



# ESSENTIAL DRUGS MONITOR

DOUBLE ISSUE – N° 25 & 26 (1998)

## Essential Drugs Monitor

The Essential Drugs Monitor is produced and distributed by the WHO Action Programme on Essential Drugs. It is published in English, French, Spanish and Russian, and has a global readership of some 200,000 to whom it is free of charge. The Monitor carries news of developments in national drug policies, therapeutic guidelines, current pharmaceutical issues, educational strategies and operational research.

WHO's Action Programme on Essential Drugs was established in 1981 to provide operational support to countries in the development of national drug policies and to work towards the rational use of drugs. The Programme seeks to ensure that all people, wherever they may be, are able to obtain the drugs they need at the lowest possible price; that these drugs are safe and effective; and that they are prescribed and used rationally.

All correspondence should be addressed to:

The Editor  
Essential Drugs Monitor  
World Health Organization  
CH-1211 Geneva 27, Switzerland  
Fax: +41 22-791-4167  
e-mail: DAPMAIL@WHO.CH

## IN THIS ISSUE:

### Managing Drug Supply 2-13

Benefits of Thailand's collective bargaining system for drug procurement

Drug supply choices: what works best? A primary distributor system for drugs in South Africa

Guatemala's strategies for improving drug supply and access  
And more...

### National Drug Policy 13-14

Meeting promotes African consumers' involvement in drug policy  
Plus articles on Belarus and Zimbabwe

### Research 15-20

Reviving the popularity of commune health stations in a Vietnamese province

Public education in rational drug use: research study shows the value and reveals the problems

### Training 20-21

Students taught how to develop a personal formulary

### Newsdesk 21-25

Change at WHO  
UK study shows patients don't get the information they need  
And more...

### Drug Information 26-27

Communicating drug safety information effectively

### Meetings & Courses 27

### Netscan 28

### Letters to the Editor 28

### Published Lately 29-30

### Rational Use 31-36

How the Netherland's pharmacotherapy discussion groups have evolved  
Essential drugs concept needs better implementation

## EDITORIAL

# Managing drug supply



Photo: WHO/E. Lauridsen

**M**OST leading causes of death and disability in developing countries can be prevented, treated or at least alleviated with cost-effective essential drugs. Despite this fact hundreds of millions of people do not have access to essential drugs.

Although the relative frequencies of specific illnesses vary among countries, health services throughout the world are presented with a fairly common set of health problems for which essential drugs have an important role. Mortality figures across developing regions reflect a huge burden of illness that can be substantially reduced if carefully selected, low-cost pharmaceuticals are available and appropriately used. And even in industrialised countries escalating costs of health care have placed evidence-based and efficient drug supply management high on the agenda. Good drug supply management is an essential component of effective and affordable health care services globally.

Within a decade after the first modern pharmaceuticals became available, efforts began to ensure their widespread availability. From the mid 1950s to the

mid 1970s basic drug management concepts began to evolve in countries as diverse as Cuba, Norway, Papua New Guinea, Peru and Sri Lanka.

Over the last 20 years countries have acquired considerable experience in managing drug supply. Broad lessons that have emerged from this experience include: that national drug policy provides a sound foundation for managing drug supply; that wise drug selection underlies all other improvements; that effective management saves money and improves performance; that rational drug use requires more than drug information; and that systematic assessment and monitoring are essential.

Over the years the Monitor has aimed to share both positive and negative experiences in this critical field. This issue reports on the strengths and constraints of some national, provincial and local initiatives to rationalise drug supply and use. It also draws on material published in the comprehensive second edition of *Managing Drug Supply*, issued in collaboration with the Action Programme on Essential Drugs. This publication, which has long been a fundamental tool in many countries, now compiles state of the art

knowledge, experience and guidance on every aspect of the drug management cycle. Watch out in future issues of the *Monitor* for a new "how to" section drawn from *Managing Drug Supply* and from accompanying training materials currently being developed.

What works best in drug supply has no simple answer. As the article posing this question on p.7 concludes, it will never be possible to state that one particular system is "the best". Each country brings unique political, economic and geographical factors to the equation. And to weigh the pros and cons of one drug supply system against another cannot be properly done from a global perspective without detailed study. The Action

Programme is embarking on just such a multicountry study to examine in depth at the country level the outcomes of the drug supply systems in use. This study will look at the advantages and disadvantages of the systems and the factors which influence the level of success or failure.

However, what the experiences of countless countries and programmes do demonstrate is that substantive and sustainable improvements in the supply and use of drugs are possible. But an equal or greater number of negative experiences show that success is by no means assured. Clear goals, sound plans, effective implementation and monitoring of performance are essential ingredients in pharmaceutical sector development. And we can be sure that if changes in a drug supply system are not based on a careful analysis of the underlying causes for the weaknesses of the existing system then they are unlikely to produce the desired outcome. Systems chosen, for example, because they function in a "successful" market economy may not prove the solution to the drug supply problems faced in the context of a developing country. □



## MANAGING DRUG SUPPLY

# Health reform and drug financing

**H**EALTH sector reform is a process aimed at improving equity, quality and efficiency in the health sector through changes in the organization and financing of health services. In this context, the role of WHO today is to explore and promote ways of organizing health services which respond better to the objectives of equity, quality and efficiency.

Nearly every aspect of national drug policy and pharmaceutical sector development is directly or indirectly affected by health reform initiatives. An addition to DAP's Health Economics and Drugs Series<sup>1</sup>, which is summarised here, focuses primarily on certain financial aspects of health reform.

## DRUG FINANCING REFORMS

Governments have the responsibility to ensure that drug financing mechanisms are managed in such a way as to achieve equity of access to essential drugs. Financing mechanisms include public financing, health insurance, user fees, donor financing and development loans.

### Public financing

Some public spending will always be needed to ensure access to drugs by the poorest in society; to ensure provision of drugs for tuberculosis, sexually transmitted diseases and other communicable diseases; and to ensure care for target groups, such as mothers and children. As a share of national economic output (GNP), public spending on health in developing countries is one-quarter to one-half that of industrialised countries. Health financing reform should improve the use of public resources, but it should not be aimed to further reduce public spending on health.

The level of public commitment for financing health care and drugs should be a matter of explicit public policy, based on an analysis of health care needs and financing options. Policy makers, managers responsible for health care financing, and essential drugs managers should be familiar with the methods for analysing public financing for drugs and for planning public expenditures for drugs.

### Health insurance

Formal health insurance and various informal community insurance programmes represent a growing source of health and drug financing in transitional and developing countries. The experience of many countries has shown that compulsory social insurance can be the critical step to a more equitable health care system. It must be recognised, however, that some developing countries will have difficulties in implementing widespread insurance coverage in the short-term for

a number of reasons, including limited formal employment and weak state mechanisms.

There are benefits in providing pharmaceutical coverage together with health coverage although challenges, such as difficulties in tracking prescriptions, exist. Policy makers and managers need to be fully informed about the value of insurance coverage, alternative mechanisms for providing pharmaceutical benefits, and methods to ensure quality of care, while controlling costs.

### User charges

User charges are increasingly being implemented by governments and local communities in countries at all levels of development, both to supplement general government revenues or insurance premiums, and to help control use (see Box 1). Often, however, such programmes have not learned from past experiences, are not well managed, and, as a result, access shows no improvement, revenue replaces rather than supplements government funding, and drugs are overprescribed.

User fees can complement government allocations for pharmaceuticals, but should not replace them. Future efforts need to ensure that the lessons from existing research and actual experience are applied to the design, implementation and monitoring of user fee programmes to ensure that access to drugs does improve, and that rational use does not suffer. When fee mechanisms are instituted at a national level, a top-down approach, starting with major national and local hospitals, may have advantages in terms of equity, reinforcement of the referral system, revenue potential, administrative capacity and impact evaluation.

### Donor financing and drug donations

Donor financing includes bilateral and

multilateral grants. For some countries, internal financing mechanisms for drugs may prove insufficient, even after reforms, and therefore external funding can prove invaluable to relieving immediate human suffering and can allow countries to develop long-term solutions.

The challenge with all external financing, but particularly when it involves the financing of recurrent costs, is to not allow this to substitute for efforts by countries to develop sustainable financing mechanisms. Transitions from external mechanisms to internal mechanisms need to be incorporated in assistance plans from their conception. But it should be recognised that sustainability may require relatively long-term commitments by donors.

To promote beneficial drug donations and to minimise unintended problems with drug donations, interagency guidelines<sup>2</sup> have been published which set out core principles and 12 specific guidelines which should be followed in all drug donations.

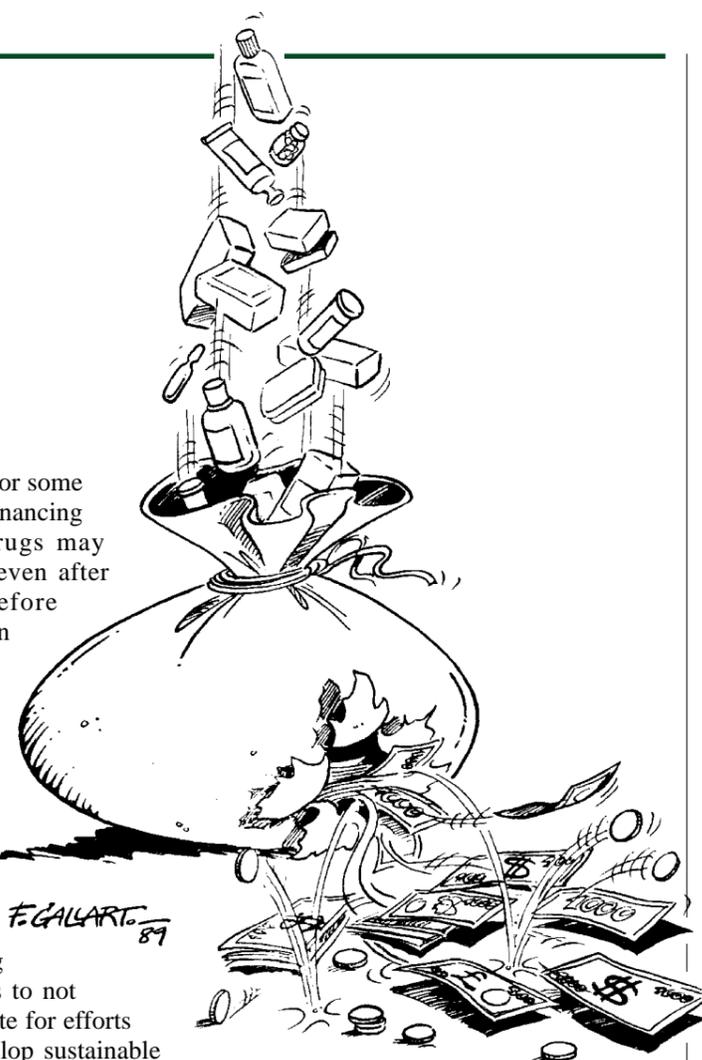
### Development loans

Development loans through the World Bank and regional development banks may contribute to long-term development of the human and physical infrastructure for the health sector. However, loans generally should not be used for financing of the cost of drug supplies, as these represent recurrent expenses. There can be certain exceptions to this which may justify the use of loans for procurement (e.g. seeding of revolving drug funds). As with donor financing, conditions associated with development loans should not distort national drug policies defined by governments.

## AFFORDABILITY AND EFFICIENCY

The appropriate choice and use of drugs is the key to the achievement of pharmaceutical policy objectives and should lead to greater economic efficiency in the health sector. A variety of cost-control measures have been applied at different levels within public and private drug supply systems. The appropriateness of different measures varies with the particular health system.

Affordability of drugs for consumers is a public health concern. Private expenditures for pharmaceuticals in developing countries typically account for 50 to 90% of all spending on drugs. Even for rural



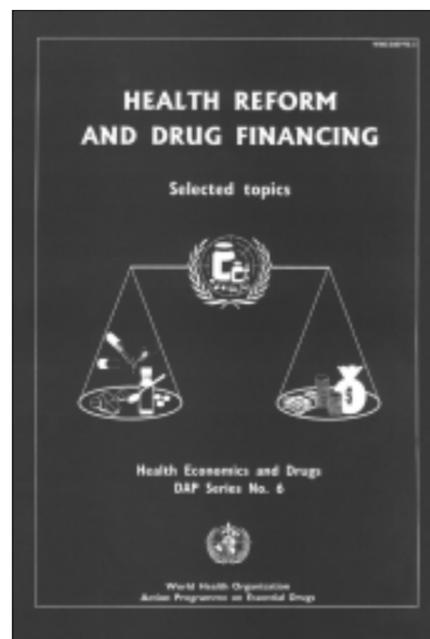
populations and the urban poor, the most common source of drugs is direct out-of-pocket purchase from the private market.

Use of generic drugs and price controls are the two most commonly pursued mechanisms to promote affordability. Generic competition with price information is effective in this regard. But generic drug markets have grown very slowly in most countries. The strength of public policy commitment to generic drugs is a major determinant of the growth of generic markets. Four essential factors for success appear to be supportive legislation and regulation, reliable quality assurance, professional and public acceptance, and economic incentives (see Box 2).

Various mechanisms exist to control producer prices and distribution margins. Wholesale and dispensing margins based on cost plus a fixed professional fee provide a better incentive for rational dispensing than margins based only on a percentage. The effects of pharmaceutical price controls have been mixed. Paradoxically, a number of developing countries are relaxing price controls on drugs, while governments in industrialised countries are becoming increasingly concerned with pharmaceutical prices. With or without price controls, price transparency should be a central objective.

## ORGANIZATIONAL REFORMS

Reforms to financing systems cannot be made without organizational reforms that should match the structure of the public and private sectors to their responsibilities in fulfilling policy objectives. Changes may include incorporation of competitive mechanisms within the public sector, decentralisation of health service provision, and a greater role for NGOs and other non commercial "third sector" entities.



**Box 1**

### Observations from user fee experiences in Africa

**Revenue generation**

In 34 countries with user charges (out of 39 surveyed), the revenue generated by these fees was generally a very small share of public recurrent health expenditures (almost always less than 10%). However, for some of the systems which have remained in place over several years, modest improvements in this percentage have been observed.

**Recovery of funds**

Of the community drug funds operating in 17 Sub-Saharan African countries (Benin, Chad, Niger, Sierra Leone, and Zaire are some examples), the success rate for the recovery of funds was about 50% with positive margins ranging from 49–83% (depending on the margin type).

Experiences of the Central African Republic indicate that public health centres which were self-managed, controlled their own drug sales, and had fees for all services, had higher cost-recovery rates than centres which did not exert as much control over drug sales and offered a range of free services.

**Utilisation of facilities and quality of care**

Demand for community health services which have user fees does seem to increase if quality, as measured by the availability of drugs, also increases. This is particularly true if accessing the next best care alternative involves significant time and travel costs.

However, because user fees do not always succeed in making drugs more available, and other factors are also involved in utilisation, decreases in use of health facilities are also frequently observed. Utilisation of community health centres, after the adoption of revolving drug funds, was noted to have increased in seven countries, and to have decreased in four.

**Equity and affordability**

Studies of health care use following the charging of fees show that the poor are more likely than other segments of the population to treat price increases as deterrents to accessing services.

Of 25 Sub-Saharan countries with cost recovery programmes, it appears that only one (Zimbabwe) had an official policy specifying national income ceiling criteria which would allow exemptions for the poor. Fourteen other countries indicated that exemptions for the indigent are permitted but did not provide criteria. The remaining 10 countries relied primarily on local and ad hoc measures for providing exemptions.

Exemptions based on income are difficult to formulate and implement where formal employment is limited. In some countries, the fairness of certain exemption policies remains questionable. Therefore, equity remains a critical issue. Easy-to-use, reliable methods for determining exemptions in mechanisms charging user-fees are not readily available.

Sources: Shaw PR, Ainsworth M. *Financing health services through user fees and insurance*. World Bank discussion paper No. 294, 1996.

WHO/SHS. *Experience with organizational and financing reform in the health sector*. Geneva: World Health Organization; 1995. WHO/SHS/CC/94.3.

**Competitive mechanisms in public drug supply**

Alternative drug supply strategies for public drug supply include the traditional central medical stores system, autonomous supply agencies, the direct delivery system, the prime vendor system and fully private supply. Several of these systems involve different public-private roles and rely on greater competition to improve efficiency.

The practical results of different mechanisms for public drug supply have yet to be clearly documented. Governments seeking to improve efficiency in public drug supply should do so with the knowledge that a number of options exist and that success depends not only on choosing an appropriate option, but also on the way in which the option is implemented.

**Decentralisation and integration in drug supply systems**

Control and decision making in health systems is increasingly being decentralised. For drugs, decentralisation may improve quantification of drug requirements, inventory control, prescribing and

dispensing. But some degree of centralisation may still be required for functions such as drug registration, development of essential drugs lists and standard treatments, quality assurance and bulk tendering.

Efforts are also being made in some countries to integrate supply systems for family planning, tuberculosis control, and other "vertical" programmes into essential drugs programmes. Resource-intensive functions such as procurement, quality assurance, storage and physical distribution may be integrated under the essential drugs programme, while financing, quantification of needs and monitoring may remain under the management of the national control programme.

**Role of the "third sector"**

Discussions of public and private roles in the pharmaceutical sector should not ignore the vital role of the "third sector". This includes NGOs' health services, not-for-profit essential drugs supply agencies, professional associations, consumer groups, and specialised NGOs such as some national pharmacopoeial organizations.

Recently some governments have explored ways of carrying out "public" functions such as standard-setting or quality control testing through innovative arrangements with third sector institutions. The various roles played by the third sector should be clearly acknowledged by policy makers, and ways to best support and involve the sector should be explored. □

*Health Reform and Drug Financing: Selected Topics* is available, free of charge, from:

Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

**References**

1. WHO/DAP. Health reform and drug financing: selected topics. Health Economics and Drugs Series No.6. Geneva: World Health Organization; 1998. WHO/DAP/98.3.
2. WHO/DAP. Guidelines for drug donations. Geneva: World Health Organization; 1996. WHO/DAP/96.2.

**Table 1**

### Public health and drug expenditures for selected countries

	Total public health expenditures		Total public drug expenditures	
	as % GNP	per capita (US\$)	as % health budget	per capita (US\$)
Bulgaria	3.8%	44.76	18.4%	8.24
Chad	0.6%	1.06	4.5%	0.05
Colombia	1.6%	20.03	18.0%	3.61
Guinea	0.4%	1.73	15.8%	0.27
India (Andhra Pradesh)	3.2%	1.93	6.8%	0.13
Mali	0.4%	0.74	18.8%	0.14
Philippines	0.5%	4.53	13.3%	0.60
Sri Lanka	1.5%	8.58	15.6%	1.34
Thailand	2.0%	33.65	5.6%	1.89
Viet Nam	1.1%	2.32	20.0%	0.46
Zimbabwe	2.8%	12.43	36.1%	4.49

Source: WHO/DAP. *Public-private roles in the pharmaceutical sector*. Geneva: World Health Organization; 1997. Data are from the most recent year available, generally in the early 1990s. Figures from Chad, Colombia, Sri Lanka and Viet Nam are still considered preliminary.

**Box 2**

### Mechanisms for promoting generic drug use

**Supportive legislation and regulation**

- abbreviated registration procedures (focus on drug quality)
- product development and authorisation during patent process
- provisions which permit, encourage, or require generic prescription and substitution
- requirement that labels and drug information contain generic names

**Reliable quality assurance capacity**

- development of substitution, non substitution lists
- procedures to demonstrate bioequivalence
- national quality assurance capability
- national drug manufacturer and drug outlet inspection capability

**Professional and public acceptance**

- involvement of professional associations in policy development
- phased implementation, beginning with permission to substitute

- required use of generic names in all education and training of health professionals
- brand-generic and generic-brand name indexes available to health professionals
- required use of generic names in clinical manuals, drug bulletins, and other publications
- widespread promotional campaigns targeting consumers and professionals

**Economic incentives**

- public and professional price information
- reference pricing for reimbursement programmes
- retail price controls that favour generic dispensing
- support by social and private health insurance organizations
- incentives for generic drug industry
- trade-offs with industry (reduced price regulation, increased patent protection)

Source: WHO/DAP. *Public-private roles in the pharmaceutical sector*. Geneva: World Health Organization; 1997. WHO/DAP/97.12.





MANAGING DRUG SUPPLY

# Good drugs at low cost: Thailand's provincial collective bargaining system for drug procurement

MONGKOL NA SONGKHLA, SUWIT WIBULPOLPRASERT, PHUSIT PRAKONGSAI\*

**D**RUG expenditure constitutes approximately 35% of total health expenses in Thailand. Attempts to procure good quality drugs at a lower price are therefore important to improve health service efficiency, particularly in the current economic crisis. This article describes one such attempt at increasing bargaining power through collective provincial bargaining by all district hospitals in one province. The system not only brings down drug prices but also improves the quality of drugs, the efficiency of the drug management system and the strength of the referral system. In 1994 the Ministry of Public Health finally took up the model, and applied it to all 75 provinces. Success was limited to only three provinces during the first three years (1995–1997). However, after the economic crisis, with the reduced drug budget and increase in drug prices, the mechanism was implemented more vigorously and successfully on a wider scale. Currently 67 (out of 75) provinces implement the system and they have achieved a 25% reduction in drug expenditure.

Thailand is a lower middle income country in South-East Asia with a population of 60 million in 1997. It consists of 75 provinces, 774 districts, 81 sub-districts, 7,255 Tambons (communes) and 66,974 villages. The health care delivery system is composed of both public and private facilities. The public facilities have a 75% share of resources while private facilities have 25%. Approximately 80% of all public health resources are located within the Ministry of Public Health, with its extensive network of provincial general hospitals, district hospitals and commune health centres. In 1997 there were 89 general hospitals, 703 district hospitals and 9,132 commune health centres<sup>1</sup>. Administratively all public

hospitals and health centres, under the Public Health Ministry in each province, report to the Provincial Chief Medical Officer.

Drug expenditure in 1993 was US\$34 per capita (retail value) and constituted roughly 35% of total health expenditure<sup>2</sup>. Drugs are distributed through all public and private facilities, including more than 10,000 private pharmacies.

Services in public facilities are not free of charge. Unless patients are covered by some kind of insurance, they have to pay a subsidised level of user fees. The public hospitals thus receive financial support through government budget (tax revenues), insurance premiums and user fees. Each hospital is authorised to use these funds to purchase drugs. According to government regulations, public hospitals have to purchase 60%–80% of their drug budget based on items in the essential drugs list.

Drugs are produced locally by 176 private factories and a few public enterprises, the biggest one being the Government Pharmaceutical Organization. Locally produced drugs have a 50%–60% market share. There are also 460 drug importers. Most public hospitals purchase drugs from both the Government Pharmaceutical Organization and private companies. Only those private drug factories with Good Manufacturing Practice (GMP) Certificates from the Thai Food and Drug Administration are allowed to sell drugs to public hospitals.

The prices of drugs from the Government Pharmaceutical Organization are fixed, and quality control is carried out

by the Organization itself. On the other hand, prices of drugs from private companies depend on direct bargaining without a good quality control system on the buyer's side.

Thus drugs are purchased, based on different hospital drug lists, at varying prices and quality levels in different hospitals. Bigger provincial hospitals usually have more bargaining power and more access to better quality drugs. Under this system, different drugs are used by different health facilities in the same provinces.

in 1990 it has been reviewed annually, and in 1997 contained 356 drugs. This is the essential initial step to *reduce unnecessary drug items* and establish a *common list for collective bargaining*. This common drug list is also used in the procurement of drugs for the commune health centres.

## 2. Drug procurement system

A drug procurement committee, comprising pharmacists from all district hospitals, invited private drug companies to join the provincial bargaining system. A short-list of companies was prepared through an extensive survey of drug factories by the committee members, relying on their previous experiences as a further determinant. In 1994, 78 companies (45 local, 27 imported) declared their intention to join the system. However, only 39 (50% – 25 local, 14 imported) of these were short-listed.

Each hospital prepares an annual drug requirement plan according to its past utilisation experience. The plans are aggregated into the provincial plan, and the short-listed companies are requested to submit offers. The companies with the lowest price for each item are selected to provide drugs to the system. The prices offered stand for a year.

Each hospital then places orders during the year, according to need, directly with the winning drug companies. After receiving the orders, the companies send their drugs and the bills directly to the hospitals. There is *no central provincial stock, no need for provincial financial*

...cont'd on pg. 6

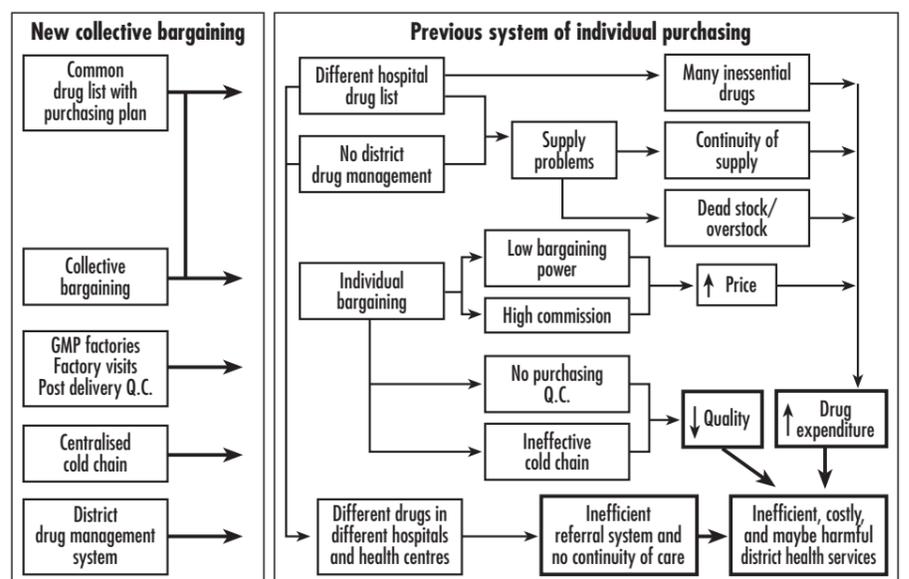
## THE PROVINCIAL BARGAINING SYSTEM

In 1990, in order to solve the problems of inefficient drug procurement – high prices and questionable quality – a collective provincial bargaining system was developed in one of the biggest provinces in Thailand, Nakorn Ratchasima. The system aims at procuring good quality drugs at lower prices, and ensuring an adequate supply of the same essential drugs to all district hospitals and health centres. The rationale of the system is summarised in Figure 1. This system consists of six sub-systems<sup>3</sup>:

### 1. Establishment of a common hospital drug list

Representatives of doctors and pharmacists in all 23 district hospitals collectively developed the common drug list of *Nakorn Ratchasima district hospitals*, under the Provincial Pharmaceutical and Therapeutic Committee. Since the first list was drawn up

Figure 1 Rationale of the provincial bargaining system



A young Thai woman being examined at a primary health care centre

Photo: WHO/A.S. Kochhar



### Thailand... cont'd from pg. 5

#### management and no provincial bureaucratic steps to follow.

Through increasing bargaining power, this collective bargaining system has resulted in 12%–20% reduction in drug prices. For example, in 1989, before the system was implemented, ampicillin injection (1 gm.) was purchased at a price of between 13–26 Baht/vial. In 1994, after establishing the new system, the price was 11.75 Baht/vial (less expensive even after five years of inflation), due to the power of collective bargaining. In 1991, 19.5 million Baht of drugs were purchased, saving 5.3 million Baht. In 1993, 20.4 million Baht of drugs were purchased, with a saving of 2.8 million Baht.

### 3. Drug quality control system

The quality of drugs purchased was controlled through the process of short-listing the companies and post procurement sampling for quality testing.

Only drug factories with GMP Certificates from the Food and Drug Administration were short-listed. Drugs from factories with GMP Certificates are three times less substandard than those from factories without GMP (8% as compared to 25%)<sup>2</sup>. In 1998, 127 of the 175 private drug factories (72.1%) received GMP Certificates. Short-listed factories were then visited by representatives of pharmacists from the district hospitals. During visits to the factories the quality of raw materials, the manufacturing processes, the drug quality control processes, and the external quality control system were thoroughly checked. Only approved factories were allowed to join the collective bargaining system.

After the drugs were received at the district hospitals, samples were systematically collected according to the sampling plans, and sent to the Regional Medical Science Centre for analysis. The sampling plans usually focus on antibiotics, commonly used drugs, drugs for specific diseases and life saving drugs.

With this system, the proportion of substandard drugs was reduced from 30% before, to under 15% after implementation of the system (see Table 1).

### 4. Low temperature drug management system

Supplying low temperature drugs to rural health facilities requires a good cold chain system. Private drug companies usually hesitate to send low temperature drugs to individual district hospitals because of the difficulty with the cold chain system. Thus the provincial health office

was designated by the committee to procure and stock these drugs to supply to all district hospitals. This sub-system not only reduces the drug price and improves quality, but also guarantees the availability of good quality low temperature drugs. In 1991, 22 such drugs were included in the sub-system.

### 5. Drug supply system to commune health centres

There are 287 commune health centres in the Province. Previously their drugs were supplied through the Provincial Health Office. There were problems of expired stock, overstock and shortages of some drugs due to unresponsiveness of the Provincial Health Office to meet the demand of various health centres.

Under this new system, the district hospitals maintain the district stock of drugs to be supplied to the lower level commune health centres according to their demand and allocated budget. This system gives more flexibility and reduces unnecessary expired stock. Most important of all it allows the *same type of drugs to be used in the district health systems*, which strengthens the referral system in the districts.

### 6. Monitoring the districts' drug management system

The ordering and sampling of drugs by district hospitals is monitored closely by the Provincial Health Office's pharmacists.

The district level drug management system is monitored through indicators covering the development and implementation of the drug management plan, continuous supply of drugs, drug utilisation, overstock and the expired stock. Forty-one specific indicators in 10 sub-groups under three main groups were developed. The scores of all 41 indicators amounted to 200. The districts were classified by grades A to F according to their level of management achievement. There was much improvement after the implementation of the system (see Table 2). Satisfaction levels of the district hospitals and commune health centres were also surveyed and it was found that the system was highly accepted.

### FACTORS BEHIND THE SUCCESS

Several factors contributed to the success of this system:

#### Strong leadership

Drug procurement often involves many vested interests and much

Table 2

### Improvement in the district drug management system

Year	% of the districts in each level of drug management *				
	A	B	C	D	F
1992	28.29	27.51	27.90	12.40	3.87
1993	59.77	23.31	11.28	3.01	2.63
1994	58.33	24.24	12.88	3.03	1.52
1995	86.06	9.84	3.28	0.00	0.82
1996	85.14	9.90	2.97	1.48	0.50
1997	80.79	15.25	2.26	1.12	0.56

\* Scoring for each level of drug management:

A = 181–200 B = 161–180 C = 141–160 D = 121–140 F = < 120

Source: Provincial Health Office, Nakorn Ratchasima Province.

inefficiency. In many cases 20%–30% commission is requested or paid to the hospital authority. Thus some hospitals did not want to participate in the system, and some were hesitant. Strong leadership both from the Provincial Chief Medical Officer and peer influence among district hospital directors was essential to the *initiation* and the success of the *preliminary phase of development*.

In the case of Nakorn Ratchasima, the Provincial Chief Medical Officer, who initiated this system in 1990, used his strong leadership and perseverance to overcome the vested interests. He was strongly supported by a few leading district hospital directors and pharmacists who dedicated their time and wisdom to design, develop and manage this system.

#### Sound justification

The system was able to show the expected outcomes – better quality drugs at lower prices, a better drug management system, and better support to the district referral systems. Only such evidence can satisfy all partners and guarantee continuity of the system.

#### Partnership

Active involvement of all district hospitals created an environment to support accountability, transparency and acceptance of the system, without increasing any bureaucratic steps or any vested interests, at the provincial level. This, backed by strong leadership and sound justification, was essential to the sustainability of the system. The system in Nakorn Ratchasima Province has been on-going up to present (eight years) despite the change of four Provincial Chief Medical Officers.

#### Publicity and strong civil society

Publicising the results created public awareness, strengthened civic movements and supported the sustainability of the system. It was also a strong advocacy tool to get policy support for wider implementation. The Thailand Health Research Institute evaluated the system in 1993<sup>4</sup>. Its report was widely publicised and finally, in 1994, discussed in the National Drug Committee chaired by the Minister of Public Health. The Minister then brought the issue into further discussion in the ministerial committee, and a Ministry policy was developed. The report,

together with information on corruption in drug procurement, also prompted the Anticorruption Committee of the Prime Minister's Office to demand the Ministry of Public Health to implement the system on a nationwide basis.

### THE WAY FORWARD: OPPORTUNITIES FOR CHANGE

The success in Nakorn Ratchasima Province prompted others to follow. In 1992 Ayuthaya Province started the system, to cover not only the district hospitals and health centres but also the *main provincial hospital*. The number of drugs for common bargaining increased from five



A pharmacy in Thailand, where collective bargaining is helping to keep Government drug expenditure down

Photo: WHO/W. Linder

in 1992 to 23 in 1995. They were able to save from 0.33 million Baht in 1992 to 4.7 million Baht in 1995. Other provinces, such as Buriram, Surin and Lumpoon, started to follow.

In November 1994, three years after the system was launched and the success story was publicised, the Ministry of Public Health put forward a policy to establish such a system in all provinces. However, during an era of high economic growth with a high drug budget (1995–1997), the response was rather weak. Evaluation of the implementation in 1996, by the National Health Foundation, found that only three provinces implemented the system as intensively as Nakorn Ratchasima. Another 30 provinces did it weakly to moderately and the rest did not implement it at all<sup>5</sup>.

The current severe economic crisis, which began in July 1997, is a good opportunity for further development. The system was promptly included in a comprehensive *“Good Health at Low Cost”* policy package. Inspector Generals of the

Table 1  
Quality of drugs before and after implementation of the system in 1990.

Year	Samples analysed	Number of substandard drugs	Percent substandard
1988	207	62	29.95
1990	32	4	12.50
1991	65	2	3.08
1992	66	2	3.03
1993	46	2	4.34
1994	70	5	7.14
1995	143	17	11.88
1996	31	3	9.68
1997	57	8	14.04

Source: Provincial Health Office, Nakorn Ratchasima Province.

...cont'd on pg. 7

## MANAGING DRUG SUPPLY

# Drug supply choices: what works best?

**P**ERSPECTIVES on the role of government in health vary from a social welfare approach (the state should provide all health and other social services except where it is unable to do so) to a self-help or market economy approach (the private market should provide most health services). In the past many governments (in both developing and developed countries) have subscribed to the social welfare approach, particularly when health technology was limited in scope and cost and was therefore affordable. Increasing complexity and technology has taken the cost of health care provision beyond the reach of most developing country governments, and there is a growing emphasis on the responsibility of the individual to provide for their own health care.

In fulfilling the goals of a national drug policy government has a central role in ensuring that drugs distributed through the public and private sectors are of acceptable quality, safe and effective. Also government has a responsibility to promote the rational use of drugs. In addition, it is necessary to actively promote drug availability (geographic access) and affordability (economic access) if a large share of low income and remote populations depend on private sector drug supply.

Among the decisions which governments have to face in the pharmaceutical sector the most complex and the most costly often concern the financing and supply of drugs for government health services. In some countries public sector drug supply is well financed and administratively efficient. In other countries the drug supply system is unreliable and shortages are common. Such systems suffer from inadequate funding, outdated procedures, inefficiency or a mixture of these and other problems.

In a situation of diminishing resources one response is to maximise them by increasing efficiency. Can private sector

mechanisms be used to improve public sector efficiency and, thereby, improve access to essential drugs through government health services? It is important to remember that one element which stimulates efficiency in the private sector is the existence of competition.

Various strategies have been tried in order to provide access to pharmaceuticals and, in particular, to essential



Photo: Sister Patricia McCusker

Effective supply of essential drugs includes rational selection, quality assurance, good procurement and storage practices, and timely distribution

drugs. At least five alternatives exist for supplying drugs to governmental and nongovernmental health services.

## ALTERNATIVE SYSTEMS OF DRUG SUPPLY

- **Central medical stores (CMS):** conventional drug supply system, in which drugs are procured and distributed by a centralised government unit;
- **Autonomous supply agency:** a centralised supply system in which the management responsibility is devolved to an autonomous or semi-autonomous Board;
- **Direct delivery system:** a decentral-

ised, non CMS approach in which drugs are delivered directly by suppliers to districts and major facilities. The government drug procurement office tenders to establish the supplier and price for each item, but the government does not store and distribute drugs from a central location;

- **Primary distributor system:** another non CMS system, in which the government drug procurement office establishes a contract with a single **primary distributor**, as well as separate contracts with drug suppliers. The primary distributor is contracted to manage drug distribution by receiving from the suppliers, storing, and distributing all drugs to districts and major facilities;

- **Fully private supply:** in some countries, drugs are provided by private pharmacies in or near government health facilities.

It is possible to identify some advantages and disadvantages for each of the above systems and to make some theoretical comparisons, but true comparisons of cost-effectiveness have not been made. In part this is because other issues have made such comparisons very complex. The introduction of policies on user charges, decentralisation, contracting-out and privatisation all have an impact on the drug supply system.

## The Central Medical Stores system

The historical approach to public sector drug supply is the Central Medical

Stores (CMS) approach, in which drugs are financed, procured and distributed by the government, which is the owner, funder and manager of the entire supply system. Selection, procurement and distribution are all handled by the central government, often by a unit within the ministry of health. Financing is usually from central treasury allocations and/or donors, though a CMS can function as a revolving drug fund.

This is a demanding approach in terms of human resources, physical infrastructure, management systems and communication systems, requiring the state to manage and fund every aspect of the system. It has been a logical approach in situations where the vast majority of items were imported through one channel; the demand was predictable; finance and administration were highly centralised; and a developed and professional private sector did not exist. Traditional CMS structures continue to be used in a number of countries including Ghana, Oman and Zimbabwe. However the distribution and financing mechanisms in use vary.

Using the traditional CMS system the availability of drugs in the public sector has deteriorated in many (but not all) countries as the nature of medical practice has changed and real financial resources have diminished. At the same time the demand for, and cost of, health service provision has increased.

The causes are many. The drug supply environment has changed drastically from a range of chemicals and galenicals to a multiplicity of manufactured finished products. CMSs have experienced problems with financial management, quantification of requirements, management of tenders, warehouse management, transport and security of drugs. These problems have also been exacerbated by political or administrative influences and

...cont'd on pg. 8

## Thailand... cont'd from pg. 6

Ministry of Public Health have been sent into each province to ensure its intensive implementation. Nine months later, the situation has improved with 67 provinces now actively implementing the system, although in other provinces the old system of individual purchasing prevails or implementation of the new system is still weak. The impact has been clear in the 67 provinces where collective bargaining is used: drug costs were lowered by 24.7%, from 622.05 million Baht (if purchased under the regular individual purchasing system) to 468.03 million

Baht, a very significant saving<sup>6</sup>. Nevertheless, this 622.05 million Baht accounts for only about 10% of the Ministry of Public Health's drug budget. Most of the drug budget is still spent on individual purchasing and procurement through GPO.

With the economic crisis, political reform, public sector reform, stronger civil society and decentralisation, a transparent and efficient public management system is essential. This will enable the provincial bargaining system to dig deeper roots and gain wider implementation in the near future. □

\* Dr Mongkol Na Songkhla is Secretary General, Food and Drug Administration, Thailand, Dr Suwit Wibulpolprasert is Assistant Permanent Secretary, Ministry of Public Health, Thailand and Dr Phusit Prakongsai is Director, Kao Sukim Hospital, Chuntaburi, Thailand.

**Update:** In December 1998 the Ministry of Public Health announced a policy aiming to use the collective bargaining system for 50% of its hospital drug expenses. This would mean that at least 5,000 million Baht worth of drugs would be purchased under the system, a possible saving of 1,250 million Baht. Improved drug quality would also be ensured, thus achieving greater efficiency and quality in the midst of economic crisis.

## References

1. Bureau of Health Policy and Planning, MoPH. Health in Thailand 1995-1996. Bangkok: The Veteran Press; 1997; p 110, 124.
2. Wibulpolprasert S. (ed.). Thai drug system: a situation analysis for further development. Bangkok: Desire Co. Ltd., 1995; p 21, 29.
3. Prakongsai P. Summary of provincial bargaining system for drug procurement in Nakorn Ratchasima Province 1990-1994; 1996 (mimeograph in Thai).
4. Tangcharemsathien V. Evaluation of the provincial bargaining system for drug procurement in Nakorn Ratchasima Province. Bangkok: Thailand Health Research Institute; 1994 (mimeograph in Thai).
5. Thailand Health Research Institute. Evaluation of the policy for provincial bargaining drug procurement system of the MoPH, 1995-1996. Bangkok: Thailand Health Research Institute; 1998 (mimeograph in Thai).
6. Rural Hospital Division, MoPH. Progress report on the drug management under the Good Health at Low Cost Policy Package. Report to the Permanent Secretary.

### Drug supply choices... cont'd from pg. 7

weak staff discipline procedures in an atmosphere of diminishing incentives. Where public financing is adequate then the public sector CMS system can be effective in providing a supply of drugs as has been demonstrated in the past in many countries and is still seen in some.

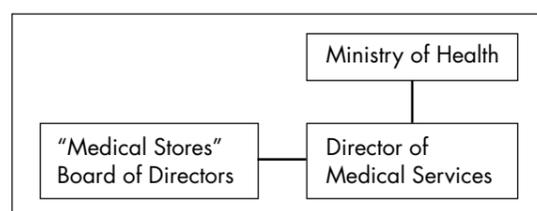
The inability of the CMS system to achieve its purposes in the current economic and commercial climate in many countries indicates a need to consider alternative mechanisms for the procurement and distribution of drugs.

### Autonomous supply agency system

The problems which have been experienced with CMS systems have led some governments to establish systems which place the responsibility for bulk procurement, quality assurance, storage, distribution and financial management in the hands of an autonomous or semi-autonomous supply agency. This model has been tried in several countries, particularly in Africa and Latin America.

Autonomous supply agencies are often constituted as parastatals, either under the ministry of health or as independent organizations, with a board of directors including representation from other (than health) government ministries. Their primary and priority client is government health services and they may or may not operate on a non profit basis. Examples of such supply agencies have been functioning in Benin, Haiti, Sudan, Tanzania, Uganda and Zambia.

A commonly seen Ministry of Health organigram is as follows:

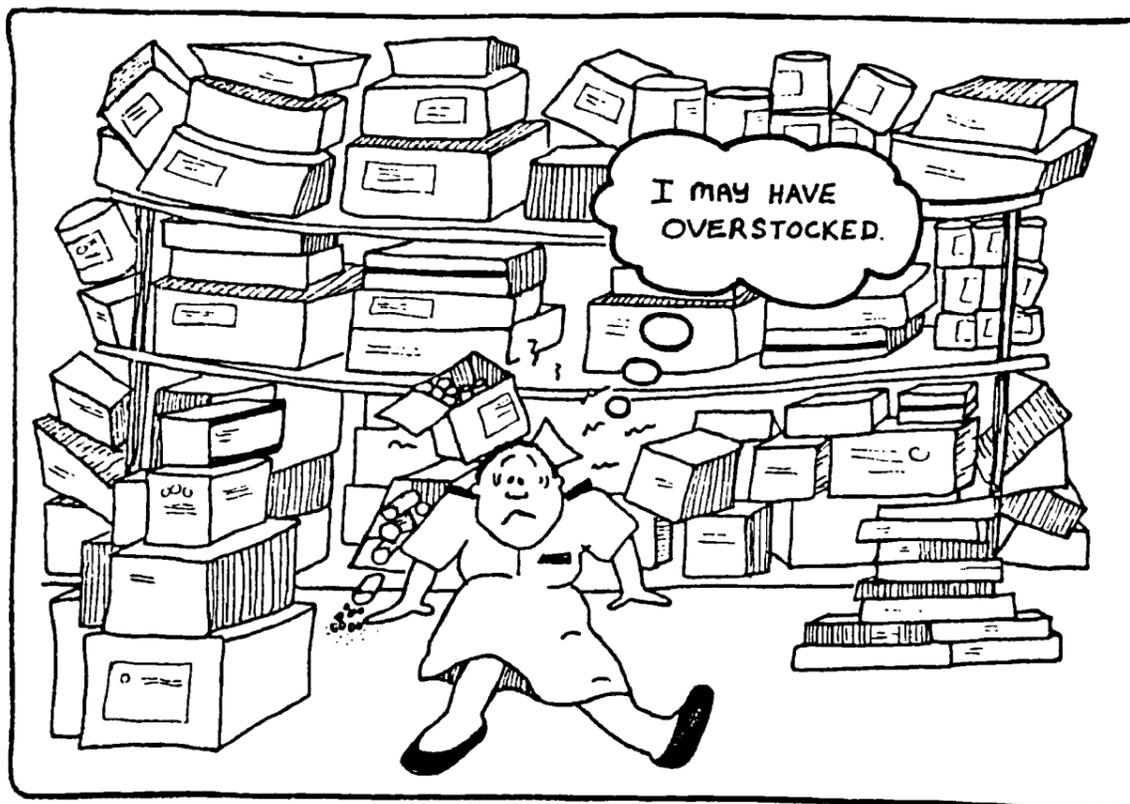


where the board is autonomous in running the agency but reports to the minister of health, who may be involved in the appointment of the chairman of the board and/or the executive officer.

The goals of establishing an autonomous supply agency are to achieve the efficiency and flexibility associated with private management and private sector employment conditions. At the same time sufficient public sector supervision is maintained to ensure that the services provide a range of essential drugs, at reasonable prices, with adequate control of quality.

The basic concept is that, under the right conditions, a well-constituted management board or board of directors will have the freedom to appoint qualified senior managers, who will in turn ensure an efficient, accountable supply agency.

Supply agencies may be established



Graphic: Zimbabwe Essential Drugs Action Programme

in the context of a public sector revolving drug fund, where fees are used to purchase drugs on a cash-and-carry basis as in Benin, or in a system where government institutions purchase drugs with centrally allocated treasury funds as in Uganda, or where budgets are still centrally controlled as in Tanzania. Whatever the financing mechanism, autonomous agencies can only function if there is a market for their products and if the client(s) has funds to purchase the products.

Autonomous agencies are likely to improve drug supply *only* if structured to overcome the constraints of the CMS approach. Experience to date, though limited, suggests that features which should be sought in establishing autonomous supply agencies, include:

- ◆ supervision by an independent management board;
- ◆ professional pharmaceutical supply managers;
- ◆ good personnel management;
- ◆ adequate financing;
- ◆ public accountability and sound financial management;
- ◆ focus on essential drugs (rather than "profitable" alternatives);
- ◆ focus on quality assurance, both in terms of products and of services provided.

The intention is that an autonomous supply agency will achieve greater value for money and improved drug availability through more efficient management. Three important characteristics that are needed to promote efficiency are flexibility, incentive and competition. The existence of competition will encourage efficiency, but in the majority of situations the monopoly of the CMS continues to apply to the autonomous agency, with no pressure to improve the quality of services and products or aim for the lowest prices.

A whole series of difficulties may occur, for example, if senior managers

are political appointees rather than professional managers appointed by an independent management board. Similarly if the government retains the authority to require distribution of drugs without charge or on a credit basis (without ensuring payment). Again, if special interests outside the agency influence drug procurement, or if the agency is required to retain staff members regardless of their ability or performance, these factors will be counter-productive.

Countries considering an autonomous supply agency should recognise that this approach will not solve problems related to lack of funding for drugs.

### Direct delivery system

In general, CMS and autonomous supply services involve bulk procurement into, and distribution from, a central warehouse. The costs and logistical problems associated with central storage and distribution are substantial. An alternative is the direct delivery system.

In this non CMS model, a government procurement office tenders to establish prices and suppliers for each essential drug, but drugs are then delivered directly by the suppliers to individual regional stores, district stores or major health facilities. Variations of direct delivery contracts have been implemented in many countries, including Chile, Colombia, the Eastern Caribbean, Indonesia, Mexico, South Africa, Thailand, UK and Peru. In Indonesia annual allocations for drugs are made on a per capita basis to each district. Using their budget and the Ministry's current price list for essential drugs, each district determines its own drug order.

Contracts for direct delivery may specify fixed quantities with scheduled deliveries (generally the approach in Indonesia) or estimated quantity tenders with orders placed by the local store or health facilities as needed. Financing arrangements can be a sensitive issue. Debts can quickly accumulate if drug supplies are not balanced against available funds. This means maintaining separate accounts for each supply point (if funding

is from central allocations) or ensuring that all supplies are paid for at the time of delivery.

Like most procurement systems, direct delivery contracts require a sole-source commitment, that is, for the tender drugs the local warehouses and facilities will order from the supplier who holds the tender contract. The local purchasers are free to order drugs that were not on the tender from any supplier.

Direct delivery supply agreements depend on and encourage further development of an effective private sector distribution system. In principle, they reduce storage and transport requirements and risks for the government by specifying in the procurement contracts that drugs are to be delivered directly to district stores and major health facilities. The government then has

only to store drugs at the regional or district level and deliver them to health centres and peripheral health units.

Direct delivery contracts preserve the benefits of centralised selection (the essential drugs list), bulk procurement (suppliers offer favourable prices to get all the business for the products they are awarded), and centralised quality control (only reputable suppliers are invited to tender). Hospitals and/or districts benefit from being able to manage their own funds and determine the exact quantities needed. Also, the problems of security, central storage and transport are shifted from the ministry to the private suppliers.

With a direct delivery system, however, district level and facility level drug management responsibilities are much greater, since the quantities and quality of drug deliveries must be confirmed. Success will depend on the ability and willingness of staff to manage the increased responsibilities. Finally, direct delivery in itself cannot solve problems of inadequate financing.

### Primary distributor system

The primary distributor system is a variation of direct delivery in which the public procurement agency tenders and establishes two types of contracts. The public procurement agency contracts with any number of suppliers to establish the source and price for each drug. But the drugs are not delivered by the suppliers directly to health facilities; instead, a separate contract is negotiated (through tender if feasible) with a single private sector distributor, the primary distributor. Two provinces in South Africa use the primary distributor system for delivery of drugs and medical supplies to hospitals (see p.10). Contracts for the procurement of drugs are negotiated nationally using competitive tenders.

The suppliers deliver tender drugs to the primary distributor, who is responsible for maintaining sufficient stocks to fill orders from regional warehouses, district stores and/or health facilities. Primary distributors may maintain their own vehicle

fleet or subcontract transportation.

Like other direct delivery contracts, this system depends on sole-source commitment for the essential drugs list, though districts and health facilities may be allowed to purchase non-tender drugs from any source. The system also requires the same level of good information and monitoring.

The primary distributor is paid a fee or commission for storage and delivery services. The primary distributor may appear to add an extra middleman and extra costs, but the expectation is that the cost of the primary distributor will be less than the cost to the government of running the warehouse and distribution system itself. Competitive bidding for the primary distributor contract is important to achieve this efficiency.

### Fully private supply system

Finally, national policy, insufficient financing or management problems have led some countries to avoid responsibility for providing hospitals and health

access for the poor, children, patients with communicable diseases and other vulnerable groups.

### IMPLICATIONS OF DECENTRALIZATION, CONTRACTING OUT AND PRIVATISATION

These health reform strategies are among many being tried in developed and developing countries to improve the efficiency and outcomes of health care delivery. They have often been initiated in response to the situation in developed countries and are being proposed as potential answers to the problems faced in the delivery of health care in developing countries. These strategies have significant implications for drug supply systems in developing countries which may not have been factors in their implementation in developed countries.

**Decentralisation** either as delegation or devolution is intended to improve the responsiveness, quality and efficiency of health services. Decentralisation aims to achieve these benefits through greater local involvement, more direct public accountability, increased flexibility to adjust to local circumstances, more rapid and more accurate communication, and quicker adaptation to changing conditions.

Problems that have occurred when attempts have been made to decentralise drug management functions include the following:

- ◆ Lack of capacity: drug management responsibility may be decentralised without ensuring there are sufficient local staff and management capacity to sustain such services.
- ◆ Lack of financial resources: responsibility is sometimes decentralised for all drug supply without providing an adequate budget. In this case decentralisation simply becomes abandonment of responsibility.
- ◆ Increased corruption: because of the money involved, interference for personal gain is common in drug supply systems. While decentralisation is meant to improve accountability, it makes it easier for local officials or other special interests to profit fraudulently.
- ◆ Increased cost: decentralisation of procurement usually means smaller order quantities. It can result in higher prices for essential drugs, although this problem can be overcome with central contracts coupled with decentralised ordering.

**Contracting-out or resourcing** in health care has most commonly been tried for non clinical services such as

equipment maintenance, laundry and food services. Contracting out services is common within the private sector. Often companies find that outside contractors who specialise in specific services such as managing staff cafeterias or repairing computers can provide those services at lower cost and higher quality than providing the service in house. The philosophy prevails in industrialised economies that if you can find someone else to do a specific task then pay them to do it rather than committing the capital resources to do it yourself; for example, distribution is usually contracted out by large supermarket firms.

Primary distributor systems, transport contracts, port-clearing services and related approaches to private sector involvement require contracting for services in contrast to contracting for products (drugs, for example). However to contract out activities requires the skills of writing, negotiating and monitoring contracts. Contracting functions most effectively where there is competition as with any tendering process. Contracting-out also demands a commitment to pay the contractors according to the terms of the contract.

**Privatisation** in health is properly defined as transfer of ownership from the public to the private sector. But the term is also applied, less precisely, to contracting government services to the private sector (as with direct delivery contracts) or introducing private sector features into the public sector (as with government owned but semi autonomous supply agencies). The full privatisation of drug supply would have implications for equitable access to drugs in an

environment where profit will become the motive for supply.

### CONCLUSIONS

If a different drug supply system is not chosen as a result of a careful analysis of the underlying causes for the weaknesses of the existing system in a particular country, the change may not produce the desired outcome. Systems chosen because they function in the climate of a "successful" market economy may not prove to be the solution to the problems faced in the supply of drugs in the context of a developing country.

To weigh the pros and cons of one drug supply system against another cannot properly be done from a global perspective without detailed study. Each country brings unique political, economic and geographical factors to the equation. It will never be possible to state that one particular system is "the best". However some basic factors will point in the direction of certain systems, for example, the existence of an effective private sector is necessary for either direct delivery or prime distributor systems to function.

The Action Programme on Essential Drugs has initiated a multicountry study to examine in depth at country level the outcomes of the drug supply systems in use. This study will look at the advantages and disadvantages of the systems, and the factors which influence the level of success in correcting problems and meeting needs. □

This article has been adapted from *Drug Supply Strategies*, Chapter 6 of *Managing Drug Supply* (see reference below).



Sometimes Central Medical Stores leave a lot to be desired, as can be seen here in a country in Sub-Saharan Africa

centres with even essential drugs. Where this is the case, retail pharmacies become the source of supply, especially in urban environments. Often the pharmacies are located very close to the hospital, and may be located inside the hospital. Such pharmacies may be part of a parastatal pharmaceutical enterprise (Sudan), or they might be an institutional enterprise (Ghana), or they may be independent enterprises. In some countries, patients receiving health care through the public sector are left to buy virtually all drugs on their own from the private sector. This situation usually results from complete lack of government funds, rather than as part of an official drug management plan.

As with revolving drug funds operated by the government, the greatest concern with fully private supply is equity of

### Some experiences with competitive mechanisms for public drug supply

#### Autonomous supply agency in Tamil Nadu, India

The Tamil Nadu Medical Services Corporation (TNMSC) was created in 1995 to contain drug costs and reduce shortages by purchasing and supplying drugs to government health care facilities. TNMSC is set up as a government company, with a Board chaired by the Secretary of Health, which is accountable to the Minister of Health. The TNMSC created a list of 267 essential drugs from the previous state drug list of 900 items.

Drugs are procured through tender and delivered directly to district level stores. Quality assurance procedures are in place, including sampling of products from manufacturers and district stores. Testing is contracted to reputable private laboratories through tenders. TNMSC adds a 5% charge to fund its own operations. Each facility is given a budget target and issued a "pass book" in which to record the value of drugs it has received. Through prompt payment and other administrative efficiencies, TNMSC has considerably reduced drug costs, while maintaining reliable supply.

#### Combined supply strategies in Zimbabwe

The Zimbabwe Essential Drugs Action Programme (ZEDAP) uses different systems for different categories of drugs. High-usage drugs on the essential drugs list are procured, stocked and distributed in bulk through the central medical stores. For high-cost, slow-moving specialist items, direct delivery contracts are used. For most specialist items an annual tender is conducted to fix the price for the year. Drugs are then ordered as needed by the roughly two dozen national hospitals and NGO hospitals which require them. Orders are delivered directly to the hospitals. Finally, for cancer agents and some other highly specialised drugs, no contract exists. Instead, drugs are purchased by the Ministry's pharmaceutical division by individual order, with permission from the Secretary of Health.

Source: Bennett S, Muraleedharan VR. Personal communication on Tamil Nadu Medical Services Corporation. 1997.

MSH/WHO/DAP. *Managing Drug Supply*, 2nd ed. Hartford, CT: Kumarian Press; 1997.

## MANAGING DRUG SUPPLY

# "Contracting-out" drug procurement and distribution: experience with a primary distributor system in South Africa

R.S. SUMMERS<sup>1</sup>, H. MÖLLER<sup>2</sup>,  
D. MEYER<sup>3</sup>, R. BOTHA<sup>4</sup>

**P**UBLIC/private sector relationships have been suggested as a means of achieving some of the goals of national drug policies and essential drugs programmes<sup>1</sup>. Because of work which showed that "contracting-out" the procurement and distribution of drugs can offer advantages and improve performance, two of the country's nine provinces have opted for this approach. South African provinces have a considerable degree of autonomy.

In this method, structure, process and outcome specifications are established by a public sector authority and offered to prospective providers on "tender". The authority, usually through a bidding process administered by a tender board, will then select and establish a formal contract with a provider.

Experience and some critical lessons learned in using this approach in South Africa are described here, providing valuable insight into one of the few documented primary distributor systems outside the USA.

## BACKGROUND

South Africa, with a total population of just over 40 million<sup>2</sup>, had a pharmaceuticals' expenditure of some 4.8 billion Rand in the private sector and 1.8 billion Rand in the public sector in 1996 (when R1 was approximately US\$0.22)<sup>3</sup>. Annual per capita expenditure on drugs for the 85% of the population who rely on public sector health services was approximately R52 (US\$11). For the remaining 15% served by the private sector the equivalent figure was around R792 (US\$174). To place this figure in context, the World Bank quotes an average drug expenditure of US\$2.1 for nine African Countries in the mid-1980s<sup>4</sup>. While in 23 Sub-Saharan African countries drug consumption was valued at less than US\$5 per capita in 1990<sup>5</sup>.

The procurement and distribution of pharmaceuticals in the public sector is centrally coordinated; the provinces provide estimated quantities to the National Tender Board, which then calls for and awards supply tenders. The provinces purchase their requirements from the successful tenderer through a provincial depot.

This system has encountered some major difficulties over the years. These mainly revolved around stock losses and inexplicable variations between recorded purchases and actual stock-on-hand. There was also a general lack of information, and the selection process was not

rational, with around 2600 items on the national pharmaceuticals tender list. (This situation is currently being changed: the National Essential Drug List Committee, as part of the process of drafting standard treatment guidelines, has established a database of conditions and related medicines, which will lead to drug rationalisation in the public sector. The EDL currently comprises just over 900 items, and is being further streamlined.)

After the 1994 elections, the newly consolidated provinces had to integrate the various pharmaceutical services, in common with health and other services. Provinces generally had their own warehouses and sent estimates of their requirements to the Coordinating Committee for Medical Supplies (COMED), which coordinates the national tender. Payment is made by the provinces directly to the suppliers.

The government of the newly constituted Province A sought to integrate the drug supply systems of four authorities as part of its efforts to establish a single health authority. Following recommendations of a 1994 evaluation, Province A, (which has high unemployment, low average individual income and a predominantly rural population), decided in 1995 to contract out the procurement, warehousing and distribution of pharmaceutical supplies. These functions were contracted out to a private company at a commission of 8.05% of the value of the products. The contract also included a 2.2% commission for computerisation of hospital pharmacies and computer training of provincial pharmaceutical staff. From January 1996, medicinal supplies have been distributed from a single depot in the centrally situated provincial capital.

In Province B, an essentially rural area with less infrastructure than Province A,

a similar contract was awarded early in 1997. A provincial warehouse was built on the western border of the province, in March 1997. A more central site would have facilitated distribution.

Contracting-out is one of the options described for public sector/private sector cooperation in drug supply<sup>1</sup>.

In South Africa all of these factors needed to be tackled:

- The public sector does not insure stock against theft, fire or natural disasters, so all losses occur at government expense, if services are not contracted out. Theft is a major problem in pharmaceutical warehouses in South Africa.
- Strikes have become increasingly common since the 1994 elections as trade unions are trying to negotiate new equitable rules and remuneration in the labour sector.
- Vehicle maintenance, cost-effective staffing and management information are areas where the public sector has not always been efficient in the past. Government departments have been notoriously overstuffed, but employees were poorly paid and often underqualified. Many motivated workers found work more rewarding in the private sector. With limited financial and logistic resources, services in remote areas were not easy to manage.

The decision of two provinces to "contract-out" procurement and distribution to hospital level provided experience from which important lessons can be drawn.

## TENDER SPECIFICATIONS

Against this background, clear structure, process and performance

specifications are essential elements for success. Tender specifications may need to vary according to the needs of different provinces. In Province A, seven years' experience – one of the former homelands had already used contracting out services prior to 1995 – have shown the following requirements to be necessary for a successful system:

◆ **Procurement:** The province must manage the procurement database and have the final say on orders, including prices.

◆ **Warehousing and inventory management:** At least one senior pharmacy manager should be on the provincial payroll for this task. The public sector should own the warehouse and equipment. This ensures independence so that if the contractor does not perform to specifications, the province has the facilities to continue operations. However, the contractor is responsible for the maintenance and insurance of the facilities and stocks.

The Department, in negotiation with the contractor, determines stock levels. This precaution ensures that adequate levels of stocks are kept in a situation where the contractor pays insurance coverage.

The contract should include the installation of adequate computer hardware and software for inventory management at hospital pharmacies, and for on-going staff training.

◆ **Distribution:** The contractor's own transport is to be used; courier and similar services are not acceptable. When other transport is used, medicines are not always regarded as priority by the transport contractor and deliveries may not be according to a schedule.

◆ **Management information:** The contractor is required to supply comprehensive management information reports at agreed intervals.

◆ **Billing:** As the contractor is paid a commission on items delivered to hospitals the billing structure must separate these costs from the cost of purchasing stocks into the warehouse. In an earlier South African experience with limited contracting out the company received a commission on stock purchased into the warehouse and not on stock delivered to clients. This arrangement left many opportunities to purchase inappropriate medicines and quantities.

◆ **Human resource development:** The entire contract must be seen as a partnership between the Department and

### Some advantages of "Contracting-Out"

1. All losses by fire, theft or natural disasters are the responsibility of the contractor.
2. The staff required to run a warehouse efficiently and effectively is expensive. Cost-effectiveness of this component will be monitored closely by the contractor, because of the effect of poor performance on profitability.
3. Strikes and industrial disputes can be a major threat to the health services in a situation where all medicines are distributed from one depot. The service provider will be responsible for ensuring continuity of services.
4. Transport is a major cost component in the distribution cycle. Adequate vehicle maintenance and efficient scheduling of deliveries become the responsibility of the contractor.
5. Management information on drug availability and use can be improved without major investment by the public sector.

See Chapter 17 of *Managing Drug Supply*<sup>6</sup> for a more detailed description of issues involved in contracting out pharmaceutical services.



the contractor. The Department must also ensure that the contract is carried out according to the specifications. This necessitates the active involvement of provincial staff members in the entire process from database management, and procurement to receipt and distribution.

**CURRENT CHALLENGES**

Sufficient data are available to enable an evaluation of how the first two elements listed above have contributed to goal of improved drug supply <sup>6</sup>.

**Procurement and financial control**

Procurement was initially effective in Province A. Towards the end of 1997, however, and for approximately the first quarter of 1998, the situation deteriorated. This situation arose because of financial difficulties within the Province which led to the transfer of funds from Health to Education to offset overexpenditure on the Education budget.

In Province B, the situation manifested major difficulties from the start. Initially, accurate demand data had not been given to the contractor. Hence, order quantities did not match requirements. Cash flow problems surfaced as a result of a backlog in payments during 1997/1998. More recently, the health budget was decentralised to district management, which caused major difficulties with cash flow at the depot. Suppliers who had not been paid suspended deliveries.

**Warehousing and inventory management**

As described earlier there were significant differences in the location and available space of the two depots.

In addition to the poor siting and inadequate space at the depot of Province B, attracting (and retaining) professional staff to the area has been a major problem. These factors significantly influenced the performance of the depot which was, reflected in a relatively high number of out-of-stock items. Between March and June 1998, the percentage of 132 essential items listed as out of stock by Province B increased from 23% to 35%. Twelve critically important drugs were listed for virtually the entire period. We have rated procurement and stock control systems as ineffective when more than 15% of items are always out of stock. The situation at the depot of Province B is therefore very poor.

Over the first six months of 1998, Province A, which operates a similar system but has a provincial chief pharmacist at its depot at all times, had a stock-out rate between 7% and 22%. This performance was also far from ideal but better than Province B.

The reasons for the stockouts included poor selection of supplier, who may have over-ordered and therefore could not deliver;

payment difficulties (see above) and poor depot management. Province A faced mainly the first two problems, whereas all three applied to Province B from time to time.

**RELATIONSHIPS BETWEEN THE PLAYERS**

To obtain a perspective of the actual difficulties involved we examined the components of the procurement and distribution cycles in terms of the relationships between, and responsibilities of, the two role players (see Figures 1 and 2).

The provincial authority is involved in every element except receipt and checking of goods at the depot and



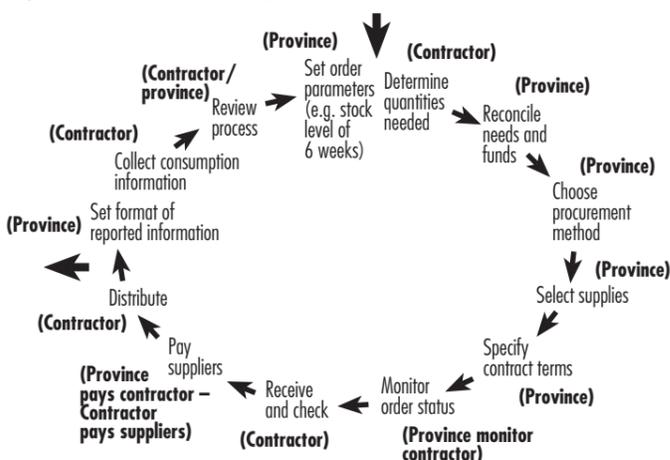
Photo: WHO/H. V. Hogerzeil

A health centre in a rural area of South Africa

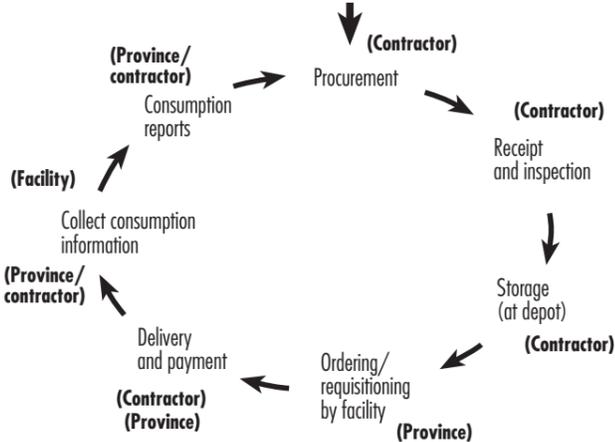
distribution from the depot to facilities. It meets this responsibility by checking the performance of the contractor through the data in the management information system, without being involved in day-to-day procedures.

Here the contractor plays the main role but is supported by important inputs from the province. In both provinces, the contractor's responsibility extends only to the hospital level. Thereafter, to the clinics, the responsibility for effective delivery and inventory control becomes that of the province. Transport and management

**Figure 1 Procurement cycle**



**Figure 2 Distribution cycle**



information at this level have often been problematic.

**LESSONS LEARNED**

Perhaps the core lesson learned is that what occurs in contracting-out is a partnership. If either partner does not deliver, and there are weak links in the chain, the process will fail!

There were differences in performance between the two provinces. These lay in the partnerships and inputs in each case. In the early stages of the process in Province A, there was extensive preparation by both parties. Facilities had adequate stock in place. Stock at different depots was checked and consolidated. This was not the case in Province B. The depot there had been newly set up and had encountered difficulties in establishing its own management information system. In addition the depot was too small for the Province B's needs. It lacked adequate senior provincial supervision, which is essential for proper control of public sector resources and funds. Too many items were listed at the various levels of pharmaceuticals distribution in this province.

Towards the end of the financial year, both provinces faced payment difficulties which inhibited procurement. In Province A, where the budget was centralised, budget over-runs in departments other than Health and Welfare led to the withdrawal of funds from Health. In Province B, decentralisation of budgets and responsibility for payment to district level management, continued to cause major cash flow difficulties with consequent difficulty in paying suppliers. These difficulties were the main reason for the high number of out-of-stock items. Commendably, in some cases the contractor paid suppliers of critical stock out of its own funds in order to maintain services to patients.

For a project like this to succeed both parties need to have insight into, and understanding of, the functioning of a department of health. This will then be manifested in the acceptance and support of the service by its users. Here too there was a significant difference between the two provinces.

In conclusion we have attempted to identify critical issues, lessons and key success factors from these two cases, which had

the common factor of the same supplier, but which differed markedly in performance.

- An integrated approach and planning by the public sector provider and the contractor is essential.
- The provincial drug list, which must have the support of its users, should be strictly applied and there should be a provincial veto on non list items.
- The storage depot needs to be carefully sized and centrally located.
- Appropriate facilities and systems need to be established for current and future requirements.
- A management information system is needed to monitor order and delivery status.
- Contractor selection should be based on previous performance and capacity to undertake the work, and include quality assurance for service delivery.
- Contractual terms and specifications must be fully detailed.
- Purchasing and payment methods need to be spelt out.
- Finally, and perhaps most critically, there has to be a sustained cash flow from recipient to contractor to supplier. □

\* Professor Rob Summers, School of Pharmacy, MEDUNSA, Helene Möller, South African Drug Action Programme, Department of Health, Pretoria, Danie Meyer, Pharmaceutical Services, Northern Province, Pietersburg, Rainier Botha, Vuna Health Care Logistics, Johannesburg.

For further information contact: Professor Summers, Head, School of Pharmacy, PO Box 218, Medunsa 0204, South Africa.

**References**

1. Bennett S, Quick JD, Velasquez G. Public-private roles in the pharmaceutical sector. Geneva: World Health Organization; 1997. WHO/DAP97.12
2. Central Statistical Services. Census '96: Preliminary estimates of the size of the population of South Africa. Central Statistics, Pretoria, 1997.
3. Summers RS, Suleman F. Chapter 8: Drug policy and pharmaceuticals. Chapter 8. In: South African Health Review 1996. Durban: Health Systems Trusts and California: Henry J Kaiser Family Foundation; 1996.
4. World Bank. Better Health in Africa. Washington: World Bank; 1994
5. Balance R, Pogany J, Forstner H. The world's pharmaceutical industry. Aldershot, UK: Edward Elgar; 1992.
6. Contracting for drugs and services. In: Quick JD, Rankin JR, Laing RO, O'Connor RW, Hogerzeil HV, Dukes MNG, Garnett A, editors. Managing drug supply, 2nd ed. West Hartford, CT: Kumarian Press; 1997. p. 256-269.



## MANAGING DRUG SUPPLY

# Improving the supply, quality control and access to essential drugs in Guatemala

MANUEL ENRIQUE LEZANA\*

**O**VER the past 15 years, Guatemala has followed through its commitment to the concept of essential drugs by developing a range of strategies and actions designed to improve the supply of drugs and ensure wider access to them<sup>1</sup>. More recently, the Guatemalan Ministry of Health has drawn up a blueprint for overall health policies to the year 2000. The proposals include: the modernisation of state health services through decentralisation of finance and administration; strengthening the capacity of governing bodies; improving sectorial and intersectorial coordination; and making better use of existing resources for health. The Ministry of Health is also committed to improving the quality of health services and ensuring wider access as well as improving the management of health services.

Within the Health Ministry's budget, the largest items of expenditure are medicines (10%), surgical materials (5%) and medical equipment, including maintenance and replacement equipment purchases (6–7%). However, over time, the administration of this budget has lacked transparency in the selection, purchase and distribution of these products. The quality of the product purchased was neither defined in advance nor checked on receipt. Meanwhile, suppliers had no guarantee of payment – resulting in price speculation of up to 400% of the original price.

One of the first steps taken was to form a group of national consultants to work with the WHO Regional Office for the Americas and the Pan American Health Organization. The group was to draw up a strategy to resolve existing problems and capitalise on the then current employment of an international company with expertise in drug purchasing systems.

## SWEEPING POLICY CHANGES

A Multisectorial Commission for Policies on Medicines was formed within the Public Health Ministry with representation from both the private and public sector as well as international health organizations. The Commission's remit was to advise the Ministry on new policies for the quality control and supply of drugs. Because of the seriousness of the problems encountered, it was decided to implement new policies across the board. These included:

- strengthening the drug regulatory authorities and the official quality control laboratory;
- setting up working groups to develop quality standards and new procedures for administration, purchasing and distribution;

- revision of the legal framework;
- new guidelines for the purchase of drugs;
- an improved system of logistics for the provision of supplies;
- establishment of a drug vigilance programme.

Reform of the drug regulatory authorities and the official quality control laboratory was achieved through strengthening the management structure, decentralisation of finance, staff training programmes and a review of salaries. Other measures included: the establishment of new administrative procedures for the register of authorised drug sales; better quality control of medicines; the creation of a standardised system for drug registration; better inspection of Good Manufacturing Practices; the purchase of laboratory equipment; and the development of a computerized data system for drugs.

Elsewhere, the Quality Standards Working Group studied the list of 1,400 drugs purchased by the Government – which contained many duplicate products – and recommended the use of the 13th edition of the US Pharmacopoeia and the US Pharmacopoeia Dispensing Information, to define the specifications of products purchased by the Government. Other products on the list had to be ratified from alternative sources, such as the British, French and Japanese Pharmacopoeias.

The Working Group also estimated supply needs on the basis of figures provided by different health units. The aim was to establish quantities that would be attractive to suppliers and ensure savings through bulk purchase orders. Medical surgical materials and medical equipment were handled in a similar way, using international standards such as those of the US Food and Drug Administration, as well as alternative standards. At every

stage, both consumers and suppliers were involved in defining the quality of the product. A second working group was established to review the legal aspects of Government purchases of medicines and medical surgical materials<sup>2</sup>.

As part of the modernisation process, the law was updated and a new Health Code issued<sup>3</sup>. The regulation<sup>4</sup> that this law implements facilitates Guatemala's participation in the globalisation process, and establishes responsibilities for all personnel involved in the supply of medicines. Meanwhile, overall control remains within the Ministry of Health.

The legal framework provides for the development of a Programme of Ease of Access to Medicines<sup>5</sup> through already established state and municipal pharmacies<sup>6</sup>, and the establishment of a Sales of Medicines for Community Benefit scheme<sup>7</sup> run by civilian groups to ensure they are self-financing and sustainable. The proposal for the Purchase of Medicine system already in force for Government purchases. This is an administrative tool with centralised negotiation and decentralised execution – designed to guarantee the quality of the product, purchased at prices previously determined at central level.

## ENSURING TRANSPARENCY IN SUPPLY

The new drug purchasing system was modified to include an open tendering system, with control over those who make the offers, and clear rules to ensure transparency and bring an end to corruption.

A computerized system has been developed for this.

Resources must be used rationally to allow for extended coverage. Meanwhile, quality must be in conformity with the US Pharmacopoeia, and all medicines referred to by their International Non-proprietary Name. Norms have been established for the qualification and awarding of suppliers and products, together with a procedure and payment guarantee to ensure successful relationships. This agreement provides for



The central drug warehouse in Solola District. The Guatemalan Government is implementing measures to improve drug supply

payment within a maximum of 30 days after receiving the product, compensation in the event of fluctuations in the exchange rate and payment of interest on delayed invoices. Sanctions can now be imposed for the supply of poor quality products and for failure to deliver within the agreed timeframe (with a maximum penalty of five years' suspension as a Government supplier).

The new system allows for a maximum of 3% deviation in the minimum price offered by a maximum of eight suppliers. Meanwhile, an inter-institutional commission has been established to oversee the operation of the open contract system and apply sanctions for non-fulfilment. The private sector participates as an observer in this commission. The Process of Public Awarding provides for the participation of personnel from the administrative units and executing officers from the public health sector as well as observers from private sector organizations and professional colleagues (doctors and pharmacists).

## FOCUS ON QUALITY

The establishment of administrative and technical norms was also necessary to guarantee that the item gets to the user in perfect condition, in the correct quantity and on time. These included a definition of the role of the professional pharmacist to ensure that drugs are used and administered correctly. Norms were



Dispensing drugs to a patient at Panajachel Health Centre, Guatemala

also established for selection, purchase, reception, storage and distribution in order to ensure the punctual delivery of the correct medicines. A system was put into place to deal with complaints about the efficacy or safety of products, and take appropriate action wherever needed.

In late 1997 doubts about the quality of medicines purchased through prescription prompted the launch of clinical studies of some products. The finding that some products were lacking in efficacy led to the establishment of the Drug Vigilance Programme – designed to assess complaints about therapeutic failure and/or adverse reactions to medicines purchased through the open contract system.

The new policies have met with opposition from some groups – including prescribers and suppliers who failed to win contracts – each preferring to maintain the status quo on drug supplies. Other problems have included inadequate supply forecasting – leading to drug shortages – and budgetary restrictions on efforts to ensure vigilance and control. However, failure by some suppliers to provide the correct amount and quality of drugs has led to the imposition of sanctions, including five-year exclusion from the Government supply system.

Among the major achievements of the new system are the savings on drug budgets and the extended coverage with low cost, high quality medicines. The Ministry of Health has saved 65% of its budget and the Guatemalan Institute of Social Security – the country's other public health service provider – saved 23% of its drugs budget. Meanwhile, through the Access to Medicine Programme – which benefits from decentralised price negotiations – medicines are now being made available to underserved communities.

Elsewhere, quality standards have been established for the purchase of medicines and sanctions put in place to deter the supply of poor quality medicines or late deliveries.

Multidisciplinary teams now participate in negotiations for the purchase of drugs and other medical items, and the decentralisation of health budgets facilitates the prompt payment of suppliers. □

\* Ing. Manuel Enrique Lezana is Chief of the Drug Coordination Office, Ministry of Health, Guatemala.

#### References

1. Working together, learning together. Essential Drugs Monitor [editorial] 1992; 13.
2. Governmental Agreement 472-96, dated 4 November 1996, related to the quality of medicines and medical surgical materials in which the purchasing standards are established.
3. Legislative Agreement 90-97 in force from February 1998.
4. This regulation is awaiting final Presidential approval.
5. Governmental Agreement 714-97 dated 8 July 1997.
6. Ministerial Agreement 161-98 dated 26 May 1998.
7. Ministerial Agreement 162-98 dated 26 May 1998.

## NATIONAL DRUG POLICY

# Belarus: progress in the pharmaceutical sector

**T**HE Ministry of Health in Belarus has set out its plans for health sector development, which include changes in the pharmaceutical sector. Among proposals are that a network of state and private pharmacies will develop in parallel, with their activities strictly regulated. At the same time, state control of drug pricing will continue. Drugs will be supplied to the population through both centralised and decentralised procurement, using the country's list of essential drugs. Other important initiatives include a campaign to promote the rational use of drugs, and plans to hold a national conference to adopt a new approach for developing the pharmaceutical education system. It is hoped the Government will adopt the public health development package by the end of 1998.

The country plans two main approaches for the pharmaceutical industry: the production of generics included in the essential drugs list for centralised drug supply, in accordance with state directives; and the modernisation and upgrading of existing pharmaceutical manufacturing enterprises. Three new factories have already begun pharmaceutical production.

Over the next five years it is planned to develop and introduce up-to-date requirements for clinical trials and standards for drug quality and production, and to review other regulations covering pharmaceutical issues.

### INCREASED ROLE FOR REGULATORS

The drug regulatory authority is expected to have a stronger role and independent status. Recently, the Ministry of Health established the Republican Centre of Expertise and Trials in Health Care. The aim is to help solve current problems in the drug supply system, and to improve the drug registration process, authorisation of products for medical use and industrial production, licensing of pharmaceutical activities, and control over drug imports to Belarus. The Ministry intends to implement national drug policy through the Centre, and through all these measures to exercise effective control over the pharmaceutical sector.

### ENSURING ACCESS

Centralised procurement of certain important medicines will continue, among them those for treating diabetes, cancer and tuberculosis. Such procurement is done on a large scale, in bulk and exclusively on a tender basis. This system allows the purchase of needed drugs to be more cost-effective, and ensures access to these vital drugs for the population. All pharmaceuticals supplied in this way are free of charge to patients.

### Important steps on the road to pharmaceutical sector reform in Belarus



**In April 1991** the first version of the essential drugs list was adopted. It has been reviewed annually since then and is widely used. The list is the basis for procurement at all levels of the health care system and ensures guaranteed coverage of the population's pharmaceutical requirements.

**In September 1992** the Principal Department of Pharmacy, Medical Equipment and Regulation was established. Within this framework the process of developing a national drug policy started.

**In December 1992** licensing of the pharmaceutical market was initiated. This allowed the Government to preserve its control of the pharmaceutical sector and to regulate newly established pharmacies, regardless of their ownership.

**In November 1993** the Pharmacological Commission was reorganized into the Pharmacological and Pharmacopoeia Committees. Requirements for drug registration in Belarus were defined and legally approved.

**In November 1993** the national programme for pharmaceutical industry development was adopted. The list of drugs produced in Belarus increased from 150 to 300 items.

**In October 1997** the Republican Centre of Expertise and Trials in Health Care was established. This facilitated reorganization of drug registration and pharmaceutical licensing procedures to meet international standards.

### MAJOR CHANGES AHEAD

Step by step over the next five years, Belarus will introduce international standards for good manufacturing practice. It will modernise and increase the capacity of existing production plants, build new plants, widen the list of drugs produced, and strengthen the State's role in drug production to better satisfy national drug requirements.

The Ministry foresees the further development of the network of newly established private pharmacies and improved regulations that will ensure increased access to drugs for the rural population. There are plans to review existing pharmacy regulations and to introduce a list of compulsory medicines



that should be available in every pharmacy at all times.

Plans are also underway to: encourage the more rational use of drugs, especially within the drug reimbursement scheme; increase the role of the essential drugs list; introduce drug treatment guidelines; improve doctors' access to drug information; encourage the procurement of drugs in the hospital package; and review the price regulation system.

### FRUITS OF COLLABORATION

International contacts, especially those established during 1993/1994, have played a significant role in allowing Belarus to make more rational decisions on how to organize its drug regulation and supply systems.

Agreements on collaboration in the pharmaceutical sector have been signed with the Health Ministries of Latvia and Ukraine, as well as with the French Medicines Agency, and the US Food and Drug Administration. This allows Belarus to receive much needed drug information more efficiently, and to organize training for its experts at these institutions. Contacts and cooperation with the Pharmaceuticals Programme at WHO's Regional Office for Europe has also broadened knowledge on all aspects of the pharmaceutical sector.

Belarus has also benefitted from an Interstate Commission for standardisation and quality control of pharmaceuticals and medical equipment established under the Commonwealth of Independent States Council for Cooperation in Health. It has allowed better harmonisation of pharmaceutical standards and requirements for products manufactured in these countries, and the simplification of their circulation within the Commonwealth's internal markets. □

This article is based on an interview with Gennady Godovalnikov, Head, Pharmaceutical Department of the Ministry of Health of Belarus, which first appeared in: Pharmaceutical Reforms, WHO News for Newly Independent States, No.3, June 1998.

## NATIONAL DRUG POLICY

# Involving African consumers in drug policy

**W**HILE many countries in Africa have adopted national drug policies these policies do nothing for the public they are meant to serve if they remain only written plans. Consumer involvement in implementing such policies is crucial in order to address the public's real needs regarding health and medicines. In many cases countries have done little to make sure national policies address consumer's health needs in a participatory and attainable way. The reasons behind these successes and failures, and strategies for ensuring consumer involvement in various aspects of these policies were the focus of HAI's second regional workshop for Africa. Entitled Networking for Rational Drug Use in Southern Africa: Consumer Involvement in National Drug Policies, the meeting was held from 30 May to 5 June 1998. It brought 34 participants – including consumer activists, NGO representatives, drug information experts, journalists, pharmacists and clinical pharmacologists from 11 African countries – to Johannesburg, South Africa.

In his introductory remarks to the workshop, Dr Harm Pretorius, Deputy Director-General of South Africa's Department of Health, spoke about this critical period for his country's drug policy. After South Africa's first democratic elections in 1994, the Department of Health had revised its policy in order to remove all of the health sector's past inequalities. The new policy was developed through broad consultation and included many stakeholders because of its far-reaching impact on all groups in society. The policy's main objective is to supply essential drugs to the majority of



Consumer groups in many African countries are realising the value of health education. Here in The Gambia women gather to listen to health messages on the radio

the people at an affordable price, ensuring safety, efficacy, good dispensing practices and patient education.

## Obstacles to overcome

However, discussions revealed that the national drug policies adopted by other countries in the region are less clear. Other problems also emerged. In many Southern African countries there is an acute shortage of public sector health care providers, especially pharmacists. This has a serious impact on the success of national drug policies. Key positions remain vacant and trained workers often leave for better-paid jobs in the private sector. Inadequate budgets, major local currency devaluations, drug shortages and emergency procurement damage the

national drug policy's possible impact. Rising drug prices make drugs inaccessible to many consumers in the region. Due to economic liberalisation, drug pricing is not effectively controlled by legislation and instead relies on market forces. Prices for the same drugs vary widely depending on where they are bought. Rational drug use goals are further upset by many countries' dependence on donations – which are often sent in an uncoordinated way.

Yet there have been encouraging developments which will help to solve these problems. In Malawi and Lesotho, for example, donors have begun to contact church groups to ask if certain drugs are needed and they then send them in usable quantities. In Zimbabwe the Consumer Council is lobbying for legislation

to control drug prices, and a number of groups attending the workshop have initiated a regional drug pricing survey to address unacceptable price variations.

## Spreading the word

Despite so many constraints groups in the region are active in making consumers more aware of the issues involved in national drug policies. For example, the meeting heard that in Mozambique a new consumers' organization has campaigned for rational use of drugs. The group, ProConsumers, has publicised the dangers of using expired drugs and broadcast radio programmes informing people about the dangers of buying drugs from the informal sector. Health Action Centre in Nigeria has relied on creative means to educate consumers, including traditional storytelling and drama presentations to point out drug hawkers' tricks, such as changing expiry dates, copying labels and substituting ingredients. The Group makes any location a potential learning place, by meeting with consumers in their homes, at schools, in churches and market places, during women's organizations' meetings or on buses.

Before the meeting closed, participants discussed the next phase in HAI's three-year project, Networking for Rational Drug Use in Africa. Plans are already well advanced for a third regional workshop, this time in francophone Africa. □

A report of the workshop is available from: HAI-Europe, Jacob van Lennepkade 334T, 1053 NJ Amsterdam, the Netherlands.

Source: HAI News, August 1998.

## Zimbabwe launches National Drug Policy

**Z**IMBABWE'S National Drug Policy was formally launched in March 1998 by the Minister of Health, Dr Timothy Stamps, at a colourful ceremony at the Harare Central Hospital. Simultaneously the Policy was launched in four other centres throughout the country. The launch is a culmination of the efforts of all sectors of the health system – including health service providers, the pharmaceutical industry, various ministries and other stakeholders.

A five-year work plan underlies the Policy, and has been in operation even before the formal launch. Dr Stamps stressed that the concept of a National

Drug Policy was not new to Zimbabwe and that work on it started soon after the country gained its independence in 1980. At the same time promotion of the rational use of drugs and production of standard treatment guidelines and essential drugs lists had also begun.

The launch of the policy is "the Government's commitment to the goals described" said Minister Stamps, whilst urging everyone to familiarise themselves with its contents and to identify their individual roles in its implementation.

Also speaking at the launch was the Consumer Council of Zimbabwe's representative, Mrs Keretia Chikowe. She explained that access to correct drug

information was a fundamental consumer right, and that increased literacy levels in Zimbabwe had increased consumer's critical awareness. Presenting a copy of the Patients Charter to the Minister, she impressed on him the need for Parliamentarians to have a clear understanding of the National Drug Policy, so that legislation to support the Policy would be put in place.

WHO Representative, Dr Levon Arevshatian, stressed the importance that WHO attaches to the development and implementation of national drug policies. Other speakers underscored the need for a concerted multidisciplinary approach for successful policy implementation. Finally, the



Aidan Chadirikere (right), Director of Pharmacy Services and Norman Nyazema (left), Professor of Pharmacology at the University of Zimbabwe celebrate the launch of Zimbabwe's new national drug policy document

choir from the Harare Central Hospital School of Nursing was on hand to sing the Zimbabwe National Drug Policy into life. □

RESEARCH

# Improving quality of care in Hai Phong Province

JOHN CHALKER\*

BACKGROUND

**I**N 1993/94 the system of commune health stations (CHSs) in Hai Phong Province, Viet Nam, was in danger of collapse. This was a system that had provided a health station in every commune in Hai Phong with a staff of four to six para-medics, trained for three to four years at the secondary medical school (these schools exist in most provinces to train nurses, midwives and medical, pharmacy and laboratory assistants). The health stations were a focus for all preventive and curative activity. They were mainly financed by the commune, but carried out Health Ministry vertical control programmes as well as providing obstetric and curative care. Each commune has an average population of around 6,000 people, and few people are more than 10 or 15 minutes from their nearest station.

It was this extensive infrastructure that was a large contributory factor to Viet Nam's excellent health statistics on infant mortality and life expectancy, which are comparable to countries with a much higher gross national product.

Since 1989, under the Government's policy of "Doi Moi" or renewal, private practice in the health sector was legitimised. This new approach, coupled with inflation, meant that in practice investment in the stations virtually ceased. At the same time many private drug sellers (both licensed and unlicensed) appeared. Salaries for health workers reduced to non living wages in real terms (about US\$6 a month). The stations fell into poor states of disrepair and equipment was not replaced.

In pre project research in early 1995, we found that the average value of drug stocks in a selection of Hai Phong CHSs was about US\$20 per station. Drugs were bought locally by the health staff, and were sold and replaced frequently via user fees. The staff had very little retraining. District supervision of quality of treatment did not exist, and treatment standards were deteriorating.

At the same time attendance fell by more than half from 1989 to 1993. People had access to drugs from the proliferating number of drug sellers. In fact more than 70% went to these drug sellers as a first recourse when sick. At the drug sellers they would very often receive the wrong, frequently poor quality drug, in the wrong dose for the wrong length of time. Important and dangerous

symptoms would be missed so that timely referral to hospital would be delayed.

The spiral of decline in the commune health workers' morale: the decreasing respect of the public; the reduction of district supervision; and the lack of a living wage which led to increasing numbers of health workers starting a private practice or taking up other income generating activities; all illustrated a breakdown of the health services.

The consequence had serious implications for preventive care. With the reduced esteem of the CHSs due to declining curative activity, there was a concomitant reduction in motivation to finance the CHS by the communes. This threatened the very existence of the institutions that delivered the preventive care.

It was the project's goal to break this cycle of decline.

THE PROJECT

The project was a co-operation between Save the Children Fund UK, and the Hai Phong Provincial Health Bureau,



This poster, used in the project, gives two pieces of advice on antibiotic use: if you think you need antibiotics go to your doctor; and if you need antibiotics take the full course of treatment otherwise they will not be as effective next time

supported by the Ministry of Health and partly financed by the European Union.

Its objectives grew directly out of the previous analysis. They were all aimed at improving the quality of curative care

at the CHSs and altering the public's awareness of issues surrounding the rational use of drugs. It was assumed that this would increase the standing of the CHSs and therefore improve the chance of the commune investing in them, preserving the preventive care that they offered.

We hypothesised that if the commune health stations offered a good service, where common diseases were well managed; where necessary drugs at affordable prices were supplied in the right doses at the right times; where people with more serious problems were referred in a timely way to hospitals; where they had the basic drugs as a well managed revolving fund; and where the necessary basic equipment was present, then several consequences would follow.

The first would be that more people would use the CHS. If this were the case, then the small profit made on drug sales would increase. These together would improve the health workers' morale and financial situation. The second consequence would be that the commune, district and provincial people's committees would realise what an excellent resource they had in the CHSs and would mobilise more funds to maintain them. In this way the institutions of preventive care would be preserved and the spiral of decline would be broken.

Strategy

We aimed to affect several aspects of quality of care. We would improve the basic medical equipment, drug availability and the level of staff training. In addition we would help them construct a sustainable accounting system for ongoing drug supply, develop standard treatment guidelines, create district supervision of the quality of prescribing and accounting, and improve the rational use of drugs.

Changing people's prescribing habits has been shown worldwide to be extraordinarily difficult. These habits are not just formed from a rational knowledge base, but are affected by many financial, social and cultural factors. Prescribing (both bad and good) is a habit. To break the bad habits and establish good habits a combination of "carrot" and "stick" need to be employed over a

considerable period. We hypothesised that if good prescribing habits could be established for more than half a year then there was every hope that they would continue. We therefore used other aspects of improving quality of care as both carrots and



Participants at one of the district workshops which drew up standard treatment guidelines

stick towards changing prescribing habits.

We reasoned as follows:

1. Carrot

**Research:** if all work was based on locally found research results, the "top down" image would be broken and we would be seen to be basing our work on the real situation.

**Treatment guidelines:** if simple guidelines were developed, then it would be easy to judge the quality of treatment. If these guidelines concentrated on the most frequently seen conditions in all districts covering more than 80% of patients, then only some 10 conditions would need to be covered.

**Limited drug list:** by looking at the guidelines and adding a few more for emergency situations, an agreed list of drugs could be determined.

**Participation:** if the health workers participated in forming these treatment guidelines and drug list, they would be more likely to have a sense of ownership of the results.

**Retraining:** by concentrating on the management of these 10 basic conditions and the limited list of drugs, retraining could be feasible and effective.

**Supervision:** regular supervision of quality of prescribing from the district health centre would be a vital aspect of in-service training, morale building and developing a unified system.

**Drug fund:** if the CHS had a sufficient drug fund to stock the needed drugs from the limited list, it could purchase these drugs locally and sell them at a competitive price to the private market. This

...cont'd on pg. 16



**HAI Phong... cont'd from pg. 15**

would please health worker and public alike.

**Accounting system:** developing an accessible, transparent book keeping system kept by the CHS would help to ensure the existence of an ongoing revolving fund.

**Equipment:** the possibility for the CHS to choose basic equipment from an agreed list every three months for nine months would act as a real incentive to change prescribing habits.

**Patient load:** with an increasing patient load, income would increase.

**2. Stick**

**Withholding of equipment:** if the agreed treatment guidelines and book keeping system were not followed, then the equipment would not be forthcoming.

**Peer pressure:** the withholding of equipment would be public knowledge.

**Supervision:** the regular supervision would also be a form of inspection.

**Public expectation:** if, through a series of television and radio programmes, leaflets and posters, the public were informed about key aspects of drug use and CHS service, then their demand for irrational treatment would decrease.

**PHASED IMPLEMENTATION**

The project was implemented, district by district, in all 12 districts in 217 communes in Hai Phong covering a population of 1.6 million people. In each district the whole process took up to one year. We started with the rural areas and ended with the urban and island districts. Work started in the first district in June 1994 and the last in January 1996. It covered a series of activities aimed at improving aspects of quality of care.

**Pre implementation in each district**

Baseline research on key drug use indicators and which diagnoses were being made at CHSs was carried out in all CHSs of the district. This was either done by retrospective examination of out patient books or if these were absent, by prospectively giving prescription pads and examining them after one month.

As a pre-condition for joining the project, each district health office had to agree to set up and run a team of supervisors to monitor the quality of treatment and of book keeping in each commune each month. This information was to be fed back to the provincial health office and project office every month, establishing a record of key indicators for each CHS and aggregated for each district. It was mainly on the basis of these records that the decision was made whether to donate or not, money for equipment to each CHS each three months. The key indicators used were those that had been shown to be most problematical during baseline research (see Table 1).

**Preparation**

In each of the 12 districts, a series of

workshops was carried out – normally two in each district but this varied with the number of staff needing to attend. The workshops were with:

► **Key commune and CHS leaders**, to agree the plan of activity of the project. This was basically to enlist their support and explain the approach. It included them approving regular supervision by district staff, the formalising of the selling of drugs, instigating an accounting system and agreeing that the CHS drug seller could purchase drugs from the agreed list from any registered drug seller. They would also understand that equipment donation was dependent on good prescribing.

► **CHS curative staff**, to create a standard treatment guideline based on the most frequent diagnoses and to agree a drug list. A senior staff member from the Ministry of Health's Education and Science Department facilitated these workshops. The standard treatment guidelines were based on commune prescribing patterns over

previous months and on the diagnoses made. This information was found either by looking at records or if these did not exist, by supplying duplicate prescription pads to all staff, collecting them after one month and analysing the data. Treatment guidelines were made for the 10 most common conditions that covered more than 80% of patients seen in each particular district. While the process was participatory, the final say rested with the facilitator, who was familiar with national and WHO policies for treating the most prevalent diseases.

Compilation of the drug list was then relatively easy, as usually eight or nine drugs had been used in the treatment guidelines and then, extra drugs were discussed and agreed, using the same facilitator. Each district's drugs list was slightly different, containing between 29 and 31 drugs. When the programme ended they were combined into one list of some 32 drugs.

► **CHS book keepers**, to develop an appropriate book keeping system.

**Box 1***The Information, Education and Communication (IEC) campaign in Hai Phong to promote the rational use of drugs***IEC campaign principles**

Messages were agreed and prioritised on the basis of research. These messages addressed the same problems found with CHS prescribing. They were repeated as often as possible, using a variety of media channels.

**Main problems identified**

- Antibiotics are used too often.
- When antibiotics are used they are used in too small a dose.
- Injections are often preferred to tablets.
- The majority of sick people are not using CHSs.

**Agreed messages**

- Never use injections if tablets will do. Injections can be dangerous and are usually not necessary.
- If you need antibiotics, you must use a full dose. Not finishing the dose means that next time you need them they may be less effective.
- When you are ill do not self prescribe, ask your local expert. Use your Commune Health Station.
- Save the Children Fund from the UK is here to help upgrade your local Commune Health Stations. Using your local CHS when you are ill is beneficial for your health and the station.

**Media used**

These were variously applied from June 1994 to November 1995.

Two posters were designed in Hai Phong for the first two messages and every CHS was given four or five of each.

Four radio programmes (short plays of five minutes starting and finishing with the message) were written and recorded first by a district radio and secondly by provincial radio. They were transcribed onto cassette and distributed to every CHS to broadcast on the commune public address system.

Four radio spots each 30 seconds long were treated the same way.

TV programmes. Provincial TV recorded four programmes, each approximately five minutes long, with a respected person talking about one of the messages. These were shown several times over several months.

TV spots of one minute were treated in the same way.

Newspaper advertisements were taken out for each of the messages on the provincial newspaper's back page.

Leaflets. A simple leaflet was designed and given to each household in five communes.

Meetings. A key physician from each district was trained on the messages, but this has not yet been taken any further.

Cost. All these inputs came to a total of US\$2,200.

► **District supervisors**, to develop and learn methods to monitor the agreed key drug use indicators that were seen to be a problem on the basis of the research findings.

At the conclusion of the workshops a ceremony was held, where each actor (from the Provincial Health Bureau, District Health Office, Commune Peoples Committee and CHS) signed a contract to agree their role in the plan of activities. A week of retraining for all curative staff was organized through the secondary medical school, to reinforce basic diagnosis and treatment for common conditions.

With this done, Save the Children Fund UK transferred an average of US\$300 to each CHS for them to set up a revolving drug fund. It also supplied books and calculators for book keeping. This took around two months in each district.

In addition an information campaign on key drug use issues was launched using television, radio, newspapers, posters and leaflets. The messages were based on survey results (see Boxes 1 and 2).

**Ongoing work**

With satisfactory results from the regular supervision of the district teams, at three monthly intervals, each CHS was allowed to choose around US\$250 worth of basic medical equipment from an agreed list. This equipment was conditional on following the treatment guidelines and book keeping system.

Initially some CHS staff found it difficult to understand and adhere to the new accounting and prescribing procedures. However, the district health team's supervisory visits and at least one early visit from a Save the Children team member helped to resolve problems. After this visit, when processing the monthly information for the district, the project wrote to the district health officer highlighting any unsatisfactory practices within particular CHSs, (such as overuse of antibiotics or injections). If, after warnings, bad practices went unchanged, the requested equipment was refused until improvements had been made.

The supervisors' motivation and abilities were another concern. If highly qualified the supervisors were reluctant to travel around to the CHSs. If they were less highly qualified they were more willing to travel but did not have the authority to advise the medical assistants on their practice. This problem was tackled differently in each district, but on the whole the supervisors managed to collect the necessary information. The head of the district health office reviewed the supervisors' progress each month when they came in to collect their salaries. The review was based on the information that had been collected. When information had not been collected for the month because the supervisors had not done their work, equipment distribution was stopped in the whole district. We also stopped delivery if the information seemed unreliable, for example if everything was scored at 100%. The reliability of the

**Box 2**

*The Information Education and Communication campaign evaluation*



**Evaluation**

Two hundred households from five communes were randomly selected and interviewed.

The results showed that the IEC campaign had been memorable:

- 89% of households could report some IEC messages.
- Only 25% claimed no change in knowledge. The other 75% claimed a change in knowledge, practice or both.

The most effective means of communication was the commune public address system. 67% of respondents remembered at least one message from these.

52% of all households remembered something from TV (51% of the households owned a TV).

53% remembered something that their CHS staff had told them.

Newspapers and posters were less effective with only 7.5% and 15% remembering something from these.

The leaflet was not remembered very often (37%), but in the communes where the leaflet was not distributed to each house, respondents were twice as likely not to remember any message.

**Conclusions**

IEC campaigns based on locally made programmes and research-based messages can be very effective and inexpensive in Viet Nam. Commune public address systems are still effective in rural areas. This is based on the decentralised media system of province, district and commune. This has profound implications for future campaigns on, for example, nutrition, weaning practices or HIV.

(A full report of the IEC evaluation is available from the address at the end of the article).

supervisors' information was checked through evaluation exercises and was found to be very good. Supervision results showed a large improvement in prescribing habits and book keeping over the first five months of activity for each district (see Table 1).

**Evaluation**

Supervisors' data were checked by quantitative evaluations in December 1995, before the project had finished and then again in September 1996, six months after the end of the external inputs.

These were retrospective studies, in the eight rural districts which the original project covered, and where the

baseline research was carried out. The studies involved randomly choosing 40 CHSs and looking at the out patient book, the accounting books, the drug cabinet and performing some interviews. From the out patient book, the last 30 treatments were looked at in each CHS for the prescribing indicators.

**A major impact**

As the project was started district by district over an 18-month period, the baseline research in new districts acted as a rolling control to the results shown. Each new district showed broadly the same pattern of results as the original baseline, thus showing that most of the impact could be attributed to the project activities.

The most significant finding was the large improvement in the prescribing parameters as can be seen in Table 1. In each district these improvements took place in the first month after the workshops, and then went on improving over the next few months to reach a plateau which was maintained to six months beyond the end of the project (see Table 1). This shows that good prescribing becomes a habit when maintained due to incentives over a considerable period.

The treatment guidelines and agreed limited list of drugs were successfully developed in each district. The week of retraining concentrated on these. Each district guidelines covered around 10 conditions that covered more than 80% of patients. The 12 district guidelines were eventually combined into one book for the Province. As shown in Table 1, the guidelines were followed in a large percentage of cases. The CHSs stocked an average of 27 of the 29 or 30 recommended drugs, but continued to stock an average of 23 other drugs, and 55% of CHSs stocked specifically non regulation drugs such as steroids, gentamycin and lincomycin. When asked they said that they sold these profitably over the counter, from their drug store, and therefore liked to stock them. Anecdotally this is an improvement on the pre-existing situation when all CHSs stocked such drugs.

The supervision system eventually functioned well in all districts. The information produced in this way was shown as reliable when compared to the evaluation research (see Table 1). In two districts, after three months, when the equipment was due, we refused to release the equipment to any of the CHSs, as we felt the supervision results were unreliable or they had not been produced. After this things improved. The conditionality of equipment donation on reliable and regular supervision proved an effective incentive.

**CONCLUSIONS**

A drug fund was supplied to each CHS, tracked by an accounting system. Interestingly only an average of US\$150 (out of the US\$300 supplied) was used

**Table 1**

*Hai Phong baseline, Hai Phong research and Hai Phong latest supervisors' reports*

	Hai Phong Baseline n = 690	Research RESULTS n = 1,200	Latest Supervision Reports n = 4,050	Research RESULTS n = 1,200	Latest Supervision Reports n = 6,510
MONTH	August 1994	December 1995		September 1996	
Patient numbers per CHS per month	76	115	120	114	137
ITEM/PT	2.3	1.4	1.5	1.5	1.4
% patients given VITAMINS	75%	8%	8%	6%	6%
% patients given INJECTIONS	33%	7%	7%	6%	6%
% patients given ANTIBIOTICS	69%	46%	45%	48%	43%
% antibiotic DOSES OK	29%	91%	98%	93%	98%
% treatments following the STG		92%	93%	86%	95%

to buy drugs, presumably because there was a consensus that this purchased enough of the products on the drug list to have a sufficient store. This has important implications for funding of projects in the future. The excess money was kept safely in reserve, and may help the drug fund's sustainability. The accounting system was only fully operated in around 65% of the CHSs. Profit was not one of the things we asked to be recorded, as this is a sensitive issue with potential tax consequences. However the average monthly purchasing of drugs was around US\$150, so assuming a 10% mark up, an extra US\$15 a month served to supplement salaries which were only \$6 a month. This was not a fortune, but was a significant addition.

All 217 CHSs eventually received the equipment they requested, although some was delayed because the station did not fulfil the criteria of good prescribing. Using the equipment donation in this way provided a much-needed leverage to give

overall profit from selling drugs should have increased due to the number of patients being seen.

The quality of care given to patients improved in the form of better drug and equipment supplies, better staff knowledge in diagnosis and treatment, and above all better prescribing.

It should be emphasised that this was first and foremost a practical project to improve the deteriorating health care situation, and only secondly a research project. The Hai Phong authorities had no interest in research as such, but wanted benefit for their people as soon as possible. The whole project was run on operational research lines. The justification was that all information used should be locally derived to increase the relevance, and that supervision data were a useful management tool and a necessary way of assessing whether equipment should be donated or not.

The project itself was multi-faceted, using innovative together with well-trying techniques that had been shown to work in other situations. This means that we cannot say which part of the project was responsible for its success. However this was never the intention. It is the very multiplicity of approaches that has now been shown to be effective. The innovation is the combination of the factors involved, with particular focus on the conditional donation of chosen equipment depending on good prescribing and the effective setting up of district wide supervision. □

\* Dr John Chalker was Project Manager for the Hai Phong Project, from December 1993 to March 1996, for Save the Children Fund UK.



At the end of a series of training workshops John Chalker presents a participant with a set of posters, a cash box plus padlock and a calculator. Inside the box are all the accounts and record keeping books necessary for one year. All commune health stations received these

an incentive towards rational drug use.

Patient attendance increased during the project and maintained that level for six months after the project's end (see Table 1). This may have been in part due to the IEC campaign (see Boxes 1 and 2). This means that although each patient may be treated more rationally, and therefore be given fewer drugs, the



For further information on the Programme contact: The Field Director, Save the Children Fund UK, 218 Doi Can Street, Ba Dinh District, Hanoi, Viet Nam. Reports on the Programme evaluations, including the public information campaign, are available from this address. Other publications are pending.



## RESEARCH

# Survey highlights failings in public education in rational drug use

**A** global survey of public education in rational drug use<sup>1</sup> has revealed that efforts in both developing and developed countries are being severely hampered by under-funding, lack of support and a shortage of expertise. The outcome, says the report, is a vicious circle in which projects are poorly planned, weakly implemented, and not evaluated rigorously enough.

The report by the Action Programme on Essential Drugs is based on the first ever global survey of public education in rational drug use. The study set out to establish who and what is being targeted by rational use programmes; who is doing the work, how and why; what are the needs and lessons learned; and what future action needs to be taken. The survey included data from about 100 questionnaires and educational material gathered from 38 countries (25 developing and 13 developed countries).

## Critical need for public education

The report points out that in many parts of the world up to 80% of illness episodes are self-treated with modern pharmaceuticals. And even where formal health care channels are used, it is the consumer – not the prescriber – who determines whether and how the drugs are used. These decisions are based on the shared beliefs of family, friends or the wider community; information from prescribers and dispensers; and promotional material. As a result, consumers need access to accurate and understandable information about the potential benefits and risks of medicines in general, including possible side effects; how they act within the body; and the limitations of pharmacotherapy and other treatment options.

“With the exception of Australia, no country – developed or developing – has undertaken a structured public educational programme, targeting all members of the community and developed by a coalition of stakeholders,” says the report. The authors point out that in developing countries it is not surprising that, in view of the wide range of other competing areas of drug policy, public education in rational drug use is often given low priority. But its neglect by developed countries is more difficult to understand.

“It is more difficult to explain the lack of commitment by developed countries to systematic and structured public education in rational drug use, given the potential economic and public health benefits,” the report states.

Until now few public education in rational drug use interventions have been documented or evaluated. As a result, experience cannot be shared or built on. The DAP survey was intended to help close this gap.

A surprise finding was that there were fewer differences than expected between the types of programmes in developing and developed countries. The most significant was the different media used. While education programmes in developed countries relied more on the printed word to get their message across, programmes in developing countries reported more frequent use of the mass media, especially radio. In developing countries, the most popular channel of communication was the mass media (76% of projects) followed by workshops (70%) and the distribution or display of printed materials (26%). Developed countries focused mainly on printed materials (61% of projects) and the mass media (56%).

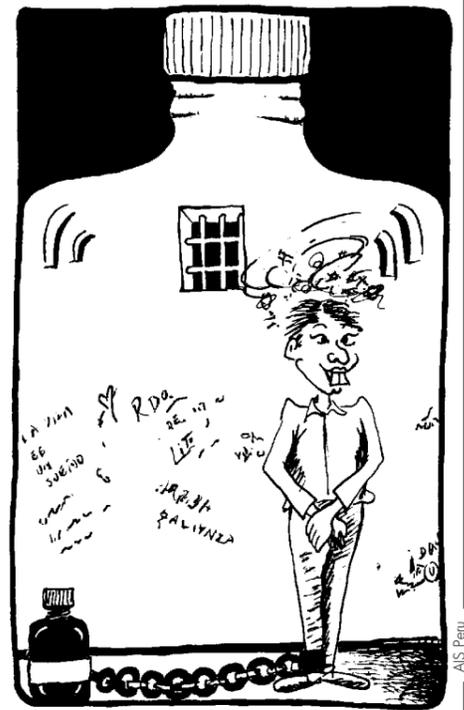
## Reaching out to schoolchildren and the elderly

School projects accounted for a large number of education programmes, especially in developed countries, but only Sweden had launched a nationwide

programme targeting all schools. Projects ranged from a novel “pill-box” information campaign in secondary schools in Belgium (see Box 1), to projects for younger children in the United States, involving the use of pharmacy students to teach drug safety and compliance, and encourage children to take responsibility for their own health.

Many of the sample school kits submitted had been developed in collaboration with the pharmaceutical industry or pharmacy organizations. Most failed to highlight the risk/benefit equation of drug use, or even that the same active substance may be marketed under different brand names and at different prices. In addition, little effort was made to encourage children to develop a more objective view of the commercial promotion of drugs.

A variety of innovative approaches are being used by groups in both developed and developing countries to get the message across. In Germany, the BUKO Pharma-Kampagne uses street theatre presentations to raise public awareness about rational drug use, while in Australia, the Medicine Information Project makes use of trained elderly volunteers as peer educators to promote rational drug use among the elderly population. Volunteers receive an initial five days’ training, updated four times a year. The topics



No words are necessary to convey this message on the dangers of becoming dependent on tranquilisers

### Box 1 “Far-Well” and “Medi-Studt”. The best medicine for students – Belgium

Students are “open” to new information; learning is their job. Students are also prone to using medications, especially in order to study well during examination time.

Knowing this, the higher-educational institutions (non university) in Belgium requested Projekt Farmaka, a non profit independent organization, to assist. The result, designed and developed by a planning group consisting of a pharmacist, prescribers and students, was an innovative “pill-box” of information destined for distribution in schools and student clubs. The choice of subject matter in these “pill-boxes” was based on the most common illnesses and complaints, and on the most commonly used medicines by students. The main message? “Use a medicine ONLY WHEN IT IS NEEDED.”

But activities went far beyond the simple distribution of the “pill-boxes”. Information stands were set up during school breaks and at lunchtime, with displays and posters. In order to get a “pill-box”, a student had to complete a quiz form with five pertinent questions. Workshops were held with the students to discuss the information. Mass media also participated, with radio interviews and television announcements.

The campaign was well-timed. It was held during the examination period, when students are prone to taking vitamins and “pep pills”, and to having sleep-related problems. The students were particularly open to discussions about medications, and wanted to learn more. Some schools have established a “medicines panel” to disseminate additional information about problem drugs, and to discuss issues like sports and diet. Other schools are organizing question-answer sessions focusing on medications.

The “pill-box” concept was innovative and sparked people’s curiosity. The materials could be improved, to be sure, and future campaigns will take into consideration more of the students’ views on content, in addition to design.

### Box 2

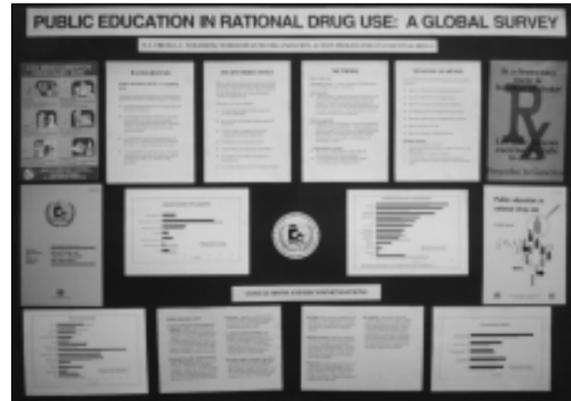
#### Michoacan, Mexico holds a campaign: Towards the Rational Use of Drugs

Given evidence of an overabundant use of medications by the general population, of an over-prescription of medications by medical doctors, and of unethical drug promotion, a nongovernmental organization in one state of Mexico embarked on a short but intense educational campaign. Participants in the planning were prescribers, government officials, community members, students, the media, and communication experts.

The campaign targeted the general public, but also prescribers and medical students. Materials developed included posters, leaflets, press articles, slides, radio and television programmes, and posters for doctors. Many of the printed materials were displayed at points of prescription; others were used during 3-day seminars held at the local medical school. The mass-media broadcasts lasted for three months, with increasing intensity just prior to the medical school conferences.

Feedback after the campaign was very positive. Medical professionals and students expressed increased awareness of the problems. The pharmacology curriculum of the local university was revised. Articles published in the local and national press suggested a significant change in general knowledge about rational drug use.

covered include consumer rights and responsibilities, use of specific medications, assertiveness, problem-solving, as well as presentational and listening skills.



Disseminating the survey results is essential to promote effective public education. Here the global survey is publicised at a pharmacists' association meeting in the Netherlands

Elsewhere, telephone services in Peru and the Netherlands have been forced to expand the service after being swamped with calls on medicine-related health issues.

**Weaknesses identified**

The authors warn that the use of a wide range of different materials in some developing country projects – inadvertently promoted by funding and supporting agencies – may lower their effectiveness by diluting the message. The report highlights the difficult balance needed between having a few, well-developed and well-used complementary materials and a large number of relatively unconnected ones.

The report reveals that almost half the projects used educational material that had never been pre-tested. Of those that did pre-test materials, most reported that the materials needed subsequent revision. Although the survey did not extend to the quality of pre-testing, the authors warn that the methodology for this is often lax. Common weaknesses in the material submitted included a proliferation of messages and the over-use of scare tactics, while some required considerable training before they could be used effectively. The report recommends the development of relatively simple methodologies to ensure that all materials can be thoroughly pre-tested and, where necessary, revised before use.

Another weak spot identified in the report is the lack of structured planning. Most projects selected fairly general themes on the basis of "perceived need" and their target groups and expected outcomes were also very broad. However, significantly more developing countries (43%) than developed countries (27%) had based their projects on research findings (including consumer and practitioner surveys, focus-group discussions, and patterns of drug sales).

Of the specific drug problems targeted, developing countries most frequently cited antidiarrhoeals and antibiotics, while developed countries focused more often on benzodiazepines and other sedatives. The illnesses most often targeted were diarrhoea and malaria in developing countries and asthma in the

developed countries.

The report highlights the failure of most projects to evaluate the impact of their activities. As a result, cost/benefit analysis is impossible – deterring many potential donors. Very few projects were able to provide evaluation reports. And, with the exception of rational use of drugs projects in Australia and Viet Nam, most focused on activity monitoring rather than impact assessment.

"This is unfortunate," the authors point out, "for public education programmes are often accused of a lack of rigour in their work, leading to a questioning of their value and consequent difficulties in obtaining support for such programmes."

However, the report also warns that the impact of public education strategies is often incremental – moving gradually from initial awareness raising, to knowledge creation, community empowerment and behavioural change. "This may be difficult to evaluate in the short-term – particularly using classical methodologies," say the authors, "and care is needed that we do not 'throw out the baby with the bath water' in an attempt to evaluate impact with scientific rigour."

In the absence of systematic evaluation studies, many projects gave estimates of the impact of their activities. In developing countries, 40% of projects judged that their project had met its objectives, compared to 66% in developed countries. Meanwhile, 60% of developing countries and 30% of developed countries said the project objectives had been partially met. No developing country and only 4% of developed countries deemed their project



Both health professionals and the general public need better information and education about when and how to use drugs

to have been a failure.

The main problems faced by projects included:

- shortage of funds;
- inadequate external collaboration and support;
- poor coordination;
- shortage of time and personnel;
- opposition from vested interests (both commercial and professional);
- unsupportive legislation.

Of these, the lack of funds was the major problem for developing countries, while for developed countries, the principal constraint was a shortage of time and personnel. On sources of funding, the survey found that developing country projects were most likely to be funded by international organizations or international NGOs, while ministries of health and professional associations were the major source for developed countries.

**Tackling the problems**

The report notes that if public education is to be properly researched, backed by the necessary tools and knowledge, and be effective and sustainable, it must be adequately resourced – ideally from a variety of funding sources. It says new, more creative and sustainable sources of funding are needed, possibly including:

- a tax on commercial drug information budgets to provide independent information to consumers and to support community projects;
- incentives to dispensers to develop community education projects or extend individual counselling – particularly in countries where dispensing is covered by social insurance schemes;
- independent consumer information for sale at a price that covers recurrent costs.

The report also highlights the need for greater advocacy at international, national and regional levels to promote the importance and rationale of public education in rational drug use. It says there is a need for greater understanding of its potential contribution to public health and savings in health expenditure. Better advocacy, say the authors, would help "avoid simplistic, unsustainable, and token approaches that contribute little to real community empowerment and understanding, but simply pay lip service to the very real information and educational needs of the community in this important area."

Also needed are opportunities for short-term training and access to simple, practical tools essential for research and development activities, especially for small-scale community-based programmes. The authors point out that no courses exist in the area of public education in rational drug use, and call for the



This Kenyan health education poster warns against one of the most common dangers in many developing countries – untrained drug vendors whose products are often substandard or counterfeit

development of an international training course through which educators could strengthen their communication skills and, in turn, train national colleagues through in-country training programmes.

"Organizations or people who intend to carry out public education projects need clear, usable guidelines to help them better plan and structure their activities, including better definitions of the theme(s), the desired outcomes of the project, and the target audience."

The report also calls for the development of supportive coalitions and partnerships which could help strengthen the work and long-term sustainability of many organizations, especially those working in relative isolation. But it also warns that organizations need to ensure they are not hijacked by powerful interests "less interested in the community's own perception of needs and empowerment, and more concerned with 'marketing' behaviour considered desirable by the dominant group."

The most encouraging finding of the survey was, despite its current failings, at its best, public education on rational drug use *can* and *does* work. Among developing countries this was the second most important lesson learned and for developed countries the third most important. In Bolivia, a primary health care project declared that it was possible to get the community to take responsibility for their health, while rational use of drugs campaigners in Bangladesh reported that effective lobbying had shown that "continuous, logical insistence to producers on rational/ethical production *works*." Elsewhere, in Australia, the Medicine Information Project noted that, "empowering consumers can drive change at all levels of the health system." □

**Reference**

1. WHO/DAP. Public education in rational drug use: a global survey. DAP Research Series No.24. Geneva: World Health Organization; 1997. WHO/DAP/97.5.

Photo: WHO/D.A. Frestle

Ministry of Health, Kenya

National Council on Patient Information and Education, USA



## RESEARCH

# Advantages of pre-packaged antimalarials

**A** Ghanaian study<sup>1</sup> has shown that treatment of malaria is more cost-effective, in terms of both time and money when antimalarials are pre-packed in daily doses. Preliminary observations in six districts indicated that some of the major problems in malaria control programmes are: high cost of treatment; high chloroquine consumption (in syrup form); long waiting times at dispensaries; and a large number of untrained/unqualified dispensers who are unable to give advice.

Two types of pre-packaging were used in the study – plastic bottles for chloroquine syrup and sealed plastic bags for chloroquine tablets. The advantages of pre-packaged antimalarials were found to include:

**Reduced cost** because of: reduction in the number of drugs prescribed; smaller volumes of syrup consumed; reduction in the number of injections given; reduction in excess chloroquine consumption.

**Improved drug management** – easier to balance books; easier to monitor drugs issued; reduced contamination; less wastage.

**Improved case management** – doses given according to weight.

**Improved compliance** – easy to understand and easy to remember instructions; more effective counselling.

**Reduced waiting times** in dispensaries.

**Sustainability** – cheap, readily available materials.

**Acceptability** – to both staff and patients.

Because of the clear advantages of pre-packaged antimalarials, Ghana's district medical officers are eager to extend the practice to other commonly used drugs.

The Ghanaian study adds to the evidence from similar research on pre packaging in South-East Asia. For example, in China, blister packaging of antimalarials produced 97% adherence to treatment compared to 83% in the control group, whose drugs were handed out in envelopes (which are often lost or disintegrate in the rainy season associated with malaria).

## Why patients need information

Other Ghanaian studies have shown how much greater the effect of pre-packaging antimalarials is when better information is provided to patients by prescribers and dispensers. These studies were part of the series being carried out by district medical teams in collaboration with the Health Ministry's Health Research Unit, in the context of Ghana's health sector reforms. A Phase 1 study had indicated that many patients who receive chloroquine are not given any information about how many tablets to take or

how often to take them. They may also be given either more or less chloroquine than they need. This is important because failure to comply with the full course of treatment affects both the patient's cure and the drug resistance of parasites.



Photo: WHO/TDR/A. Crump

The packaging process for antimalarials, seen here at the National Institute of Medical Research, Lagos, Nigeria. Pills are bagged, heat sealed and labelled with dosage instructions

The follow-up intervention ensured that prescribers and dispensers provided full information to patients about the duration of therapy and the quantity of chloroquine to take each day. As well as verbal instructions patients were given a diagrammatic explanation to take home.

Following the intervention there was a significant increase in adherence to treatment – from 25% to 50% – in the

number of patients strictly complying with these instructions. The proportion of people obtaining at least enough chloroquine on each of the three days of treatment increased from 29% to 54%. The proportion of children who obtained

at least the recommended minimum dose of chloroquine syrup on each of the three days increased from 59% to 85%. Sample sizes used in the study were between 55 and 75 patients.

This work shows that a little time invested in providing appropriate information to the user at primary health care facilities will, in the long run, pay dividends in terms of increased patient adherence to treatment. □

For further information contact: World Health Organization, Special Programme for Research and Training in Tropical Diseases, 1211 Geneva 27, Switzerland.

Source: TDR Newsletter No. 54, October 1997.

## Reference

1. The study was part of a project to improve malaria control in Ghana, co-sponsored by the UK's Department for International Health, Liverpool School of Tropical Medicine (UK), the Ministry of Health in Ghana and WHO's Special Programme for Research and Training in Tropical Diseases (TDR).

## TRAINING

# Course offers flexible approach to community-based health education

**I**n publicising one of its newest courses, Leeds Metropolitan University in the UK sets out clearly the benefits of health education: the awareness it creates among the community, policy makers and health care providers of the advantages of a rational drugs programme and the proper use of medicines; the increase in the skills of health care providers in the delivery of sensitive, appropriate and effective patient education; and the encouragement it gives for community and political action to prevent the misuse of drugs and medicines.

The University is offering a 10-week course in community-based health education and health promotion with specialist options, including one on medicines and essential drugs. Participants either finish after 10 weeks and receive a certificate of attendance or study further by distance learning within their own

workplace for a diploma, based on implementation of a project that they designed at Leeds.

The aims of the course are to provide skills in research, planning, management and evaluation of health education, and provide opportunities to apply these skills to a problem from the participant's own work setting. Applicants should be experienced managers and staff within field projects who require a short course to improve their capacity to plan, implement and manage the health promotion components of projects.

## Module on medicines and essential drugs...

Among topics covered in this module will be:

- Appropriate use of medicines, including an introduction to: the essential

drugs concept and appropriate use of medicines; the work of WHO's Action Programme on Essential Drugs, international pressure groups and consumer movements; and problems arising from inappropriate use of medicines.

- Health seeking behaviours: self-medication, informal market sectors for medicines and problems of implementing essential/rational drug policies.
- Assessment of needs for health education/health promotion support for appropriate use of medicines.
- Community, social and economic influences on use of medicines and the role of multinational companies.
- Health education and health promotion methods in various settings: national campaigns, mass media,

patient education, community self help groups, community pressure groups, training of pharmacists, and training in the informal sector.

- Planning for programmes to promote appropriate use of medicines: selection of indicators for monitoring and evaluation.

The course is expected to cost £3,000 for academic tuition and field visits, with subsistence/accommodation expenses of approximately £2,500. □

For further details contact: Overseas Admissions Tutor, Health Education, Room F505, Leeds Metropolitan University, Calverley Street, Leeds LS1 3HE, UK. Tel: + 44 113 28322600, fax: + 44 113 2835921, e-mail: health-promotion@lmu.ac.uk

## TRAINING

# Personal formulary system helps university students

THEO P.G.M. DE VRIES\*

**T**HE development of a personal formulary system by university teachers in the Netherlands is proving to be a valuable tool for students in learning how to prescribe drugs rationally. The personalised compendium of drugs not only helps students learn about the drugs they prescribe, it also helps them choose alternatives in case one drug is unsuitable for a particular patient.

The personal formulary is a practical elaboration of the P(ersonal)-drug concept, which is outlined in Part 2 of the WHO *Guide to Good Prescribing*. It consists of a sequential approach for selecting a personal set of drugs for the treatment of specific diseases. By using a loose-leaf notebook and a small manual, practical information about the selected diseases and P-drugs can be inserted, changed or deleted. In this way a personal formulary can be developed.

The personal formulary is divided into sections. The first section is used to list selected diseases. For each disease, a chosen standard drug and non-drug treatment can be described extensively or merely summarised. For example, (Dutch Standard Guidelines):

Essential hypertension: start with weight, salt, and stress reduction. If no result:

1. atenolol or hydrochlorothiazide; if no result:
2. atenolol + hydrochlorothiazide; if no result:
3. captopril; if no result:
4. consider calcium antagonist, alpha 1-blocker, or referral.

The second section contains practical information for prescribing the drugs listed in the previous section. Each page has information on a single drug, and the information is organized along the lines of the sequential approach to treating patients (outlined in Part 3 of the

*Guide to Good Prescribing*).

One side of the page contains the information needed to check not only whether a specific drug is indicated for the disease but also whether the drug is suitable for the individual patient (see Figure). If the doctor or student has decided that the drug can be prescribed, they then turn to the other side of the page. Here a prescription can be made out together with the necessary information and instructions for the patient, as well the date of the next appointment, where appropriate (see Figure). Information about monitoring the drug treatment can also be inserted here. With the loose-leaf system, the content of the personal formulary can be easily changed.

The simplest way is to write or type the information about each P-drug. A computer programme has been developed for this with technical support from the WHO Collaborating Centre for Pharmacotherapy Teaching and Training at Groningen University. Using this programme, the data can be typed, and printed in a standard format as shown in the Figure. Students can also add and remove drugs, and revise any of the information about an individual drug. In this way students build up their own personal formulary. To help make it more personalised, each printout includes the name of the student. The programme can be installed on a computer network – a university network, for example – or on

Betty H. O. Student    12-06-98    Pharmac 95			Page 1
<b>tablet 25,50,100 mg</b>	<b>Beta blocker</b>	<b>atenolol</b>	
Atenolol is a selective beta blocker without intrinsic sympathicomimetic activity. It depresses myocardial contractility and reduces the heart rate. This initially causes a fall in blood pressure. With continued treatment the cardiac output returns to normal but blood pressure remains low because the peripheral vascular resistance is 'reset' at a lower level. In addition it may also increase the perfusion of the ischaemic area. It has very limited solubility in lipids (limited capacity to pass Blood Brain Barrier).			
<b>Check indication</b>			
Indication	Angina pectoris, Hypertension		
Alternatives	Hydrochlorothiazide, Captopril		
<b>Check suitability of the patient</b>			
Side effects	Hardly any in normal dosages. Sometimes slight sedation, reduced exercise tolerance, or bronchospasm.		
Contra-indic.	Sinusbradycardia, AV block, hypotension, cardiogenic shock, heartfailure, asthma.		
Interactions	Some calcium antagonists, some anaesthetics.		
Betty H. O. Student    12-06-98    Pharmac 95			Page 2
<b>tablet 25,50,100 mg</b>	<b>Beta blocker</b>	<b>atenolol</b>	
<b>Dosage</b>			
Adjust to each patient individually, start as low as possible. Raise the dose after 2 weeks if needed. Higher dosages do not increase therapeutic effect, but may increase side effects.			
Hypertension	Start with 50 mg in the morning; average 50–100 mg per day		
Angina pectoris	100 mg per day in 1–2 doses		
<b>Give patient information</b>			
Information	Hypertension: drug decreases blood pressure. You will usually not notice any effect but the drug is needed: it will prevent complications of high blood pressure (angina, heart attack, stroke). Angina pectoris: decreases blood pressure, prevents heart from working too hard, preventing chest pain. Hardly any side effects; sometimes slight sedation. In some cases shortness of breath; in that case phone me.		
Instructions	Take the drug ... times per day, for ... days;		
Warnings	Angina pectoris: do not suddenly stop taking the drug		
Appointment	Hypertension: one week Angina pectoris: within one month, earlier if attacks occur more frequently, or become more severe.		
Follow-up	Hypertension: first few months check BP and pulse weekly; try to decrease dosage after three months, and to stop after one year. Angina pectoris: in case frequency or severity of the attacks increase, more diagnostic tests or other treatment are needed. Try to stop drug treatment from time to time.		

a personal computer.

In the computer network of the Free University of Amsterdam, information on over 90 drugs has been included in the reference database. Clinical experts within the university consider these drugs appropriate for the treatment of 129 diseases and symptoms. At the end of the six-year undergraduate course medical students must be able to treat correctly, within 10 minutes, a real patient suffering from any one of these diseases. At the start of the second year, students receive a personal formulary with a printed version of the basic information on the full range of over 90 drugs and can copy this information to their personal database. Next they are trained in developing and using their personal formulary. Up to the fourth year they practice in small groups by treating both textbook and simulated patients. A syllabus has been developed for this which includes about 200 textbook cases together with treatment plan forms (following the sequential approach of the *Guide to Good Prescribing*) and suggestions for patient role-playing exercises. During the internships in the fifth and sixth year, the students practice with real patients. Students can buy a personal

formulary and the syllabus for US\$20. They also receive the *Dutch Drug Compendium* free of charge from the National Sick Fund.

Initial results so far from the personal formulary system have been promising. During a realistic training session, involving three simulated patients, the second year students taught in this way prescribed drugs more rationally and correctly than graduates who had followed the traditional curriculum. □

\* Theo P.G.M. de Vries is Professor of Pharmacotherapy at the Free University of Amsterdam, Van der Boechorststraat 7, 1081 BT Amsterdam, the Netherlands. Fax: + 31 20 444 8100.

## Guide to Good Prescribing available in more languages

To add to the list of locally produced versions of *Guide to Good Prescribing*, editions have now been published in Brazil (Portuguese), in India (in Bengali), Iraq, Italy, Japan and Pakistan. A Spanish edition will follow by the end of 1998.

## NEWSDESK

## Addressing supply issues in the Eastern Caribbean

**M**ANAGEMENT Sciences for Health and the Eastern Caribbean Drug Service offered a special eight-day course on managing drug supply, held in Dominica from 19–28 January 1998. The 18 participants included central medical stores' managers and hospital drug supply managers from all nine countries in the Organization of Eastern Caribbean States.

The course was specially designed to address the specific drug supply issues of the island countries, including: lack of national drug policies; lack of current

quantification of needs, drug donations, medical store management and inventory control and drug utilisation reviews. Participants discussed their own experiences and worked hard to complete realistic work plans and timelines for improvement projects to be implemented upon their return to work. These plans were shared with the Ministries of Health and will receive support and follow up from the Eastern Caribbean Drug Service. □

Source: INRUD News, February 1998.

## NEWSDESK

## Change at WHO

**T**HE Fifty-first session of the World Health Assembly, meeting in Geneva in May 1998, elected Dr Gro Harlem Brundtland of Norway to be Director-General of WHO for a five-year term which started on 21 July 1998. Dr Brundtland had been nominated to the position by the 101st Session of the WHO Executive Board in January 1998. Former Prime Minister of Norway,



Dr Gro Harlem Brundtland, Director-General of WHO

and the first woman to become Director-General of WHO, Dr Brundtland studied medicine at the University of Oslo and has a Masters degree in Public Health from Harvard University, USA.

After taking the oath of office, Dr Brundtland addressed the World Health Assembly. She immediately affirmed her conviction that societies can be changed and that poverty can be fought. "The challenge goes to all of us. WHO can and must change. It must become more effective, more accountable, more transparent and more receptive to a changing world". Referring to the complex processes of transition that WHO must cope with, the new Director-General said: "The transition from one century to another sees changes which will be faster and more dramatic from an economic, social and health perspective...Still we are faced with daunting challenges. Above all they

are linked to the persistence of poverty. The imbalances are striking. People in developing countries carry over 90% of the disease burden, yet have access to only 10% of the resources used for health. As regards the transition from the communicable to the noncommunicable diseases, Dr Brundtland noted: "We need to fight both. The burden of disease is the burden of unfulfilled human development".

Dr Brundtland concluded her speech saying: "My motivation will be this: making a difference – being able to make an effort – being one of many dedicated people working together for what we believe in. I envisage a world where solidarity binds the fortunate with those less favoured. Where our collective efforts will help roll back all the diseases of the poor. Where our collective efforts will assure universal access to compassionate and competent health care. Bringing the world one step closer to that goal is our call for action".

On her first day in office Dr Brundtland announced her new management team. Of the 10 cabinet members, eight come from outside WHO, and six are women. Members are evenly split between the North and the South, and all WHO regions are represented.

### Governments pledge support for WHO campaign

The week that Dr Brundtland was elected Director-General and announced that one of her goals was to "Roll back malaria", good news came from the G8 summit meeting of the world's foremost industrialised nations. Leaders attending the UK summit in May 1998 agreed to support WHO's campaign against infectious and parasitic diseases, particularly malaria. □

## Rational use conference in Palestine

**T**HE first Palestinian conference on rational use of drugs brought together an enthusiastic group of health workers, nurses, pharmacists and doctors from throughout the health sector. Speakers from international and local NGOs, Palestinian universities, and physicians' and pharmacists' associations helped to raise awareness of rational use issues. Discussions ranged from the impact of inappropriate drug use to standard treatment guidelines, essential drugs policy, drug information, continuing education for pharmacists, quality assurance and drug donations. The event is seen as an important step in moves to design a

health policy that meets the needs of all Palestinians.

Held at Beir Zeit University in October 1998, the conference was organized by the Union of Palestinian Medical Relief Committees with the support of the French Government and the United Nations Development Programme. □

For further information, contact: Nadine Kamal, Head Pharmacist, Union of Palestinian Medical Relief Committees, P.O.Box 51483, Jerusalem. Tel: + 972 2 5834 021, fax: + 972 2 5830 679, e-mail: NadineKamal@hotmail.com

## Executive Board acts on Revised Drug Strategy

**M**EETING on 19 May 1998, WHO's Executive Board decided to establish a two-tier method of working to explore the complex issues, (including those related to globalisation and trade), raised by Resolution 24 on the Revised Drug Strategy, passed by the Board in 1997. An ad hoc working group would be open to all Member States wishing to participate; and a sub-group would be created to assist WHO in its contacts with relevant partners. These include the World Trade Organization, the World Intellectual Property Organization, the pharmaceutical industry and NGOs. The Board decided that the sub-group would comprise the Chair of the drafting group on the Revised Drug Strategy, established during the 51st World Health Assembly in 1998, and two Member States from

each region (of which at least one would be currently entitled to designate a person to serve on the Executive Board).

As directed by the Board, WHO's Regional Committees discussed the Revised Drug Strategy at their autumn meetings, and nominated their representatives for the sub-group. The group met for the first time in Geneva in October 1998, and fulfilled its main objective of drafting a new resolution on drug strategy. A total of 59 Member States participated in the meeting. As part of the sub-group's deliberations a one-day panel discussion was held, which included presentations from interested international and nongovernmental organizations. The Executive Board will discuss the draft resolution at its 103<sup>rd</sup> session in January 1999. □

## African countries share information on drug prices

**A**LTHOUGH the availability of essential drugs in Africa has improved during the last decade, it is estimated that one-third to a half of the 700 million people in the region still do not have regular access to the drugs they need. Over 40% of deaths in Africa are due to infectious diseases for which effective medicines exist, but which are not available to those who are ill.

Drug shortages remain chronic in most African countries due to such factors as inadequate national supply systems and weak implementation of national drug policies. Poor knowledge of the international drug market and the lack of effective national quality assurance systems can lead to excessive prices and low quality products. Appropriate and objective information on drug prices and quality standards is therefore essential for drug procurement agencies.

In order to help countries in the region to address these issues, WHO's Regional Office for Africa, in collaboration with the Action Programme on Essential Drugs, has developed the AFRO Intensified Essential Drugs Programme. The new programme will focus on capacity building, strengthened drug supply systems, including quality assurance, and the rational use of drugs.

One priority activity is the *AFRO Essential Drugs Price Indicator*. This new publication shares information on current drug procurement prices in Africa with the aim of providing purchasing bodies with a better negotiating position. Data in the first edition are based on the latest

regular tender information received from public drug procurement agencies, such as central medical stores, in 16 African countries. The information covers drug designation, package size, unit, price, supplier, currency used and exchange rate in US\$. A comparison of prices from international suppliers, compiled by Management Sciences for Health, is also included to provide a global perspective. □

Copies of the *AFRO Essential Drugs Price Indicator* are available, free of charge, from: Essential Drugs Programme, WHO Regional Office for Africa, P.O. Box BE 773, Belvedere, Harare, Zimbabwe, or from Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

## ESSENTIAL DRUGS MONITOR

The Essential Drugs Monitor encourages the reproduction of articles for non profit uses.

Please clearly credit WHO's *Essential Drugs Monitor* as the source, and send us a copy of the reprinted article to the address given on page 1.

## NEWSDESK

# First national formulary for Australia

**T**HE first edition of the *Australian Medicines Handbook* is the culmination of seven years' planning and hard work. The need for an independent and up-to-date source of drug information to foster rational prescribing in Australia has long been discussed. In February 1991, the Consumer Health Forum and the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists convened a meeting to discuss how drug prescribing in Australia might be improved. Representatives of prescribers and pharmacists, teachers of pharmacology and therapeutics, government and consumer groups attended the meeting. There was unanimous agreement that Australia should develop a national formulary, like the *British National Formulary*, which since 1981 has achieved a reputation as an indispensable and widely used source of independent drug information.

The task of developing a national formulary, to be called the *Australian Medicines Handbook*, was ultimately taken by three organizations: the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, the Pharmaceutical Society of Australia and the Royal Australian College of General Practitioners. These organizations obtained a grant from the Commonwealth Department of Health and Human Services in 1995 to produce a hard copy of the first edition of the *Handbook*. Work began on the content in 1996. Whilst modelled on the concept of the *British National Formulary*, the *Handbook* was to be totally Australian

and its contents were to reflect contemporary Australian clinical practice. To this end, the editors recruited a large number of expert reviewers from all disciplines and all parts of the country.

## SERVING READERS' NEEDS

The philosophy of the *Australian Medicines Handbook* is to use the best available evidence to support prescribing and dispensing recommendations, and thus the publication actively discourages the use of drugs where the evidence for their efficacy is lacking or poor. The purpose of the *Handbook* is two-fold: firstly, to provide a readily accessible, concise, up-to-date source of independent drug information to facilitate effective, rational, safe and economical prescribing and dispensing; secondly, to provide an educational tool for practitioners and students. Readers are likely to use the formulary in different ways. Students might want to read a whole chapter to learn about a drug class, whilst prescribers might want to focus only on specific information, such as the dosage or the common adverse effects of a drug.

The first 20 chapters contain information which provides, in part, a theoretical framework for the reader to use the individual drug monographs. These monographs are organized within chapters, each of which represents an organ system, and the major therapeutic drug classes within the system. Comparative information about different drugs within the same class, or for other drugs for the same indication, is highlighted so that the reader can make an informed



choice about the most appropriate drug to use. Since a book of this size cannot be exhaustive, the writers and members of the editorial advisory panels have included only that material which they consider to be the most relevant and useful for rapid reference by the busy health professional. The *Handbook* should be supplemented, where necessary, by

more comprehensive texts and by the manufacturer's product information. It will complement existing publications, such as the journal, *Australian Prescriber*, and the *Therapeutic Guidelines* series (see EDM-24 Published Lately).

Future editions of the *Australian Medicines Handbook* will be published annually and all relevant material updated. The next edition will be expanded to contain information on fluids, electrolytes and nutritional agents; anti cancer drugs; and emergency drugs; and will provide more expansive information on anaesthetics and psychiatric drugs. An electronic version will be available later in 1998.

The three organizations participating in this project have high expectations of the *Handbook*. Firstly, the independent evidence-based material it contains should enable practitioners to make informed choices for their patients, which will improve outcomes, reduce unwanted drug effects and provide value for money. Secondly, students should be able to use the formulary to acquire a strong grounding in therapeutics as undergraduates and to continue to use it when they become practitioners. Finally, the *Handbook* can become an important vehicle for enhancing the quality use of medicines in Australia to the benefit of all. □

Australian Medicines Handbook Pty Ltd, PO Box 240, Rundle Mall, Adelaide SA 5000 Australia. Tel: + 61 8 82225861, fax + 61 8 82225863, e-mail: gmisan@amh.adelaide.edu.au and homepage: <http://www.amh.net.au> Price: AUS\$125 and AUS\$85 for students.

## UK study says patients not receiving information they need

**P**ATIENTS in the UK are being denied access to reliable information about treatment options, according to a new study<sup>1</sup> from the King's Fund, an independent British health charity. Health professionals either do not know the answers to questions, withhold the information or simply fail to present the whole picture about benefits and risks. Despite endless surveys demonstrating that patients want good, clear information, the study concludes that it is not forthcoming. Yet it is highly likely that good information would save the health service money in the long run, the Fund believes, since it would help patients to look after themselves in terms of prevention and self-treatment.

The study report, *Informing Patients: An Assessment of the Quality of Patient Information Materials*<sup>1</sup>, demonstrates that good quality information can improve the effectiveness of patient care. Without it, patients are unable to make informed

choices about treatments and are in effect excluded from the decision making process.

The report details a study in which 62 patients and 28 clinical experts reviewed a wide range of leaflets, videos and audiotapes in current use. It concludes that the information they contained was often out-of-date and inaccurate, and sometimes seriously misleading. It did not include full details of treatment options, information about outcomes and treatment effectiveness was often omitted or was unreliable, and patients' questions were left unanswered.

## Change necessary

The patients involved in the study felt that many of the leaflets were patronising and failed to recognise their right to be actively involved in decisions about their care. The report recommends that above all, information should start by

answering the questions and concerns raised by patients. The language used should be simple without being patronising. It should be honest about benefits and risks of treatment. So far, the National Health Service Executive has failed to take the initiative on patient information, the report states. *Informing Patients* recommends that they should fund development and evaluation of materials about common clinical conditions. These could be used alongside the clinical guidelines to be commissioned by the National Institute for Clinical Excellence. There should also be a system for accrediting written and computerized materials, the Fund believes.

A patient participating in one of the focus groups for the research, said: "When they measured my cholesterol levels, I tried to find out what the numbers meant, what the safe levels were and the role of triglycerides. I also asked whether the tamoxifen I am taking for breast

cancer would have an effect on my cholesterol and on my heart. "I was completely brushed aside; they ignored the knowledge I had acquired from my own research and I was told not to read too much! They also said no one else had complained about lack of information. I'm still none the wiser about the facts and my own condition."

The King's Fund is urging the Government, the National Health Service Executive and health authorities to support good quality information, to enable patients to participate in decisions about their treatment and to improve the effectiveness of clinical care. □

*Informing Patients: An Assessment of the Quality of Patient Information Materials* is available from the King's Fund Bookshop, 11-13 Cavendish Square, London, W1M 0AN, UK. Tel: + 171 307 2591. Price: £16.95.

## Reference

1. Materials were studied about the following conditions: back pain, cataract, depression, glue ear, high cholesterol, hip replacement, infertility, menorrhagia, prostate and stroke.

## NEWSDESK

## Controlling research data and updating for the Internet: journal editors revise guidelines

**A** group of editors of general medical journals met informally in Vancouver, Canada, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group, which expanded, evolved into the International Committee of Medical Journal Editors, and has gradually broadened its areas of concern.

Opinions differ on how editors of medical journals should handle the question of commercial influences on research that they report. After reflecting at length on this complex issue, the International Committee of Medical Journal Editors (still commonly known as the Vancouver Group) altered its guidelines when it met in Boston, USA, in May 1997.

On the issue of controlling research data, the Vancouver Group agreed that: "Scientists have an ethical obligation to submit credible research results for publication, and should expect to do so. As the persons directly responsible for their work, the authors as individuals should not enter into agreements that interfere with their control over the decision to publish."

On the precise influences that a sponsor might have in a research setting, the Group wrote that: "Editors should require authors to describe the role of these sources, if any, in study design, collection, analysis and interpretation of data, and writing of the report. If the supporting source had no such involvement, the authors should so state. Because the biases potentially introduced by the direct involvement of supporting agencies in research are analogous to methodological biases of other types (e.g. study design, statistical and psychological factors etc.), the type and degree of involvement of the supporting agency should be described in the methods section. Editors should also require disclosure of whether or not the supporting agency controlled or influenced the

decision to submit the final manuscript for publication."

The second issue that the Group tackled was the standards for posting medical and health information on the Internet. The principles that apply to advertising in journals must now be adapted for the Internet. The Vancouver Group tackled this rapidly changing area with the expectation that their statement will need to be revised as web technology develops. The Group agreed that: "Electronic publishing (which includes the Internet) is publishing. Authors, editors and publishers of biomedical journals who post medical and health information on the Internet connected to these publications should follow the policies established by the International Committee of Medical Journal Editors as the *Uniform Requirements for Authors Submitting Articles to Biomedical Journals* and related statements.

The nature of the Internet requires some special considerations within these well established and accepted policies. As a minimum, sites should indicate the names of editors, authors, and contributors and their affiliations, relevant credentials, and relevant conflicts of interest; documentation and attribution of references and sources of all contents; information about copyright; disclosure of site ownership; and disclosure of sponsorship and commercial funding.

Linking from one health or medical Internet site to another may be perceived as recommendation of the quality of the second site. Journals thus should exercise

caution in linking to other sites. If links to other sites are posted as a result of financial considerations, such should be clearly indicated. All dates of content posting and updating should be indicated. In electronic, as in print layout, advertising and promotional messages should not be juxtaposed with editorial content. Any commercial content should be

clearly identified as such."

In practice this guidance means that advertising banners for drugs should not appear on the same screen as editorial content. Also all links from one website to another should be carefully reviewed. □

Source: The Lancet, vol. 349, 17 May 1997.

## IDA celebrates and looks to the future

**T**HE International Dispensary Association (IDA) celebrated its 25th anniversary in November 1997 with a symposium entitled "25 years of Essential Drugs: the Challenge Remains". Over 100 people gathered at the Royal Tropical Institute, Amsterdam, to hear seven speakers representing international governmental organizations, national authorities from recipient countries, researchers and pharmaceutical suppliers. The symposium was chaired by Professor Graham Dukes of Oslo's Institute of Pharmacotherapy.

The opening paper set the current scene, arguing that the money available for drug treatment of populations is insufficient and often not used optimally. Sometimes the wrong drugs are purchased, often they are poorly distributed and very commonly they are used unwisely, the audience was told.

### IDA's emphasis on quality

Quality assurance issues were highlighted in papers from representatives of the International Federation of Pharmaceutical Manufacturers Associations and IDA. The latter explained how IDA has integrated a full quality assurance system in its operations. In this way it has overcome one obstacle to the wider use of generic drugs in countries where resources are limited. Speakers from Sudan and Uganda presented their views on "Acceptance, Acceptability and

Availability of Essential Drugs". They stressed the need to ensure that generic drugs of assured quality were trusted and accepted both by prescribers and patients. They argued that all countries need to develop and maintain a national drug policy to ensure continuing progress in the pharmaceutical sector.

A representative from DAP discussed WHO's role, stressing that it would continue to be complementary to that of bilateral organizations, industry and non profit suppliers in moving from assistance in acute relief situations to the stage of progressive development.

The time reserved for discussions and questions saw a lively interaction between the audience and speakers. Debate ranged over many topics, including the importance of national drug policies and rational drug use; the need to control drug donations; the harmonisation of registration rules; the role of national quality control laboratories; and the need to further develop the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce.

On this memorable occasion IDA had sought to provide a forum for the exchange of facts and ideas – to look at what has been achieved in the area of essential drugs and what remains to be done. Guests left the symposium with a much better understanding of the problems and the opportunities in this critical area. □

## Primary health care systems for the 21st Century – the need for vision and values

**T**AKING stock of the challenges to health that will confront the world in the coming century and assessing their implications for future health systems is a daunting task. Yet this was the remit of the Seventh Consultative Committee on Organization of Health Systems Based on Primary Health Care. The Committee met in Geneva in February 1997, and, in view of the far-reaching implications of its findings for WHO's future agenda, it was decided to issue a short Statement summarising its conclusions. □

Copies of the Statement and the full report of the Seventh Consultative Committee on Organization of Health Systems based on Primary Health Care are available, free of charge, from: World Health Organization, Division of Analysis, Research and Assessment, Health Systems Development Programme, 1211 Geneva 27, Switzerland.



Professor Graham Dukes, opening IDA's symposium

## NEWSDESK

## Increased local production of essential drugs on agenda in Africa

**T**HE first meeting on the local production of essential drugs in the African Region was held in Praia, Cape Verde, from 14 to 18 September 1998. Organized by the WHO Regional Office for Africa, it was attended by 44 participants from 19 countries in the Region. They included directors of pharmaceutical services and national supply agencies, national drug regulatory authorities, local drug manufacturers and specialists in local production, as well as representatives of the United Nations Industrial

Development Organisation, the West African Pharmaceutical Federation and WHO.

In his opening speech, the Prime Minister of Cape Verde insisted on the need to promote the development of a viable local pharmaceutical industry. The industry should be capable of producing good quality drugs at affordable cost, within an appropriate regulatory environment, in order to improve the population's accessibility to essential drugs.

Participants held in depth plenary

and group discussions on five major themes:

- information exchange on the local production of pharmaceuticals;
- mechanisms to improve management and increase local production;
- bulk purchasing mechanisms at national, intercountry and regional levels;
- strategies for improving quality assurance and regulatory mechanisms;
- industrial production of traditional medicines and their use in the health care delivery system.

annual event, in order to evaluate progress made on local production and related issues. He also confirmed WHO's readiness to assist Member States in their pharmaceutical sectors.

Delegates concluded that the meeting had proved a good opportunity to exchange experiences related to local production of essential drugs in the Region. It was also the first step towards the development of the existing potential of the pharmaceutical industry in Africa. For this potential to be realised, participants agreed that there is a need for greater political commitment, development of national drug policies supportive of local production, improved management, and human resources and technology development. □

A report of the meeting is available from: Essential Drugs Programme, WHO Regional Office for Africa, P.O. Box BE 773, Belvedere, Harare, Zimbabwe.

## Brazil's doctors turn on to evidence-based medicine

**T**WENTY thousand Brazilian doctors, approximately 10% of the country's total, regularly watch a primetime television show dedicated to promoting the practice of evidence-based medicine. The Brazilian Cochrane Centre and the Sao Paulo Medical Association created the programme, Medicina Baseada em Evidencias, three years ago. It regularly

attracts an audience of some two million, to watch the presenter, a doctor trained in evidence-based medicine, interview experts on medical topics. The show's message is spreading beyond Brazil's borders, via satellite to viewers in Argentina, Paraguay and Uruguay. □

Source: The Lancet, 8 August 1998.

### Moving forward

After discussions a series of recommendations were made for each of the five areas, to move the initiative forward in a practical and concerted way. The WHO Regional Director for Africa expressed his wish to see the meeting becoming an

## Goodbye AHRTAG, welcome Healthlink Worldwide

**H**EALTHLINK Worldwide is the new name for Appropriate Health Resources and Technologies Action Group (AHRTAG) which has been active in the field of health information since 1977. The new name reflects the organization's focus on health and describes its way of working globally – linking information and health workers, linking partners, linking policy and practice.

Healthlink Worldwide continues AHRTAG's aim of improving the health of poor and vulnerable communities by strengthening the provision, use and impact of information. Working with more than 30 partner organizations in developing countries, Healthlink Worldwide runs programmes to support particular health needs. These include continuing education and training for health workers in Africa and the Middle East, and programmes on AIDS and sexual health, child health and disability.

Healthlink Worldwide's practical training and education materials in printed and electronic forms reach nearly two million health and development workers all over the world. The organization provides technical support to partner organizations and others in setting up and developing resource centres and information services. This work draws on the organization's extensive collection of health learning materials from developing countries. □

For further information contact: Healthlink Worldwide, Farringdon Point, 29–35 Farringdon Road, London EC1M 3JB, UK. Tel: + 44 171 242 0606, fax: +41 171 242 0041, e-mail: info@healthlink.org.uk, website: <http://www.healthlink.org.uk>

## Drugs sold on Internet: WHA acts

**D**ELEGATES at the Fifty-first World Health Assembly (WHA), in May 1998, expressed concern at the advertising, promotion and uncontrolled sale of medical products by electronic communication. There are fears that this rapidly developing phenomenon may present a hazard for public health as well as a risk for the individual patient – particularly with regard to fraudulent product information and lack of individual counselling for consumers. At the 1997 Assembly delegates had already expressed the view that advertising, promotion and sale through the Internet might result in uncontrolled cross border trade of medical products or fraudulent imitations that may be unevaluated, unapproved, unsafe, ineffective, or used inappropriately.

The Fifty-first WHA adopted a plan for tackling these concerns. While the plan leaves it up to individual governments to decide their own course of action it urges them to: review their existing legislation, regulations and guidelines; take regulatory action where appropriate against violation of their national laws; and set up and/or strengthen mechanisms to monitor problems. Delegates also urged governments to collaborate on a range of issues, especially the exchange of information on "difficult cases", and specific national

measures for enforcement.

The Assembly appealed to industry and consumer organizations to "encourage their members to promote the formulation and use of good information practices, where applicable, consistent with the principles embodied in the WHO Ethical Criteria for Medicinal Drug Promotion". Delegates also urged the development of a model guide for governments to "educate people using the Internet on how best to obtain reliable, independent and compatible information on medical products".

### Fears for the future

Consumer groups were critical of the current lack of controls on companies, with HAI issuing a report at the Assembly calling for new international agreements to regulate product promotion and sales on the Internet. The group wants commercial or educational information from commercial sources to have the company name clearly and prominently stated on the screen. HAI argues that all advertisements should have to meet the same regulatory standards for content as advertisements in other media, and direct links to a company's home page should be regulated as if they originated from the company. □

Source: Scrip No. 2336, 1998.

## DRUG INFORMATION

# Getting the message across: communications and pharmacovigilance

BRUCE HUGMAN\*

**T**HE difficulty of balancing benefit and risk in drug therapy, drug scares, patient non adherence to treatment, anxiety and uncertainty about the risks of drugs, and secrecy and suspicion in pharmaceutical matters, were among the pressing concerns which gave rise to an international conference on Effective Communications in Pharmacovigilance, held in Erice, Sicily, in September 1997.

Over 70 professionals from 30 countries, representing patients, doctors, nurses, pharmacists, pharmaceutical companies, lawyers, academics, regulators, journalists and communications experts put their collective brain power to the question of how drug safety information could be better communicated between all interested parties in the ultimate interest of patient welfare.

It was acknowledged that even the best scientists and clinicians may lack the specialised skills of effective modern communications, and that insufficient time and priority had been given to discussion and training in this area. Much more attention needed to be paid not only to the content of communications, but also to their form, production quality and the media chosen for their dissemination.

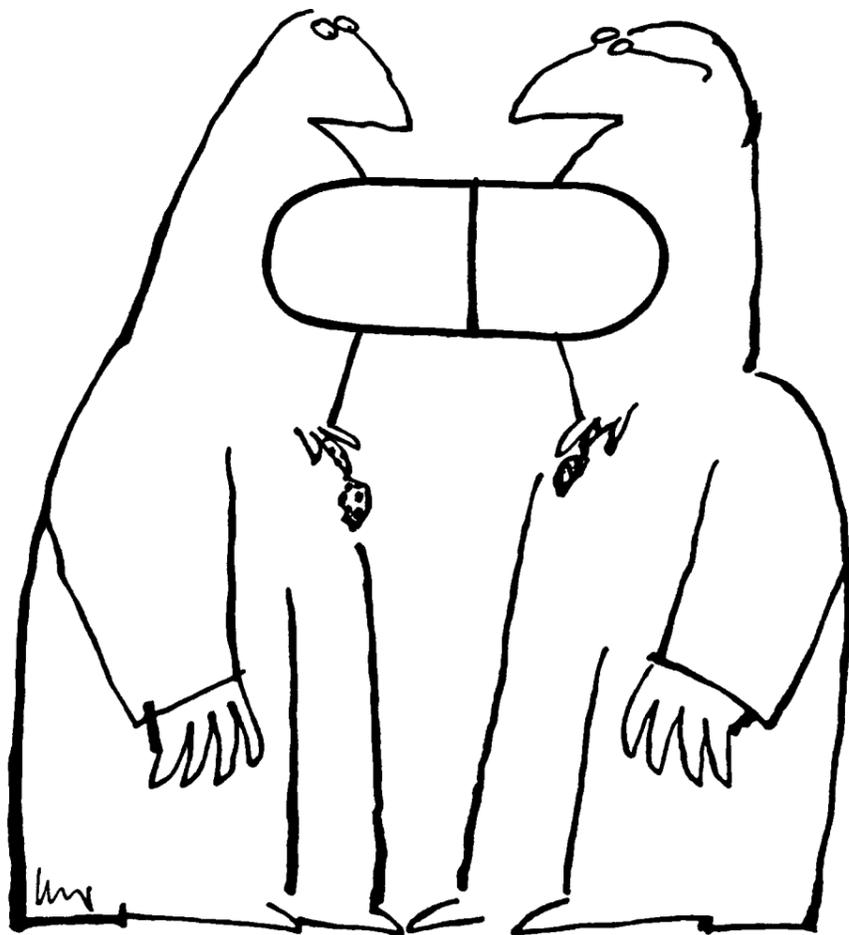
## The danger of secrecy

The climate or context in which communication takes place was also seen as a critical variable: in a climate of secrecy, suspicion and uncertainty would flourish, and leaks of information and media scares would be all the more likely. These, in their turn, would lead to an undermining of public confidence in medicine, in the judgement of doctors, and in the integrity of clinicians and pharmaceutical companies in general.

Participants from developed and developing countries alike agreed that a climate of openness and trust, particularly in relation to the activities of regulators and pharmaceutical companies, was an essential prerequisite to a better understanding of benefit-risk issues and to increasingly rational therapy. Accessibility of information was a core requirement. Practitioners needed to be encouraged to see feedback of information from practice, especially adverse drug reactions, as a major professional responsibility.

## The value of partnership

The concept of *partnership* was seen as the ideal to be pursued in the whole area: partnership especially between clinician and patient (the notion of *informed choice* by patients was seen as a high priority); between professionals and the media (so often at apparent variance with each other); and between professionals in



Quality of care starts with communication

this field with professionals in other areas where significant influence can be exercised (with teachers and schools, for example, where children's attitudes and knowledge are established).

Conflicts between public health priorities and the needs of individual patients were noted among the dilemmas to be faced. This was one of the many aspects, which could be resolved only by

multidisciplinary partnership in which the varying objectives and wishes of all the players were negotiated as between equals. Patients and consumers, especially, need a stronger voice in determining not only the risks acceptable to them individually, but also to society as a whole. For this, more and much better communication was essential.

The conference produced a declaration of principles, the Erice Declaration, which is available on the Internet<sup>1</sup> and from the Uppsala Monitoring Centre (see address below). A full report of the conference proceedings is currently in preparation.

The work of the conference will form the basis of a working group of the Council of International Organizations of Medical Science (CIOMS) which will publish its findings and recommendations in late 1998. The work will be continued in a series of CIOMS meetings, leading to guidelines for good practice in 1998. □

\* Bruce Hugman is Managing Director, EQUUS Communications, London, UK.

For further information contact: The Uppsala Monitoring Centre, Collaborating Centre for International Drug Monitoring, Stora Torget 3, S-753 20 Uppsala, Sweden. Tel: + 46 18 656060, fax: + 46 18 656080, e-mail: who.drugs@who.pharmasoft.se

## Reference

1. www.who.pharmasoft.se

## Improving drug information in Moldova

**I**N the Republic of Moldova the collapse of the Soviet system has brought a flood of medicines on to the market which are virtually unknown to doctors and pharmacists. The sale of medicines by prescription has almost ceased, with doctors' recommendations often ignored as patients are lured by drug store offers. Collaboration between doctors and pharmacists has diminished dramatically. The risk of patients purchasing unsafe medicines is increasing as some drug store staff, driven by the profit motive, advise patients to buy the most expensive rather than the most appropriate drugs.

A modern information system for medicines is seen as a priority to improve the situation, and a prerequisite is to train personnel. Therefore Moldova's Association "DRUGS", a pharmacology information centre, organized a training course entitled "A Model of a Modern Information Network on Rational Drug

Use" from 13-17 April 1998. Thirty-six postgraduate students and residents from the Pharmaceutical Faculty of the State Medical and Pharmaceutical University of Moldova joined other faculty members, and staff from the State Quality Control Laboratory on the course.

The five days passed quickly, with an atmosphere of trust rapidly developing between all involved, as discussions, working groups and business games broke down any initial barriers. Students who had only intended participating in a few sessions found themselves reorganizing their schedules to remain on the course. Among the topics discussed were: the essential drugs concept, national essential drugs lists; guidelines for drug donations; the role of independent drug information centres; systematic approaches to information searches; analysis of major references, (such as *Martindale*, the *US Pharmacopeia Drug Index* and the *British National*

*Formulary*); structures for disseminating information on medicines; the creation of hospital formulary lists and formulary committees; drug information for patients; and the role of advertising in drug promotion. Course training materials were drawn from WHO, HAI, University of Arizona, USA, the US Pharmacopeia, and the US Food and Drug Administration.

The post course questionnaire revealed that the participants' high level of motivation can partly be explained by the fact that for the majority (76%) the information they received was new (31%) or new in many aspects (45%). The course ended with participants presenting their own ideas for a structure to facilitate the flow of drug information. All participants were convinced of the benefit of introducing such a structure at every level of Moldova's health system, but stressed the need for state support to achieve this. □

## DRUG INFORMATION

## United and committed: Asia-Pacific's drug bulletin editors meet

**I**NFORMATION is a vital component in ensuring the efficacy and safety of medicine, and commitment to providing such information is evident in the increased number and quality of drug bulletins in the Asia-Pacific Region. Thirty editors, representing countries extending from Pakistan to New Zealand, attended the first Asia-Pacific Regional Meeting of the International Society of Drug Bulletins (ISDB). Held from 6-7 October 1997 at the Universiti Sains in Penang, Malaysia, the meeting showed that, despite their diversity, bulletins in the region share common issues, opportunities and challenges. These include the need to provide information on safe and effective drug use to consumers. This is especially true in countries where consumers can access prescription medicines with little or no advice from health professionals. The need for bulletins to be reader-friendly was highlighted, as in many countries bulletins were competing for doctors' reading time against the profusion of pharmaceutical company literature.

### Working together

The meeting, which received DAP support, was highly interactive with numerous workshops on offer. Lengthy debate followed the sessions which focused on criteria for producing useful, quality bulletins. The need to marry scientific information with practical implications was discussed, as were readability, author credibility, referencing and peer review. Participants developed an action plan covering issues such as collaboration\*, improving access and use of technology, and establishing an evaluation methodology for bulletins.

The willingness of editors to share, learn and commit to

providing quality drug information in the Asia-Pacific Region was evident throughout the meeting. The challenge is to put into practice the many ideas and concepts that were discussed before the next meeting, which is planned for 1999. □

A report of the meeting is available from: International Society of Drug Bulletins, PO Box 459, 75527 Paris Cedex 11,

France. Tel: + 31 1 47003320, fax: + 31 1 47002864, e-mail: ISDB@compuserve.com

\* Editors at the meeting decided to create an e-mail network to facilitate exchange of information. The network offers the possibility to post short announcements and news of common interest, and initiate discussion on topics of mutual interest. To participate in this exchange contact: dzul@prn.usm.my



The number of drug bulletins in the Asia-Pacific Region is increasing

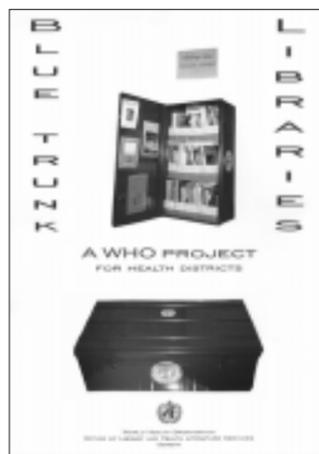
## WHO information on the move: introducing the blue trunk library

**R**EADY-TO-USE "mini-libraries" have been compiled by WHO Library Services, to help to ensure that district health teams in English- and French-speaking African countries receive the medical and health information they need. The selected books are contained in blue metal trunks for their protection and easy transportation. Priority is given to practical manuals edited by WHO. Modules on essential drugs, general medicine and nursing, maternal and child health, diarrhoeal diseases and primary health care are among those available. As well as choosing the books, WHO Library staff index and package them, and have created an electronic database to go with the mini-library.

Providing much needed publications is only one part of the blue trunk library project. Another element concentrates on raising the awareness of health workers about the importance of information, and of strengthening documentation services in ministries of health. The aim is to set up a network capable of sharing medical and health information in Member States.

The price of the mini-library, containing around 100 books and four journals is US\$2,000, including administrative, transport and training costs. □

For further information contact: World Health Organization, Office of Library and Health Literature Services, World Health Organization, 1211 Geneva 27, Switzerland.



## MEETINGS &amp; COURSES

### International Congress on Clinical Pharmacy

To help commemorate the 20th anniversaries of the founding of both the European Society of Clinical Pharmacy and the American College of Clinical Pharmacy, the two organizations are holding an International Congress. Scheduled for 11-14 April 1999 in Orlando, Florida, the main theme of the Congress will be Documenting the Value of Clinical Pharmacy Services.

For further information contact: Theda Mansholtstraat 5b, 2331 JE Leiden, the Netherlands. Tel: + 31 71 572 24 30, fax: + 31 71 572 24 31, e-mail: secretariat@escp.nl

### The Pharmaceutical Society of Australia

With the theme of "Practice Excellence through Technology", the Commonwealth Pharmaceutical Association Conference and the Pharmacy Australia Congress will be held from 11-15 March 1999. The occasion will provide an opportunity to hear a variety of speakers on the application of technology in all areas of pharmacy

practice, and to network with colleagues from around the world.

For further information contact the Secretariat at: ICMS Pty Ltd, 84 Queenbridge Street, Southbank, 3006 Victoria, Australia. Tel: + 61 3 9682 0244, fax: + 61 3 9682 0288, e-mail: cpapac@icms.com.au

### Efficient drug management

The Robert Gordon University's tenth postgraduate certificate course, "Efficient Drug Management and Rational Drug Use", will be held from 17 May to 16 July 1999. Run in collaboration with the Action Programme on Essential Drugs, the course is intended for health care professionals, especially pharmacists, who are involved in the management and control of pharmaceuticals at national, institutional and programme levels. Fees are £3,300, including course books/materials and accommodation.

For further information contact: Marthe Everard, Course Tutor, School of Pharmacy, The Robert Gordon University, Schoolhill, Aberdeen AB10 1FR, Scotland, UK. Tel: + 44 1224 626559, fax: + 44 1224 262555, e-mail: edmrdu@rgu.ac.uk

### Problem-based pharmacotherapy teaching course

This course introduces a logical, step-by-step approach to patient problems: setting therapeutic objectives, selecting appropriate (pharmaco)therapy, and monitoring the response to therapy. It also emphasises the importance of correct prescribing and good patient-doctor communication. Intended for teachers of pharmacology and therapeutics, the course (developed at the University of Groningen in the Netherlands) is now available in a growing number of countries.

The next course based at the University of Cape Town, South Africa, will be held from 29 November to 8 December 1999. For further information contact: Department of Pharmacology, Medical School, University of Cape Town, Observatory 7925, South Africa. Tel: + 27 21 406 6355, fax: + 27 21 448 0886.

### And make a note...

Course dates for the University of Groningen course are 19 to 30 July 1999. For further information contact: Dr Wessel

Sloof, WHO Collaborating Centre for Pharmacotherapy Teaching and Training, Department of Clinical Pharmacology, University of Groningen, A. Deusinglaan 1, 9713 AV Groningen, the Netherlands. Tel: + 31 50 363 2810, fax: + 31 50 363 2812, e-mail: summer.course.pharmaco@med.rug.nl, web site: <http://www.indepth.org/courses>

The problem-based pharmacotherapy teaching course will be held in the Philippines, in 1999. For further information contact: Professor Tony Smith, WHO Collaborating Centre on Pharmacotherapy Teaching and Training, University of Newcastle, University Drive, Callaghan NSW 2308, Australia. Fax: + 61 6 289 8846, e-mail: smith@mail.newcastle.edu.au

La Plata, Argentina, will be the venue for the first South American course (this will be held in Spanish), in either July or November 1999. For further information contact: Professor Hector Buschiazzi, School of Medicine, National University of La Plata, 60 & 120 (1900) La Plata, Argentina. Tel/fax: + 54 21 820117.



## NETSCAN



### Website on WHO health-trade related issues

For information on health care, trade disputes and WHO see: <http://www.cptech.org/ip/health/who/>



### Evidence-based medicine list in Spanish

EVIMED provides a new electronic forum in Spanish for those wanting to discuss new ideas, research, education or practice of evidence-based health care. Primarily dedicated to the Spanish health care community, non Spanish, particularly Latin American, views are also welcome.

To subscribe contact: [RafaBravo@bitmailer.com](mailto:RafaBravo@bitmailer.com)

### WHO's Model List of Essential Drugs available on Internet

The 10th WHO Model List of Essential Drugs is now available on the web site of the WHO Division of Drug Management and Policy: <http://www.who.ch/dmp/edl-10.htm>

The List of Essential Drugs is a model guide to countries and health services in developing their own national and local lists. Such lists should be evidence-based, considering prevalent diseases, treatment facilities, training and experience of health personnel, financial resources, and genetic and demographic factors. Over the last 20 years the WHO Model List of Essential Drugs has been an invaluable tool for saving lives and improving health through more rational use of drugs, wider access to drugs and improved drug quality.

One important advance in the new Model List is the addition of a new drug, tricloabendazole, for the treatment of liver and lung flukes. This illustrates the way the List can be used to highlight a therapeutic need and speed up availability of new drug treatment.



### Two new web sites

The Medical Lobby for Appropriate Marketing (MaLAM) is up and running with its new web site at <http://www.camtech.net.au/malam>

So too is the International Society of Drug Bulletins at <http://prn.usm.my/sites/isdbdrul.html>

### DAP's homepage

The Action Programme on Essential Drugs' homepage on World-Wide-Web introduces users to the essential drugs concept, national drug policies, and the work of WHO and the Action Programme. The information, which is frequently updated, is being made even more user friendly.

The titles of selected WHO, DAP and other pharmaceutical publications are available on the homepage. The complete English, French and Spanish versions of the *Monitor* (from number 22 onwards) can be found in PDF format. In addition, text from other selected DAP publications can be viewed and downloaded. For example, users can print out the *Guidelines for Drug Donations* and *Guide to Good Prescribing*.

You can find DAP's homepage at: <http://www.who.ch/dap>

## LETTERS TO THE EDITOR

### Working for change in Ghana

#### Dear Editor,

By chance I recently came across a copy of your journal, the *Essential Drugs Monitor*, and although it was a 1993 issue it was very educative. Since completing my pharmacy studies in Ukraine and returning to Ghana I have found misuse of drugs (particularly antibiotics and sedatives) on a massive scale. I have come to the conclusion that irrational drug use is mainly due to the lack of effective sources of information for patients, pharmacists and doctors. At my community pharmacy I have tried in my own small way to educate people, but their insults and the potential loss of revenue for my business sometimes overwhelm me.

The *Monitor* gave me the idea of creating an effective, independent drug information service, where information will be given free of charge, or, when necessary, for a token fee. While I work on turning this idea into reality, I would appreciate it if you could continue to send me your journal and also help me to contact organizations that already have a drug information unit. We can then liaise and I can benefit from their experience to create a substantive, effective, independent information unit for my people.

—Justice Dogbey, Pharmacist,  
P.O. Box KB516, Korle-Bu, Accra, Ghana.



### Drug donations in Rwanda

#### Dear Editor,

Drug donations to developing countries have become a key factor of international humanitarian assistance in the field of health. People respond enthusiastically to each emergency appeal made by NGOs, out of a desire to help those most in need. Nevertheless, the well

intentioned but misinformed individuals and institutions that wish to make their modest contribution can hardly imagine the harmful consequences that result from large-scale donations for the recipient countries. Lack of training in the management of essential drugs often means that part of the donations are useless.

In almost two years experience in Zaire and Rwanda, during the refugee crisis of 1994–1996, I witnessed the arrival of tons of drugs that nobody had requested. Many of them are still stored there – either they have expired or the local population does not know how to use them – pending a means of eliminating them without risk either to health or to the environment.

At the time, any form of assistance was welcome, but attempting to make use of the unclassified drugs arriving from Spain took away valuable time from an essential task: distributing drugs to pharmacies and health centres, and advising local workers on their correct use.

For more than three months, four of us, pharmacists responsible for managing drugs provided by Spanish assistance, had to spend on average four hours each day sorting out those that were suited to immediate needs. Those we threw away included drugs that had expired, others that were unsuited to the diseases prevalent in the area, others in amounts which were insufficient to treat a patient, many not included in WHO's Model List of Essential Drugs and many others.

Despite all these drawbacks I must emphasise that many of the drugs were used and helped to treat thousands of patients, thereby saving considerable expenditure. Nevertheless it might have been preferable to load one of the humanitarian assistance aircraft sent from Spain with urgently needed drugs which had been purchased directly from specialist firms. Alternatively the drugs might have been sorted more systematically in Spain before they were sent, so that the work of

the hundreds of volunteers taking part in the campaigns and of the pharmacists working in the field could be truly effective.

Since self sufficiency in drugs for all countries is a long way off, we have to be realistic and work in more than one direction at once. As donations will still be needed in the future, we should direct our efforts towards ensuring that 100% of the donations made are actually of use to the recipient. To this end society must be informed and educated.

Knowledge of the problems, of its causes and possible solutions, the realisation that the situation can be changed and a commitment to put change into practice is the main challenge facing health professionals in general and health cooperation NGOs in particular<sup>1</sup>.

—Natalia Herce,  
Pharmacist and Medicus Mundi's  
Project Manager in Rukoma, Rwanda.

1. For further information on improving drug donations see: *Guidelines for Drug Donations*. Geneva: World Health Organization; 1996. WHO/DAP/96.2.



### Indian survey reveals doctors' misgivings on training in RUD

#### Dear Editor,

Criticism about the lack of input on rational therapeutics in India's undergraduate medical curricula was voiced by a number of participants at a national consultative meeting on the rational use of drugs (RUD) held in Calcutta in 1995. Delegates called for an increased focus on needs-based clinical pharmacology teaching at undergraduate level, and for the gap between students' knowledge about drugs and knowledge of their optimal use to be narrowed.

Concerns expressed at the Calcutta meeting prompted a survey of 2,200

junior doctors in India. This has shown that most received no information on the essential drugs concept during their training. Carried out by the Calcutta-based NGO, Foundation for Health Action, the pilot survey aimed to discover what recently qualified doctors thought about the adequacy of their undergraduate training in rational use of drugs. It also sought their opinion on the feasibility of initiating a compulsory refresher course on rational use towards the end of medical training.

A structured multiple-choice questionnaire was given to the doctors, who worked in various disciplines at seven training institutions in four regions of the country. Analysis of responses showed that most participants wanted standard therapeutic guidelines to be produced for commonly occurring ailments. Almost all were in favour of a compulsory refresher course on rational drug use for interns during the internship period. It is anticipated that such a course would be held for two hours weekly over four weeks, and run collaboratively by staff from departments of pharmacology and clinical medicine. The emphasis would be on causes and consequences of therapeutic failures, assessment of therapeutic outcomes, alternative drug therapy, adverse drug reaction monitoring, drug interactions, and risk-benefit and cost-effectiveness of drug therapy.

The study concludes that there is an undoubted need for reinforcement of knowledge. In particular it demonstrates a need for further inputs on prescribing guidelines in the later stages of the undergraduate curriculum.

—Krishnangshu Ray,  
Assistant Professor of Pharmacology,  
Department of Pharmacology, Calcutta  
National Medical College, 32 Gorachand  
Road, Calcutta-700014, India,  
and Pijush Kant Sarkar,  
Professor of Pharmacology and Director,  
School of Tropical Medicine,  
Calcutta, India.



## PUBLISHED LATELY

**Important**

The Action Programme on Essential Drugs cannot supply the publications reviewed on these pages unless stated otherwise.

Please write to the address given at the end of each item.

**Understanding Rational Therapeutics, M. Hasnain, 1997, 234 p.**

Sub-titled "Therapeutics is something more than prescribing drugs", this publication advises doctors on how to work effectively, rationally and ethically. Looking in depth at some of the major problems they face, it will be of value to doctors in Pakistan and elsewhere who wish to improve their skills. In three sections, the book first provides guidance on the fundamentals of rational therapeutics – how a patient should be approached, and factors involved in making an optimal therapeutic decision. Effective communication skills are a prerequisite for a successful doctor-patient relationship. The author calls them the "backbone of rational prescribing", and looks in detail at the communication process. The following chapters examine the factors to consider when planning therapeutic interventions, how to remain up-to-date about drugs, and best practice in prescription writing.

The book's second section analyses what influences doctors' judgement and decision making. There is a discussion of what the author views as some of the shortcomings of medical education, including: too little attention given to applied aspects of pharmacology and therapeutics; and too little emphasis on teaching problem-solving techniques, critical evaluation of drug information, and preventive aspects of medicine.

During clinical and internship training,

time, equipment and guidance are rarely in short supply. In contrast, once they have qualified, many doctors have to work unsupervised with too many patients and limited facilities. As a result new graduates have to adapt their training to their working situation. The book warns against some irrational methods of patient evaluation and management doctors may learn during the adaptation process. In view of the difficulty in obtaining objective information on drugs it discusses the influence the pharmaceutical industry may have on doctors' choice of treatment. In the complex interaction between doctor, patient and family members all bring their own set of values and cultural beliefs, social and financial pressures, personal likes and dislikes, and family and professional priorities. The publication looks at how these factors can influence a doctor's therapeutic approach and prescribing behaviour.

In conclusion the book highlights the irrational use of some common drugs and provides guidelines on using them optimally. Antibiotics, psychotropics, nonsteroidal anti-inflammatory drugs, antiepileptics and vitamins are among the drug categories covered.

Available from: *The Network, Association for Rational Use of Medication in Pakistan, H No. 60-A, Str. 39, F-10/4, P.O. Box 2563, Islamabad, Pakistan. Price US\$6.*

**Internet, Telematics and Health, M. Sosa-Iudicissa, M. Oliveri, C.A. Gamboa, J. Roberts, (eds.), Pan American Health Organization, 1997, 530 p.**

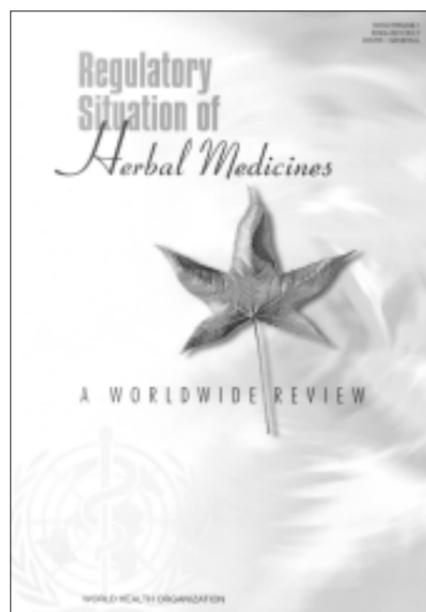
This publication offers academic, political and professional viewpoints on the health related impact of informatics, from first-hand experiences around the world. It gives practical guidance on how to begin using the Internet or to enhance its use in the health care field. The book also presents a range of informatics and telematics information currently available to medicine, and includes a CD-Rom, containing a directory of health-related sites on the World-Wide-Web.

Available from: *PAHO Sales and Distribution Centre, PO Box 27, Annapolis Junction, MD 20701-0027, USA. Price: US\$79.*

**Regulatory Situation of Herbal Medicines. A Worldwide Review, WHO, WHO/TRM/98.1, 1998, 45 p.**

Population growth in the developing world and increasing interest in the industrialised nations have greatly expanded the demand for medicinal plants and the products derived from them. The evaluation of traditional medicinal products, and ensuring their safety and efficacy through regulation and registration present important challenges. This document describes experiences from 52 countries in formulating policies on traditional medicinal products, and in introducing measures for their regulation and registration. Regular updates are planned as contributions become available from more countries.

Available free of charge from: *World Health Organization, Traditional Medicine Programme, 1211 Geneva 27, Switzerland.*

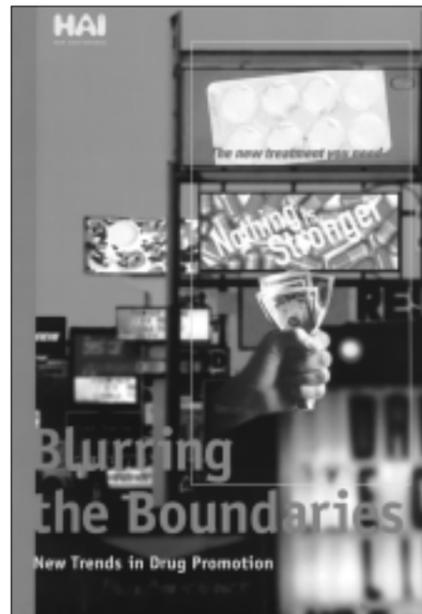
**Blurring the Boundaries: New Trends in Drug Promotion, B. Mintzes, HAI-Europe, 1998, 64 p.**

HAI's latest publication describes new trends in the way medicines are marketed, adding to the long-standing debate on methods used by the pharmaceutical industry to sell its products. A large part of the publication is dedicated to direct-to-consumer drug promotion, with other sections addressing sponsorship of patient groups, Internet

promotion, promotion targeted at prescribers and pharmacists, and industry sponsored research. The author believes that the question is not whether consumers should obtain information about treatment options, but whether drug promotion – which aims to sell a product – can provide the type of information that consumers need. She argues that there is a deliberate and disturbing blurring of the boundaries between drug promotion and objective information. Mintzes believes this is all the more dangerous at a time when shrinking public health budgets have created a new climate of partnership between the public sector and industry, without the necessary examination of what such partnerships might mean.

*Blurring the Boundaries* explores the implications this situation has on consumer health, access to appropriate health services and the information on which treatment decisions are based. It also sets out a series of recommendations on how various players involved in drug regulation can work to control drug promotion effectively, in order to encourage rational use of drugs.

Available from: *HAI-Europe, Jacob van Lennepkade 334T, 1053 NJ Amsterdam, The Netherlands. Price: NLG25 plus postage and handling.*

**Health Conditions in the Caribbean, Pan American Health Organization, 1997, 326 p.**

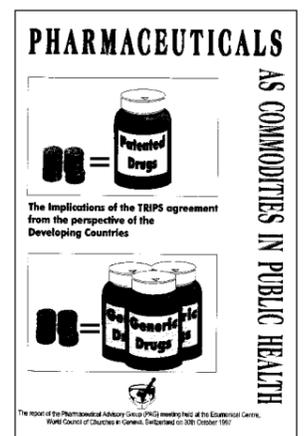
The publication presents an overview of the challenges and conditions faced by health systems in the Caribbean Community (CARICOM) member countries. It highlights the general health status of the Caribbean people, as well as policies and legislation that impact health programmes. The publication then describes those health programme areas which correspond to the major causes of morbidity and mortality in the Caribbean.

Available from: *PAHO Sales and Distribution Centre, PO Box 27, Annapolis Junction, MD 20701-0027, USA. Price: US\$36, US\$26 in Latin America and the Caribbean.*

**Pharmaceuticals as Commodities in Public Health: the Implications of the TRIPS Agreement from the Perspective of Developing Countries, Pharmaceutical Advisory Group, World Council of Churches, 1998, 18 p.**

Why is the TRIPS Agreement important for the pharmaceutical sector? Are patents the right way to stimulate research and development? What are the implications of TRIPS on local drug production? These are some of the questions addressed by speakers at the World Council of Churches, Pharmaceutical Advisory Group meeting held in Geneva in October 1997. The meeting report is now available and provides a useful insight into the complex issue of Trade Related Aspects of Intellectual Property Rights.

Available from: *The Bookshop, CMC World Council of Churches, P.O.Box 2100, 1211 Geneva 2, Switzerland. Price: Sw.fr.3.*

**International Strategies for Tropical Diseases Treatment: Experiences with Praziquantel, WHO, DAP Research Series No. 26, WHO/DAP/CTD/98.5, 1998, 94 p.**

This report identifies national and international policies that have facilitated or hindered the availability of praziquantel, especially in the world's poorest countries in Africa, where schistosomiasis is endemic. Analysis of praziquantel's production and pricing illustrates more general problems in the design of national and international policies for tropical disease products, and suggests strategies for future research and action.

The report raises questions about the international systems that affect the availability of new drugs in poor countries. It looks at how these systems could be improved for each of the four major actors discussed in the report: national governments, the pharmaceutical industry, international agencies and nongovernmental organizations.

Available, free of charge, from: *Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.*

## PUBLISHED LATELY

**Globalization and Access to Drugs, WHO, Health Economics and Drugs, DAP Series No. 7, WHO/DAP/98.9, Nov. 1997, 58 p.**

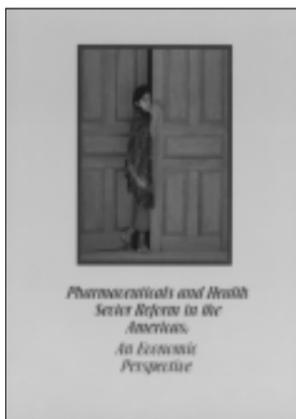
The latest in DAP's series on health economics and drugs informs people in the health sector with no particular legal background about the impact of globalization on access to drugs. In particular it focuses on the World Trade Organization agreement on intellectual property (the TRIPS Agreement) that may have repercussions in the pharmaceutical field. The first part of the document gives an introduction to the international commercial system from the

General Agreement on Tariffs and Trade to the advent of the World Trade Organization. The second part analyses the section on patents of the TRIPS Agreement in relation to access to drugs.

Available, free of charge, in English, French and Spanish from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

**Pharmaceuticals and Health Sector Reform in the Americas: An Economic Perspective, I. Madrid, G. Velasquez, E. Fefer, WHO/PAHO, 1998, 93 p.**

Do health services work proactively or reactively? Why are pharmaceuticals important? What is health sector reform? What is the scope of pharmaceutical reform? What can be done to ensure that reform leads to progress and not simply change? These key questions, addressed by this publication, are particularly important when increasing pressures on health systems and economic changes in many Latin American and Caribbean countries make health sector reform imperative. Directed particularly to decision makers in health and finance, the publication helps them to evaluate and put into operation necessary changes.



The authors argue that the fundamental principle of optimal health sector reform is that access to quality health services is a universal right. Each country must shape health sector reform in accordance with its priorities and social and economic conditions. Pharmaceutical sector reform must be incorporated within health sector reform and should seek to ensure that all individuals have access to essential drugs and to quality health services. The publication focuses on five areas central to reform strategy: the roles of the public and private sectors; drug financing alternatives; pricing policies; generics strategies; and rational use of drugs.

Available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

**European Pharmacopoeia Supplement, 3rd ed., 1998.**

The updated 3rd edition of the *European Pharmacopoeia* provides a single regulatory reference for the quality of medicines in 25 European countries, including those of the European Economic Area. The supplement contains 120 new standards or "monographs" and 130 revised monographs that incorporate the latest scientific advances. These 250 new harmonised European monographs became obligatory in 25 European countries on 1 January 1998, superseding the national standard where one existed on the same subject.

In total the *Pharmacopoeia* contains approximately 1,300 European standards on subjects ranging from synthetic molecules to biologicals to vaccines for human or veterinary use to herbal preparations; 250 general methods of analysis and 800 reagents; and a specific chapter on dosage forms.

The publication is available in English and French. For further information contact: Council of Europe, 226 Avenue de Colmar, BP 907-F67029, Strasbourg, France. Tel: + 33 3 88 41 20 36, fax: +33 3 88 41 27 71.

**District Health Care, 2nd ed., R. Amonoo-Lartson, G.J. Ebrahim, H.J. Level, J.P. Ranken, 1996, 296 p.**

The publication gives practical advice and support to district medical officers and district health teams in planning, organizing, managing and evaluating health services. Since the first edition in 1984 health care costs have escalated, even in richer countries. There is increasing emphasis on preventive and promotive care – the fundamental principles on which primary health care is based, the authors argue. They believe that as countries have oriented their services towards primary health care, the need for planning, managing and evaluating service programmes is greater than ever.

many of the evolving principles of management which have been adapted for application to health care, and which will be of use in restructuring health services. Drawing on their experience in a number of developing countries, the authors have produced a valuable aid for medical, health and nursing personnel involved in the planning, organization and running of district health services.



Available from: Macmillan Education Ltd, Houndmills, Basingstoke, Hampshire RG21 6XS, UK. Price: £10.50.

**Evaluación de la Situación de los Medicamentos en el Perú, Ministerio de Salud, Dirección General de Medicamentos, Insumos y Drogas, 1997, 136 p.**

This overview of the drug situation in Peru is intended for all those working in the public health sector, but principally in drug authorities. The publication aims to help readers to analyse problems in the pharmaceutical field and to facilitate planning and interventions.

The authors state that drugs should be available to all Peruvians, adequately selected in terms of efficiency, safety, cost and need, be of guaranteed quality and be used rationally. They recommend that drug



programmes should be systematically evaluated to determine if the programmes' objectives are being met.

The publication includes information on the National Formulary, the Health Ministry budget, and drug purchasing policies. It also provides statistical information on patient's access to drugs in different areas of the country.

Available from: Ministry of Health, Avda Salaverry, Lima, Peru.

**Antimicrobial and Support Therapy for Bacterial Meningitis in Children. Report of the Meeting of 18–20 June 1997, WHO, WHO/CHD/98.6, 1998, 25 p.**

Bacterial meningitis is an important cause of childhood morbidity and mortality, and a number of differences exist in its management from one region to another. This is a report of a WHO meeting to review current treatment and make recommendations for future practice. Chapters cover four issues concerning the management of bacterial meningitis in children in developing countries:

the choice of antimicrobial therapy and the implications of antimicrobial resistance; the pharmacokinetics and current use of chloramphenicol; the role of dexamethasone; and fluid management in bacterial meningitis.

Available, free of charge from: World Health Organization, Division of Child Health and Development, 1211 Geneva 27, Switzerland.

**Update on new formularies, treatment guidelines, essential drugs lists, drug bulletins and newsletters**

The Action Programme on Essential Drugs has a new publication, *Progress of WHO Member States in developing national drug policies and in revising essential drugs lists, 1998*, (WHO/DAP/98.7). This comprehensive global listing also includes details of which countries have produced national formularies and standard treatment guidelines, and of progress made in providing access to essential drugs. The publication is available, free of charge, from the Action Programme.

Listed below are some recent additions to DAP's global index. (Please note that we are unable to supply copies of the publications themselves. Requests should be made direct to the countries concerned).

- ◆ Chad: *Guide de Diagnostic et de Traitement des affections courantes au Tchad*, 1998. Ministère de la Santé Publique. Intended to increase rational prescribing among doctors and paramedics at the first and second health care levels. The publication covers the main illnesses found in Chad and includes advice on information, education and communication interventions.
- ◆ Gabon: *Liste nationale des Médicaments Essentiels*, 1997. Ministère de la Santé Publique et de la Population. The Essential Drugs List by generic name in 24 therapeutic groups. The List will be updated every two years.
- ◆ Mali: *Formulaire Thérapeutique National*, 1998. Ministère de la Santé, des Personnes Agées et de la Solidarité. The Formulary begins with advice on good prescribing and storage practices, and then presents drug monographs, organized in alphabetical order by generic name for three levels of care.
- ◆ Nepal: *Hospital Formulary*, 1997. Tribhuvan Teaching Hospital, Institute of Medicine. This teaching hospital's formulary includes 371 drugs and 16 non drug items. The drug list is based on the WHO Model List of Essential Drugs.
- ◆ Spain: *Manuel del Medicamento*, 1998. Farmacéuticos sin Fronteras de España. A drug manual which includes donation guidelines and WHO's Model List of Essential Drugs.
- ◆ The Gambia: *The Standard Drug Treatment Guidelines*, 1998. Department of State for Health, Social Welfare and Women's Affairs. Covers diagnosis and treatment of the country's main health problems to achieve more rational and cost-effective use of drugs in hospitals, health centres and dispensaries.
- ◆ Uzbekistan: *National Drug Formulary*, 1998. Ministry of Health. The country's first national formulary, which includes the Essential Drugs List.

**Drug bulletins and newsletters**

- ◆ The WHO Regional Office for Africa's Essential Drugs Programme has produced the first in a series of monthly newsletters. The *AFRO Pharmaceuticals Newsletter* will report on what the Regional Office is doing in the pharmaceutical field in collaboration with Member States, and on developments in the Region's pharmaceutical sector. For further information contact: Dr Moses Chisale, WHO Regional Office for Africa (Attention EDP/AFRO), P.O. Box BE 773, Belvedere, Harare, Zimbabwe.
- ◆ A change of name for *Drugs Today*, the newsletter of the Christian Medical Association of India, which is now called *Rational Drugs*.

## RATIONAL USE

# Pharmacotherapy discussion groups in the Netherlands under the spotlight

GEERT KOCKEN\*

**A** FACT-FINDING study of pharmacotherapy discussion groups in the Netherlands has highlighted a major shift towards establishing standards and guidelines for prescribing, coupled with a growing determination to monitor compliance by general practitioners (GPs).

The study, carried out by the Dutch Institute for Effective Use of Medication, reveals that the number of discussion groups has increased by a third to more than 800 over the past five years, and that up to 95% of the country's GPs and pharmacists are now involved.

The nationwide network of local pharmacotherapy discussion groups was launched by the Institute in early 1992 (see EDM-20). The idea was to promote rational drug use by bringing together GPs and pharmacists to exchange information about pharmacotherapy and develop local guidelines.

Since then a team of 16 advisers (communications consultants) have helped establish regional networks as well as providing support to individual groups of GPs and local pharmacists which meet regularly. The aim is to draw on the expertise available within these two professions in order to improve the prescribing practice of individual GPs.

## Latest findings...

The new survey was initiated in 1997 to update information about the organization and operation of pharmacotherapy discussion groups and to find out whether any changes had occurred since the 1992 study. The number of groups had increased from 629 in 1992 to 827 in 1997, and 83% of these took part in the latest survey.

The study found that an increasing number of both GPs and pharmacists played an active role in organizing group activities (up from 78% in 1992 to 88% in 1997). Most groups meet six times a year and about two-thirds of them are assisted by an adviser recognised by the Dutch Association of General Practitioners.

Contacts with specialists in hospitals – a need highlighted in the earlier study – have become more frequent (41% compared with 27% in 1992). The Institute for Effective Use of Medication is currently trying to improve communication between pharmacotherapy discussion groups and hospitals at the interface between primary and secondary care. The discussion group infrastructure

offers a good opportunity for improving intermediate pharmaceutical care.

The study identified a major shift in the objectives of discussion group consultations since the previous survey. While information exchange and discussion on prescribing practices are still high on the agenda, there is an increasing emphasis on the need to reach agreement on standards, policies and guidelines. The



These folders are used for preparing discussions at the local groups of doctors and pharmacists

survey found that 72% of groups were making efforts to draw up policies and guidelines, while 27% planned to monitor compliance with them (compared with 49% and 9% respectively in 1992).

In preparing activities groups rely heavily on the use of specially developed working materials. Most groups (82%) have, at some time, used the series of preparative booklets issued by the Institute for Effective Use of Medication. Both GPs and pharmacists were very positive about the booklets and the case studies. During 1995–96, the most frequently discussed topics were asthma, hypertension, the use of antibiotics in the treatment of respiratory infections, the use of antimicrobial drugs to treat urinary tract infections and the use of antidepressants (50%–60% of groups).

Although the Institute advises groups not to discuss new medicines until these have been assessed by authoritative publications, such as the *Dutch Pharmacotherapy Compendium* (Farmacotherapeutisch Kompas), the *Dutch Society of General Practice Standards*, and the *Dutch Drug Bulletin* (Geneesmiddelenbulletin), 70% of groups reported having done so. Indeed, many groups have agreed not to prescribe new medicines before consultations within the pharmacotherapy discussion group.

## Prescriptions watchdog...

The survey showed that 68% of groups were using relevant prescription data, due in part to efforts by the Dutch Pharmacological Society, health insurance companies and the Dutch Institute for Effective Use of Medication to ensure the availability and proper use of relevant data. At present, the figures are used mainly to gain an insight into existing prescribing patterns. For just over half the groups these data serve as a tool in policy development, while 44% of groups using the data do so to check adherence to the policies and guidelines agreed within the discussion group.

One of the conclusions of the 1992 survey was that regular monitoring of prescription data was essential in order to bring about effective change in prescribing practices. However, only a minority of groups currently monitor GPs' prescription practices for compliance with agreed group guidelines and policies. More widespread monitoring of data would offer a way of comparing prescribing practices among colleagues, and of verifying compliance with agreed standards, policies and guidelines.

## What GPs and pharmacists think...

Over 80% of GPs and pharmacists rate the pharmacotherapy discussion group process as "useful" or "very useful", while two-thirds of them also said it was efficient. However, 8% of groups are less satisfied, complaining that the results are not specific enough.

The GPs said they had gained a better understanding of the scope of their prescription practices, partly as a result of participation in a group. In addition they report improved relations with other GPs and pharmacists. Meanwhile, the discussion group system has helped define the pharmacist's role as an adviser to the GP. Pharmacists are now paying more attention to supervising medication schemes and giving advice to GPs, due in part to their participation in pharmacotherapy discussion groups. Pharmacists also say they are now more inclined to contact a GP when they have a query. Another improvement, noted by both GPs and pharmacists, is that both parties have a clearer understanding of how tasks should be shared between them.

On ways of improving the discussion group system, almost a third of the groups maintained that consultations need to become more efficient, while over 40% said the agreements reached should become less voluntary – a view expressed more frequently by pharmacists than GPs. Greater use of prescription data would not only help develop and clarify policies but, more importantly, also enable groups to more effectively monitor compliance with agreed policies and guidelines.

## The way ahead...

Regular assessments of the effectiveness of the pharmacotherapy discussion group network remain essential in order to modify goals and develop fresh approaches, methods and content. Other challenges include the development and implementation of regional formularies – exploiting the full potential of computerized data – and an increase in international cooperation. In Eastern Europe, the Dutch Institute for Effective Use of Medication recently responded to a request from WHO to give presentations on rational drug use strategies. Elsewhere, collaboration is already underway, with similar discussion networks in Belgium, Canada, Germany and the UK. In November 1998 the Institute collaborated with the WHO Regional Office for Europe in organizing a consultative meeting to share problems experienced with guideline implementation and to discuss pharmacotherapeutic committees.

Meanwhile, Institute advisers are working on new programmes – generic prescribing, polypharmacy among the elderly, pharmaceutical care and transmutal pharmacotherapy (where people are



A patient information leaflet from the generic prescribing project. It says that you can have the same medicine in a different coat – generic drugs are just as good but cheaper

referred from hospital to have their prescription dispensed in a community pharmacy) – to ensure that all GPs, pharmacists and specialists have expertise in auditing and cost-effective use of medication. In addition, the Institute continues to offer a range of new working materials and support to pharmacotherapy discussion groups to boost their effectiveness. This can involve evaluation exercises, help in solving cooperation problems or in starting up compliance monitoring, or efforts to revitalise the discussion group process whenever it gets bogged down. □

\* Geert Kocken is a health consultant at Stichting Doelmatige Geneesmiddelen Voorziening (DGV) Dutch Institute for Effective Use of Medication, Postbus 3089, 3502 GB Utrecht, the Netherlands. Tel. + 31 24 360 6200, fax: + 31 24 360 6644, e-mail: berkldgv@wxs.nl

## RATIONAL USE

# Essential drugs concept needs better implementation

KRIS WEERASURIYA, PASCALE BRUDON\*

**T**HE concept of essential drugs – first launched over 20 years ago – has been widely adopted today by countries throughout the world. But its implementation is proving a lot more difficult than envisaged.

The idea – providing priority drugs to meet the health care needs of the majority of the population – was simple, socially just, and both technically and economically sound. By having a carefully designed, scientifically sound list of a limited number of drugs, procurement could be made easy, the drug storage problem simplified, prescribers would have safe and effective drugs, and costs could be reduced.

The system entailed no reductions in health services, and health administrators did not have to make difficult choices between the competing needs of different groups or assess the social and health implications of different strategies. The money allocated for pharmaceuticals – 20%–40% of limited health care budgets – could now be spent on less expensive, essential drugs, facilitating wider access to drugs without any increase in costs. Rarely had administrators been offered such a clear, simple solution to so many problems. The essential drugs concept was an idea whose time had come.

But the simplicity was beguiling. Although the concept was well accepted by most countries, its implementation has proved a daunting task. More than two decades after it was conceived, the essential drugs concept has still to make the full impact that was anticipated – demonstrating that technical soundness and economic rationality do not necessarily ensure political viability<sup>1</sup>.

## ESSENTIAL DRUGS CONCEPT UNDER FIRE

At the outset, direct opposition to the essential drugs concept came mainly from the pharmaceutical industry – unconvinced by the argument that lost sales on more expensive drugs would be offset by the enlarged market for essential drugs. However, initial outright rejection of the concept was followed by grudging acceptance that it might be appropriate for poorer countries that cannot afford to have an unrestricted amount of pharmaceuticals available on the market. And with the increasing popularity of the essential drugs list, many manufacturers have seen its potential and sought to have their drugs included in the list.

Many doctors were also opposed at first – viewing the list as an unnecessary restriction on their freedom to prescribe. Concern was voiced mainly

by doctors working in the private sector, who had a larger range of drugs to choose from than those employed in the public sector. However, this opposition has lessened, over time.

Another frequent criticism is that the essential drugs list is a “second class” list, determined on the basis of financial stringency rather than the effectiveness of the drugs. However, the belief that countries will abandon the list, once the economic situation improves, and switch to better drugs is based on a misconception. The list does not include less effective drugs simply because they are cheaper. The aim is to include more cost-effective drugs that can be used by the majority of the population. For example, among the H<sub>2</sub> receptor blockers, ranitidine has an advantage over the much less expensive drug cimetidine, in that it can be used by the elderly and has fewer interactions with other drugs. However, cimetidine was chosen for the model list not only because it was cheaper but because it has similar efficacy to ranitidine, and because the majority of patients using it would be neither elderly nor

receiving drugs which could interact with cimetidine. While a particular health technology may be superior in a few situations, another cheaper one may be equally effective in the majority of situations – making it more cost-effective.

The essential drugs list is also criticised for failing to include a drug for a particular disease. However, the list was never meant to cover all diseases. The aim was to ensure the availability of drugs to treat the majority of diseases that occurred in a specific country. The exclusion of a drug from the list does not prevent it from being purchased if needed. The fact that the essential drugs concept accommodates this should be seen as its strength.

## IMPACT IN DEVELOPING COUNTRIES

Over 120 developing countries have now adopted the essential drugs concept and developed a national essential drugs list based on the WHO Model List<sup>2</sup>. The exclusive use of generic drugs in the list has contributed to increasing awareness of generic names. While some countries have closely followed the criteria for selection of drugs, others have lists that include over 350 products (Pakistan) or two or more similar drugs rather than the recommended single drug (Tanzania)

from each therapeutic category. Some of these deviations may be due to attempts by doctors to get a particular drug included in the national essential drugs list – thereby enabling hospitals to buy the drug and ensuring its inclusion in reimbursement schemes.

As countries have increasingly recognised the need for a national drug policy, the national list has provided the cornerstone for this policy development. Meanwhile, the knowledge that a limited list of drugs can meet the majority of health care needs has also created an awareness that “more is not necessarily better” and that “newer is not necessarily better”. The list has also enabled health administrators to assess whether appropriate drugs are being supplied.

Although the essential drugs concept has consistently focused on the importance not only of the selection but also the proper use of the drugs, progress in encouraging the rational use of drugs has been slow. Even where essential drugs are available, their full potential is not being realised. This is mainly due to the failure to provide unbiased drug information for prescribers. Whereas suppliers of other forms of goods routinely spend a proportion of sales revenue on evaluating how the goods are used, very few developing countries have access to independent drug information – let alone the capacity to spend a proportion of their drugs budget

on providing information on the rational use of drugs. It is estimated that both developing and developed countries currently spend less than 1% of their drugs budget on rational drug use. However, the essential drugs concept has been influential in preventing the import of ineffective drugs.

In some developing countries, the implementation of the essential drugs concept has been hampered by efforts to industrialise. Many governments hoped that a vigorous and profitable pharmaceutical industry, producing drugs that were mainly outside the essential drugs list, would contribute to a general increase in both living standards and improved health. As a result, essential drugs were ignored and sometimes difficult to obtain, while more expensive, non essential drugs were freely available. Now, after finding that the impact on living standards is less than anticipated, some countries are rethinking their policy and are likely to place greater emphasis in future on essential drugs. This development should help increase the



**More expensive doesn't necessarily mean better**

accessibility and affordability of essential drugs.

Although the essential drugs concept was designed to meet the health care needs of the majority of the population, the private sector has tended to drag its feet in implementing the concept. This is largely due to fears that the resulting changes in the pharmaceutical sector might have an adverse effect on multinational corporations, the urban elite, and, to a lesser extent, physicians. In order to succeed, the concept should have broadly-based support which reaches to the highest political levels. However, with the exception of the Philippines and Sri Lanka, this has rarely occurred<sup>3</sup>.

The lack of acceptance of the essential drugs concept within the private sector is also due to the fragmented nature of health care in this sector in developing countries. Patients pay for their drugs "out of pocket" and are individual buyers who purchase what the doctor prescribes. However, large health care providers such as insurance schemes, which are common in the developed world, can persuade prescribers to use a restricted list of drugs known to be effective. When such schemes are established in the developing world the same trend towards using known effective drugs would develop.

### A RESPONSE TO RISING PRICES

Acceptance of the essential drugs concept and the essential drugs list faced different hurdles in developed countries, due to the different socioeconomic and industrial circumstances. In the developed countries, governments saw the pharmaceutical industry as a vibrant one, providing useful products as well as contributing to the economy through the employment of skilled labour, the production of substantial export earnings, and a contribution to scientific and industrial research. Money was usually available to buy more expensive pharmaceutical products and it was believed that restricting access to these products would be counterproductive in the long run. Unlike the developing countries, health care providers in developed countries (either the state or state-sponsored social insurance schemes) had immense buying power and could negotiate a reduction in prices. However, these products are becoming increasingly expensive and are often beyond the reach of cash-strapped health service providers. As a result, both governments and health service providers in the private sector have now adopted the essential drugs concept – albeit by another name.

Most countries have adopted a two-step procedure for introducing a new product into the health system. In Australia a new drug is scientifically

evaluated for quality, safety and efficacy<sup>4</sup>. Once registered, a drug is then assessed for possible inclusion in the reimbursement scheme. Approval at this stage depends on evidence of cost-effectiveness. This two-stage process has resulted in the registration of drugs, such as finasteride, that are expensive but



*Essential drugs are not a poor man's medicine, and the essential drugs concept is as important today as it was 20 years ago*

minimally effective – without their approval for reimbursement.

Elsewhere, in the UK, where 17 benzodiazepines are available, the National Health Service supplies only five of these, each a generic drug. Although the other 12 benzodiazepines are equally effective, they are more expensive and not reimbursable. Although this is not a strict interpretation of the essential drugs concept (which allows only one drug from a therapeutic class) a focus exclusively on drugs that are known to be safe, effective, and cost-effective is in keeping with the spirit of the concept. However, both countries promote the export of these drugs – a clear example of industrial priorities overtaking health ones outside the country's own borders.

### INTERNATIONAL ORGANIZATIONS PROMOTE THE CONCEPT

Although, initially, a number of international organizations failed to appreciate the relevance or importance of the essential drugs concept, today most accept and promote it as a good tool for organizing the pharmaceutical sector and improving health care. The World Bank, which plays an increasing role in the health sector in the developing world, has based most of its activities in pharmaceuticals on the concept and national drug lists – mainly to facilitate managerial efficiency<sup>5,6</sup>.

UNICEF's activities involving pharmaceuticals have been guided by the essential drugs concept in order to ensure equity, and donor countries/institutions have focused on national lists when supplying drugs. Meanwhile, the guidelines for drug donations developed by WHO and other agencies have also stressed the importance of donating only drugs that are included in national lists<sup>7</sup>.

The Model List is revised regularly by WHO with the latest revision in 1997. The number of items included has risen from 208 in 1977 to 306 today – as new products are added and older, less effective products removed. Programmes covering malaria and cancer control have helped refine the selection of drugs included in the List. Meanwhile, the participation of the pharmaceutical industry associations provide an opportunity for them to discuss the List as well as propose products for inclusion. On several occasions, inclusion of a drug in the Model List has encouraged pharmaceutical companies to either continue manufacturing the drug or to start manufacturing it.

### BETTER IMPLEMENTATION NEEDED

The essential drugs concept is today a key issue on the international health agenda. Together with the concept of primary health care, it is one of the major achievements of WHO over the last two decades, and its most durable pharmaceutical initiative. Other initiatives, such as promoting the local production of pharmaceuticals, have achieved neither the sustainability nor the prominence of the essential drugs concept.

Yet, while the concept's scientific validity remains unchallenged, it has still to be implemented to its full potential. One of the problems is that it is a public health concept and not a curative intervention. When drugs are made available

in this way it is taken for granted and not seen as a major advance. Because of this, it is a difficult concept to promote.

Another problem is the wide range of objectives involved: equity in the provision of basic health care needs, efficient use of available resources, and responsiveness to societies rather than to market forces. While this elicits widespread support, the involvement of numerous players with different strengths and objectives can hamper the concept's implementation.

In developed countries, the weak implementation of the essential drugs concept has been driven by fears that the international pharmaceutical industry would suffer – a prospect that generated strong opposition from powerful groups and governments. Meanwhile, in some countries, implementation strategies have not been carefully thought through. Effective implementation of the concept requires careful planning, backed up by strong political commitment at country level, together with a clearer understanding of the role of the different players involved. Better implementation of the essential drugs concept could make all the difference between success and failure. □

\* Kris Weerasuriya is Professor, Department of Pharmacology, Faculty of Medicine, University of Colombo, Sri Lanka, and Pascale Brudon is Chief, Development of Programme Evaluation, WHO and was formerly a Scientist in the Action Programme on Essential Drugs.

### References

1. WHO/DAP. Comparative analysis of national drug policies. Second workshop, June 1996. Geneva: World Health Organization; 1997. DAP Research Series No.25. WHO/DAP/97.6.
2. WHO/DAP. WHO essential drugs strategy: objectives, priorities for action, approaches. Geneva: World Health Organization; 1997. DAP/MAC(9)/97.4.
3. Reich MR. The politics of health sector reform in developing countries: three cases of pharmaceutical policy. Health Policy. 1995; 32:47–77.
4. Murray M. Australian National Drug Policies: facilitating or fragmenting health? Dev. Dialogue. 1995;1:148–192.
5. World Bank. World development report 1993: Investing in Health. New York: Oxford University Press; 1993.
6. World Bank. Better health in Africa. Experience and lessons learned. (Report No.12577-AFR). Washington DC: The World Bank; 1994.
7. WHO/DAP. Guidelines for drug donations. Geneva: World Health Organization; 1996. WHO/DAP/96.2.

## New Belgian committee promotes rational prescribing

**T**HE Belgian Minister for Public Health, Dr Marcel Colla, has set up a scientific committee aimed at encouraging rational and cost-effective prescribing. The committee, which will implement a project for "independent information on medicines" will be made up of representatives from the Belgian pharmaceutical information centre, the transparency commission, the Health Ministry, the pharmaceuticals inspectorate and general practitioners' associations, *Le Journal du Médecin* reports. Other health professionals, such as specialists and pharmacists, may also be asked to participate. A number of product categories have already been put forward for examination, including anti-ulcers, antidepressants and antibiotics for upper respiratory tract infections. □

Source: Scrip, No. 2312, 25 February 1998.

## RATIONAL USE

# MSF Research Group on Essential Drugs: fighting for the underprivileged

JACQUES PINEL\*

**L**IKE other medical aid organizations, Médecins sans Frontières (MSF) is facing new problems as international pharmaceutical trade is reorganized to the detriment of the world's poor. In a new initiative MSF has set up a "Research Group on Essential Drugs", which will benefit from the knowledge and experience of MSF's medical teams in 50 countries. The teams not only work with national decision makers and prescribers but are in contact with a wide range of people, and can provide valuable insight into the current problems. In seeking solutions the Group will also use MSF's influence in industrialised countries. In collaboration with other specialists, members will initiate activities to defend the health of people who are underprivileged in terms of their access to drugs.

## Vital drugs may disappear

The therapeutic options available for treating tropical diseases have generally

existed for a long time, and people often wait in vain for new drugs. Pharmaceutical research and development have frequently been abandoned because there would be no return on the required investment. The same market economy logic has resulted in drugs that are obsolete in developed countries no longer being made – even when the drugs are still useful in developing countries (where price affects both access and adherence to treatment).

**Action:** The Research Group on Essential Drugs will make a detailed analysis of the problems arising from non availability of essentials drugs in developing countries. Disease by disease and drug by drug, the objective will be to find solutions involving "orphan" tropical drugs.

## Need to guarantee quality

In developing or recently industrialised countries, the technology and the legal framework needed to guarantee drug quality are often missing. Local supplies can therefore include good quality

drugs and unacceptable or even dangerous drugs, with adverse consequences both on occupational health (ineffective treatment) and public health (development of resistance).

**Action:** In collaboration with organizations involved in supplying quality essential drugs, the MSF Research Group will set up a network for drug quality monitoring that will identify countries, manufacturers and distributors with good control procedures. The network will also draw attention to dubious or definitely dangerous production lines or any illegal distribution circuits that are discovered.

## Making all essential drugs affordable

Cost and the lack of coverage for the poor restrict access to treatment in developing countries. Overall, the price of essential drugs, which is usually presented as the primary cause of their inaccessibility, has come down, thanks to the development of generic essential drugs policies, initiated mainly by WHO and UNICEF. But it is important to remember that not all essential drugs are old: recent drugs, which are therefore protected by patent, remain beyond the reach of developing countries.

**Action:** By making contact with the manufacturers and international organizations concerned, ad hoc agreements can be made to take account of both the commercial constraints of pharmaceutical companies and the resources of poor populations. However, more lasting solutions must be sought to match the prices of vital modern drugs with the resources of poor countries. The current debate on AIDS treatment illustrates the urgency of the problem. With other organizations working on the same question, the Research Group on Essential Drugs will help to promote the idea of international solidarity in access to drugs.

## Promoting rational use

Achieving the rational use of essential drugs remains a constant struggle: it becomes imperative in times of shortage. There is still much work to do in promoting the essential drugs concept, in view of the number of useless or dangerous drugs that are still used in most countries. At the same time, a considerable proportion of available essential drugs is badly managed. In terms of information, independent medical journals and guides can provide prescribers and other health professionals with reliable advice, but in most countries, most pharmacotherapeutic information is distributed by drug companies. Dubious promotional activities and misleading advertising are



Reaching out to the people: an MSF worker in Palala, Liberia, during a vaccination campaign

Photo: Médecins sans Frontières

## Pakistan's largest Province focuses on drug sector reform

**T**HE Chief Minister of the Punjab, Pakistan's largest Province, has initiated a major campaign to reform the pharmaceutical sector. Disturbed by increasing news of spurious/substandard drugs and aware of the non implementation of the 1988 Drug Rules, the Chief Minister, Muhammad Shahbaz Sharif, has set up a Task Force to try to find a long-term solution to the problems. As a start he has suspended all of the Province's drug inspectors and put a moratorium on issuing any new licences for setting up retail pharmacy outlets.

## No compromise on quality

The Government is publicising its campaign in front-page articles in all the main local and English language newspapers, which invite suggestions from the public on how to improve the situation in the pharmaceutical sector. The campaign received a major boost with a special report on a range of drug quality and rational use issues which appeared in a Sunday newspaper<sup>1</sup>.

Although the issue of spurious/substandard medicines is central, in the Task Force's first meeting the authorities made it clear that they are very serious about changing the whole system. Three sub-committees were formed: one

to review the Drug Act of 1976 and the 1988 Drug Rules, the second to screen the Province's medical stores in the light of existing licensing policy and to take steps against those violating the law; and the third to suggest measures, including further legislation, against unqualified people practising medicine. □

## Reference

1. The News on Sunday, 9 August 1998, p.28–29.

A clear message from the Punjab Government, which appeared in several popular newspapers

## RATIONAL USE

# Making injections safe

**I**NFORMATION reaching WHO and UNICEF consistently highlights the widespread occurrence of unsterile injection practices, and points to insufficient supplies of syringes and needles as a major cause. Unsafe injections can result in the transmission of bloodborne pathogens from patient-to-patient, patient-to-health worker and, more rarely, health worker-to-patient. The community at large is also at risk when injection equipment is used and then not safely disposed of. In many instances, used equipment is reused, sold or recycled because of its commercial value.

During 1996, in the developing world, routine immunization of children under one year and immunization of women of childbearing age with tetanus toxoid (TT) accounted for nearly 800 million injections. In addition to routine immunization, emergency disease-outbreak control operations delivered more than 240 million injections in the same year.

As part of the drive to eliminate neonatal tetanus as a public health problem, 74 million women are being targeted in high risk areas of developing countries. By 1999 this will generate an estimated 220 million injections in special immunization activities.

By the turn of the century, hepatitis B vaccine should be in use worldwide, and new vaccines should be in the process of being introduced into immunization programmes. Acceleration of special activities aiming at better measles control will be in progress, with elective mass immunization potentially targeting about 3.1 billion children under 15 years of age by 2005.

These increases in immunization services, including elimination and

initiatives which aim to improve the safety of injections; these include the introduction of steam sterilisers, development of auto-destruct syringes, and development of training materials and courses.

As part of an overall strategy to further improve the safety of immunization injections and emphasise the need for "one sterile syringe and one sterile needle for each injection", it is essential to prevent the reuse (within or outside the health sector), of large numbers of the syringes introduced into countries for mass campaigns.

WHO and UNICEF have agreed to implement a strategy to assure that special attention is paid to the safe administration of vaccines during mass immunization campaigns. They have issued the following policy statement which defines their position.

## WHO-UNICEF policy statement for mass immunization campaigns

"The reuse of standard single-use disposable syringes and needles places the general public at high risk of disease and death.

The auto-destruct syringe<sup>1</sup> presents the lowest risk of person-to-person transmission of bloodborne pathogens because it cannot be reused. The auto-destruct syringe is (a) the preferred type of disposable equipment for administering vaccines; and (b) the equipment of choice for conducting mass immunization campaigns.

"Safety boxes"<sup>2</sup>, puncture-resistant containers for collecting and disposing of used disposable and auto-destruct syringes, needles and other injection materials reduce the risk posed to health staff and the general public by contaminated needles and syringes.

For all elective and emergency mass campaigns, vaccines must, as a rule, be systematically supplied together with auto-destruct

syringes and safety boxes as a "bundle" (see below).

All donors supporting immunization campaigns are requested to finance not only the vaccines but *the safe*

*administration of the vaccines* by planning and implementing the "bundling" strategy as well as supporting training and supervision of the process during the campaigns.

**WHO and UNICEF recommend that auto-destruct syringes and safety boxes are used in all elective and emergency mass immunization campaigns. Donors are requested to "bundle" the supplies: vaccine, auto-destruct syringes and safety boxes.**

### What is "bundling"?

The term "bundling" has been chosen to define the concept of a theoretical "bundle" which must comprise each of the following items:

- ◆ Good quality vaccines
- ◆ Auto-destruct syringes
- ◆ Safety boxes.

The implication is that none of the component items can be considered alone; each component must be considered as part of a "bundle" which contains the other two. "Bundling" has no physical connotation and does not imply that items must be "packaged" together.

### Costs

Indicative costs for the safe administration of vaccines most commonly used in immunization campaigns are listed below. Each estimate includes the cost of one dose of vaccine (in 20 or 50 dose vials), one auto-destruct syringe (about 10US cents), and a fraction of the cost of the safety box (less than US\$1.00 for 100 syringes)." □

For copies of the policy statement (ref. WHO/EPI/LHIS/97.04) and further information contact: World Health Organization, Global Programme for Vaccines and Immunization, 20 Avenue Appia, 1211 Geneva 27, Switzerland. Tel: + 41 22 791 4373, fax: + 41 22 791 4193, e-mail: gpv@who.ch

1. Designed to give a single standard dose of vaccine after which the syringe blocks permanently, preventing further use of contaminated syringes. The needles are either fixed or standard, but non-detachable, to prevent reuse (WHO/EPI Standard Performance Specification E8/DS1).
2. Designed to collect and transport syringes and needles (without caps) safely, to minimise the risk of accidental needle-stick. The safety boxes are supplied flat-packed for simple, one-step local assembly and should be incinerated with the load of contaminated syringes and needles (WHO Standard Performance Specification E10/IC.1 or E10/IC.2).

Vaccine	Cost of a safe administration (US\$)
TT	0.16
Measles	0.26
DTP	0.19
Td or DT	0.18
Yellow fever <sup>1</sup>	0.27-0.31
Meningitis <sup>1</sup>	0.31-0.41
Hepatitis B <sup>2</sup>	0.65- 0.85

1. Price range calculated from lowest and highest bids to UNICEF.

2. The WHO/Expanded Programme on Immunization does not recommend campaigns with hepatitis B, but some countries may decide to do catch-up campaigns for a target-age group after the introduction of the vaccine in the routine immunization programme.



Immunization for a young Bolivian in the competent hands of a community health worker

eradication campaigns, offer an opportunity for improvement and make it imperative that injections are made safe for people. Over the past years, WHO and UNICEF have launched a number of

## CDMU's new leadership training on rational use of drugs

**T**HE first in a series of leadership training courses on rational use of drugs attracted doctors and senior health workers to the Udayani Jesuit Institute, Calcutta, in February 1998. The course was organized by the Community Development Medicinal Unit, Calcutta, a non profit voluntary organization which maintains a drug distribution network for NGOs in India's eastern region.

While many CDMU courses provide information on essential drugs and rational therapeutics, on this occasion the aim was specifically to train leaders who could disseminate this information, and assume a major role in putting theory into practice. The five main modules generated lively debate and covered: the essential drugs concept and its implications; drug formularies; treatment guidelines for common diseases; drug control, drug policy (including patents) and drug promotion in India; and inventory management. □

## RATIONAL USE

# Stepping beyond with Community-Directed Treatment

**R**ADICAL", "a kind of mini-revolution"; Professor Oladele Kale\* is excited by the prospects for Community-Directed Treatment (ComDT). "It's not so much a brand new approach to primary health care, but more a logical extension of the concept. It is primary health care at a more basic and practical level – not only is it health of the people, and for the people, but it is also by the people."

Dissatisfaction with the old primary health care system, with its inefficiencies and diversions, led a group of scientists and researchers in Bamako, Mali, in June 1994 to the idea of Community-Directed Treatment, which goes a step beyond most community involvement. It goes beyond merely asking the community about its wants and needs, beyond mere partnership between the client and the care provider, to ownership by, and empowerment of, the community. Not only is the community consulted about its wants and needs, as in community-based treatment, but afterwards the community designs and implements the delivery of treatment too (whereas in community-based treatment the control programme designs and implements the delivery of treatment; in other words, the control programme tells the community what to do). In 1994 it was not known whether the concept was at all practical; there was only a lack of satisfaction with community-based treatment as it was then practised and some anecdotal evidence (from Mali in particular) that Community-Directed Treatment might be better. Many people felt that communities would not be able to handle the responsibility for drug distribution; and even the communities were sceptical.

## Ivermectin study shows the benefits

The mass distribution of ivermectin to populations at risk from onchocerciasis was used to test the concept of Community-Directed Treatment in a study which was completed in 1996<sup>1</sup>. Although ivermectin had been donated to the countries, the primary health care systems were not efficient at delivering it in the right quantities to the right people. Therefore a multicountry study was conceived in which ivermectin-delivery systems designed and implemented by communities themselves were compared with those designed and implemented by control programmes. The study involved eight sites in five African countries, which

together covered a total population of some 1.5–2 million. Study findings showed that, in all respects (effectiveness, acceptance, coverage), community-designed systems were better than programme-designed systems. Community-directed distributors adhered well to treatment procedures, and were able to differentiate between those who should and should not receive the drug; they gave the correct dose, to within half a tablet, in over 90% of cases; and they were able to identify severe adverse reactions and refer such cases to the nearest health facility. The study was successful to the extent that Community-Directed Treatment has now



Community-Directed Treatment with ivermectin, near Kita in Mali. The house-to-house distributor fills in the paperwork, while his colleague holds the measuring stick used to determine dosage by height

been adopted by the African Programme on Onchocerciasis Control and 19 countries are committed to making it work.

## The value of "ownership"

What are the reasons for the success of Community-Directed Treatment? Primarily, success rests in the philosophy of ownership and empowerment. During the study, and as the communities became more confident, the part played by "ownership" became quite clear. Giving communities the freedom to design their own system, to select the distributors they want, and to change the system when necessary, means flexibility. Programme-designed systems, in contrast, are relatively inflexible.

Benefits that can be expected from Community-Directed Treatment include less diversion of drugs (the possibilities for diversion are less when the people are in charge themselves); better indicators for sustainability (less dependence on health care from outside); and least distraction of village life (having a distributor in the village means that drugs can be distributed at night, when it is convenient to the villagers, and not in the daytime, when it is convenient to the health workers).

The main difficulties encountered during the study were poor reporting (a problem which was actually more apparent in programme-designed systems) and failure in supply (which depends on support from the health system). Less of a problem was the resistance of some health workers, who felt apprehensive about Community-Directed Treatment – that they were being displaced and their status threatened.

## Assessing information needs

What remains to be done, therefore, is to fine-tune Community-Directed Treatment, in particular to define more clearly how it fits into the orthodox health service. The main points of contact between the two occur when dealing with cases of adverse reaction and with ivermectin supply to communities. Consequently, one of the next steps will be to look at what information is needed – by both control programmes and communities. The communities will not only be asked what information they want, but also how they are going to go about getting it – thus taking the concept of Community-Directed Treatment

a step further (usually the health service tells the community what information it wants and then gets it). Other points of contact between the health service and Community-Directed Treatment include supervision and training. In the multicountry study, some basic supervision by local health service staff was associated with better performance in terms of treatment coverage than no supervision at all. And the "open" training (when the community could look on) not only reinforced acceptance by the community but also resulted in indirect monitoring of the trainees' performance by the communities themselves. Involving health workers at the interface right from the start, in meetings with the community, in the training of distributors and in supervision, helped overcome resistance.

Another issue to be addressed concerns cost sharing and cost recovery. In the multicountry study, ivermectin was mostly provided free of charge. But in Cameroon, where a programme of cost recovery was in place, coverage was less. We need to know, therefore, how paying for a drug affects performance, since drugs are not always free of charge and Community-Directed Treatment is applicable only in mass treatment programmes.

Here lots of people without signs and symptoms of the disease, who may not perceive the need for treatment, have to be reached.

## The next phase

These are some of the issues that will be looked at in the next multicountry study planned for 10 onchocerciasis sites in Africa. The challenge now is to see if Community-Directed Treatment works in "real life", as opposed to the experimental conditions of the multicountry study. The challenge is to persuade governments and control programmes to accept the philosophy – to accept that people can be empowered and that they have the intelligence, willingness and ability to look after themselves.

But can the concept of Community-Directed Treatment be extended any further? It is only suitable for mass treatment, where a single drug is to be given in a single distribution (no more than twice per year). It must be easy to determine who should and who should not receive treatment. And, preferably, there should be no need for laboratory diagnosis. Some obvious candidates, therefore, might be lymphatic filariasis, schistosomiasis and intestinal parasites. A study of Community-Directed Treatment in lymphatic filariasis is already planned for eight sites in Africa and Asia. With time, communities may be able to take on responsibilities of a different nature, such as disease surveillance. The guineaworm programme has shown that villagers can be used as village-based health workers for control programmes and this approach has not been fully exploited. And what about the Expanded Programme on Immunization? The health care system must be persuaded to think of programmes other than drugs that could benefit from the Community-Directed Treatment approach.

All in all, Community-Directed Treatment could be a technically important means of health delivery. At the very least, it promises to be the most cost-effective and sustainable variant of community-based mass delivery/distribution systems for chemotherapy-based disease control programmes. □

\* Professor Oladele Kale is Professor of Preventive and Social Medicine, University of Ibadan, College of Medicine, Department of Preventive and Social Medicine, PMB 5116, Ibadan, Oyo State, Nigeria. Tel. and fax: + 234 2 8103563, e-mail: sysop@nga.healthnet.org (mark message for the attention of Professor Kale). This article is based on an interview with Professor Kale, which was first published in TDR Newsletter, No. 54, October 1997.

## Reference

1. WHO. Community directed treatment with ivermectin. Geneva: World Health Organization; 1996.