PHARMACEUTICAL SECTOR IN TRANSITION – A CROSS SECTIONAL STUDY IN VIETNAM

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Abstract. Increasing efforts are being made to improve pharmaceutical sector performance in low- and middle-income countries. An essential tool for such work is an objective and standard method of assessment which can be used to promote evidenced based National Drug Policy development and implementation. The average drug expenditure per capita has steadily increased in Vietnam and at the time of this study a National Drug Policy was being developed. This study assessed the Vietnamese pharmaceutical sector 1991-1994, focusing on the standard of the drug quality control system, availability of drugs and rational use of essential drugs in the private and public sectors by means of standardised indicators. The results from this study show that the quality control system is impaired and does not have capacity to quality control all drugs on the market. The availability of essential drugs is good whereas essential drugs are poorly prescribed, injections common and there is a high average number of drugs per prescription, both in the public and private sectors. Violations are common and enforcement of regulations weak. On top of this there is an active commercial advertising and marketing of drugs. These findings identify priorities for action to improve the present situation where the development and implementation of the Vietnamese National Drug Policy will be of major importance.

INTRODUCTION

The Democratic Republic of Vietnam was formed in 1945. It initiated an era of socialism with central planning in the northern part of the country and where the southern part was socialized after the end of the Vietnam war 1975. Vietnam has been progressive in dealing with its basic health problems. A strong emphasis was placed on the development of a highly structured and centralized health care service. A primary-health care approach with small community based health centers and public health programs as vaccination was initiated. The health system was heavily subsidized with all drugs and services supplied free of charge (Witter, 1996). Health indicators like infant mortality rate was reduced to 46 out of 1,000 births and life expectancy have increased to 65 years, which are higher levels than most other comparable countries (Chalker, 1995). These achievements was done despite a low economic growth rate of 0.4 % a year between 1975 and 1980, isolation from the international community and a costly post war reconstruction (Bloom, 1998). In the late 1980s when the assistance from the USSR declined and inflation rates soared the financial support to the health sector was substantially reduced. As a consequence a tremendous shortages of medicines appeared (Chalker, 1995). In 1986 an economic reform, the "Doi Moi" renovation was initiated and was reinforced with greater emphasis in 1989. The renovation towards market economy resulted in devaluation, demand credit and openness to foreign trade and an end to price regulation and subsidizing of state owned companies. As a result the annual inflation fell from more than 700% to roughly 10% in the early 1990s. The impact of the renovation politics on the health care sector was dramatic. The health care system now years later involves private practices, commercial sale of pharmaceuticals, medical insurance and fee for service medical care. Health transactions between providers and consumers have evolved from bureaucratic management and subsidized health care to free and virtually unregulated market exchanges (Chalker, 1995).

In 1992 it was estimated that the liberalization of pharmaceutical production had led to a three-fold increase in drug production and a ten-fold increase in drug imports during the prior 5 years (Witter, 1996). Per capita drug consumption including drugs brought in unofficially by traders and overseas Vietnamese was estimated to have risen from US$ 0.5 in value 1986 to US$ 3.2 in

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1994 (Ministry of Health, 1995). The liberalized economy, rapid increase of pharmaceuticals available on the market and increased domestic demand has resulted in a situation where private sector increasingly are taking over and where profits from drug sales has led to a temptation to over-prescribe/dispense (Cederlöf and Tomson, 1996; Lönnroth *et al*, 2000).

The aim of this study was to analyse the Vietnamese pharmaceutical sector 1991-1994, focusing on the standard of the drug quality control system, availability of drugs and rational use of essential drugs by means of using standardized indicators.

MATERIAL AND METHODS

The data were collected during 1994 in the course of a larger on-going comparative national drug policy research project organized jointly by the WHO (EDM), Harvard School of Public Health and the Karolinska Institute (IHCAR). The methodology used in this project has been presented in detail previously (Brudon-Jakobowicz *et al*, 1994). Briefly, the pharmaceutical sector was analysed using background information, quantitative and qualitative indicators covering the fields of legislation and regulation, information and continuing education on essential drug (ED) use, media, manufacturing, accessibility, availability, prescribing and dispensing. Qualitative information was based on data available at central level but was also obtained together with quantitative information through field surveys. The background indicators provide data on the demographic, health, economic and pharmaceutical contexts in Vietnam. The structural indicators provide qualitative information to assess the pharmaceutical systems capacity to achieve its policy objectives. The process indicators provide quantitative information on the process by which a national drug policy is implemented. The outcome indicators measure the achieved results of an explicit or implicit national drug policy on availability, affordability, quality and rational use of drugs. The surveys in Vietnam were conducted during June to December 1994.

Sample area

Stratified sampling was used, based on demographic, financial and logistic conditions. Vietnam can be divided into three different demographical areas: major cities, delta provinces and remote mountainous provinces. Out of Vietnam's 53 provinces 6 were selected to represent the Vietnamese pharmaceutical situation, 2 from each kind of demographical area and of these one in the south and one in the north. Hanoi and Ho Chi Minh City (HCMC) were selected to represent major cities. Thanh Hoa and Khanh Hoa representing delta provinces and Cao Bang and Lam Dong representing remote mountainous provinces were selected at random (Table 1).

Sampling procedures and size

Forty public district health facilities with drug outlets and forty private pharmacies in the major cities and provinces as well as twenty remote mountainous health facilities in the delta provinces and remote mountainous provinces were selected by proportional stratified sampling methodology.

In each area a proportionate number in relation to total number of pharmacies in each type of health facility were selected, *eg* in Hanoi there are 1,033 private pharmacies, this number was

Table 1
Sampling design.

	Major cities		Delta provinces		Remote provinces	
	Hanoi	HCMC	Thanh Hoa	Khanh Hoa	Cao Bang	Lam Dong
Population	2,641,000	4,989,600	3,553,100	993,500	565,700	854,100
Area (Km^2)	972	2,090	11,168	5,267	8,445	10,137
HF	6	12	11	5	-	-
Public DO	6	12	11	5	-	-
Private DO	15	21	2	2	-	-
Remote HF	-	-	4	2	6	8

HCMC= Ho Chi Minh City; HF=health facility; DO=drug outlet

divided with the total number of pharmacies in the study areas, 2,592, and multiplied with total number of pharmacies selected for the study, 40. Twenty remote health facilities, classified by the Vietnamese government in a national list of remote mountainous health facilities outside the main road system, were selected, 14 in the remote areas and 6 from the delta provinces.

Data collection

A reference basket of 10 ED were selected among the most used ED of major public health importance in the country to investigate dispensing, prescribing, availability and accessibility of ED (Table 2). Thus they were expected to be available at all times in adequate quantity and appropriate dosage forms. Background, structural and process indicators were collected from official sources by means of interviews with officials at different departments including the Ministries of Health, Finance and Education as well as from the faculties of pharmacy and medicine in Hanoi. To assess the outcome indicators the following information was collected: the first 30 prescriptions on the visiting day in public and private drug outlets; names of the 30 first sold drugs in the private drug outlets; names of the 30 best selling and cheapest drugs from each private drug outlet. Five interviews with randomly selected prescribers and 5 medical records of children under five with diarrhea was collected in each of the district health facilities (Table 3). The collected information consisted of 2,400 prescriptions, 1,200 names of drugs sold, 200 interviews with doctors and 200 medical records. The value of forty treatment records (prescriptions) for pneumonia were collected from each health facility and the average price was calculated. Twenty bills from the remote mountainous health facilities were collected. In order to evaluate the average stock out time for the basket of 10 ED, twenty record books were collected.

RESULTS

Drug financing and pricing

In 1995 the public drug expenditure for Vietnam was US$ 64.6 million and the international aid US$ 9.6 million which adds up to about one dollar per capita. The total drug expenditure was US$ 266 million and hence US$ 191.8 million was spent by the households representing 70% of the total drug expenditure. Of Vietnams 4,300 private pharmacies 3,100 were situated in the three major cities, Ho Chi Minh City, Hanoi and Haiphong. There is no price regulation for the private sector and there are no incentives for the private pharmacies to sell ED at low price. The margin added by wholesalers and retailers is on average more than 35% compared to the drug price at the port of entry (CIF price). The total value of local drug

Table 2
Basket with 10 ED used for surveys.

Drug	Quantity
1. Acetylsalicylic acid	Tab 500 mg
2. Cimetidine	Tab 200 mg
3. Ampicilline	Cap 250 mg
4. Chloroquine	Tab 150 mg
5. Ferrous salt	Tab 60 mg
6. Levamisole	Tab 150 mg
7. Metronidazole	Tab 250 mg
8. Paracetamole	Tab 100 mg
9. Phenoxylmethyl penicilline	Tab 400,000 UI
10. Sulfamethoxazole + Trimetoprim	Tab 480 mg

Table 3
Data collection.

Facility	Prescriptions	First sold drugs	Best selling drugs	Cheapest drug	Interview's	Medical records	Drug basket
HF (40)	-	-	-	-	5	5	-
Public DO (40)	30	-	-	-	-	-	-
Private DO (40)	30	30	~30	~5	-	-	-
Remote HF (20)	-	-	-	-	-	-	~8
Total	2,400	1,200	1,216	228	200	200	161

HF=health facility; DO=drug outlet

Table 4
Selected general indicators for Vietnam in 1994.

Country information		**Health systems data**	
Population	72million	Prescribers	63,947
Annual population growth	2%	Pharmacists	7,500
Rate of urbanization	20%	Pharmacy technicians/assistants	16,375
Life expectancy	65	Public pharmacies and drug outlets	22,400
GNP per capita	220 US$	Private pharmacies	4,300
Rate of inflation	5%(93)14%(94)	Private agencies and drug outlets	15,000
		Private pharmacies in the three major	
Health information		urban areas	3,100
Infant mortality rate	46 per 1,000	Drug manufacturing units	84
Life expectancy	65	Wholesalers	132
		Registered drugs	6,000
		Drugs on the ED list	188^{1989} 255^{1995}

ED: essential drugs

production in Vietnam was US$ 87 million and the total value of drug import was US$ 152 million (chemicals for manufacturing excluded).

Prescribers and providers (Table 4)

There were a total of 63,947 prescribers including medical doctors, nurses and midwives in Vietnam 1994. The doctors have the authority to prescribe, but in case of absence nurses and midwifes also have a delegated right to prescribe. There were 7,500 pharmacists and 16,375 pharmacy technicians and assistants. The total number of drug outlets was approximately 41,700; of these 22,400 were public drug outlets, 15,000 were private drug outlets including commune drug outlets and 4,300 were private pharmacies. Private pharmacies are owned by pharmacists and the pharmacists are required to be present during duty hours.

Quality control

In 1994 there was 84 drug-manufacturing units, 132 wholesalers and a total of 6,000 registered drugs. There was a licensing system in place. Vietnam was not using the WHO Certification Scheme on the quality of Pharmaceutical products moving in international commerce. There were formal procedures for registering drugs and a drug registration committee. Drug registration and renewal is required at least every 5th year. There is a quality control system including institutions where quality control is carried out, but provincial quality control stations can only perform control of antibiotics, antipyretics, analgesics, vitamins and a few other substances. All drugs produced by Vietnamese manufactures were tested by the manufacturer. To assess the function of the drug quality control system the number of drugs that could not be quality control tested the day of the survey was investigated. Out of the 80 collected samples of 10 ED obtained from 80 drug outlets and tested in 4 drug quality control stations, 25% could not be quality control tested at the day of survey. From 1991 to 1994 there were 15,962 inspections in total in 46 provinces and cities. Violations were found in 84 % of the inspections and included minor violations such as not wearing a white coat and that the pharmacist in charge was absent during the visit. Sixty-five percent of the violations resulted in sanctions and administrative measures. To assess the frequency of expired drugs in the sampled pharmacies 1,216 samples were investigated and two of the samples had expired.

Availability of ED

To assess the availability of ED, the number of drugs from the basket of 10 drugs (Table 3) available in 20 remote health facilities was investigated. It was found that on average 80 % of the representative ED were available at the day of the survey (Table 5).

Affordability of ED

To assess the affordability in both the public and private sectors regarding the treatment of one of the most common diseases, pneumonia, the average retail price of a standard treatment of pneumonia provided by the National Institute for Tuberculosis and Lung Disease was compared with the average retail price of a basket of food suf-

Table 5
Outcome indicators.

Measure	Description	Result
Availability	Number of drugs from a basket of drugs available in a sample of remote health facilities, out of total number of drugs in the same basket.	80%
Availability/Affordability	Number of drugs at the lowest price from a basket of drugs, out of total number of drugs in the same basket.	53%
Affordability	Average retail price of standard treatment of pneumonia (Public Sector) out of the average retail price of a basket of food.	189% (Public) 180% (Private)
Affordability	Value of a basket of drugs, out of the value of the same basket with the cheapest drugs.	2.6
Quality	Number of drugs/batches that could not be quality control tested, out of the total number of drugs/batches surveyed.	25%
Quality	Number of drugs beyond the expire date, out of the total number of drugs surveyed.	0.2%
Rational use	Average number of drugs per prescription out of the total number of prescriptions surveyed.	3.8 (Public) 3.6 (Private)
Rational use	Number of prescriptions with at least one injection.	32% (Public) 17% (Private)
Rational use	Number of children under 5 with diarrhea receiving anti-diarrheal drugs, out of the total number of children under 5 with diarrhea surveyed.	10%
Rational use	Number of drugs from the national ED list, out of the 50 best selling drugs in the private sector.	78%

ED: essential drugs

ficient to feed one person one day (2,100 kcal) provided by the Institute for Nutrition. It was found that the standard treatment obtained in either private or public pharmacies was roughly two-fold more expensive than the basket of food (Table 5). To assess the price difference between private and public sectors 2,400 prescriptions were collected from public and private pharmacies. It was found that the average expenditure per prescription was US$ 3.3 in private pharmacies and US$ 2.3 in public drug outlets.

Prescribing practices

The average number of drugs per prescription was 3.8 in the public sector and 3.6 in private. It was found that 17% of prescriptions from private pharmacies and 31% from public pharmacies contained one injection or more. To assess prescriber practices of ED 2,400 prescriptions were collected in public and private pharmacies. It was found that 36% and 40% of the drugs prescribed were on the ED list in private and public pharmacies, respectively. Of all drugs sold one third were listed on the ED list in private pharmacies. Thirty-nine of the 50 best selling drugs (78%) in private pharmacies were on the ED list.

Education and training

Hanoi College of Pharmacy and Ho Chi Minh City Medical and Pharmaceutical College are responsible for graduate and post-graduate training. The annual output of graduate pharmacists is

250-300. There is one Drug Information Center at Hanoi College of Pharmacy, which provides information for prescribers and dispensers accompanied with a monthly clinical pharmacy bulletin. Of the interviewed prescribers 70% had attended at least one training session defined as any meeting, workshop or seminar on rational use of drugs. Only 31% had direct access to drug information.

DISCUSSION

In Vietnam the drug expenditure per capita has steadily and markedly increased with 180% from 1991 to 1994 based on official drug import and production data. Official figures state that the total drug expenditure was US$ 5.2 per capita for 1997, in 1996 the same figure was US$ 4.6 and in 1995 US$ 4.2. This implies an average annual increase of about 14%. The pharmaceutical market in Vietnam has been anticipated to increase dramatically the coming years providing one of the largest potentials for growth of the pharmaceutical market in the world (VCF, 1997).

Of the roughly 6,000 registered drugs in Vietnam 1995 approximately 3,400 were locally produced and contained about 150 active substances. A large share of these are combination drugs and only sold as brand name drugs. Approximately 2,600 drugs were imported containing an estimate of 600 active substances, many which are combination drugs as well as duplicates. For example, among the 6,000 registered drugs there are 255 different brand names of products containing paracetamol, both imported and locally produced.

Regarding quality control of drugs, only 75% of the drugs could be quality tested at the day of the survey. This indicates problems in the capacity and standard of the quality control laboratories in Vietnam. These laboratories have the responsibility to be able to control all active substances from the pre and post market as well as to be able to test all imported and locally produced drugs. The manufacturers have the responsibility to test all the produced drugs according to standards set up by the quality control institute in Hanoi and Ho Chi Minh City. The pharmaceutical market is expanding rapidly in terms of number of products on the market and thus the diversity of substances, which require testing is increasing (Wolffers, 1995). The quality control laboratories often lack reference substances needed for quality control. In one study samples of antimalarials were assessed for their contents and expire date by the Institute of Drug Quality Control in Hanoi. Of the 218 samples of drugs examined by the Institute, over 96% met the quality requirements. However, a 10% sample of these drugs were independently assessed by the World Health Organization and revealed a different picture: 70% of them failed to meet the standard specifications required (Cong *et al*, 1998). Likewise about 50-60% of a random sample of ED was of substandard quality in neighboring Lao PDR (Stenson *et al*, 1998). The Ministry of Health has set objectives in 1996 to improve the situation and to restructure the quality control facilities, upgrading management systems and improving staff skills and training in quality control techniques (Ministry of Health, 1996).

Sixty-five percent of the violations reported by the drug outlet inspectors resulted in sanctions and administrative measures due to for example storage of expired drugs, the selling of restricted drugs without prescription (*eg* CNS active drugs, digitalis, steroids) or selling of illegally imported or substandard drugs (World Health Organization, 1999). One reason for the high violation rate found during the inspection visits might be that the sanctions are often not severe enough (verbal warning) to discourage further violations. Enforcement is generally given low priority. The fact that only 2 of the 1,216 drugs collected in the survey had expired show that the basket of drugs used in this survey included popular drugs with a high turnover in contrast to the drugs identified as expired by the inspectors.

The relatively high drug availability found in the survey in the remote health facilities indicates that most of the essential drugs can be found in most parts of the country. Remote health facilities received a subsidy responding to US$ 1 per inhabitant per year for drug purchase and basic ED are provided by the provincial wholesaler. It was found that the average time between order and delivery of drugs to the remote health facilities was five days. As a result of the "Doi Moi" and the private sector expansion drugs are easily available throughout other parts of the country. This finding is also supported by Witter (1996).

In many low and middle income countries the fact that the public has a large variety of affordable drugs easily available together with the sometimes low quality of the private health care (Chalker 1995; Lönnroth *et al*, 2000; Ross-Degan *et al*, 1992; Trostle, 1996), market failure (Falkenberg

and Tomson, 2000; Cederlöf and Tomson, 1996), weak regulations of private practice (Brugha and Zwi, 1998; Stenson *et al*, 1997) and aggressive marketing of drugs including antibiotics both by national and international drug manufacturers (Finer, 1999) have lead to an inflated public demand and irrational use of drugs. In Vietnam, a case study in two private pharmacies in Hanoi showed that patients often bypass the health care system and turn directly to the pharmacies without prescriptions for self medication (Chuch, 1999). Pharmacy staff knowledge of rational use of modern pharmaceuticals is often insufficient in Vietnam (Wolffers, 1995; Landinsky, 1985). In recent studies we have shown that knowledge is significantly better compared to practice in private pharmacies in Hanoi regarding case management of childhood acute respiratory infection (unpublished observations) and sexually transmitted diseases (Chalker *et al*, 2000) as well as in the selling of prescription steroids and antibiotics (unpublished observations). The relatively low cost of drugs (on average less than US$ 1 per drug) as shown in the present study certainly contributes to the inappropriate treatment of major public health problems and overuse and short courses of antibiotics intake (Cederlöf and Tomson, 1996; Van Duong *et al*, 1997).

Regarding quality of use of drugs including dispensing and prescribing there were signs of irrationality found in this study. The number of drugs per prescription (3.8) is high and corresponds to findings from other low-income countries (Hogerzeil *et al*, 1993). Two or more drugs per prescription is considered to indicate a problem in the prescription practices as defined by WHO (Brudon-Jakobowicz *et al*, 1994). The high rate of injection per prescription is alarming and has also been reported from other low income countries (Birungi *et al*, 1994; Hogerzeil *et al*, 1993). According to the prescribers interviewed this was due to that many patients, especially in mountainous areas, expected injections of vitamins (C, B1, B6 and B12). About one third of the public drug outlets where in the mountainous area Thanh Hoa and this contributed to the high frequency of injections found in the survey. This result is worrying considering the risk for local infections as well as transmission of HIV and B hepatitis viruses in badly sterilized material (Ministry of Health, 1996). Education and information to improve the situation is necessary. In this study the number of training sessions on drug use for the group of drug sellers, pharmacists and prescribers increased from an average of 5 sessions annually 1991-1993 to 18 in 1994. However the information was generally from commercial sources. In a recent thesis (Finer, 1999) it was shown that the quality of drug information in mass media was generally low. Effective educational programs has been described to improve drug use (Santoso, 1996; Wahlström *et al*, 1997). A good example is where the Ministry of Health has been active through regular information campaigns directed towards health workers to increase use of ORS and decreased use of antidiarrheals for childhood diarrhea. This could explain the finding that 90% of the surveyed prescribers did not prescribe anti-diarrheals for childhood diarrhea.

The low level of ED prescribed (40%) underlines a priority for action (Hogerzeil *et al*, 1993). One reason for the low rate could be that the ED list had not been updated since 1989. A draft of a revised ED list containing 255 ED was circulated in the end of 1995. Another reason for the low prescription rate might be that some doctors are unaware of the ED concept. The prescribers might also have other stronger incentives to prescribe non EDs as brand name drugs yield higher profits (Cederlöf and Tomson, 1996; Lönnroth *et al*, 2000).

In Vietnam there is general lack of good pharmaceutical sector statistics. Thus this survey instrument with indicators for different elements of a NDP is of potential value for better planning and more of evidence based policies. An NDP was developed by the Vietnamese Ministry of Health in collaboration with the World Health Organization (WHO) and Sida. The results presented in this article provided a part of the background information used in the development of the Vietnamese NDP in 1996.

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