this exercise. Their experience was collated and reviewed for conformity with overall industry tactics and standards, and a presentation script was developed. The pharmacists used actual materials that had previously been given to the university’s pharmacy by the manufacturer of the drug being “detailed.” The pharmacists practised the presentations individually and together to assure that the standardised goals were accomplished and that the presentations, while designed to accent the benefits associated with the drug being promoted, sounded believable, and did not contain any outright untruths. In addition, the presentations were scripted so that each contained the following elements:

1. Anecdotal references to use by physicians at another university hospital;
2. Somewhat exaggerated (favourable) claims about toxicity and side effects;
3. Claims of effectiveness citing information based on doses different from those used in common practice;
4. Mention of adverse effects;
5. Assumptions about relative efficacy without supporting documentation;
6. No information about costs;
7. Reference to “their” product by its trade name, but to all products of potential competitors by generic name only.

After the presentation, the students were encouraged to ask questions. If the following questions were not asked by students, faculty were instructed to ask how much the drug cost relative to competitors, what the side effects of the drug were, how it was compared with other drugs, and whether there had been any trials comparing the drug head-to-head with competitively marketed agents (other second-generation antihistamines). Once all questions were answered (in a standardised, reproducible manner, as well as carefully calculated) the drug reps were thanked and left the room. Students were then led through an exercise intended to critique the presentation, and specifically addressed whether:

- the presentation had been balanced;
- the presentation had been accurate;
- the presenter had adequately backed up his or her claims;
- the presenter had discussed economic implications of use of the drug;
- the presenter had fairly compared the promoted drug with alternatives;
- this had been a useful educational experience; and
- the student would be more or less likely to use the drug in question after hearing the presentation.

Following this 20-minute discussion, the “drug rep” was invited back into the classroom and reintroduced to the students as a university pharmacist and drug information consultant. The hospital pharmacists were asked to explain how their presentations reflected actual marketing strategies, as well as to point out any distortions or omissions they had made during their initial presentation.

The pharmacists talked with the students about the training and background of pharmaceutical details, and the process of preparing and delivering promotional material, including the use of claims and compensations, gifts, and sponsored talks. In addition, the students explored how and why pharmaceutical companies generate information to benefit sales of their products. The group discussed what impact promotional activities have on health care, the impact of detailing on the costs of drugs to consumers, and possible reasons and rationales physicians give for accepting or refusing to accept gifts from manufacturers. As the last part of the exercise, the students were shown how to access unbiased, evidence-based drug information using the university’s hospital-based computer system. This completed the educational intervention.

**Pre-post-intervention survey**

Before the small-group sessions began, the students completed a self-administered, anonymous questionnaire that had been pilot tested, containing 26 items dealing with the interface between the pharmaceutical manufacturers and the medical profession. We also administered a post-intervention survey 12 weeks after the educational session.

**Attitudes toward interactions with pharmaceutical manufacturers**

Students’ attitudes toward drug company sponsorship of research, drug company – physician interactions (detailing), and drug advertisements as educational tools changed after their participation in the educational programme (see Table 1). In each case, these changes were mostly reflected by increases in the numbers of students who had initially been confident that the issue in question was not problematic, but who then had become uncertain about it. For example, responses to the post-intervention questionnaire showed that, while a few more students disagreed with the...
statement that “drug company-sponsored research is indispensable,” many more were unsure whether the research was biased. The same effect was found regarding their views about whether material presented at drug company-sponsored seminars is “unbiased.” Whether “such drug company-sponsored research is as likely to reach negative conclusions about the company’s drugs as research from an alternative sponsor,” whether “when drug companies give physicians pens, calendars, or other non-educational materials, this biases the subsequent behaviour of those physicians,” and whether product information presented in drug advertisements serves an educational purpose.

Physicians prescribe pharmaceuticals throughout their professional lives, but because new drugs are being approved and marketed so quickly, it is likely that most current medical students will ultimately prescribe a great many medicines about which they had received no training in medical school or residency. The pharmaceutical industry spends enormous amounts of money promoting its products to physicians, and pharmaceutical promotions are indeed one of the primary sources of information many physicians rely upon in making drug choices, as well as in “learning about” unfamiliar medications.

There is evidence, however, that promotional material may not always be balanced, accurate, or fair, such that uncrn-
tical acceptance of claims made by a proprietary interest can lead to widespread prescribing patterns that are hard to justify on the basis of the medical literature.4 Habits learned in medical school may affect behaviours throughout physicians’ careers, so we designed this exercise to try to encourage students to think critically when presented with promotional material from pharmaceutical companies.

We chose the exercise, rather than merely presenting information from the literature reflecting concerns about pharmaceutical promotions, because we felt that the latter approach would probably be met with skepticism. Many physicians respond with disbelief, or even hostility, when it is suggested that their judgements can be influenced or distorted by “gifts” and favours from industry. It is our experience that many students, likewise, feel patronised, or offended, when “lect-
tured to” about ethical issues such as those raised by physicians’ interactions with pharmaceutical representatives (particularly when these interactions come with financial inducements attached). Although we did feel some discomfort about having hospital pharmacists pretend to be actual company representatives, we ultimately felt that this was not a major concern because students would learn the true nature of the exercise before leaving the session. Furthermore, we felt that the stimulation associated with this “live” presentation would give us the opportunity to make an impression upon students and facilitate serious discussion of complex issues.

We made every effort to assure that the exercise itself was fair by asking the UCLA Department of Pharmacy to de-
sign a presentation that honestly reflected standard industry presentations. The pharmacists who participated had all had extensive experience with drug rep-
resentatives and company promotions, and all had studied this issue extensively during their own training at UCLA.

The pre- and post-intervention results, while far from definitive, do suggest that the students’ attitudes were affected by this exercise. The primary impact seems to be that the students became more un-

certain about the issues raised, rather than that they adopted frankly negative beliefs or feelings. Regardless of whether the questions dealt with the accuracy of com-

pany’s promotions and presentations, the quality of sponsored research, the nature of interactions between physicians and company representatives, or students’ individual behaviours in the future, a majority of the students apparently had no concern or ethical doubt prior to the exercise, whereas a greater number of such students expressed uncertainty about the same matters three months later.

We have no idea to what extent these probable changes in attitude are durable, or whether (even in the short term) they would actually be associated with changes in behaviours. We do not believe

---

**Table 1**

<table>
<thead>
<tr>
<th>Third-year Medical Students’ Pre- and Post-intervention Responses to Statements Concerning Pharmaceutical Companies’ Interactions with Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Statement</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>When drug companies sponsor physicians to go to seminars or resort locations this biases the subsequent behaviour of those physicians (e.g., they prescribe more of the company’s product)</td>
</tr>
<tr>
<td>When drug companies give physicians textbooks or other educational materials, this influences their subsequent prescribing</td>
</tr>
<tr>
<td>When drug companies give physicians pens, calendars, or other non-educational materials, this biases the subsequent behavior of those physicians</td>
</tr>
<tr>
<td>Drug company promotions are less likely to be about unique drugs than drugs that are essentially similar to ones already marketed</td>
</tr>
<tr>
<td>Drug company gifts to physicians do not significantly increase health care costs to patients</td>
</tr>
<tr>
<td>Drug company promotions presented in a drug advertisement provides you with educational material about the drug</td>
</tr>
<tr>
<td>They have finished their formal training, physicians have no alternative but to rely on drug company detailing to learn about new drugs</td>
</tr>
</tbody>
</table>

* p < .05, † p < .01

---

**References**

2. Wolfe SM. Why do American drug companies spend more than $12 billion a year pushing drugs? Is it edu-

3. Winkel K, Chau M, Essawi MA, Choragia vs. typi-

6. Davis SM. Why do American drug companies spend more than $12 billion a year pushing drugs? Is it edu-

Drug companies spend enormous sums of money promoting their products around the world to doctors. In 2000 over US$13.2 billion was spent in the USA, the 1998 figure for Italy was US$1.1 billion, and in developing countries spending accounted for 30% of the sales dollar goes into promotion. There are currently over 80,000 sales representatives in the USA1, and many other countries world wide. In Canada and the European Union. Growth in spending on DTCA in the USA has been dramatic, with nearly US$2.4 billion being spent in 20002.

The companies would not be spending billions of dollars if there was no return and, according to the evidence, promotion does increase sales. For every dollar spent on magazine and television advertising there is a return of US$52.1 and US$1.69, respectively3. Increases in the sales of the 50 drugs most heavily advertised, the US$20.8 billion increase in retail spending on prescription drugs from 1999 to 20004.

Promotion influences prescribing and health care much more than most health professionals realise5,6,7,8,9,10,11,12,13. And many advertisers say in effect: promotion provides us with the opportunity to reach doctors, and if doctors prescribe more of our products, this will increase sales.

An increase in sales may or may not be a good thing, depending on how appropriately the drugs are being prescribed and how well they are being used. Details in developed countries consistently fail to spontaneously talk about safety information regarding the drugs that are being promoted4,14. The incomplete nature of the information that representatives provide probably accounts for the fact that studies in Belgium16, the United Kingdom16 and the USA17,18 have all shown a correlation between the use of information from sales representatives and inappropriate prescribing.

Pharmaceutical companies have used their promotional activities to influence health care expenditure much more than most health professionals realise. In many developed countries, drug expenditure rises by 15–20% per year; in the USA the increase between 1999 and 20005 was 19.1%.

In developing countries the situation is even worse, as both doctors and consumers there have far less access to objective sources of information. A 1988 survey of Pakistani doctors with a substantial paediatric practice found that 41% were prescribing a drug with well-recognised dangers to children with diarrhoea, despite the well-recognised dangers of this drug19. Fourteen percent of the doctors prescribed an anabolic steroid, as an appetite stimulant. Ninety-five percent of these doctors cited detailed and up-to-date promotional materials as their main source of prescribing information. There are strong arguments that even in the USA, and elsewhere in developed countries, there may be similar results. The heavy advertising of medications can also create a dependence on a particular form of therapy – modern, brand-name and often prescription medication – and the agents and institutions that make them available in the community. In Australia, El Salvador, this dependence has altered local health care traditions and the means of coping with illness that were previously common in the community, drawn away resources without providing any long-term improvement in living conditions, and actually increased illness20.

Now the much-needed database is ready to be launched, with WHO providing the funding to get the project off the ground. The project is described in two ways: through the keywords and also by putting each entry into one or more “groups.” These groups are an additional method of broadly describing the main topics covered by the entry. The database includes an introduction for users, and is designed to be easily searchable so that people can find information on any aspect of promotion.

Many different interest groups can benefit from the database (see box).

Drug companies will be able to see how promotion influences the choice of drugs and the appropriateness of prescribing. pharmaceutical industry

Consumer organizations These groups can use the database to see what criticisms have been made about their promotion in order to help them develop better internal controls. The database will also help pharmaceutical manufacturers’ associations to strengthen their voluntary codes.

Public and private sector payers These groups can use promotion affects drug use and therefore drug costs.

New WHO/NGO database on drug promotion launched

A the 1997 Roundtable on the WHO Ethical Criteria for Medicinal Drug Promotion, there was firm agreement that inappropriate pro-motion is the biggest problem facing doctors in developing and developed countries. The Report by WHO’s Director-General to the 49th World Health Assembly states that “There continues to be an imbalance between commercially produced drug information and independ-ent, comparative, scientifically validated and up-to-date information on drugs for prescribers, dispensers and consumers.” This was the situation facing the 1999 WHO/NGO Roundtable. It was then decided to develop a comprehensive database on drug promotion, based on information from NGOs around the world, and to place the database on a web site. As Joel Lexchin describes below, the site is about to be launched and will provide valuable input to the growing debate on the effects drug promotion has on health and health care. As can be seen from the articles and references in this issue of the Monitor, evidence is building that pro-motion is costing the health care system more and more each year.

Drug companies spend enormous sums of money promoting their products around the world to doctors. In 2000 over US$13.2 billion was spent in the USA1, the 1998 figure for Italy was US$1.1 billion2, and in developing countries spending accounted for 30% of the sales dollar goes into promotion. There are currently over 80,000 sales representatives in the USA3, and many other countries world wide. In Canada and the European Union. Growth in spending on DTCA in the USA has been dramatic, with nearly US$2.4 billion being spent in 20004.

The companies would not be spending billions of dollars if there was no return and, according to the evidence, promotion does increase sales. For every dollar spent on magazine and television advertising there is a return of US$52.1 and US$1.69, respectively5. Increases in the sales of the 50 drugs most heavily advertised, the US$20.8 billion increase in retail spending on prescription drugs from 1999 to 20006.

Promotion influences prescribing and health care much more than most health professionals realise7,8,9,10,11,12,13. And many advertisers say in effect: promotion provides us with the opportunity to reach doctors, and if doctors prescribe more of our products, this will increase sales.

An increase in sales may or may not be a good thing, depending on how appropriately the drugs are being prescribed and how well they are being used. Details in developed countries consistently fail to spontaneously talk about safety information regarding the drugs that are being promoting14,15. The incomplete nature of the information that representatives provide probably accounts for the fact that studies in Belgium16, the United Kingdom16 and the USA17,18 have all shown a correlation between the use of information from sales representatives and inappropriate prescribing.

In developing countries the situation is even worse, as both doctors and consumers there have far less access to objective sources of information. A 1988 survey of Pakistani doctors with a substantial paediatric practice found that 41% were prescribing a drug with well-recognised dangers to children with diarrhoea, despite the well-recognised dangers of this drug19. Fourteen percent of the doctors prescribed an anabolic steroid, as an appetite stimulant. Ninety-five percent of these doctors cited detailed and up-to-date promotional materials as their main source of prescribing information, versus 6% who used discussions with pharmacists and 2% who cited discussions with colleagues20.

The heavy advertising of medications can also create a dependence on a particular form of therapy – modern, brand-name and often prescription medication – and the agents and institutions that make them available in the community. In Australia, El Salvador, this dependence has altered local health care traditions and the means of coping with illness that were previously common in the community, drawn away resources without providing any long-term improvement in living conditions, and actually increased illness21.

Now the much-needed database is ready to be launched, with WHO providing the funding to get the project off the ground. The project is described in two ways: through the keywords and also by putting each entry into one or more “groups.” These groups are an additional method of broadly describing the main topics covered by the entry. The database includes an introduction for users, and is designed to be easily searchable so that people can find information on any aspect of promotion.

Many different interest groups can benefit from the database (see box).

Potential data users and benefits:

Individual health professionals Doctors, pharmacists and other health workers will be able to see what promotional techniques the pharmaceutical industry uses, and how promotion influences the choice of drugs and the appropriateness of prescribing.

Professional associations These groups can use the database to see what guidelines other groups have adopted for interaction between health professionals and the pharmaceutical industry in order to help them formulate their policies.

Governments and other regulatory bodies The database can help governments and regulatory bodies to see what methods have been tried to control promotion and their success or failure.

Academic researchers The database will let researchers who have been studying promotion, or who are investigating the methodology others have used and what areas are priorities for future research. In addition, they can look at trends in pharmaceutical promotion over a 30-year period.

Consumer organizations These groups can use the database to see what help they lobby for effective control over pharmaceutical promotion and to help educate consumers and potential patients about what promotion has over the choices that health professionals make. They can also use the database to see better acquainted with emerging issues, such as direct-to-consumer advertising of prescription drugs.

Pharmaceutical industry Drug companies will be able to see how promotion influences the choice of drugs and the appropriateness of prescribing. pharmaceutical industry

 promote networking of groups and individuals concerned about promotion by providing links through the web site. Promotion was broadly defined using the WHO definition: “all informational and persuasive activities by manufacturers, the effect of which is to induce the pres-cription, supply, purchase and/or use of medicinal drugs.” Using this definition over 2,000 different items dealing with all aspects of promotion were collected from books, videos, journal articles, magazine and newspaper stories, drug bulletins, ra-dio and television transcripts and guidelines from organizations and professional bod-i es. Hundreds more journal articles will be added in the near future. At present there is only material in English but soon it is hoped to add material from other languages including French and German. Depending on the source of the material, each entry has been catalogued in some or all of the following fields:

Author

Title

Source (address, e mail address, etc. of the group/organization producing the material)

Web site addresses where available, including sites where journal articles that are available on-line can be obtained

Abstract

Keywords

Date material produced (for journal entries complete identifying data, e.g., year, journal volume and page numbers)

Entries on studies that generated new data and/or reported specific methodolo-gical designs include notes on strengths or potential weaknesses in how the study was carried out and limitations in the generalisability of the results.

There is little content on the impact of promotion on health and health care.

The database has already helped to de-fine areas where further research is critical. Little research has been done in how to edu-cate consumers and health professionals about promotion. Even less is known about the long-term effectiveness of the work that has taken place. And despite many entries concerning the regulation of promotion there has also been virtually no work done look-ing at the cost-effectiveness of various forms of regulation. The area of tools for the crit-ical evaluation of drug promotion there are only six entries in the entire database that address this issue in a general way, and only two of these deal with this topic in the context of developing countries.

Putting the database on the web is not the end of this project but only the beginning. Negotiations are underway to ensure that it is kept up-to-date, and reviews of selected topics are possible to help outline what is and is not known about: attitudes to pharmaceutical promotion; the impact of pharmaceutical promotion on attitudes and behaviour; the impact of regulation and control activities; interventions to counter promotion and their impact. It is hoped that there will be funding to extend this project into other areas, and preliminary discussions have already started on the development of tools to help educate health personnel.
and consumers about drug promotion. In the US, the drug industry has been the major force in increasing the sales of its products. Our task is to understand and educate both health professionals and consumers about the impact of drug promotion.

This issue of Essential Drugs Monitor continues the discussion of ethical issues in the pharmaceutical industry. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) released a new code of conduct that reflects the industry’s commitment to best practices in drug promotion. The code aims to ensure that promotional activities are transparent, honest, and in the best interests of patients. However, some critics argue that the code does not go far enough in addressing the concerns of health professionals and patients.

In this issue, we also feature an article on the role of pharmaceutical representatives in influencing the prescribing practices of health professionals. The article provides an in-depth analysis of the activities and interactions between pharmaceutical companies and healthcare providers. It highlights the potential conflicts of interest and the ethical implications of these interactions.

In conclusion, drug promotion is a complex issue that involves multiple stakeholders. It is crucial for policymakers, healthcare providers, and the public to be aware of the potential impacts of drug promotion on healthcare decision-making and patient care. By promoting evidence-based practices and encouraging transparency, we can work towards a more balanced and ethical drug promotion system.
The Australian Pharmaceutical Manufacturers Association Code of Conduct: guiding the promotion of prescription medicines

Libby E. Roughhead*

Promotional messages are designed to be persuasive. Pharmaceutical promotion can influence not only the use of a product, but also our beliefs about medicines. For this reason, it is essential that the information provided within promotional material is accurate, balanced, and not misleading. In Australia, the promotion of prescription medicines is regulated by legislation and guided by the Australian Pharmaceutical Manufacturers Association Code of Conduct. The Code sets standards for promotional activities, including the information content. The system is dependent upon a complaints mechanism for ensuring promotion complies with the Code, as most promotional material is not monitored prior to publication or broadcast. Health professionals are encouraged to lodge complaints against misleading or inappropriate promotion to enhance the effectiveness of the system.

Advertising and promotion are part of everyday life. In the USA, people may be exposed to as many as 5,000 advertisements each day. Health professionals are particularly exposed to the promotion of medicines. This appears in our journals, on the pens and notepads on our desks, on displays at the conferences and symposia we attend and it is brought to our attention during the visits and pharmaceutical representatives. It is a major source of drug information, but also our beliefs about medicinal products showing the image of the tagged lower drug. What this advertisement did not say – and a public health message might – is that there is no reliable evidence that lipid-lowering drug prevents death in patients without pre-existing heart disease or in women. Men with previous heart disease are known to be undertreated and to benefit from cholesterol-lowering drugs. However, this is a much smaller market.

The need for regulation of promotion

Pharmaceutical promotion is a persuasive communication. It involves the conscious attempt to move health professionals from being unaware of a drug to being willing and able to include it in the management of patients. Advertisements designed to be persuasive.

Unfortunately, in many countries promotion is not factual nor evidence-based. Inaccurate and inappropriate promotional claims abound and this has the potential to contribute to irrational drug use. For example, aspirin is commonly promoted in developing countries as suitable for use in children, while antibiotics are promoted as appetite stimulants and other medicines as brain tonics. Consequently, many countries around the world have regulated the promotion of medicines. WHO advocates the regulation of promotion, urging all its Member States to develop guidelines for promotional practice, which are consistent with national health policy and which support rational drug use. WHO has published Ethical Criteria for Medicinal Drug Promotion as a model for such guidelines.

How is promotion regulated?

In Australia, promotion of medicinal drugs is regulated by Government legislation including the Therapeutic Goods Act. The Australian Pharmaceutical Manufacturers Association (APMA) Code of Conduct is a guide for industry on how to advertise and promote prescription medicines. Acceptance and observance of the Code is a condition of membership of the APMA. The current membership covers 95% of the prescription medicines industry.

What activities are regulated?

The APMA Code contains standards for all types of promotional material including all printed and audiovisual promotional material. The Code also articulates standards for pharmaceutical representatives, sample supply, hospitality, industry-sponsored market research and presentation, the use of major trade displays and communications targeting the general public.

References


* Barbara Mintzes is a researcher at the Centre for Health Services and Policy Research, University of British Columbia, Canada.
the latter does not conflict with product information.

The Code of Conduct restricts many activities, including those proscribed by legislation. For example, prescription medicines cannot be promoted to the general public. Responsible companies, however, usually screen material in-house. The APMA has established a monitoring subcommittee that monitors promotional material retrospectively. The subcommittee reviewed 380 pieces of promotional material concerning anti-infectives and antihypertensives between July 1990 and June 2000. Overall, 88% of the 269 items concerning anti-infectives were considered to be in accord with the Code. Of the 111 items concerning antihypertensives, 76% were in accord with the Code [3].

How does the APMA Code work?

The majority of promotional material is not screened by an independent body before publication. Responsible companies, however, usually screen material in-house. The APMA has established a monitoring subcommittee that monitors promotional material retrospectively. The monitoring committee reviewed 380 pieces of promotional material concerning anti-infectives and antihypertensives between July 1990 and June 2000. Overall, 88% of the 269 items concerning anti-infectives were considered to be in accord with the Code, while 92% of the 111 items concerning antihypertensives were considered in accord with the Code.

The main means for ensuring that promotional claims are in accord with the Code’s standards is through a complaints mechanism. Health professionals, pharmaceutical companies and other interested parties are encouraged to lodge complaints with the APMA when they perceive promotional practice to be inappropriate. Complaints have to be in writing and include “the nature of the practice being complained about and a simple explanation of the reason(s) for the objection”. Once lodged, complaints are heard by the Code of Conduct Subcommittee, which is chaired by a lawyer with experience in trade practice, and includes medical, industry and consumer representatives. In the year 1 July 2000 to 30 June 2001, the APMA Code of Conduct Committee evaluated 27 complaints, of which 17 were found to breach the Code. Deciding if a piece of promotion is misleading can be difficult, particularly if promotional messages are new to the reader for the first time. However, there are some common causes of misleading claims. These include claims based on poorly designed studies, obsolete data, information outside of approved product information and the word “safe” cannot be used unless it is substantiated.

How does the Code breach?

Where promotional claims have been found to be in breach of the Code, the APMA Code of Conduct Subcommittee may impose a sanction. Sanctions include the requirement to cease or modify the promotional practice, or publishing corrective letters or retraction statements, the imposition of fines of up to $75,000 or expulsion from the APMA membership. For example, a complaint was lodged in 2000 regarding a product for hormone replacement therapy, claiming “protection of bone mineral density” and “cardiovascular protection”. The claim regarding cardiovascular protection was ruled to be inaccurate, potentially misleading and not an approved use in Australia. The company was required to withdraw the promotional material and was not entitled to use it again. A $5,000 fine was imposed.

Is the Code effective?

There has been much debate over whether codes of conduct are an effective mechanism for controlling pharmaceutical promotion. A series of studies by clinical pharmacologists, conducted between 1985 and 1992, led to the conclusion that the quality of information in advertisements had improved over that time. The adherence of many other activities, such as symposia and the activities of pharmaceutical representatives, to the Code has not been well studied. A small study of pharmaceutical representatives’ presentations to doctors suggested that the information provided was not always accurate, nor in accord with the Code.

The current system is limited by the retrospective detection of Code breaches.

Complaints against misleading or inaccurate promotional messages can only be lodged after the messages have been published, by which time they may have had the potential to influence practice. Monitoring does not overcome this, as it is also retrospective. While promotional messages which are in breach of the Code may be required to be withdrawn and not appear in future, this does not redress their prior dissemination. The only recourse for re-education under the current system is the publication of corrective letters. The success of such letters as a method for righting erroneous beliefs that have resulted from misleading promotion is an area that requires more consideration. The distribution of printed material alone as a mechanism for improving use of medicines has been shown to have little effect, so is unlikely to be effective in this arena.

Although fines can be imposed for Code breaches, when compared with promotional budgets these may not be significant. The uppermost sanction that can be imposed is expulsion from membership of the APMA, a sanction which has not yet been employed. A further limitation is that non-member companies are not bound by the Code.

These limitations highlight the need for a co-regulatory approach to pharmaceutical promotion. Government must take an active stance in regulating promotional practice where the Code is limited. Further, evidence has shown the regulatory system is strengthened if an active, interested third party operates a “watchdog” role. Support for an organization of this type is warranted. In Australia, the Medical Lobby for Appropriate Marketing (MalAM) Australia has undertaken this role in the past with funding from the Australian Government. MalAM Australia ceased to exist after funding stopped. MalAM International is still in operation, now known as Healthy Skepticism.

Limits to the Code

Even if the Code worked optimally, practitioners should be aware that promotional messages can be accurate but may still not support the quality use of medicines. This situation arises because medicines may be promoted for any indication listed in product information, which may not be in accord with recommendations in sources of objective information such as the Therapeutic Guidelines or the Australian Medicines Handbook. For example, dextropropoxyphene is indicated for mild to moderate pain, but the Australian Medicines Handbook recommends its use should be avoided.

Conclusion

Enforcement of the legislation and Code of Conduct guiding promotional practice is vital to ensuring that promotional material is accurate, balanced, not misleading and promotes appropriate use of medicines. The current self-regulatory system relies on a complaints mechanism for recognising Code breaches and can only be effective if complaints are lodged whenever there is concern that promotional practice is inappropriate. It is essential that health professionals become more active participants in this process. The effectiveness of the system is equal dependent on appropriate sanctions. It would appear that current sanctions may not be severe enough to act as a barrier to inappropriate promotional practice and should be increased. Further, governments must be prepared to play an active role, where codes appear to be failing, and provide funding for independent ‘watchdog’ activities to increase the effectiveness of the system.

References

Growing concern about this situation and its negative impact on rational drug use, and the need to alert the medical profession has long been a subject of debate. Controversy exists over the large sums of money some companies spend promoting their products to doctors, often with gifts, free meals, travel subsidies and sponsored symposia. Now a study has concluded that the issue needs to be addressed both at policy level and during medical training.

The study set out to identify the extent of the relationship between physicians and the pharmaceutical industry and its representatives, and its impact on doctors’ knowledge, attitudes and behaviour. A Medline search was done for English-language articles published from 1994 to January 2000, with review of reference lists from retrieved articles. In addition, an Internet database was searched and five key informants were interviewed. Twenty-nine studies published in peer-reviewed journals were included in the research. Of these 16 addressed the extent of the physician-industry interaction, 16 identified the attitude of the physician towards the interaction and 16 evaluated the effect of the interaction on the practitioner. Articles using an analytic design (having a comparison group) were considered to be of higher methodological quality.

**Effects on prescribing behaviour**

Research showed that physician interactions with pharmaceutical representatives were generally endorsed, began in medical school, and continued at a rate of about four per month. Meetings with representatives were associated with requests by doctors to add the drugs discussed to the hospital formulary and changes in prescribing practice. Drug company-sponsored continuing medical education preferentially highlighted the sponsor’s drug(s) compared with other continuing education programmes. Attending sponsored medical education events and accepting funding for travel or lodging for educational symposia were associated with increased prescription rates of the sponsor’s medication. Attending presentations given by pharmaceutical representatives was also associated with non-rational prescribing.

The study concludes that the present extent of physician-industry interactions appears to affect prescribing and professional behaviour. It calls on policy-makers and educators to address this complex issue and the ethical considerations raised.

**Reference**

A   n increasing number of pharmaceutical products are available in the world market, and there has been rapid growth in both drug consumption and expenditure. However, many people throughout the world cannot obtain the drugs they need, either because they are not available or too expensive, or because there are no adequate facilities or trained professionals to prescribe them. Although hard data are unavailable, WHO has estimated that at least one-third of the world’s population lacks access to essential drugs; in poorer areas of Asia and Africa this figure may be as high as one-half. Millions of children and adults die each year from diseases that could have been prevented or treated with cost-effective and inexpensive essential drugs.

Even people who have access to drugs may not receive the right medicine in the right dosage when they need it. Many people buy, or are prescribed and dispensed, drugs that are not appropriate for their needs. Some use several drugs when one would do. Others use drugs that carry unnecessary risks. The irrational use of drugs may unnecessarily prolong or even cause ill-health and suffering, and results in a waste of limited resources. In many countries drug quality assurance systems are inadequate because they lack the necessary components. These include adequate drug legislation and regulations, and a functioning drug regulatory authority with adequate resources and infrastructure for enforcement. All these factors may have serious health and economic consequences.

These problems persist despite much work to improve access to essential drugs, to ensure drug quality and to promote rational drug use. The reasons are complex and go beyond simple financial constraints. To understand them it is necessary to look at the characteristcs of the drug market, and to study the attitudes and behaviour of governments, prescribers, dispensers, consumers and the drug industry. Health sector development, economic reform, structural adjustment policies, trends towards liberalisation, and new global trade agreements all have a potential impact on the pharmaceutical situation in many countries. They may also affect the ultimate goal of achieving equity in health.

Changes in the patterns of disease and drug demand also represent major challenges. The rise of new diseases, such as acquired immunodeficiency syndrome (AIDS), the re-emergence of other diseases and increasing drug resistance of potentially fatal diseases, such as malaria and tuberculosis, all contribute to increased spending on drugs and growing pressure on health resources. Changes in life expectancy and in lifestyles have led to an increase in chronic diseases and diseases of the elderly, and an increase in the need for drugs to treat these.

A common framework to solve problems

Experience in many countries has shown that these complicated and interdependent problems can best be addressed within a common framework. Piecemeal approaches can leave important problems unsolved and often fail. In addition, the different policy objectives are sometimes contradictory, and so are the interests of some of the stakeholders. On the basis of this experience, WHO therefore recommends that all countries formulate and implement a comprehensive national drug policy (NDP).

Its new publication, How to Develop and Implement a National Drug Policy1, discusses key policy components.

What is a national drug policy?

A commitment to a goal and a guide for action

A national drug policy is a commitment to a goal and a guide for action. It expresses and prioritises the medium- to long-term goals set by the government for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and the private sectors, and involves all the main actors in the pharmaceutical field.

A national drug policy, presented and printed as an official government statement, is important because it acts as a formal record of aspirations, aims, decisions and commitments. Without such a formal policy document there may be no general overview of what is needed; as a result, some government measures may conflict with others, because the various goals and responsibilities are not clearly defined and understood.

The policy document should be developed through a systematic process of consultation with all interested parties. In this process the objectives must be defined, priorities must be set, strategies must be developed and commitment must be built. The importance of the process is discussed further in relation to policy development in Australia, Lao People’s Democratic Republic, Thailand, and the Philippines (see p 26).

Box 1

Why is a national drug policy needed?

A national drug policy is needed for many reasons. The most important are:

- to present a formal record of values, aspirations, aims, decisions and medium- to long-term government commitments;
- to define the national goals and objectives for the pharmaceutical sector, and set priorities;
- to identify the strategies needed to meet those objectives, and identify the various actors responsible for implementing the main components of the policy;
- to create a forum for national discussions on these issues.

The consultations and national discussions preceding the drug policy document are very important, as they create a mechanism to bring all parties together and achieve a sense of collective ownership of the final policy. This is crucial in view of the national effort that will later be necessary to implement the policy. The policy process is just as important as the policy document.

The main objectives of ensuring equitable access, good quality and rational use are usually found in all national drug policies, but clearly not all of these policies are the same. The final definition of objectives and strategies depends on the level of economic development and resources, on cultural and historical factors, and on political values and choices.

A national drug policy is an essential part of health policy

A national drug policy cannot be developed in a vacuum – it must fit within the framework of a particular health care system, a national health policy and, perhaps, a programme of health sector reform. The goals of the national drug policy should always be consistent with broader health objectives, and policy implementation should help to achieve those broader objectives.

The health policy and the level of service provision in a particular country are important determinants of drug policy and define the range of choices and options. On the other hand, the drug situation also affects the way in which health services are regarded. Services lose their credibility if there is no adequate supply of good quality drugs, or if these are badly prescribed. Thus the...
national drug policy

How to develop... cont'd from pg. 23

implementation of an effective drug policy promotes confidence in and use of health services. There are also economic arguments. In many countries a large proportion of health care spending is on drugs. Health care financing is therefore closely related to drug financing. It is very difficult to implement a health policy without a drug policy.

Objectives of a national drug policy

In the broadest sense a national drug policy should promote equity and sustainability of the pharmaceutical sector. The general objectives of a national drug policy are to ensure:

- Access: equitable availability and affordability of essential drugs
- Quality: the quality, safety and efficacy of all medicines
- Rational use: the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers

The more specific goals and objectives of a national policy will depend upon the country situation, the national health policy, and political priorities set by the government. In addition to health-related goals there may be others, such as economic goals. For example, an additional objective may be to increase national pharmaceutical production capacity.

It is critical that all the drug policy's objectives are explicit, so that the roles of the public and private sectors, the various ministries (health, finance, trade and industry) and government bodies (such as the drug regulatory authority) can be specified.

Importance of the essential drugs concept

The essential drugs concept is central to a national drug policy because it promotes equity and helps to set priorities for the health care system. The core of the concept is that use of a limited number of carefully selected drugs based on agreed clinical guidelines leads to a better supply of drugs, to more rational prescribing and consumption.

By the end of 1999, 156 developed and developing countries had national or institutional lists of essential drugs for different levels of care, in both the public and private sectors. 127 of these lists had been updated in the previous five years, and 94 were divided into levels of care. There is substantial evidence that the use of national lists of essential drugs has contributed to an improvement in the quality of care and to a considerable saving in drug costs.

The national drug policy process

A national drug policy involves a complex process of development, implementation and monitoring. First, the policy development process results in the formulation of the national drug policy. Second, strategies and activities aimed at achieving policy objectives are implemented by the various parties. Finally, the effect of these activities is monitored and the programme adjusted if necessary. Throughout the process careful planning and the involvement of all parties are needed, and the political dynamics have to be considered at all times.

A drug policy without an implementation plan remains a dead document. Careful planning of the implementation steps and activities necessary to arrive at the expected outcome is important throughout the process.

Involving all parties

Throughout the policy process (and not only in the development phase) there should be consultation, dialogue and negotiations with all interested groups and stakeholders. These include other ministries (higher education, trade, industry), doctors, pharmacists and nurses, local and international pharmaceutical industries, drug sellers, academia, nongovernmental organizations (NGOs), professional associations and consumer groups. It is also important to consult with provincial and district medical and administrative personnel, and to make an effort to include traditional and herbal medicine practitioners. Other government agencies (such as the drug regulatory agency), insurance companies and groups paying for health care must be involved. The media can be helpful, and support from international organizations is important. It is recommended that the national drug policy committee meets regularly to review the implementation of the policy with all interested parties in a national drugs forum.

There is likely to be some disagreement among the various stakeholders. For example, drug manufacturers may feel that their commercial interests are threatened, and doctors may fear the loss of clinical freedom. Any party that benefits from the existing situation will be worried about change. It is a real challenge to create and maintain a process that delivers the broad consensus essential to implementing the policy. In general it can be said that the more the existing pharmaceutical system needs to be improved, the more important it is to involve all interested parties in discussing the necessary reforms.

Political dynamics

Formulating and implementing a national drug policy are highly political processes. This is because such a policy usually seeks to achieve equity of access to basic health care, primarily by making the pharmaceutical sector more equitable and cost-effective and responsive to health needs. Such responsiveness may include redistribution of goods and power, leading to increased competition among the groups affected by reform. Given the diverse interests and the economic importance of the issues involved, opposition to the new policy and attempts to change it during implementation can be expected, as happened in Bangladesh and the Philippines.

For this reason it is important to identify political allies, and to maintain their support throughout the process. Strategies to deal with opponents should be developed and ways of working with them must be identified. Decisions and priorities touching on the interests of these stakeholders must be balanced on the basis of estimated gains and losses. Strong political leadership and sustained commitment are vital for the formulation and implementation of a national drug policy.

Formulating a national drug policy

By the end of 1999, 66 countries had formulated or updated their national drug policy within the previous 10 years. Very often an acute emergency or an important political change created a window of opportunity to start the policy formulation process. In some countries this was a change in government committed to reform; in other countries it was an economic or political change, such as the sudden devaluation of the CFA (Communauté financière d’Afrique) Franc, or the collapse of the Union of Soviet Socialist Republics, which created the need to harmonise and improve certain aspects of the pharmaceutical system. Other factors could be a political drive towards expansion of the local industry or the implementation of global trade agreements.

Step 1: Organize the policy process

The ministry of health is the most appropriate national authority to take on the role of formulator of the national drug policy. The first step is to decide how to organize the development process that will identify the structure of the policy, its major objectives and its priority components.

At this stage it is important to identify all the interested parties that need to be involved, the necessary resources, and how these can be obtained. The need for assistance from WHO, donors or countries with relevant experience should also be assessed. This stage can be carried out within the ministry of health with support from a small committee of selected experts.

Step 2: Identify the main problems

In order to set realistic objectives a thorough analysis and understanding of the main problems in the pharmaceutical sector are needed. There are various ways of carrying out an initial situation analysis.

One successful approach has been to bring together a small team of experts, some of whom should have performed similar analyses in other countries. These experts should come not only from the ministry of health but also from other disciplines and backgrounds. They should be tasked to examine the issues systematically, to identify the main problems, to make recommendations about what needs to be done and what can be done, and to identify possible approaches. They should act as impartial advisers. Once they have formulated their recommendations, there should be support and engagement from a multidisciplinary workshop, in order to formulate consolidated advice to the government. Examples of such reports are available from the WHO Department of Essential Drugs and Medicines Policy.

Step 3: Make a detailed situation analysis

A more detailed situation analysis of the pharmaceutical sector and its components may be needed. This could further analyse the sources of the problems, in order to identify potential solutions, choose the most appropriate strategies, set priorities, and serve as a baseline for future systems of monitoring and evaluation.

Step 4: Set goals and objectives for a national drug policy

Once the main problems have been defined, goals can be set and priority objectives identified. For instance, if one of the priority problems is lack of access to essential drugs, one of the priority objectives should be to improve the selection, affordability and distribution of essential drugs.

The selection of appropriate strategies to achieve the objective is more complex, since it may involve choosing from among very different approaches. A workshop involving a small number of key policymakers may be helpful. The situation analysis should justify the choices and serve as the basis for decisions. Once the main objectives and strategies have been outlined, they should be discussed with all interested parties. Broad consultation and careful consideration of conflicting interests and structural constraints are necessary to set achievable objectives and to formulate appropriate strategies to attain them.

Step 5: Draft the text of the policy

Once a thorough analysis of the situation and an outline of the main goals, objectives and approaches have been completed, the draft text of the national drug policy should be prepared. It should set out the general objectives of the policy. In most countries this will be to ensure that essential drugs are accessible to the entire population; that the drugs are safe, efficacious...
and of good quality; and that they are used rationally by health professionals and consumers. The specific objectives should also be described, followed in each case by the strategy to be adopted. Drafting of the policy can be done by a small group of experts who have been involved in the earlier stages of the process. Examples of national drug policy documents from other countries may be consulted.

**Step 6: Circulate and revise the draft policy**

The draft document should be widely circulated for comment, first within the ministry of health, then in other government ministries and departments, and finally to relevant institutions and organizations outside the government, including the private and academic sectors. Endorsement by government sectors responsible for planning, finance and education is important, since the successful implementation of many elements of the policy will depend on their support as well. Once this consultation is complete, the draft document should be revised in the light of the comments received, and finalised.

**Step 7: Secure formal endorsement of the policy**

In some countries the document can then go to the cabinet or parliament for endorsement. In others it will remain an administrative document that serves as a basis for implementation plans and changes in the law and regulations. In some countries the entire national drug policy document has become law. This is a powerful demonstration of political commitment but it can also cause problems, as future adjustments to the policy may become difficult. It is therefore recommended that only certain enabling components of the policy are incorporated into law, without too many operational details.

**Step 8: Launch the national drug policy**

Introducing a national drug policy is much more than a technical task. To a large extent the policy’s success will depend on the level of understanding of different sectors of society, and on their support for its objectives. The implications and benefits for all interested parties should therefore be stressed.

The policy should be promoted through a clear and well-designed information campaign. Public endorsement by respected experts and opinion leaders can be very useful. Information should be disseminated through a variety of channels to reach different target groups. The media can play a major role in ensuring public understanding and support for the policy. Some countries have organized high profile launches.

**Implementing a national drug policy**

A policy, however carefully formulated, is worthless if it is not implemented. Every drug policy needs an overall implementation plan or “master plan”; each component of the policy needs a detailed strategy and specific action plans (see Box 2).

**Priorities for implementation**

For each country the priorities for implementation will be different. For example, when health care coverage is broad and access to drugs is not a problem, rational use and cost of drugs are likely to be of concern. In such a situation, implementation of a drug policy will focus on regulating the market and on containing costs without decreasing sustainable access and equity. In least developed countries total spending on health and pharmaceuticals may be very low, and the private sector not geared to meeting the needs of the majority of the population. In this situation the focus of the policy will be more on increasing access to essential drugs.

Priorities for implementation should be based on the severity of the problems, and on the potential for success in achieving the objective and making an impact with available resources.

**Monitoring national drug policies**

Monitoring is a form of continuous review which gives a picture of the implementation of planned activities and indicates whether targets are being met. A variety of methods can be used, but it is essential to:

- Identify the right questions: focus on questions with answers that are relevant for management decisions.
- Limit data collection to data that are relevant and are likely to be used. If too many data are collected the process will become expensive, and data analysis will become too complicated and probably less accurate.
- Establish a reliable data collection system; remember that the data will be reliable only if they are also of relevance to the people who collect them. Whenever possible, build on and strengthen existing systems; data collection should as much as possible be built into the routine functioning of the system. This requires staff to be trained and resources to be allocated. Rapid feedback of results is important.
- Report the aggregated results to the central policy and management level, to be used for management decisions, as well as being used by district or provincial health managers. If the data are used to prepare a monitoring report, the report should be shared with all those who contributed to it, including those who collected the data.

**Periodic evaluations**

The national drug policy should be evaluated periodically, for example, every four years. Independent consultants or professionals from other countries or from WHO may be invited to complement a national evaluation team. Such evaluations should be an integral part of the pharmaceutical master plan, with the necessary resources allocated from the start.

**A vital framework**

In summary, national drug policies are crucial because they promote equity and sustainability in the pharmaceutical sector and provide a framework to identify national goals and commitments. The key questions are how to help countries to develop and implement a comprehensive policy, appropriate to their own needs and resources. They are already proving an invaluable resource for health professionals, policy-makers and researchers.

[References]


**Brazil boosts information on generics**

The Brazilian Health Ministry has begun a campaign to disseminate information on generics to patients, doctors, hospitals and pharmacies, reports Escrivo (12 October 2001). The campaign, launched in October 2001 to coincide with new labelling for generic drugs, (all packs have a yellow band with a blue G) includes television and radio spots to help consumers recognize generic products. Pharmacies have received posters and display models listing generic medicines. Doctors are being sent pocket-size generic information guides with the list of approved generic medicines and their technical details. To facilitate prescribing, the guides give generics in alphabetical order, by order of the reference product, and by therapeutic category. Doctors working in the public health system, who are obliged to prescribe generically, are also being sent prescribing information, while hospitals will be provided with posters and basic patient leaflets on generics.

...And a web site

Brazil’s Health Ministry and Medical Association have set up a database on generic medicines available in the country, manufacturing companies, reference products, therapeutic categories, dosage and pharmacetical form. The database can be searched by generic name, reference product, company or therapeutic category. The site is at: http://www.medicamento genericos.br/
How to implement national drug policies successfully

Souly Phanouvong, Simon Barraclough, Ken Harvey

It is more than a decade since WHO advocated that its Member States develop and implement national drug policies (NDPs), with the goal of making effective and safe drugs of good quality available and affordable to all, and promoting their rational use. Many countries have re- responded to the call by developing such policies. Seventy-two countries have official drug policy documents, which they have sought to implement with varying degrees of success. This article suggests five essential elements for effective policy implementation. These elements emerged from the findings of a study entitled Medicines for All? The challenge for developing and implementing national medicinal drug policies in Australia, Thailand, the Philippines and Laos. Methods used for data collection combined a comprehensive analysis of original policy documents, secondary literature, interviews with 125 local and international informants in all four countries. The study was conducted at La Trobe University, Melbourne, Australia, between 1995 and 1998.

While successful implementation depends on a range of general prerequisites, such as adequate funding, effective organizational structures, committed and qualified human resources, and the recognition of the plurality of opinions, five elements were conspicuous in each country’s experience. These are: setting realisable goals and objectives; political will and commitment on the part of government decision-makers, particularly at ministerial levels. In most countries studied, the ministers for health and the cabinet played a crucial role in policy initiation. Following on, the role of these initial key players diminished. Rather, implementation was partly due to legislation and regulations passed by parliament or changes of government. In Thailand, the Philippines and Australia, once the policy was launched, the ministers for health and the cabinet played a crucial role in policy initiation.

However, with the exception of Australia, once the policy was launched, the role of these initial key players diminished. Rather, implementation was largely dependent upon the capability of policy implementers at sub-ministerial level, as well as the degree of government commitment to provide resources. There was a strong perception amongst study informants that a decrease in initial political will and commitment had occurred in Laos, Thailand and the Philippines, and that this had slowed the progress of NDP. In other words, in these countries, initial political will was not sustained; it reached a peak at the formulation stage then declined as the policy aged and governments changed. By contrast, in Australia where successive governments showed commitment to continued funding of NDP programmes (despite some subsequent cuts), the policy was implemented more effectively.

It is important that policy-developers possess some skill in mobilising and convincing key government officials (especially the minister and vice-ministers for health and finance), and political figures to make resources available. Several informants suggested that government officials, especially in health and pharmaceutical sectors (including health legislators and administrative officials), together with those in related fields, should all be actively involved in the NDP formulation process. When changes of health minister or changes of government are imminent, policy advocates in the bureaucracy and outside should start to educate and lobby the potential new ministers and political figures for support and cooperation. The experience of Thailand, the Philippines and, to a lesser extent, Australia, showed that new governments or new ministers were often initially reluctant to provide continuing support for NDP, especially if they were from a political party with different attitudes and priorities.

2. Political will and commitment

Political will is one of the most important elements in an NDP. Not only should there be commitment on the part of the government, including the health minister, the prime minister and the cabinet, but also the key stakeholders. The success of introducing an NDP largely stemmed from the willingness, capability and commitment of the key players at the individual, ministerial and parliametary levels. In most countries studied, the ministers for health and the cabinet played a crucial role in policy initiation.

However, with the exception of Australia, once the policy was launched, the role of these initial key players diminished. Rather, implementation was largely dependent upon the capability of policy implementers at sub-ministerial level, as well as the degree of government commitment to provide resources. There was a strong perception amongst study informants that a decrease in initial political will and commitment had occurred in Laos, Thailand and the Philippines, and that this had slowed the progress of NDP. In other words, in these countries, initial political will was not sustained; it reached a peak at the formulation stage then declined as the policy aged and governments changed. By contrast, in Australia where successive governments showed commitment to continued funding of NDP programmes (despite some subsequent cuts), the policy was implemented more effectively.

In an ideal policy environment, prescribing and dispensing should be kept separate for professional and ethical reasons. In practice, however, these two activities are conducted concurrently by many doctors and pharmacists in the Philippines and Thailand, and even more so in Laos, in their private practices. This is partly due to legislation and regulations on prescribing and dispensing practices not being effectively implemented. However, in order to separate prescribing and dispensing functions, the attitudes and behaviour of prescribers, dispensers and also consumers need to be changed towards rational drug use. Attitudinal and behavioural change can be achieved through an effective enforcement of the relevant laws and regulations, the implementation of educational programmes, and by introducing incentives. Experience in other countries has shown that effective implementation of a legal framework can be achieved through strict sanctions and penalties where the parties concerned (doctors, pharmacists and health workers) are mandated to perform their work under strict regulation.

4. The need for legitimacy

Regulatory measures are more effective if they are considered legitimate by those being regulated. Legitimacy is not the same thing as legality. Policy development and implementation must involve seeking to establish the legitimacy of NDPs.

In countries where people have a culture of respect for the rule of law and government policies, NDP programmes were more likely to achieve their objectives. For example, in Australia, the high acceptance of stakeholders of the National Health Act, contributed to the success of equity of access policy implementation. To increase the acceptance of the Philippine NDP and to legitimise the Bioethics Act, policy-makers mobilised not only Government officials, political figures, academics and health professionals, but also consumers, the media, and the Church. While the...
pharmaceutical companies have complied with the policy in terms of generic labelling, this aspect of policy is actively opposed by the Philippine Medical Association for prescribing. The Association did not accept general prescribing as legitimate, even though it was legislated. In Australia, persuasive means were used by the Government to enhance policy legitimacy. Economic incentives to increase the policy’s level of acceptance and compliance with legislation could be offered through an insurance scheme or the Government reimbursement and remuneration systems.

Good policy-making requires listening to stakeholders’ views; this, in turn, requires an effective mechanism of communication and coordination and sufficient time for comments on the draft policy document. Key stakeholders should be invited to the earliest stage of policy development, i.e. conceptualisation or initiation, to give their opinions and involvement in order to become part and owner of the development process. Later this will promote key stakeholders’ acceptance of the policy and engage their responsibilities in the implementation. Failure to receive the plurality of opinions can result in policy unfeasibility.

5. Co-option and cooperation of stakeholders

Co-option involves the absorption into the policy-making elite of actual or potential opponents in order to contain or influence their motivation and capacity to oppose. Such absorption is usually brought about by both persuasion and the judicious use of inducements – commonly in the form of an offer of a position at some level of actual or symbolic leadership or participation in decision-making. Co-option is a recognised political tactic for dealing with opposition. If there is strong opposition from one of the key stakeholders, the policy is unlikely to succeed. For example, the generics labelling and advertisement policy in Thailand was aborted during its introduction, despite a ministerial order for its promulgation. This occurred largely because the pharmaceutical industry did not accept the policy. The Food and Drug Administration took the case to the Judicial Council for an opinion. The Council, by a majority of votes, ruled that the Ministerial Order on generic labelling was unconstitutional. The resistance of the drug industry was a reaction, in part, to consumer groups urging the Food and Drug Administration to withdraw from the market all drugs without generic names on their labels.

In contrast to the failure of the Thai policy reformers to win over their opponents, Australian policy-makers ultimately succeeded in mollifying opposition. In the 1940s initial attempts to introduce a free access scheme for 139 essential drugs were opposed by the Medical Association and were unsuccessful. When a new Government was elected in 1949, lessons had been learned. It was realised that any health plan, including the pharmaceutical benefits scheme, could not be enacted without the co-option of the medical profession. A cooperative approach to the profession was achieved partly by the appointment of a prominent member of the Medical Association as Minister for Health8. Similarly, in the 1990s, Australia used the co-option strategy with all key stakeholders in its attempt to implement the Quality of Medicines Policy in a partnership-building approach.

Realism, consultation and understanding

The problems accompanying the introduction of NDPs in many countries were not only related to technical, legal, socio-economic and cultural issues, but were also political. This was because the policy had major consequences for the interests of key groups, including government, medical and pharmaceutical professionals, the pharmaceutical industry and consumers. Conflicts of interest, opposition and attempts to prevent policy implementation were a common feature in all four policy processes. The more radical the proposed changes were, the more the process of policy development was problematic and political. Policy formulation must therefore be based upon realistic goals and must involve all interest groups – even those opposed to the policy. Moreover, policy-makers must both think and act in a strategic way to ensure that an effective regulatory framework underpins policy and, more importantly, the need for policy reform is understood and accepted by both health care providers and consumers.

* Dr Souly Phanouvong is Technical Advisor for Drug Policy and Global Assistance Initiatives, The United States Pharmacopoeia, Dr Simon Barrocailo and Dr Ken Harvey are Senior Lecturers, School of Public Health, La Trobe University, Australia. For further information contact Dr Phanouvong at The United States Pharmacopoeia, 1260 Twinbrook Parkway, Rockville, MD 20852-1790, USA. Tel: +1 301-816-8582, fax: +1 301-816-8374, email: sgp@usp.org

** Data obtained from the WHO world drug situation survey 1999.

References


USA: problems of access to drugs

Out of America’s most vulnerable elderly who do not have prescription drug coverage, the majority does not suffer from drug coverage because manufacturers feel the “market is not worth investing in”. MSF contends.

The wheel of misfortune

Starting at the “wheel of misfortune” which assigns the visitor one of five different roles and situations, MSF volunteers running the exhibition invite visitors to take on the identity of an imaginary person. Depending on that circumstance, just like the patients MSF treats in developing countries, this person falls ill. Following a coded path through the exhibit, visitors will learn more about real people sharing the same fate. The organization says it will make visitors aware of diseases that are neglected by pharmaceutical companies and governments alike, and about treatment options which are often dramatically limited in developing countries.

By involving those who visit the exhibition in the dynamics of their campaign for Access to Essential Medicines, and raising awareness of the issues, MSF hopes to help mobilise public action to bring life-saving medicines to patients in poor countries.
Developing clinical practice guidelines?

Australia updates methodology

R A T I O N A L   U S E

As research continues to confirm the value of clinical practice guidelines as an element of good medical decision-making, Australia’s National Health and Medical Research Council has published a revised edition of A Guide to the Development, Implementation and Evaluation of Clinical Practice Guidelines. Below we reproduce extracts covering key principles, guideline development, levels of evidence and dissemination. The Guide’s development was prompted by concern over unjustifiable variations in clinical practice; the increasing availability of new treatments and technology; uncertainty as to the effectiveness of many interventions; and a desire to make the best use of available resources. Traditionally, guidelines have been based on the development of consensus among experts, although this process has limitations and can lead to flawed conclusions. There is growing recognition that guidelines should be based, where possible, on the systematic identification and synthesis of the best available scientific evidence. This revised edition of the Guide also reflects concern that greater emphasis should be placed on guideline implementation and evaluation.

Key principles for developing guidelines

There are nine basic principles for developing guidelines:

1. Processes for developing and evaluating clinical practice guidelines should focus on outcomes. Outcome measures can range from survival rates to quality-of-life attributes.

2. Clinical practice guidelines should be based on the best available evidence and include a statement about the strength of their recommendations. Evidence can be graded according to its level, quality, relevance and strength. The “level” of evidence refers to the study design used to minimise bias: the highest level involves a systematic review of randomised controlled clinical trials (see Box 1). “Quality” refers to the methods used to minimise bias in the design and conduct of a study. “Relavance” refers to the extent to which research findings can be applied in other settings. The “strength” of evidence relates to the magnitude and reliability of the treatment effect seen in clinical studies: strong effects are more likely to be real and more likely to be clinically important. Ideally, recommendations would be based on the highest level of evidence, but this may be difficult to achieve in public health and social science interventions.

3. The method used to synthesise the available evidence should be the strongest applicable. Taking the evidence – of whatever level, quality, relevance or strength – and turning it into a clinically useful recommendation depends on the judgement, experience and good sense of the group developing the guidelines. Evidence from a high level study does not automatically result in a good clinical recommendation.

4. The process of guideline development should be multidisciplinary and should include consumers. If guidelines are to be relevant, those who are expected to use them or to benefit from their use should play a part in their conception and development. Involving a range of generalist and specialist clinicians, allied health professionals, experts in methodology, and consumers will improve the quality and continuity of care and make it more likely that the guidelines will be adopted.

5. Guidelines should be flexible and adaptable to varying local conditions. They should include evidence relevant to different target populations and geographic and clinical settings, take into account costs and constraints, and make provision for accommodating the different values and preferences of patients.

6. Guidelines should be developed with resource constraints in mind. They should incorporate an economic appraisal, which may be helpful for choosing between treatment options.

7. Guidelines are developed to disseminate and implemented taking into account their target audiences. They should also be disseminated in such a way that practitioners and consumers become aware of them and use them.

8. The implementation and impact of guidelines should be evaluated.

9. Guidelines should be revised regularly.

Guideline development

When selecting guideline topics there must be a clear problem or concern that would be redressed if guidelines were developed. A multidisciplinary panel should clarify the purpose of the guidelines – such as specifying what conditions and clinical problems they will cover – and identify the desired health outcomes. Rigorous and systematic review of the scientific evidence is essential (see Box 2).

All members of guideline development groups should make declarations of their interests available to appropriate bodies. Both personal and non-personal interests should be declared; for example, personal shares in companies, consultancies to companies, corporate support for specific research, or general departmental activity.

Box 2

The role of a multidisciplinary panel

In formulating guidelines, the panel should:

◆ document the purpose for which the guidelines were developed;

◆ describe the natural history of the disease or condition in question and the various treatments that are possible;

◆ identify situations where any recommendations might not apply;

◆ detail the probable outcomes;

◆ ensure that the guidelines are comprehensive and flexible;

◆ describe the support services that may be required for each potential treatment;

◆ include information, for consumers and clinicians, on any special clinical training or equipment that is needed;

◆ compare the costs associated with the various options;

◆ provide a statement of the scientific basis on which the guidelines were developed and clearly specify the level, quality, relevance and strength of the evidence on which the recommendations are based;

◆ document the uncertainty associated with any conclusions;

◆ document the economic appraisals used in formulating the guidelines.

If consensus-based recommendations are to be issued, they should acknowledge the desirability of developing evidence-based recommendations. Where non-consensus-based statements are issued, there should be clear reference to each of the schools of thought, and consumers should be made aware of the lack of consensus.

Different versions of the guidelines should be developed for different audiences – consumers, general practitioners, specialist nurses, and so on.

During the guideline development phase the panel should also develop a plan for disseminating and implementing the guidelines, and a plan to ensure that the guidelines are evaluated properly and revised as necessary.

Once drafted, the guidelines document should be assessed to determine whether it conforms to the principles outlined in this guide. The draft should be
referral for consultation to a wide range of interested parties.

**Strategies for dissemination and implementation**

Although the guideline document may support a specific strategy for adapting guidelines to local conditions, the guideline development panel may need to help local groups with the adaptation process. There is evidence that a range of dissemination and implementation strategies can be effective. It is probable, however, that those strategies will depend on the nature of the guidelines and which group is being targeted. Possible strategies include:

- producing short summaries for use in a range of forums, including on the Internet and web sites;
- using the media – local, regional or national, or a combination – to publicize both the development process and the availability of the guidelines;
- asking respected clinical leaders to promote the guidelines;
- providing economic incentives;
- using the educational processes of relevant colleges, professional organizations and consumer groups, including conferences, workshops, seminars and specialist journals;
- incorporating the guidelines in routine procedures – such as quality assurance and review processes – of institutions and organizations that provide care;
- piloting the draft guidelines in practices, clinics or hospitals, to facilitate assessment of their relevance, applicability, comprehensiveness and flexibility.

Inclusion of the guidelines alone will not change practitioners’ behaviour. Doctors and other clinicians are most likely to change if they themselves are involved in the change process and if that process involves interventions that directly affect consultation between patient and practitioner. A variety of approaches have been shown to change behaviour or health outcomes, including educating patients, endorsement of the guidelines by key clinical groups, and reminder systems incorporated in clinicians’ daily work.

Workshops for members of guideline development working parties may be beneficial in bringing together multidisciplinary groups as well as consumers to consider the need for clinical practice guidelines, and the methods to be used in their preparation, dissemination, implementation, evaluation and revision.

**References**


---

**Germany: action on overprescribing**

Many German patients, particularly older ones, have developed a dependency on products such as tranquillisers and antisympotics, and actions need to be taken to persuade doctors to change their prescribing habits. These are the conclusions of a report by the Grunder ErsatzKasse (GEK), a health insurance fund in southern Germany. In its annual report for 2001, GEK states that 58,000 of its 1.4 million members, mainly elderly, were being treated with diazepam, most of them for longer than four weeks. As it has members nationwide, the fund believes that its data – from an analysis of 20 million prescriptions – are representative of the country as a whole.

A consultant to the GEK from the University of Bremen claimed that 1.2 million people in Germany were addicted to tranquillisers and hypnotics, with over two-thirds of them women and most aged over sixty. Another finding was that in general women were less adequately treated than men. For example, although there are more female diabetics than men, men tended to receive more insulin or other antidiabetics.

According to the report, 10% of doctors were responsible for 30% of the prescriptions in question. The GEK intends to contact these doctors to get them to change their prescribing behaviours.


---

**China’s first problem-based pharmacotherapy teaching workshop**

The western Chinese town of Chengdu hosted the country’s first workshop on problem-based pharmacotherapy teaching of medical students in August 2001. Some 25 university teachers from Chengdu Medical University and more than 20 from other Chinese medical schools were enthusiastic participants. China CLEN, the national branch of the International Clinical Epidemiology Network (INCLEN) organized the event with support from WHO.

A busy first day was spent on general presentations covering the concepts of essential drugs and rational drug use. Chinese researchers reported on drug use studies in their country, most of which showed a variety of irrational use patterns. Among the problems they encountered was widespread utilisation of different expensive and sophisticated antibiotics, often given intravenously.

The second day was spent on presentations and demonstrations of problem-based pharmacotherapy, and participants divided into small groups to practise the new teaching method. The day closed with role-plays on prescription writing, and giving information, instructions and warnings to patients.

**Theory into practice**

Before the workshop ended participants discussed possible interventions to promote rational drug use in China, and the practical implications of introducing problem-based teaching in traditional curricula. To ensure that the impetus created by the workshop continued, action plans were created for each of the participating universities. The workshop provided an excellent opportunity to promote the growing interest in problem-based pharmacotherapy teaching – an opportunity which participants looked forward to building on in their own work.

---

**US study shows cost-cutting potential of generics**

More appropriate use of generic medications, particularly to treat ulcers and arthritis, could reduce the price of a Medicare prescription drug benefit by more than 16%, says a study released in the USA in January 2002. Medicare is the country’s largest health insurance programme, covering over 39 million Americans.

Researchers from the Schneider Institute for Health Policy at Brandeis University used data provided by the USA’s largest pharmacy benefit management firm, to calculate what percentage of drugs used by the Medicare-eligible population is generic. Pharmacy benefit managers contract with insurers to structure and deliver prescription drug coverage in a cost-controlled way. They found that boosting the rate of generic use by roughly 50% would reduce drug spending per person from $1,647 to $1,377, and save a total of $250 billion between 2003 and 2012.

The study concluded that nearly half the savings could come from increased use of generics to treat ulcers and arthritis – two conditions for which brand-name drugs are now most heavily advertised.

According to the researchers, health plans that use larger proportions of generics include not only “tiered co-payments” that give consumers a financial incentive to use cheaper medicines, but also comprehensive physician education programmes. “Counter-detailing” is used as part of the programmes to demonstrate to practitioners that newer, more expensive drugs are not always better or more appropriate.

Reference


---

**Clinical practice guidelines flow chart**

- Define topic
- Is the topic related to clinical decision-making
- Are there suitable existing guidelines?
- Is there Level 1 IV evidence in respect to each recommendation?
- Develop evidence-based, recommendations or update existing recommendations
- Develop consensus-based recommendations that indicate lack of clear evidence but acknowledge consensus
- Make brief non consensus-recommendations (decreases confidence in recommendations)
- Disseminate and implement
- Evaluate and revise
- Consultation and pilot testing

---

**References**


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.


This basic text on pharmacoeconomics is mainly intended for pharmacy students. It provides information from well-designed scientific studies on the factors that influence the use of antibiotics by health providers, dispensers and community members in low-income countries. It concludes that practices tend to be determined by a complex and multi-layered network of factors which can lead to the development of more effective policies and programmes to address antibiotic use. The report argues that the most productive approach would be a combination of quantitative and qualitative evidence that the human rights dimensions of issues affecting such groups and their access to TB cure. Limits on access to treatment are created by stigma, inadequate information, and treating HIV/AIDS, and management of nevirapine donations are also covered. The document is intended for policy-makers, programme managers and practitioners.


Antibiotics play a key role in treating diseases of bacterial origin in developing countries. High levels of consumption, often clinically unnecessary, have led to a steady increase in drug resistance, particularly to antibiotics used in treating high prevalence diseases. This review provides information from well-designed scientific studies on the factors that influence the use of antibiotics by health workers, dispensers and community members in low-income countries. It concludes that practices tend to be determined by a complex and multi-layered mix of medical, psychosocial, cultural, economic and political factors. Understanding these factors can lead to the development of more effective policies and programmes to address inappropriate antibiotic use.

The authors call for concerted action by governments, public and private institutions and medical leaders to stem the rapid growth of antimicrobial resistance. To achieve lasting change they argue that interventions will need to be multifaceted, long term and based on solid understanding of the behaviours involved. Highlighting the lack of research on determinants of antibiotic use, the report argues that the most productive approach would be a combination of quantitative and qualitative studies. Quantitative research on the patterns of antibiotic use would complement the great variety of qualitative methods, including case simulations, focus group discussions, in-depth interviews and illness diaries to explore determinants.


Although knowledge and experience of effective drug management is spreading rapidly in India, there is still a great need to publicise the benefits of good management. This booklet is part of the campaign to do that. It presents short reports of research interventions in seven states, which covered rational prescribing, improving essential drug availability, dispensing practices and patient adherence, and reducing treatment costs.

Available from: Delhi Society for Promotion of Rational Use of Drugs, National Institute of Immunology, Aruna Asaf Ali Marg, New Delhi–110 067, Fax: 9111 616 2125, e-mail: dsprud@satyam.net.in


In October 2000, WHO convened a consultation on prevention of mother-to-child transmission of HIV, and this document contains the technical notes from the meeting. It provides basic information on the design of a comprehensive mother-to-child transmission-prevention programme, and the choice of antiretroviral regimens. The efficacy and safety of nevirapine for preventing transmission, and for preventing and treating HIV/AIDS, and management of nevirapine donations are also covered. The document is intended for policy-makers, programme managers and practitioners.


Many factors contribute to vulnerability to tuberculosis (TB). Being poor, a minority group, a migrant or refugee, a child or prisoner, or having a weak immune system due to HIV or substance abuse are all factors that can make someone more likely to get TB.

This document looks at the human rights dimensions of issues affecting such groups and their access to TB cure. Limits on access to treatment are created by stigma, inadequate information and inadequate resource allocations for those most in need, the authors state. They call for a cross-sectoral approach with increased synergy among the various health and development sectors, and an end to fragmented interventions. The document examines key human rights principles, such as the right to information and education, in order to generate new thinking and action in the global response to stop TB.

Available, free of charge, from: World Health Organization, CDS/STB, 1211 Geneva 27, Switzerland.


The publication explains public health approaches to developing effective health services and preventive care programmes. It gives practical methods for assessing health needs and working with communities to improve health services. Chapters cover key public health skills, such as managing medicines, communicable disease control, health financing and implementing health services and programmes. With its numerous examples, illustrations and case histories, the publication will be a useful resource for doctors, nurses and other health professionals.

Available from Oxford University Press Book Shop, 116 High Street, Oxford OX1 4RZ, UK. Tel: + 44 1865 242913, fax: + 44 1865 241701, e-mail: bookshop@oup.co.uk (http: //www.oup.com). Price: £24.95.
Essential Drugs Monitor


Various types of traditional medicine (TM) and medical practices referred to as complimentary or alternative medicine (CAM), are increasingly used in both developing and developed countries. National policies and regulations on TM/CAM could ensure the safety, quality and efficacy of these therapies and products, and help to promote integrated health care systems. However, relatively few countries have developed policies and regulations on TM/CAM so far. The present document provides a summary of the legal status of several major practices in TM/CAM from 123 countries. Data are included on the current use of TM/CAM, the regulatory situation of TM/CAM remedies and practitioners, health insurance coverage and practitioners’ education and training.


Currently, fewer than 5% of those needing antiretroviral treatment can access these medicines in resource limited settings. These guidelines serve as a framework for selecting the most potent and feasible antiretroviral regimens as part of an expanded national response. They are intended to be used as a starting point. The publication presents options for first- and second-line regimens, bearing in mind the needs of health systems that often have limitations in staffing and monitoring facilities, without compromising the quality and outcomes of treatment.

For further information contact: Dr Beto Vareldizlis at the Department of HIV/AIDS. Tel: +4 122 7914670, e-mail: vareldizlis@who.int


In recent years, increasing parasite resistance has rendered antimalarial drugs such as chloroquine virtually useless in parts of East Africa. As a result countries in the region are about to change national malaria treatment protocols and MSF has issued a report calling for them to think carefully about their long-term strategies.

According to the report, malaria experts agree that to offer patients effective treatment and prevent further spread of resistance, MSF recommends that treatment regimens should include drug combinations with the Chinese drugs known as artemisinin derivatives. However, because of a lack of resources and what the report terms donor preference for cheap solutions, many health ministries are considering changing protocols to transition strategies, using combinations of drugs that in MSF’s view are often no better than placebos.

As the context of public health provision changes rapidly, new forms of funding are emerging through increased collaboration with the commercial private sector and private foundations. This publication looks at one such joint public-private initiative, the Global Alliance for Vaccines and Immunizations (GAVI), which was formed in 1999.

Based on research in Ghana, Lesotho, Mozambique and the United Republic of Tanzania, the publication examines GAVI’s impact on national health priorities and public health systems. It focuses on country experiences of applying for support, the capacity of systems to incorporate and use new vaccines effectively, and sustainability. The authors conclude that most countries are pleased about the political interest immunization systems are gaining through GAVI. However, there are concerns about what countries viewed as the pressure to make rapid decisions on vaccine selection, the usefulness of reward and evaluation criteria, and delays in vaccine availability. The report also discusses serious health system weaknesses that are an obstacle to safe and effective vaccine delivery.

A formula to calculate budgetary allocations to health districts in a South African Province

C. Ferdi Blok, Monika Zweigarth, Robert Summers

Budgets allocated to health districts in Mpumalanga, one of South Africa’s nine provinces, still reflect the inequitable pattern of past years, with a lack of guidelines and statistical data to calculate actual requirements. As the main instrument for health care delivery in the Province, the 16 health districts receive financial allocations from the Provincial Health Department, including for their pharmaceuticals. Currently, these allocations do not reflect the districts’ needs, as they are based on historical allocations. Three main problems prevent the allocation of equitable budgets to health districts in Mpumalanga. They may reflect a typical situation in South Africa and in many other developing countries.

Historical budgeting

The allocation of pharmaceutical budgets is mainly based on the previous year’s budgets. Hence, in South Africa’s case, it reflects the results of apartheid, whereby certain districts were advantaged, while others were severely disadvantaged. Health service infrastructure is still based on this outdated principle and cannot be changed overnight. As all the allocated budgets are fully used, no additional funds are available to cater for the actual needs of disadvantaged districts. Equity can only be attained if a proper basis for resource allocation is developed and applied.

Right to service

According to Government policy, no patient can be turned away at the institution of his or her choice. As patients disregard district, provincial and national boundaries, population figures used at the moment do not reflect the actual number of users of services. This problem, although recognised, is not reflected at all in the allocated budgets. The lack of up-to-date and accurate statistics aggravates the present situation.

Lack of budgeting guidelines

No clear guidelines exist at the provincial Department of Health for the allocation of a fixed amount per capita (or a proportion of the budget) to pharmaceutical services.

Developing a formula

Methods to redress imbalances in the allocation of health care resources in South Africa have been described previously. In consultation with the Provincial Department of Health of Mpumalanga, the authors developed a formula to be applied to the calculation of health care budgets for districts. The formula can be adapted to suit the allocation process for different services at provincial and national levels.

Initially this formula will not address the allocation of a budget to the provincial pharmaceutical service as a whole, but applying the formula to the current budgeted amount will give a good indication of the validity of this process. The formula is based on the area, population and patient visits of each district. A percentage score is calculated for each district in terms of its share in these three elements in the provincial total. Each score is weighted. For pharmaceutical services, the scores were weighted as follows: area x 1, population x 2 and consultations x 5. This weighting reflects the view that for pharmaceutical services the most important factor is the number of consultations in a district, as it may directly determine the quantity of medicines used. The number of people living in the district is also important as it reflects potential need. The area of the district is relatively unimportant for pharmaceutical services, but might play a role, for example, for transport allocation.

The three weighted scores for each district are added up to give an aggregate score. This total is divided by the sum of the weighting factors to give an aggregate percentage, which represents the district’s share in the total provincial budget.
community health centre or a hospital was taken as one consultation, a hospital in-patient day was counted as three consultations. Table 1 shows the model calculation.

Allowance must be made for previously disadvantaged districts’ upgrading needs. Depending on the department’s policy, the amount to be allocated for this purpose can be either a specific allocation for development or part of the budgeted amount for pharmaceuticals. In this model, the latter approach has been adopted. For each financial year the calculated proportion can be decreased or increased by a certain percentage. The resulting calculated proportions, which will not necessarily add up to 100, are converted to percentages and are applied to the total available budget to determine each district’s calculated allocation.

This factor should be used in a gradual, long-term approach. Care should be taken to prevent a collapse of existing services if decreasing a district’s resources, and wastage or non-usage of funds if increasing them.

Comparison with actual budget and expenditure

The School of Pharmacy at the Medical University of Southern Africa (MEDUNSA) has tested the proposed formula for pharmaceutical budgets. Data on past budgetary amounts and expenditure on pharmaceuticals for the period April 1998–March 1999 were obtained from the Chief Pharmacist, Department of Health, Mpumalanga.

Overall, the provincial budget was overspent by 3%. However, there were considerable differences between amounts budgeted and spent for each health district, ranging between 36% under expenditure and 71% over expenditure, indicating an inadequate distribution of funds between districts. No controls exist to improve adherence to the budget, i.e. incentives to stay within the limit or penalties for exceeding it. Figure 1 compares amounts budgeted and spent with theoretical allowances calculated with the approach described here.

In the majority of cases, the calculated amounts matched actual expenditure more closely than the budgeted allocation. The tendency of the model to increase allocations where the budget and expenditure are low, and to decrease them where budget and expenditure are high, is clearly shown. It must be noted that the Provincial data on area, population and consultations may not consistently reflect the same health district boundaries, which have frequently been changed in the past 25 years.

Figure 1 shows only a tentative result.

A versatile model

The model we have designed and used to analyse pharmaceutical expenditure across districts in Mpumalanga clearly shows maldistribution and inequity. It also allows remedial action to be based on specific needs and parameters, by offering guidelines for equitable allocations.

Hence, a relatively simple formula will enable management to allocate budgets to the districts based on actual needs, and to redress the imbalances of the past. The use of the formula will also stimulate districts to devote more effort to accurate record-keeping and enhance interaction between health professionals.

community health centre or a hospital was taken as one consultation, a hospital in-patient day was counted as three consultations. Table 1 shows the model calculation.

Allowance must be made for previously disadvantaged districts’ upgrading needs. Depending on the department’s policy, the amount to be allocated for this purpose can be either a specific allocation for development or part of the budgeted amount for pharmaceuticals. In this model, the latter approach has been adopted. For each financial year the calculated proportion can be decreased or increased by a certain percentage. The resulting calculated proportions, which will not necessarily add up to 100, are converted to percentages and are applied to the total available budget to determine each district’s calculated allocation.

This factor should be used in a gradual, long-term approach. Care should be taken to prevent a collapse of existing services if decreasing a district’s resources, and wastage or non-usage of funds if increasing them.

Comparison with actual budget and expenditure

The School of Pharmacy at the Medical University of Southern Africa (MEDUNSA) has tested the proposed formula for pharmaceutical budgets. Data on past budgetary amounts and expenditure on pharmaceuticals for the period April 1998–March 1999 were obtained from the Chief Pharmacist, Department of Health, Mpumalanga.

Overall, the provincial budget was overspent by 3%. However, there were considerable differences between amounts budgeted and spent for each health district, ranging between 36% under expenditure and 71% over expenditure, indicating an inadequate distribution of funds between districts. No controls exist to improve adherence to the budget, i.e. incentives to stay within the limit or penalties for exceeding it. Figure 1 compares amounts budgeted and spent with theoretical allowances calculated with the approach described here.

In the majority of cases, the calculated amounts matched actual expenditure more closely than the budgeted allocation. The tendency of the model to increase allocations where the budget and expenditure are low, and to decrease them where budget and expenditure are high, is clearly shown. It must be noted that the Provincial data on area, population and consultations may not consistently reflect the same health district boundaries, which have frequently been changed in the past 25 years.

Figure 1 shows only a tentative result.

A versatile model

The model we have designed and used to analyse pharmaceutical expenditure across districts in Mpumalanga clearly shows maldistribution and inequity. It also allows remedial action to be based on specific needs and parameters, by offering guidelines for equitable allocations.

Hence, a relatively simple formula will enable management to allocate budgets to the districts based on actual needs, and to redress the imbalances of the past. The use of the formula will also stimulate districts to devote more effort to accurate record-keeping and enhance interaction between health professionals.

Conference calls for action on neglected diseases

INTERNATIONAL experts have issued an urgent plea for research and development of new medicines for diseases such as sleeping sickness, kala azar and malaria that kill millions each year in the developing world. At a conference in New York in March 2002 over 400 people, including representatives from the US Government, the European Union, WHO and the pharmaceutical industry, addressed problems need-
WHO fact sheet on drug price information services

In response to requests from Member States, WHO is working with partners to provide drug price information services. These include three major guides: *International Drug Price Indicator Guide; Sources and Prices of Selected Drugs and Diagnostics used in the Care of People Living with HIV/AIDS; and Pharmaceutical Starting Materials/ Essential Drugs Report*. Regional price information services are also supported and are proving very much in demand. To make an increasing amount of information more accessible, EDM has prepared a summary sheet on these services, which is reproduced below. The summary is on the web in English, French, Russian and Spanish at: http://www.who.int/medicines/organization/par/ipc/whointernationalpricingservices.shtml

Hard copies are available in Arabic and Chinese from: World Health Organization, Department of Essential Drugs and Medicines Policy, 1211 Geneva 27, Switzerland.

**International pricing services managed jointly with UN and/or NGO partners**

1. International drug price indicator guide on finished products of essential drugs

This includes 282 active ingredients in 499 dosage forms, and lists indicative prices of generic products on the international market. It has been issued annually, by Management Sciences for Health since 1986 and in collaboration with WHO since 2000. It is available as a printed document and on the web (May 2001), with Management Sciences for Health/Gates Drug Management Centre. It lists indicative prices of generic products on the international market. Web address: http://erc.msh.org/mainpage.cfm?file=1.cfm&id=1&temptitle=Introduction&module=DMP&language=English

Hard copies can be obtained from Management Sciences for Health Publications, 165 Allandale Road, Boston, MA 02130, USA. Tel: +617 524-7799, fax: +617 524-2825; e-mail: bookstore@msh.org Price US$15.

2. Sources and prices of selected drugs and diagnostics used in the care of people living with HIV/AIDS on selected HIV-related drugs

This includes 33 active ingredients in 82 dosage forms, and is issued twice-yearly, available in printed form and on the web sites of WHO and all partners (Médecins Sans Frontières, UNICEF and UNAIDS). This joint project on sources and indicative prices started in 1999 and the first publication came out in 2000. This project will be closely linked with the Expressions of Interest launched as part of the Accelerated Access Initiative. The May 2001 report included an additional section on HIV testing kits and offers of donation/price reductions of antiretrovirals up to 15 April 2001. It also contains a listing of manufacturers in the 2000 price survey by therapeutic groups of drugs produced. An updated report is expected in May 2002. Available on the web at: http://www.who.int/medicines/library/par/hivrelateddocs-sourcesandprices31may01.pdf

Or copies are available from: World Health Organization, Department of Essential Drugs and Medicines Policy, 1211 Geneva 27, Switzerland.

3. Pharmaceutical starting materials/essential drugs report on starting materials (“raw materials”) of essential drugs

This includes over 200 active ingredients. Updated monthly and available in English, French or Spanish to paying subscribers. Lower subscription rates for developing countries and free of charge for least developed countries. Reports available online since January 2002 via password. The partner is the International Trade Centre, which is operated jointly by the WTO and UNCTAD. Web address: http://www.itracen.org/tns/pharma.html

Further information is available from: International Trade Centre, UNCTAD/WTO, Palais des Nations, 1211 Geneva 10, Switzerland.


The second edition of the Essential drugs price indicator published by WHO AFRO contains price information for nearly 300 essential drugs and dosage forms. Price information was provided by 24 Member States and two international low-cost essential drugs suppliers. AFRO produces it with the WHO Collaborating Centre for the Quality Assurance of Medicines, University of Potchefstroom, South Africa. The next edition is expected by the end of 2002. Hard copies can be obtained from AFRO/EDM by sending a request to WHO Regional Office for Africa, Patenryanwata Hospital, P.O. Box BE 773, Harare, Zimbabwe.

Copies are also available from: WHO Health Organization, Department of Essential Drugs and Medicines Policy, 1211 Geneva 27, Switzerland. E-mail: edmdoccentre@who.int

5. WHO Regional Office for the Americas/Pan American Health Organization (AMRO/PAHO): Acquired ImmuneDeficiency Syndrome (AIDS) and Antiretrovirals (ARV) in the Americas.

Web address: http://www.paho.org/Project.asp?SEL=TP&LANG=ENG&CD=AIDSS

AMRO/PAHO provides three pricing information resources:

**Price comparison of antiretroviral treatment**

This PowerPoint presentation gives a comparison of prices of antiretroviral treatment as of December 2000. The purpose is to show the range of prices for a specific drug in Latin American and Caribbean countries. At: http://reunionARV.pricess.pps

**Precios de compra de los antiretroviraless por el Ministerio de Salud en Brasil, actualizados al año 2000 y con datos preliminares del año 2001. (Price of antiretrovirals bought by the Ministry of Health, Brazil, 2000, with preliminary data for 2001.**

In Spanish: http://www.paho.org/Spanish/HCAPreciosBRA.doc

http://www.paho.org/Spanish/HCAPreciosBRA.pdf

**Antiretrovirals in Latin America and the Caribbean**

This page presents information on the prices and uses of antiretroviral treatments, as well as policies concerning access to these drugs.

In English: http://www.paho.org/English/HCP/HCA/antiretrovirals_HP.htm

In Spanish: http://www.paho.org/Spanish/HCP/HCA/antiretrovirals_HP.htm

For further information contact: The World Health Organization, Regional Office for the Americas/Pan American Health Organization (AMRO/PAHO), 525, 23rd Street, N.W. Washington, DC 20037, USA. Tel: +1 202 974-3000, fax: +1 202 974-3663, e-mail: postmaster@paho.org, web site: http://www.paho.org

**Disease-specific price information services**

**HIV/AIDS**


Setting objectives: is there a political will? http://www.accessmed-msf.org/pred/publications.asp?scntid=49200113585&contenttype=PARA&


**Tuberculosis**


**WHO Member States’ price information services**


Brazil: http://www.saude.gov.br/banco/ingles/index_ingles.htm

Denmark: (in Danish): http://www.dma.dk/lagemiddel/oplysninger/priser.asp


India: www.nppaindia.nic.in (Government of India, National Pharmaceutical Pricing Authority)

Latvia: http://www.zca.gov.lv/en/start.htm contains prices of the positive list

Malaysia: (recommended retail prices): http://www.bpfk.org.html/search_product_database_f.htm can be searched by ingredient, product, holder and manufacturer


The United Kingdom: Price information is available on the British National Formulary at: http://nhs.vsh.net/home/

The value of drug donations as a means of galvanising support for developing countries' beleaguered health systems is not in doubt; but neither is the potential for damage. In 1996 WHO published interagency guidelines for drug donations. Now, in an attempt to increase the number of donors who follow these guidelines, comes further advice, in the form of a step by step guide called Good Drug Donation Practices, born out of a 1999 expert seminar of the Medicines Crossing Borders Project. The Project, which is aided by the European Commission, is run by an International Health Consor-tium of four organizations – Wemos, a Dutch health and development NGO, DIFAM from Germany, Prosalus from Spain and ReMed, France. The idea is to inform an increasingly wide spectrum of donors, from medical students and sympathetic tourists to NGOs, pharmacists, church groups and the pharmaceutical industry. Available in English, Dutch, French, German and Spanish, the guide comes in the form of a checklist to ensure the quality of donations once ready for shipment, or to evaluate a donation once made.

Donations may endanger local production of affordable generic drugs based on local needs because they are unable to compete with what is sometimes seen as the “dumping” of free drugs. There are relatively few countries that are entirely dependent on imports and donations. Some, such as the Dominican Republic and Pakistan, have industry capable of producing finished products for their domestic market from imported compounds. The example of Eritrea is telling. Frustration at having to wait for donated medicines which, when they arrived were often of little or no use, led the Eritreans to develop their own plant manufacturing the most commonly used medicines. This now forms the basis of its national manufacturing programme.

Of course there are donation success stories, such as the programme for treating onchocerciasis launched in 1987, which claims 25 million people treated in 32 countries by 1998. With no commercial market, the donor company simply announced it would donate its drug to all who needed it. However the onchocerciasis programme enjoyed many favourable factors; the disease is endemic in a limited geographical area, can be eradicated and has a simple treatment protocol. The programme also addressed the main corporate drawback, ‘sustainability’, by offering the drug for as long as it was needed. These factors do not necessarily apply elsewhere. In other cases there may be questions about the impact on wider national health policies, the ability of public sector services to deal with the programme, and the effect of creating a need that cannot be afforded once the donation stops.

Positive outcomes

Local campaigning successes include an end to the practice of returned drugs becoming donations in The Netherlands. In Germany, Health Minister, Ulla Schmidt, has strongly recommended implementing a declaration on good donation practice (see below), while Spanish NGO, Farmaceuticos Mundi, has started sending generic medicines to NGOs in developing countries rather than returned drugs. The Consortium is pressing for a monitoring system to ensure that the Guidelines for Drug Donations are used as intended – as a practical document for sustainable change. It is also calling for donations that do not meet the guidelines to be banned by a decree or resolution from European Union countries.

The Consortium

The Medicines Crossing Borders Project – improving the quality of donations

making drug donations better with care, have been produced to get the message across to NGOs and the public in as many countries as possible. A web site has also been launched: http://www.drugdonations.org

Inappropriate generosity

The new initiative is necessary because the desire to do good without first seeking proper advice continues to cause waste, frustration and despair among needy developing countries. The Zambian mission hospital that had to bin a box of amphetamine-based appetite suppressants or the Danish medical students bearing a large box of vitamin A injections for a hospital in Tanzania, which the hospital does not use, are examples.

More serious can be the huge cost of disposing of inappropriate donations according to international standards. Of the donated drugs received in Albania during the Kosovo refugee crisis, it was estimated that 50% were inappropriate or useless and would have to be destroyed. Sixty-five per cent of drugs had an inadequate expiry date and 32% were identified only by brand names, unfamiliar to Albanian health professionals. None of the short shelf-life donations were requested, and according to aid workers they could not be distributed and used quickly enough. Inappropriate donations can also undermine local efforts to promote rational prescribing and standard national drugs lists based on effective treatment of common diseases. For example, in French-speaking African countries efforts are being made to organize public health centres using essential generic drugs, but the constant flow of donations from collected drugs has upset these sustainable national systems. Significantly the youngest nation in the world, East Timor, already has a national standard drugs list and a procurement policy that prevents inappropriate donations.

Donations may endanger local production of affordable generic drugs based on local needs because they are unable to compete with what is sometimes seen as the “dumping” of free drugs. There are relatively few developing countries that are entirely dependent on imports and donations. Some, such as the Dominican Republic and Pakistan, have industry capable of producing finished products for their domestic market from imported compounds. The example of Eritrea is telling. Frustration at having to wait for donated medicines which, when they arrived were often of little or no use, led the Eritreans to develop their own plant manufacturing the most commonly used medicines. This now forms the basis of its national manufacturing programme.

Of course there are donation success stories, such as the programme for treating onchocerciasis launched in 1987, which claims 25 million people treated in 32 countries by 1998. With no commercial market, the donor company simply announced it would donate its drug to all who needed it. However the onchocerciasis programme enjoyed many favourable factors; the disease is endemic in a limited geographical area, can be eradicated and has a simple treatment protocol. The programme also addressed the main corporate drawback, ‘sustainability’, by offering the drug for as long as it was needed. These factors do not necessarily apply elsewhere. In other cases there may be questions about the impact on wider national health policies, the ability of public sector services to deal with the programme, and the effect of creating a need that cannot be afforded once the donation stops.

Positive outcomes

Local campaigning successes include an end to the practice of returned drugs becoming donations in The Netherlands. In Germany, Health Minister, Ulla Schmidt, has strongly recommended implementing a declaration on good donation practice (see below), while Spanish NGO, Farmaceuticos Mundi, has started sending generic medicines to NGOs in developing countries rather than returned drugs. The Consortium is pressing for a monitoring system to ensure that the Guidelines for Drug Donations are used as intended – as a practical document for sustainable change. It is also calling for donations that do not meet the guidelines to be banned by a decree or resolution from European Union countries.

Germany’s new drug donation declaration

In its drive to improve health care in developing countries, the German Pharma Health Fund (GPHF) has published a declaration on good drug donation practice in Germany, reports Scrip. (16 Nov. 2001). Signatories undertake to align drug donations with the guidelines published by WHO. They must base donations on certain criteria, including maximum benefits for recipients, a uniform quality standard, and effective consultation between donor and recipient. The GPHF is offering to coordinate drug donations between pharmaceutical companies and relief organizations in the case of humanitarian emergency situations. The initiative on drug donations, which was taken in collaboration with the German Red Cross, the German Institute for Medical Missions and Deutsches Medikamenten-Hilfswerk, a drug donation organization, has had a good response. Already the German branch of Pharmaciens Sans Frontières has signed up to it, as has Germany’s major relief organization. And the country’s Health Minister, Ulla Schmidt, has strongly recommended the declaration’s further distribution and implementation.

Further information is available on the web at: www.gphf.org/web_en/projekte/index.htm

Reference

The growing interest in the implementation of the Doha Declaration by those in health, trade and intellectual property policy circles was evident from the large turnout at a conference in Geneva in March 2002. Médecins Sans Frontières, Consumer Project on Technology, Health Action International, and Oxfam jointly organized this one-day meeting on “Implementation of the Doha Declaration on the TRIPS Agreement and Public Health: Technical Assistance — How to get it Right.” Some 175 delegates attended from national and regional patent offices, the World Trade Organization (WTO) the World Intellectual Property Organization (WIPO), WHO and other UN agencies, academia, industry, donors and NGOs.

The event came immediately after a WIPO conference on the international patent system, at which access to medicines and the appropriateness of having one uniform intellectual property model arose. These issues are at the forefront of the international health agenda following the Doha Declaration, made at the November 2001 WTO Ministerial Conference (see Monitor 30). The Declaration strongly affirmed that the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” As this was the first major international gathering of concerned countries and NGOs since the Doha Ministerial meeting, many participants were eager to make progress towards implementing the Declaration. There was also a desire to assess what role WIPO, as the UN body charged with developing intellectual property systems worldwide, could play in the process. Major conference themes included the nature of WIPO’s technical assistance to low-income countries, the elements necessary for appropriate technical assistance, the ‘production-for-export’ question, and putting compulsory licensing into practice.

Making technical assistance meaningful

Some participants voiced concerns that WIPO’s mandate to strengthen intellectual property protection worldwide may not be consistent with the need for differing levels of intellectual property protection. These levels would take into account varying stages of economic development and local conditions in developing countries, especially given the crisis in access to essential medicines.

In his keynote speech, Deputy Director General of WIPO, Mr Roberto Castelo said that WIPO has now given technical assistance to 134 developing country Member States in a “demystified and very transparent way.” He assured the audience that WIPO’s legal advice took into consideration all the flexibilities available in TRIPS.

There was discussion on the viability of having a model law for TRIPS’ implementation in developing countries, with some participants urging WIPO to provide such a model, incorporating all the flexibilities confirmed by the Doha Declaration. Some pointed to legal precedents, including ways to put compulsory licences into practice.

Implementing Doha provisions

Later discussions focused mainly on the specifics of the Doha Declaration. Professor Carlos Correa, of the University of Buenos Aires, pointed out that least-developed countries face a serious practical hurdle, as Article 31.f of the TRIPS Agreement requires compulsory licences to be used “predominantly for the supply of the domestic market.” This clause may restrict developing countries that do have domestic drug production capacity (e.g. India) from exporting sufficient quantities of medicines to those that do not, making compulsory licensing a meaningless measure for many least-developed countries, Professor Correa argued. Recognising the problem, the Doha Declaration charged the TRIPS Council to “find an expeditious solution” by the end of 2002. He outlined some current proposals to address this situation, urging that “whatever the approach followed, there must be sufficient incentive for generic companies to supply markets that may need more quantities of a given medicine at a low price.”

According to Professor Correa, compulsory licences are “an integral part of the patent system to ensure some competition.” Given the subject’s importance many participants were eager to see how compulsory licensing measures had been implemented in industrialised countries, particularly in the US and UK. In both places the practice of “government use” is current, and delegates heard from two speakers how this often serves the same purpose as compulsory licensing.

From the industry perspective, however, "compulsory licensing is not needed to improve access to quality affordable care,” according to Dr. Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers Associations. He instead asked participants to “encourage the governments to take up the offers made by my companies” such as drug donations and discounted pricing.

Another key issue was the possibility of long, expensive legal challenges brought by patent holders if a country attempted to issue a compulsory licence. Again various solutions were proposed which some participants felt could enable WIPO to expedite proceedings.

There was also discussion of technology transfer as a necessary element to build production capacity for a truly sustainable solution. Under the terms of the Declaration, developed country Members are obligated to submit reports to the TRIPS Council by the end of 2002, detailing their efforts to create incentives for technology transfers to least-developed countries.

Moving forward

The conference revealed much enthusiasm among developing countries for implementing the Doha Declaration’s provisions, heard from speakers about the impact of technology transfers on essential medicines. Concrete proposals for taking advantage of the Declaration emerged, including ways to put compulsory licences into practice and examples of possible model legislation.

It was clear from the broad range of conference participants that intellectual property rights are increasingly of concern – not only to intellectual property rights specialists – but also to policy-makers involved in health, development and trade. Copies of their Conference report are available from Médecins Sans Frontières, PO Box 6090, 1211 Geneva 6, Switzerland.

The conference explored intellectual property issues post-Doha

Canada had had “a model compulsory licensing law,” referring to legislation, which had been “acceptable to the generic and brand companies for many years” prior to the North American Free Trade Agreement. Mr. James Quashie-Idum, Director of the Cooperation for Development at WIPO, affirmed that his Organization would “take fully into account the Doha Declaration in technical assistance.” Mr Castelo also informed participants that WIPO was holding a meeting for least-developed countries in Dar es Salaam in April 2002, at which the Doha Declaration and intellectual property would be discussed. WHO and WTO would participate.

The conference revealed much enthusiasm among developing countries for implementing the Doha Declaration’s provisions, heard from speakers about the impact of technology transfers on essential medicines. Concrete proposals for taking advantage of the Declaration emerged, including ways to put compulsory licences into practice and examples of possible model legislation.

It was clear from the broad range of conference participants that intellectual property rights are increasingly of concern – not only to intellectual property rights specialists – but also to policy-makers involved in health, development and trade. Copies of their Conference report are available from Médecins Sans Frontières, PO Box 6090, 1211 Geneva 6, Switzerland.