

# HAI News

THE NEWSLETTER OF HEALTH ACTION INTERNATIONAL

NUMBER 130

JULY-SEPTEMBER 2004

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**HAI News** reports on developments in national and international campaigns on health for all. This newsletter highlights activities of network contacts involved in improving access to medicines, rational drug use and poverty eradication.

HAI News is produced by HAI Asia-Pacific Coordinating Office

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Health Action International (HAI) is a network of individuals and NGOs involved in health and pharmaceutical issues.

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ISSN 0128 1321

# MEASURING COSTS FOR CONSUMERS: THE WHO/HAI MEDICINE PRICES PROJECT

By Jeanne Madden \*

In May 2003, Health Action International (HAI) and the Department of Essential Drugs and Medicines Policy of the World Health Organization published a working draft of a manual to collect and analyze the prices people pay for a selection of important medicines, as well as to identify price components (taxes, mark-ups, etc.) and the affordability and availability of key medicines.

Governments, NGOs, and other groups concerned with medicine prices are encouraged to undertake surveys using the methodology outlined in the manual. Reliable data is the first step to exploring policy options and taking action. This paper outlines several aspects of the WHO/HAI methodology, using examples from surveys in 2001-2003.

## Collecting Medicine Prices to Consumers

For local investigators, conducting a WHO/HAI medicine prices survey involves the collection of price data from medicine outlets. A sample of outlets is visited in different health sectors. For example, in most cases, the study team looks at prices to patients at twenty or more government-sponsored clinics and also at twenty or more private for-profit pharmacy shops. They may also decide to add a third sector, such as charitable or mission facilities, parastatal cooperatives, or health facilities created for employees of a major industry. The survey manual gives guidance on choosing sectors and then identifying a representative sample of outlets to be visited.

Each WHO/HAI survey targets a set of 30 specific essential medicines, such as cotrimoxazole syrup and diazepam 5mg tablets. Study teams are encouraged to add other medicines of local interest to this core list. Data collectors on the local study team visit the medicine outlets and ask to see each of the medicines in three versions. First is the innovator or originator brand version of the medicine. Next is the generic version of that medicine that is most commonly sold in the country. (The name and manufacturer are identified by the team before field work begins) Finally, the survey gathers prices for the lowest-priced generic version seen in each outlet. (In some outlets, this generic may be the same as the nationally “most sold” generic) In public facilities, there is often just one simple generic version of a medicine; the innovator brand and most popular branded generics are not seen. Prices are only collected when the medicine versions of interest are available. Otherwise, spaces on survey forms are left blank.

Prices are gathered on paper data collection forms in the field, checked for mistakes, and then entered into computer spreadsheets. A Microsoft Excel workbook of spreadsheets has been customized for the WHO/HAI survey and is included in the manual. This electronic workbook provides a clear structure for entering all the field data. After data entry, several key analyses are produced automatically and immediately.

## Analysis of Results for Specific Medicines

Figure 1 shows a small portion of the Excel workbook, after data have been entered. These data are from the 2001 survey in Kenya. Ordinarily, the first nine columns of this section would be shaded blue. These columns identify the surveyed products and present some automated analyses. The last two columns (headed “1” and “2”) are not shaded and are where field data is entered by the local study team. The numbers below the header in the last two columns are prices for one unit of medicine, in local currency. Thus, in the first outlet surveyed, a 1gm vial of innovator brand ceftriaxone cost 2300 Kenyan shillings (KSh). The price of the same product in the second facility was considerably lower (1890 KSh). The generic forms of ceftriaxone were cheaper still in the first facility (both were 1400

KSh), but were not available in the second facility. A total of 26 for-profit facilities were surveyed in Kenya (columns not shown).

**Figure 1**

***Partial View of the WHO/HAI Workbook for Entering and Analysing Medicine Prices Data***

No.	Medicine Name	Medicine Type	Median (MPR)	25 <sup>th</sup> ile	75 <sup>th</sup> ile	Min	Max	% with med.	1	2
9	Ceftriaxone injection	Brand	18.56	17.18	19.51	16.24	19.76	50.0%	2300	1890
9	Ceftriaxone injection	Most sold	12.03	12.03	12.60	8.59	14.15	19.2%	1400	
9	Ceftriaxone injection	Lowest price	8.59	6.87	12.03	6.01	14.15	34.6%	1400	
10	Ciprofloxacin	Brand	122.98	116.15	127.08	102.49	134.26	65.4%	372	373
10	Ciprofloxacin	Most sold						11.5%		
10	Ciprofloxacin	Lowest price	10.76	8.54	21.52	5.12	81.99	61.5%	15	40
11	Co-trimoxazole suspension	Brand	11.27	10.76	12.30	10.28	15.59	26.9%	4.55	
11	Co-trimoxazole suspension	Most sold	1.88	1.71	2.48	1.37	2.74	46.2%	0.5	
11	Co-trimoxazole suspension	Lowest price	2.06	1.71	2.74	1.20	10.79	92.3%	0.5	1

Once data are entered, the column headed “% with med.” instantly presents results on medicine availability. We can see that half of the surveyed shops had the innovator brand of ceftriaxone in stock. The generic forms were less often found - about 19 per cent of shops had the leading generic brand, and 35 per cent had at least one generic version.

Columns 4 to 8 in Figure 1 summarize price data from the field. However, these numbers are not in local currency. These are *price ratios*: local prices converted to US dollars and then divided by an international reference price. The most expensive ceftriaxone found was in that first facility, 2300 KSh, which in 2001 was equivalent to US\$29.15. The international reference price (from bulk generic distributors) for ceftriaxone was US\$1.48 per vial. (Reference prices are entered and visible elsewhere in the WHO/HAI workbook). The *maximum price ratio* for innovator ceftriaxone in the survey, seen at the top of column 8, therefore was  $29.15/1.48 = 19.76$ . In other words, the maximum retail price found in any shop was about 20 times the international bulk generic price. The *minimum price ratio* seen for innovator brand ceftriaxone was 16.24 (shown in Column 7). The remaining price ratios were of course between the maximum and minimum. The workbook also calculates the 25<sup>th</sup> and 75<sup>th</sup> *percentile of the price ratios*, which together mark off a more “typical” or central range. Finally, the *median price ratio* (or *MPR*, Column 4) is the result which is most representative among all the shops visited.

**What is a Median Price Ratio (MPR)?**

In the WHO/HAI medicine prices survey, most results are expressed in the form of “Median Price Ratios” (MPRs). The MPR is a ratio of the local price, in USD, over an international reference price (also in USD).

A reference price serves as an external standard for evaluating local prices. Reference prices are available from many sources. The MPR results in the WHO/HAI pilot surveys being based on reference prices taken from the MSH International Drug Price Indicator Guide (<http://erc.msh.org/>). This MSH guide puts together information from the price lists of large, generic medicine suppliers. These suppliers mostly sell in bulk to governments and non-governmental organizations. Their prices tend to be on the low end. Nevertheless, their prices offer a standard that is easily accessed and makes international comparisons easy.

The WHO/HAI Excel workbook automatically calculates the median among all the prices collected in field surveys for a specific product in a specific sector. This is the most “typical” local price charged to patients. Then the workbook converts that price into USD, and then divides it by the reference price for the medicine. The resulting MPR tells the investigator how many times higher the “typical” local price is compared with a global standard.

### **Comparing Prices for Different Versions of a Medicine**

Generic versions of surveyed medicines are almost always less expensive than the innovator brands. We can see this pattern in Kenya's results in Figure 1. Typical prices for the leading generic competitor to innovator brand ceftriaxone are only two-thirds as high (MPR 12.03 versus MPR 18.56). Additional generic versions are also available, as we can see from the "lowest price" generic product results (MPR 8.59). For ciprofloxacin tablets, the contrast between innovator brand prices and generic prices is even sharper. The "lowest price" generic version in retail shops costs about 11 times the international reference price, while the innovator brand costs about 123 times the reference. Too few examples of the leading generic ciprofloxacin were found. At least 4 are required to produce the price ratio statistics.

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

### **Summarizing Price Results for Many Medicines within a Sector**

The WHO/HAI medicine prices survey can produce a fairly accurate picture of prices in an entire sector by summarizing results for all the medicines targeted in the survey. Again, the main measures used are MPRs, or ratios of local prices to international reference prices. Figure 2 shows a portion of the workbook that automatically presents summary analyses for a sector. This time, the data are from the private for-profit sector in the Philippines, 2002. The energetic Philippines study team collected data from 77 retail outlets. They found enough price data for 21 innovator brand products, 9 nationally "most sold" generic products, and 15 generics in their "lowest priced in shop" version.

The simplest way to make an overall comparison between, say, innovators and generics would be to take the median of the MPRs for all those innovator products, and compare that to the median of MPRs for all the "lowest priced" products. The workbook does compute and display these two results (not shown here). However, it is not wise to use this raw comparison. There are 21 innovators widely available but only 15 generics. Therefore, the two groups do not include the same medicines, and are not truly comparable. The workbook also offers a better analysis, shown in Figure 2.

There are three pairs of boxed columns in Figure 2. In each pair of columns, summary price ratios for *pairs of equivalent products* are compared (private for-profit sector only). There were just nine surveyed medicines that were found in both their innovator brand and their nationally most sold generic versions. Statistics for these two types of medicines appear side by side in the first two boxed columns of Figure 2. The median among the nine MPRs for the innovator versions of the medicines was 18.28. The median among the nine "most sold generic" MPRs was 16.21. So we can say that in the Philippines private sector, innovator brand medicines are estimated to cost about 13 per cent more than their most popular generic equivalents.

**Figure 2**

**Partial View of WHO/HAI Workbook, Comparing Results for Groups of Medicines**

Private Sector Medicines Outlets (n=77 in survey) Includes Both Core and Non-Core Medicines (n=29 on list)						
Analysis Includes Only Medicines With Prices Found for Both Types in Pair						
	Brand	Most Sold	Brand	Lowest Price	Most Sold	Lowest Price
No. of meds. included	9	9	14	14	9	9
Median MPR	18.28	16.21	15.37	7.69	16.21	6.77
25 %ile MPR	8.74	6.63	9.24	5.78	6.63	6.67
75 %ile MPR	46.32	21.94	22.26	11.89	21.94	21.94
Minimum MPR	4.93	4.18	4.38	3.38	4.18	4.16
Maximum MPR	57.25	56.06	57.25	53.45	56.06	53.45

Reference Price Data Used = MSH

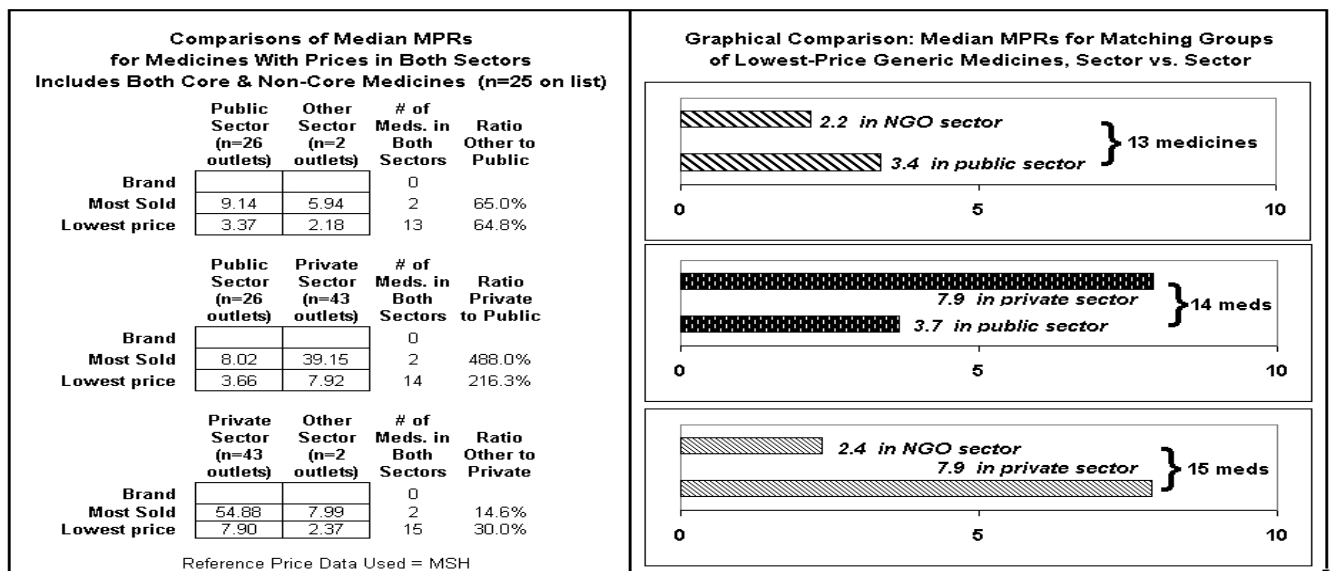
In the 3<sup>rd</sup> and 4<sup>th</sup> columns in Figure 2 (headed “Brand” and “Lowest Price”), prices for equivalent groups of innovator brand medicines and lowest price generic versions are compared. For this comparison, 14 medicines were found to be widely available in both categories. The survey found that innovator brand medicines in the Philippines for-profit sector cost, overall, about twice as much as equivalent lowest-price-in-shop generics (median of MPRs 15.37 versus 7.69). Finally, in columns 5 and 6 (headed Most Sold and Lowest Price) a comparison is made between paired generic products. For these nine pairs the most sold generics were more than twice the price of the lowest price generics (16.1 versus 6.77). The implication of this finding is that, in the Philippines at least, making good choices among generics is very important.

**Comparing Summary Price Results among Different Sectors**

The workbook also makes comparisons among different sectors, based on information summarized for many medicines. On the left side of Figure 3 is a view of some tables in the workbook which present instant cross-sector analyses. On the right side of Figure 3, portions of these analyses have been presented graphically for the purpose of this article. (At present, there is no graphing function in the WHO/HAI workbook. However, graphs like these can be produced quickly and easily in Excel by local investigators).

**Figure 3**

**Cross-Sector Results, in the WHO/HAI Workbook and in some basic graphs**



As in Figure 2, the cross-sector analyses shown in Figure 3 compare only similar groups of products. These are data from the 2002 survey in Peru. Medicine prices for patients were collected in the public sector, the private for-profit sector, and an NGO sector. Innovator brand versions of the surveyed medicines were available only in the for-profit sector, so no cross-sector analyses could be produced for innovator brands. Only a few of the nationally most sold generic medicines were found outside the private sector, so it is preferable to compare “most sold generics” among sectors on a medicine-by-medicine basis (Because two product examples are insufficient to draw solid conclusions on the entire sector).

However, the Peru study produced a lot of interesting results for the category of “lowest priced generics”. In the first lowest price row on the left side of Figure 3, we see a summary comparison of public sector and NGO sector prices for lowest-priced generics. Thirteen surveyed medicines were found in generic versions in both sectors. (If there were several generic versions of a substance available in a single outlet, then the lowest price among these was recorded as “lowest price”.) The median of the MPRs for the 13 medicines in the public sector was 3.37. That means, in general in the public sector, patients pay a little more than three times the international reference price for essential medicines. For the same medicines in the NGO sector, patients pay a little more than double the international reference price (median MPR 2.18). Therefore, for matching groups of equivalent medicines, the Peru study found that the NGO sector was less expensive for patients than the public sector. The workbook also automatically expresses this comparison as a ratio of NGO sector prices to public sector prices: 64.8 per cent. On the right side of Figure 3, this cross-sector analysis has been presented graphically.

The second “lowest price” row on the left of Figure 3 presents a cross-sector comparison of the public sector to the private for-profit sector. Retail medicine prices are estimated to be 216.3 per cent of government prices, based on equivalent sets of 14 medicines. Again, this contrast is shown graphically on the right. And finally, along the bottom right of Figure 3, we find a comparison of generic medicine prices for the private for-profit sector versus the NGO sector. Overall, from these three analyses we can conclude that the private sector has the most expensive generics, followed by the public sector. The least expensive medicines in Peru are apparently offered in the NGO sector.

### Public Sector Procurement Prices

In addition to patient price data collected in the field at health facilities and pharmacies, the WHO/HAI survey aims to collect *procurement price data* from the public sector. Procurement prices are usually obtained from large recent government orders. These are entered into the survey Workbook in the same way as patient prices, then automatically compared to international reference prices (as above, in the form of price ratios). This is an excellent tool for evaluating the efficiency of public bidding processes for medicines. Other interesting analyses of procurement prices include

medicine-to-medicine comparisons, innovator brands versus generics, changes in prices from one order to the next, or difference between procurement price and prices to patients (i.e., mark-up).

### **Data Subsetting**

For all types of price data entered into the survey workbook, a useful tool is *data sub setting*. Before looking at any automated analysis, the local investigator can decide whether to include data from all the outlets surveyed in a sector, or whether to select a limited subset. Sub setting is done by using a simple “switch” in the workbook. For example, within a public sector, medicine prices to patients are often collected from both hospitals and smaller clinics. An investigator may wish to compare results for these two different types of public facilities. To do so, the investigator first includes only hospital outlets, then prints out the resulting price ratios and sector summary statistics (or copies them into a separate spreadsheet). These results are only for hospitals. Next, the investigator un-selects the hospitals, and selects the remaining outlets, which are the small clinics. The second set of results is printed, or copied into the separate spreadsheet. Finally, the two sets of results are compared, either manually or with the help of a spreadsheet. This sort of sub setting is also useful for comparing results among different provinces, for rural facilities versus urban facilities in a private sector.

### **Comparisons of Patient Price Results from Different Countries**

When findings from WHO/HAI medicine price surveys are compared among countries, results can be dramatic. Nine countries were involved in two rounds of pilot studies from 2001 to 2002. The main measure we use to compare results is the median price ratio or MPR, but affordability (number of days’ wages needed to purchase treatment) is also informative (see following section).

In cross-country analyses, MPRs can be compared for a single medicine or for groups of medicines. All 9 pilot surveys used MSH 2001 as an international reference price set. The reference price for a 150mg tablet of ranitidine in 2001 was almost 3 US cents. However, consumers in different countries saw a wide range of prices for ranitidine. The innovator brand version was selling in the private for-profit sector at about 6 times that amount in Sri Lanka, and 44 times that amount in Ghana. Prices for popular brands of generic ranitidine ranged from 2 to 23 times the reference price (in Armenia and South Africa, respectively; some countries were missing data on the price of the leading generic).

There may be many reasons why patient price for one product varies among countries, including differences in the location of production, the manufacturer’s selling price, the structure or strength of the national economy, and the sales volume for a product.

To summarize MPR results for many medicines, we can take the median MPR for a group of them. For example, there were 10 innovator brand medicines found in the Armenia survey. The brand medicine with the lowest MPR was the salbutamol inhaler, with an MPR of 2.2. The highest MPR was for brand ciprofloxacin tablets, with a price 95.5 times the reference. Among all 10 of the innovator brand medicines, the median MPR was 10.4.

In a single country, we compare the prices of innovator brands and generics using the median MPR for the brands and the median MPR for the generics. It is important to drop any medicines where either the brand or the generic was not found. Only 8 medicines sought by the Armenian survey were widely sold in both their innovator brand version and the nationally leading generic equivalent. So, there can be 8 “matched pairs” of equivalent medicines. The median MPRs for the 8 branded medicines and their 8 leading generic equivalents are presented at the top of Figure 4. The median MPR for the innovator brands among the 8 matched pairs was 10.4, whereas the median MPR for the generic versions of the same medicines was about 3.2. “Brand premium” is a term meaning how much larger brand prices are compared to generics. For essential medicines in Armenia, a “typical brand premium” is about 330 per cent (that is, 10.4 median MPR for brands divided by 3.2 for generics).

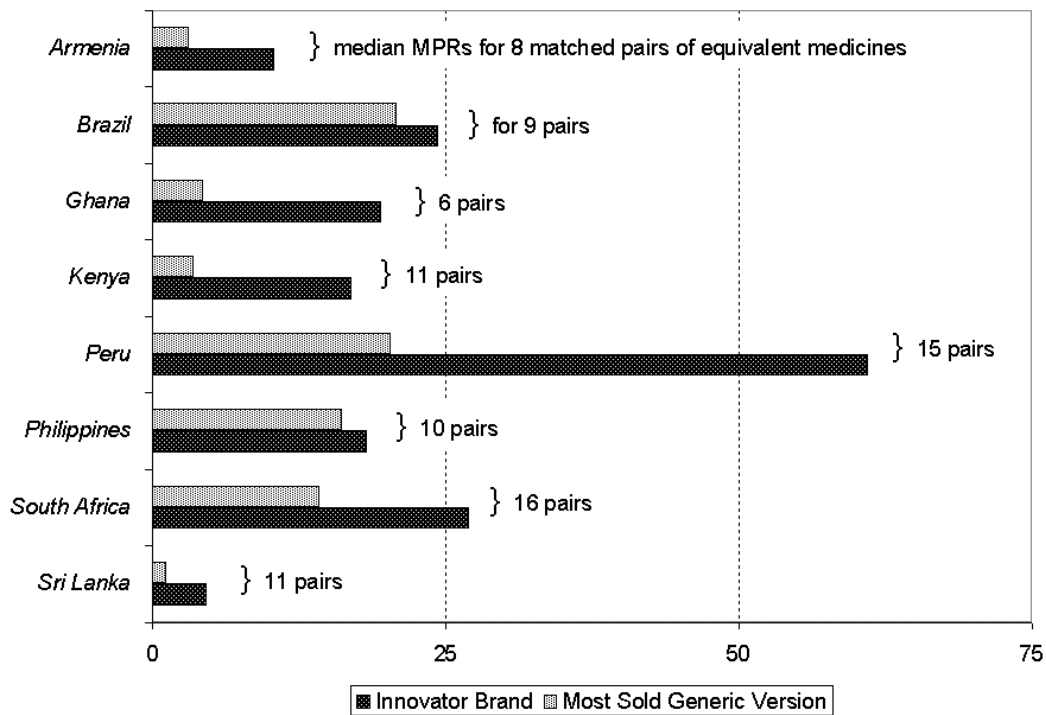
Figure 4 shows the median brand MPRs and median most-sold generic MPRs for 8 of the pilot country studies (private sector pharmacies only). For each country, the results shown are only for pairs of medicines where both the innovator brand and most sold generic version were widely found. The

specific medicines that make up these matched pairs are slightly different from country to country. Nevertheless, because the median is the observation in the middle of all the observations, it is considered fairly representative of both the survey results and the entire private sector in each country. These were not unusual results, but rather the most typical results found.

High brand premiums were seen in most of the pilot countries in Figure 4. That is to say, the darker innovator bar is longer than the lighter generic bar. In cases where the two bars are similar in length (in Brazil and the Philippines, especially), brand medicines seem to be about as expensive as they are in other countries. But in these two countries, the most popular generics are also quite expensive – roughly 15 to 20 times the reference prices. Two other countries that stand out as unusual are Peru and Sri Lanka. Peru’s generic prices are high compared to other countries, and their innovator brand prices are extremely high – typically around 60 times the reference prices. Meanwhile, Sri Lanka has the smallest MPRs in both the brand and the most sold generic categories.

**Figure 4**

***Medians of MPRs in Private Pharmacy Outlets, for Pairs of Equivalent Medicines, as Found in Pilot Surveys***



### **Two Measures of Price: MPRs and Affordability**

As mentioned earlier, the main measure of medicine prices in the WHO/HAI survey methodology is the Median Price Ratio (MPR). The MPR tells us how many times larger (or smaller) the typical local price paid by patients is when compared with the prices offered by international non-profit bulk medicine suppliers.

Figure 5 shows several MPRs for omeprazole and ranitidine as found by the 2002 pilot survey conducted in the Philippines. Both medicines are treatment options for ulcers of the digestive tract. Brand name omeprazole, produced by the original manufacturer, is found at similar prices in both private pharmacies and public facilities – at 5.1 and 4.5 times the international supplier price, respectively. Brand name ranitidine, on the other hand, is found in both sectors at more than 20 times the reference price. Generic ranitidine was found in the private sector only, at almost 12 times the reference price.

This analysis suggests that, in the Philippines, there is a greater degree of overpayment for ranitidine than there is for omeprazole. In other words, especially for ranitidine treatment, Filipinos pay considerably more than the international price available from non profit suppliers.

However, there is another way to look at medicine prices. In addition to comparisons with international supplier prices, the WHO/HAI survey methodology makes comparisons between local medicine prices and local wages. The price to patients for a course of treatment is divided by the amount an unskilled worker is paid for one day of government work. The result is the number of days' wages needed to purchase the treatment. This is a measure of affordability, not market efficiency.

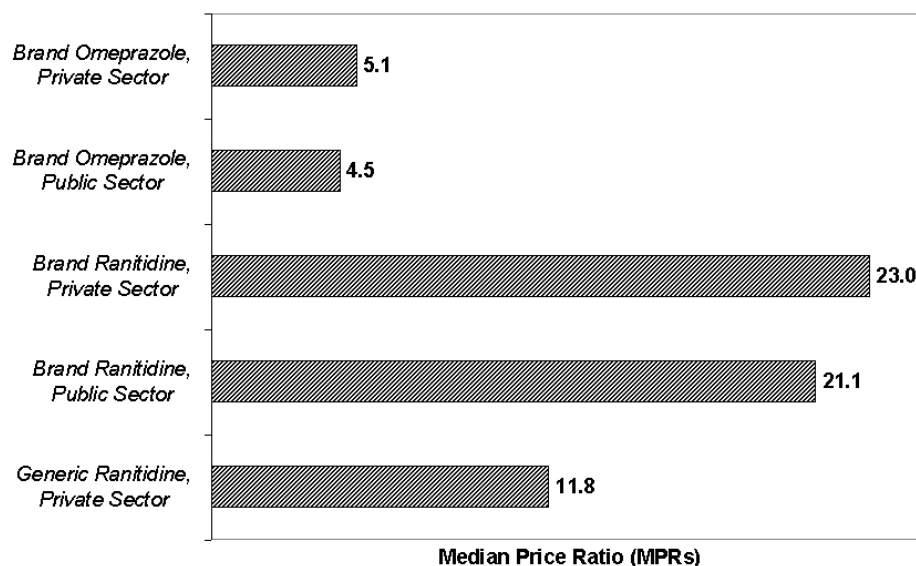
Internationally, omeprazole is more expensive per tablet than ranitidine: about USD \$0.34 per tablet for omeprazole, versus about USD \$0.03 for ranitidine (2001 MSH reference prices). For chronic ulcers, the standard monthly treatment is 30 omeprazole tablets of 20mg each or 60 ranitidine tablets of 150mg each.

So, even though omeprazole is found in the Philippines at prices that are relatively closer to the international supplier prices, omeprazole is less affordable than ranitidine because, it is a more expensive course of treatment. Figure 6 compares the affordability of omeprazole and ranitidine in two sectors in the Philippines. In a typical private pharmacy, an unskilled government worker would have to pay out more than 18 days' earnings for one month (30 days) of brand omeprazole treatment. In a public facility, the medication is slightly cheaper: about 16 days' wages. Brand name ranitidine is cheaper still: 13.2 days' wages or 12.2 days' wages, respectively, in the two sectors. Finally, generic ranitidine can be found in the private sector for about 7 days' wages.

The results in Figures 5 and 6 illustrate two very different ways that the WHO/HAI survey methodology examines medicine prices. The first measure, the MPR, can focus a spotlight on certain medicines that could probably be bought at lower prices, if pharmaceutical supply systems and policies were to be improved. The second measure, affordability, highlights how difficult it is for local people to purchase medicines at current prices. Figure 6 provides clear evidence that for chronic ulcer treatment in the Philippines, two essential options are beyond the financial reach of most people.

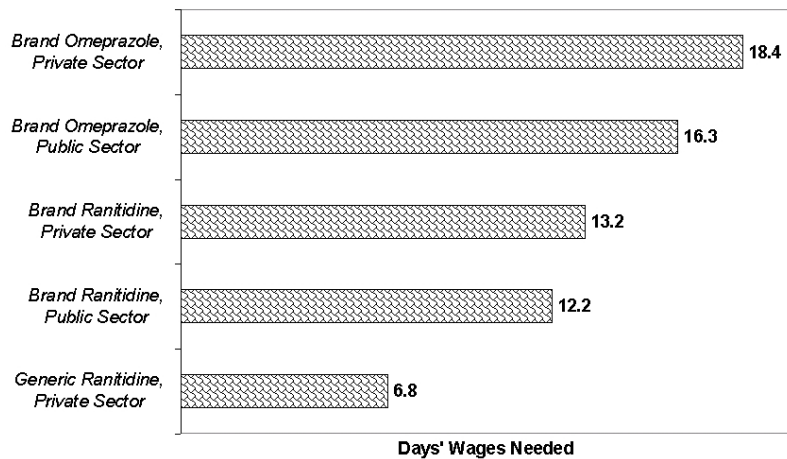
**Figure 5**

***Omeprazole and Ranitidine in the Philippines: Ratios of Prices Faced by Patients to International Suppliers Prices (MPRs)***



**Figure 6**

## *Omeprazole and Ranitidine in the Philippines, Affordability in Terms of Days' Wages Needed to Purchase One Month of Ulcer Treatment*



### **Components of Patient Prices**

The WHO/HAI survey project also seeks an understanding of the structure underlying medicine prices. Through interviews with experts in local pharmacy systems and a review of government policies, investigators try to separate the component parts of prices to consumers.

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

The typical mark-ups from CIF price to consumer price vary from country to country. This is partly because of differences in government policies on entry procedures, taxes, and allowable mark-ups. Also, countries differ in how their private markets are structured - for example, how many links there are in the distribution chain, whether there is real competition, the size of profits sought and obtained by local businesses, and other factors. If someone believes that medicine prices are too high for consumers, the first step towards possible change must be to describe the structure that lies beneath prices.

Figure 7 shows findings from the 2001 WHO/HAI pilot surveys in Sri Lanka and Kenya. These represent the “maximum” price mark-ups as are usually seen in these two countries' private sectors. (However, in Kenya, retailer mark-ups were occasionally found to be much higher than shown here, especially for the cheapest generic medicines. Retailers told the study team that they must mark these up very high, because their customers believe that medicines that are “too cheap” cannot be effective.)

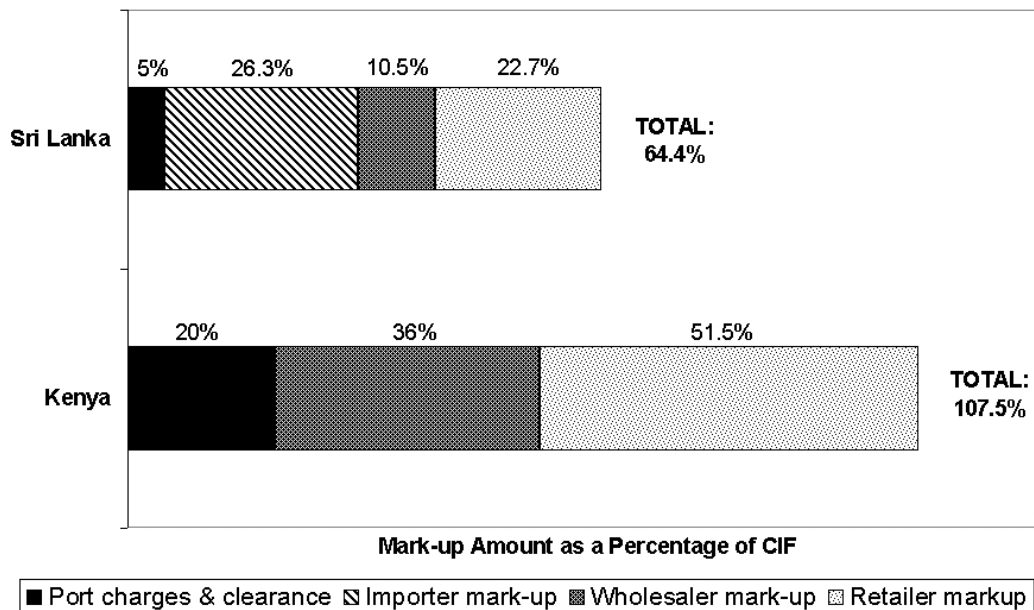
Note that the mark-up amounts in Figure 7 are presented as a percentage of the CIF price. Because mark-ups are normally added in a sequence, small percentages added late in the chain look large because of the cumulative effect. For example, in Sri Lanka, private retailers add 16 per cent onto the price that they pay for medicines. Because the price of medicines has already been marked up about 42 per cent over the CIF price before the retail stage, the retailer’s mark-up is about 23 per cent of the CIF price.

A large importer mark-up was found in Sri Lanka but not in Kenya. Otherwise, all mark-up amounts in Kenya were found to be much larger than those in Sri Lanka. Neither Kenya nor Sri Lanka had a

Value Added Tax (VAT) on medicines. However, in some of the other WHO/HAI pilot surveys, VAT as high as 18 per cent were found at the point of retail sale.

**Figure 7**

**Local Mark-ups Over CIF Price for Imported Medicines: Private Sectors in Sri Lanka and Kenya**



**Availability of Essential Medicines**

Starting in 2003 with the current working draft manual, the WHO/HAI methodology takes a systematic look at medicines availability. The first survey to do this was conducted in Rajasthan, India. The Rajasthan team gathered data on 36 different substances, including 27 substances on the WHO/HAI core medicines list, and nine locally-selected substances. For each substance, price and availability data were gathered on the original innovator brand, the most popular generic version in the region, and whatever happened to be the lowest-priced generic version in each outlet.

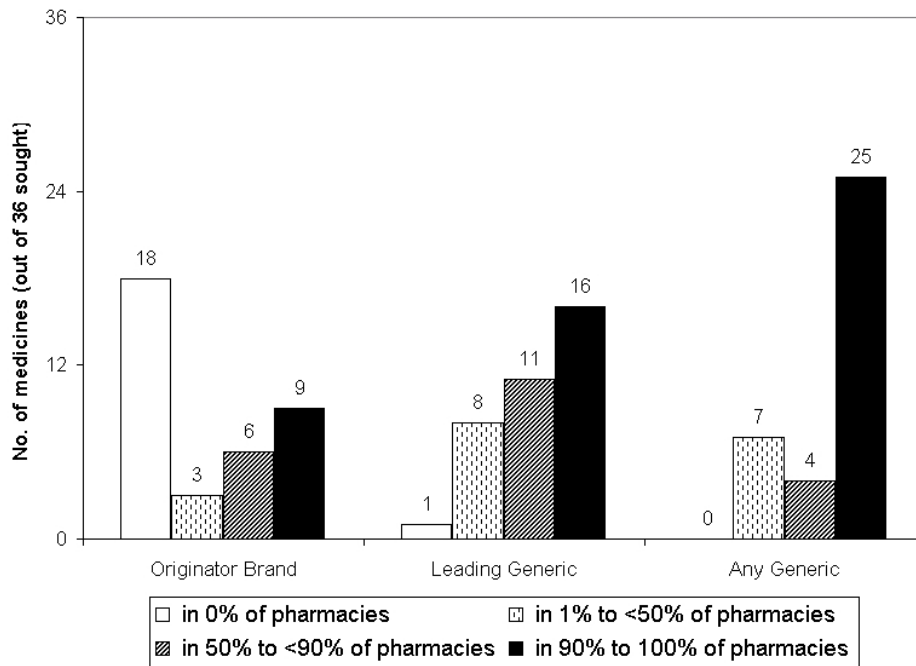
For Figure 8, Rajasthan results for each product category in the private sector have been grouped into four levels of availability. Some product versions were never found in the sector; some products were hard to find in the sector (<50 per cent of surveyed outlets); some products were seen in most places (>=50 per cent of outlets had the product in stock, but <90 per cent); and, finally, other products were almost always available (90 per cent or more of surveyed outlets). All surveyed medicines were found in the private sector in at least one version. The private sector has the widest variety of medicines. Three WHO/HAI core medicines not found in any version in the private sector nor were also not found in other sectors, and were not included in the survey.

Half of the surveyed medicines (18) were not found in any pharmacy in their innovator brand version. But three quarters of the medicines (27) were found in their most popular generic name in at least 50 per cent of shops. Only one lead generic product could not be found anywhere. Twenty-five medicines were found in at least some generic version in at least 90 per cent of shops. These data confirm India’s status as a country with a strong generic orientation.

Predictably, the only medicines found in the public sector (not shown) were generics, and only very rarely the leading generic name (just 2 medicines, found in a minority of public outlets). Overall, availability was uneven in the public sector, and 7 surveyed medicines were found in no public outlets, mostly because they were not on the essential medicines list for local-level facilities. A third sector in the Rajasthan survey, limited-profit “cooperative” outlets (not shown), was found to have an availability picture somewhere in between that of the public and private for-profit sectors.

**Figure 8**

**Availability of 36 Surveyed Medicines in Three Market Categories: Private For-Profit Pharmacy Shops in Rajasthan, India**



*\* Jeanne Madden is a Research Fellow and Project Director at the Department of Ambulatory Care and Prevention of the Harvard Medical School*

# *-Network News-*

## **International**

### **Health Action International Statement on the Global Fund Board decision regarding medicines donations**

Health Action International (HAI) welcomes the announcement from the Board of the Global Fund for AIDS, TB and Malaria that the issue of the Fund accepting direct in-kind donations of pharmaceuticals has been dropped from their agenda.

#### **Not sustainable**

In terms of increasing access to medicines, on first consideration one might assume donations would be simple and beneficial, or at the very least not harmful. However, the details and history of medicine donations have been widely investigated, and in fact, they are often complex to manage, and in certain circumstances may even be dangerous. Overall, for poor countries struggling to address the barriers to accessing medicines for their populations, the problems and complexities associated with medicines donations are a hindrance to their efforts in developing sustainable health systems.

#### **Numerous drawbacks and restrictions**

The following objections to medicines donations are widely referenced in the literature:<sup>i ii</sup>

- Donation programs usually involve extensive restrictions, including boundaries for location, and limits on quantities, indication and duration. It is difficult, if not impossible, to ensure equity among those accessing a donation program.

- Donations must often be managed as vertical programs, thus causing more burdens to overwhelmed health systems.
- When donations are found to be undesirable or inappropriate, it is most often the receiving country left to manage the costly and labour-intensive disposal.
- Rational drug use, including the use of Standard Treatment Guidelines and Essential Medicines Lists, may be abandoned in favour of using a donated product.

- Certain medicine donations jeopardize competition from the generic industry – since there is no avenue to compete with “free” medicines, the generic manufacturers may abandon their products, thus paving way for a future monopoly for the donor company’s medicine.

### **Not reliable for the Global Fund diseases**

HAI acknowledges that various small-scale donations have been well managed by NGOs and that individuals have unarguably benefited from them. Such donations have usually been successful because of the characteristics of the affected population to be treated: within defined geographic area, and for a disease with a simple and short treatment regimen and with possibility for eradication.<sup>ii</sup> But it is clear that for the diseases the Global Funds address and treat, donations are not reliable: AIDS, tuberculosis and malaria have no borders, treatment is either long term or often needs to be repeated, and although full disease eradication may be the ultimate goal, the prospects of achieving it soon are poor.

HAI is committed to supporting our partners in understanding the merit of the Global Fund Board’s decision to drop pharmaceutical donations from its agenda. HAI encourages governments and intergovernmental institutions involved in health policy formulation to exclude donations from their policies. Access to essential medicines is a human right which can be assured for all through the creation of effective, efficient and functional health systems. These depend on strong policy, political will, and committed budget allocation -- and not on donation programs, which are by their very nature unreliable and unsustainable.

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<sup>i</sup> [www.drugdonations.org](http://www.drugdonations.org)

<sup>ii</sup> <http://www.accessmed-msf.org/upload/ReportsandPublications/492001217138/Hidden%20price%20tags.pdf>

## **EUROPE**

Wemos addresses Health Ministers of the European Union

***Wemos and its partners sent the letter, reproduced below, to EU Ministers of Health sharing with them deepest concern about recent developments within the EU single market.***

Your Excellency,

The undersigned organisations, all of which work in partnership with Wemos on issues related to health and trade, wish to share with you our deepest concern about recent developments within the EU single market.

The services sector is an important component of the European economy and a top priority on the agenda of the Dutch EU-presidency. More specifically, the Dutch Presidency aims to adopt the draft EU Directive on Services in the Internal Market. As you may be aware, this Directive aims to create a single and free EU-market for services through the elimination of obstacles for the establishment of service providers and the facilitation of cross-border service provision.

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The services sector also includes the publicly and collectively organised health sector. The availability, accessibility and quality of services provided by this sector are essential for the achievement of the highest attainable standard of health for all throughout Europe. We are concerned about the way in which this Directive may affect health for all. We therefore wish to draw your attention to the following:

1. We fear that the Directive would threaten the ability of national governments to regulate the health sector in the pursuit of (national), social and development goals, which is in line with the concerns raised around the WTO General Agreement on Trade in Services (GATS). This would undermine the ‘solidarity-based’ character of these services, and health services will become market commodities to be bought and sold purely for profit, which will endanger public health. In this respect we wish to remind you that, according to the UN Committee on Economic, Social and Cultural Rights, all signatories to the International Covenant on Economic, Social and Cultural Rights have a *duty* to regulate both public and private service providers, ensuring good quality health care, accessible and affordable at all times for all citizens.

2. It is not clear at all what the consequences of the Directive would be for public health in the EU, also in line with GATS. To start with, several fundamental *legal problems* have to be solved, one of them being the definition of what constitutes a ‘service’. In addition, far deeper insight is needed into the consequences of the *implementation* of the Directive for the health of the European populations. We are especially concerned about the consequences for poor and vulnerable groups like refugees, migrants and minorities. Only through ex-ante impact assessment studies the impact of the Directive on health can be determined.

Again, we wish to remind you that according to the UN Committee on Economic, Social and Cultural Rights, retrogressive measures taken in relation to the right to health are not permissible.

Health should be at the very heart of economic and trade policies, as health generates wealth for all. Here we identify a clear role for the EU, to ensure that trade negotiations both within the context of the single European market and within the WTO enable universal access to health care. Trade should never take precedence over internationally accepted human rights and social concerns.

That is why we call upon you, the Minister of Health, in your capacity as member of the Council of the European Union, to:

- reject the draft Directive on Services in the Internal Market in its current wording
- oppose the liberalisation of services as long as it is not clear what the consequences are for public health in general and the health situation of poor and vulnerable populations in particular
- take a similar stand during the upcoming WTO-GATS negotiations

We hope you will raise the above during the Informal Health Council Meeting on 9 and 10 September, where the issue of the internal market in services and goods is discussed.

Yours sincerely,

Dr. Nina Tellegen  
Director

On behalf of:

Acción Internacional para la Salud Bolivia (AIS), Bolivia  
Consumers Information Network (CIN), Kenya  
Corporate European Observatory (CEO), The Netherlands  
Interchurch organisation for development co-operation (ICCO), The Netherlands  
International People’s Health Council (IPHC), based in Nicaragua

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Medact, United Kingdom  
Trans National Institute (TNI), based in The Netherlands

This letter has been sent to all Ministers of Health of the EU

Cc: -EU Commissioner David Byrne  
- EU Commissioner Frits Bolkestein

House of Representatives :

- Standing Committee Foreign Affairs
- Standing Committee European Affairs
- Standing Committee Health, Welfare and Sports

## **Asia and the Pacific**

### **Closely matching INN & brand names**

An International Non-proprietary Name (INN) for a new chemical entity that is to be marketed as a pharmaceutical preparation, also known as a generic name, comes about after much deliberations and meetings with experts. It is essentially an exercise to select a single name derived from the chemical nomenclature of the active pharmaceutical ingredient and is acceptable worldwide. It is this name that is known to the industry and figures in the pharmacological texts that are referred to by the medical profession.

The World Health Organization has recently written to the Drug Controller General of India (DCGI) expressing its displeasure at some INN names being used by Indian pharmaceutical companies to be closely matching the brand names these companies have given to the respective products. The drugs pointed out by the WHO are C Grel and Logrel by Chennai-based Triton Healthcare, Oplatin of Mumbai-based Rajvi Bhagat and Sartan of Lupin Laboratories, Mumbai. While not objecting to the clash of these brand names with the INN per se, the larger objective of the WHO in ensuring safety and avoiding confusion in end-users, be it the medical profession or the ultimate consumer, should not be lost sight of. On this count, there is no doubt that Indian companies owe a lot of explanation. Perhaps, it must be with their habit of using anything that is in 'public domain.'

However, in this issue the WHO should have approached the Office of the Registrar of Trade Marks in Mumbai as the brand names are registered with the Registrar and do not fall under the purview of the DCGI. Sources pointed out that under the existing law there is no provision not to allow a particular brand name if it does not create copyright violation of any sort. Medical experts when contacted informed that if rightly used the generic stem would make it convenient to recognize the generic content of the drug.

The WHO points out that the above condition would be useful only if the full generic name is used with a prefix or suffix as the case may be citing the example of the practice by the Canadian generic firm Apotex which names its drugs with a prefix Apo to the generic name. The examples in this case are Apo-Captopril, Apo-Naproxen, Apo-Diclofenac, etc. However, in India what is found is subversion of health for commerce. Pharmaceutical companies with their eyes set on profits aggressively promote brand names rather than generic names. It is widely observed that medical practitioners across the country are seldom aware of the generic names/generic equivalents of the brands they prescribe leading to bordering on virtual malpractice. The generic names contain the vital information necessary to make right clinical decision.

It should be noted that the MNCs seldom use the generic names as a tool for branding. Viagra as a brand name is completely different from sildenafil, its generic name. The only explanation marketing personnel in pharma companies give is that their names have to be such that it is easy for doctors to remember. This is indeed true, but many doctors in this country are so used to Indian companies

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playing around with the generic names that one wonders how many of them really keep track of INN or generic names.

It is not that one cannot come out with excellent brand names derived from generic names. There have been instances when Indian companies have done so, but these are far and few between. But the general norm is to drop or add a letter or stem here or there to come out 'pronto' with a name. One cannot hide the fact that there is a general paucity of ideas and creativity in the marketing or medico-marketing departments of Indian companies.

And there is the need to rush to register and market because of too many players in the market. Two different companies branding roxithromycin and rofecoxib with similar sounding names can confuse the pharmacist who will dispense an antibiotic in place of a non-steroidal anti-inflammatory drug (NSAID). There are instances galore and an entire report can be done on such names. The WHO is perfectly justified in raising concerns of safety. It is another matter that it has addressed it to the wrong office. The problem is that there are too many ministries and offices controlling the industry. The Trademarks office that registers product names hardly understands pharmaceuticals, leave alone the finer nuances. As long as people without knowledge of drugs continue to hold high offices, safety will continue to be compromised.

The World Health Organisation collaborates closely with INN experts and national nomenclature committees to select a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical. To avoid confusion, which could jeopardise the safety of patients, trade-marks should neither be derived from INNs nor contain common stems used in INNs.

**Source: *Express Pharma Plus*, 1 July 2004**

WHO/SEARO letter to the Drugs Controller General India regarding protection on International Non proprietary Names (INN)

Dear Mr Kumar,

We have been informed of the following applications for trade-mark registrations in India:

C Grel	No. B1130564	Triton Health Care, Chennai 60030
LOGREL	No. 1132917	Triton Health Care, Chennai 60030
OPLATIN	No.B1182221	Rajvi Vipul Bhagat, Mumbai 400 019
SARTAN	No. 825986	Lupin Laboratoies, Mumbai

C Grel and Logrel contain the INN stem "-grer" for platelet aggregation inhibitors. Platin is very similar to the INN "*oxaliplatin*" published in List 27 of recommended INN and is identical to the INN stem "*platiri*", a stem for antineoplastic agents, platinum derivatives. Sartan is identical to the INN stem "*sartan*" a stem for angiotensin II receptor antagonists, antihypertensive (non-peptidic). The registration of C Grel, Logrel, Platin and Sartan is particularly harmful as there are 17 INN ending in "-gre/", 18 INN ending in "*platin*" and 17 INN ending in "*sanan*" It is, therefore, important that such well-established stems should not be allowed to be used in or as trade-marks. Anything your administration can do to prevent the registration of trade-marks similar to INN, or including well-established stems, would be greatly appreciated. On the other hand WHO has, of course, nothing against the commercial use of the INN as a non-registered product name alone, or combined with other letters or numbers. In fact, this is also emphasized in the resolution *WHA46.19*, adopted by the World Health Assembly in May 1993, a copy of which has already been sent to you previously.

Yours Sincerely  
Dr Balocco Mattavelli  
INN Programme

## Rational drug use in China: lessons learnt through introducing antibiotic guidelines to surgeons - by Yan Zhang & Ken Harvey

Dr Yan Zhang, a doctoral student at the School of Public Health of University of La Trobe along with Dr Ken Harvey, Senior Lecturer, School of Public Health of the same university have recently completed a study (to be published soon) based on the experience of introducing antibiotic guidelines in a general teaching hospital in Beijing, China. Objectives: This article is aimed at introducing locally acceptable hospital guidelines for antibiotic surgical prophylaxis, including both principles and specific recommendations for particular surgical procedures in a general teaching hospital in Beijing, PR China. The research also involved interviewing a range of people from the government drug committees and the Ministry of Health about factors involved in rational drug use in China.

The methods employed for the study were as follows. A 1200-bed general teaching hospital, a high status teaching institution and a powerful medical organization in Beijing were chosen while qualitative methods (interviews and focus groups) were used to gather opinions, attitudes and the responses of both high level informants and junior surgical staff about factors influencing antibiotic use.

The study revealed that antibiotic use in a large hospital is influenced by various factors. A major problem is the perverse effect of government policy which expects hospitals to support themselves largely through the sale of drugs. In addition, prescribers had particular personal and social perspectives such as insufficient knowledge, low status, concerns about litigation by patients and excessive reliance on information from the pharmaceutical industry, all of which shaped their attitude towards rational antibiotic use.

In conclusion the study stated that we have started on a long journey that includes the need to set up a more authoritative system for distilling therapeutic guidelines, augmenting and monitoring their impact with education campaigns and drug utilization studies and, ultimately, improve national medicinal drug policy and reform the funding of Chinese hospitals. Last, but not least, there is a need to link with international colleagues because all the countries face the same problems and all can learn from each other.

*Source: Abstract of Yan Zhang and Dr Ken Harvey's publication titled, "Rational drug use in China: lessons learnt through introducing antibiotic guidelines to surgeons"*

### Traditional Medicines in Kiribati

The Republic of Kiribati, situated on the equator in the Pacific Ocean, is made up of about thirty islands. Although these islands are widely dispersed, their vegetation is similar. They are all atolls, inhabited by people who all speak the same language and make up the Kiribati nation. Management of resources like traditional medicines under these geographic conditions would seem almost impossible. However, the Republic of Kiribati is establishing a system to develop and protect their practices and resources. The aim is to harmonize traditional medicines practices throughout Kiribati and set them within a formal structure enshrined under the Traditional Medicines Act.

From 9-11 August 2004 a workshop to address the above issues was held in Tarawa for traditional healers and community leaders from all islands along with health practitioners and Health Ministries. The Traditional Medicine sector is administered by:

**1. The Traditional Medicine Federation**, which includes among others, the Director of Public Health, a Pharmacist and a Representative from the Attorney General's Department. This body registers persons to practice, negotiates standards of practice, restricts and regulates practice, approves

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courses, supervises examination of persons seeking registration, keeps the register and produces a certificate. The Federation may strike off or suspend practitioners who contravene conditions of practice or it can impose conditions, and reprimands as needed.

**2. The Traditional Medicine Tribunal** which is a body for appeal concerning decisions made by the Federation. The Traditional Medicines sector in Kiribati provides an excellent example of intersectoral collaboration. As well as its close relationship with the Ministry of Health the Federation works collaboratively with many other Ministries. The Ministry of Agriculture has developed a garden where registered traditional healers can acquire seeds and advice. Research is undertaken on different species and the conditions in which they grow in order to improve crops and yield. Species with high levels of medicinal ingredients that produce good seeds are favoured.

The Ministry of Foreign Affairs (MFAI) and Immigration collaborates closely with the Federation because it is necessary to monitor the activities of researchers and travellers. It is required that researchers provide evidence of their own government support before they can apply to the MFAI for a permit to undertake research on medicinal plants in the Republic of Kiribati, or to travel to outer islands. When applying to the MFAI for a permit, a researcher must describe proposed activities and explain how they will benefit Kiribati. The MFAI checks the purpose, duration of stay and dates of arrival and departure. If the MFAI is satisfied, after consultation with the Ministry of Health and other relevant Ministries, e.g. Environment, Agriculture, Marine Resources, a fee will be paid and a permit issued. However, if the Ministry of Health requires research, that Ministry does not need to consult the MFAI.

Because the Federation is concerned that decisions could be made at the top, with insufficient consultation with relevant community people, a sub-committee will be formed to ensure adequate consultation with, for example, traditional healers, their communities and with fisheries, environment, lands and agriculture departments. The Ministry of Internal Affairs is involved because they are the peak body for the Island Councils – local government bodies of individual islands – and each island has a Traditional Medicine Committee registered by the Island Council. The committee members are from within the community.

The Federation acknowledges the need for registration of products to protect Kiribati ownership. It also acknowledges the need for ensuring safety and for standardization of products and dosage, which will need the involvement of professional scientists working alongside registered traditional healers. However, it has been decided that no public documentation will be published in the English language. It is recognized that the relationship between the formal health sector and the traditional medicine sector should be complementary and Kiribati may provide an excellent example from which other small nations could benefit.

*Source: Reported by Ariane Kienene, Director of Pharmacy, Republic of Kiribati and Beverley Snell, Centre for International Health, Macfarlane Burnet Institute for Medical Research and Public Health, August 2004*

## ACASH observes World Breastfeeding Week

World Alliance for Breastfeeding Action (WABA) proposed 'Exclusive Breastfeeding – The Gold Standard Safe Sound and Sustainable' as the theme for observing and celebrating the World Breastfeeding Week 2004. It envisaged to stimulate all those involved in protecting, promoting infant health and nutrition including the health professionals, government officials, policy makers and public service organizations to make sustained efforts at protecting, promoting and supporting breastfeeding particularly exclusive breastfeeding during the first six months and continued breastfeeding for 2 years and beyond along with adequate complementary feeding after six months of age.

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The tenth five year plan of the Government of India (2003-2007) also aims to reduce infant and childhood mortality and improve the health and development of infants in the range of 0-5 years. This could primarily be achieved only when the rate of exclusive breastfeeding is increased to at least 80 per cent from the present 15 per cent during the first six months and by increasing the rate of initiation of breastfeeding within one hour of birth from 15 per cent to 50 per cent and introduction of safe complementary homemade foods from 33.5 per cent to atleast 75 per cent after the age of six months.

In keeping with the above theme and goals set by WABA and the Government of India, ACASH intensified its efforts by reaching out to several community based organizations, educational institutions and the media by providing accurate knowledge and information so as to sustain safe, sound and healthy young and infant child feeding and caring practices. Not restricting and limiting its activities only during the World Breastfeeding Week (from 1-7th August), ACASH launched this campaign beginning from the end of June extending it up to almost the end of August 2004 and beyond.

ACASH lined up several activities on this theme some of which were “Breastfeeding for Child Survival” for Community Health Workers and Community Women; “Infant and Young Child Feeding Practices” for Pregnant and Lactating Women and Adolescent girls; “Maternal and Infant Health and Nutrition” for Community Health Workers, Balwadi Teachers and Community Women; “Protecting Infant Health and Nutrition” for community Women and Staff of Krupa Kendra- Jyoti Kalash, a Training Programme on Breastfeeding Management and Child Care Practices for Programme Officers and Staff of Mobile Creches of 18 Centres; “Planning for motherhood” for female students and staff of Dr. B.M. Nanavati College of Home Science; “Healthy Babies-Breastfed Babies” for Pregnant and Lactating mothers; Breastfeeding is Best feeding for female Students of B.M. Ruia Womens College; “Protecting Promoting and Supporting Breastfeeding” for Women Construction Workers; “Caring for maternal and child health and nutrition” for Visually impaired women and staff of National Association for the Blind; a Training of Trainers Programme on Breastfeeding management, complementary feeding and child care practices for NSS Student leaders affiliated to various colleges of SNDT University.

*Source: ACASH (Association for Consumers Action Safety and Health) 2<sup>nd</sup> Floor, 417, S V P Road, Girgaum, Mumbai 400 004, India*

## **Latin America**

### **Access to Medicines and Free Trade Agreements**

In July 2004, the Andean Community of Nations and the Andean Health Organization convened a meeting in collaboration with the Ministry of Health, Peru, the Pan American Health Organization and the United Nations Development Programme to discuss the possible implications of the Free Trade Agreement being negotiated between the United States and Peru, Ecuador and Colombia.

It is very well known that the proposal of the United States regarding Intellectual property is ADPIC PLUS (French translation of TRIPS plus), and it obliges the countries to grant: a) patents for animals and plants; b) patents for second uses of already known molecules; c) patents for therapeutics methods; d) extension of the exclusivity of patents through compensations of “unjustified delay” to grant a patent and compensation on the period it takes to get the authorization for marketing a drug; e) protection of data for at least five years.

As a result of the dialogue during the meeting, the official representatives agreed that an ADPIC PLUS would not be convenient for the Andean countries and therefore agreed to have a counter proposal to the one submitted by the United States.

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The meeting was attended by official representatives from Ministries of Health and Ministries of Commerce from Ecuador, Bolivia, Peru, Colombia and Chile as well as representatives from the private sector and civil society. It is important to note that German Velásquez (WHO-Geneva), Jose Luis Difavio (PAHO, Washington), Dr. Carlos Correa (South Centre) and Jorge Bermudez (Fiocruz, Brazil) were among the participants.

*Source: AIS LAC July 2004*

# -JOURNAL SCAN-

## **Drug Makers Deceive Doctors**

Peter (not his real name) is a physician-scientist who, a couple of years ago, was finishing his research training in Canada. Shortly before returning to his native Australia, Peter received an interesting offer. A pharmaceutical company was ready to pay Peter several thousand dollars to write an opinion piece for a prominent medical journal. Peter is smart, and a good writer. Producing the article would be a cinch. It was an attractive proposition. Well, a couple of catches. First, Peter would have to follow the company's direction about what to say. Second, when the article was published, Peter's name would not appear. Rather, a respected Senior Researcher who has conducted many studies funded by the pharmaceutical industry would get the credit.

Peter refused the offer. The company probably succeeded in finding a different, willing ghost-writer. Like all unethical practices, it is difficult to establish the size of the medical ghostwriting problem. Senior authors will never threaten their prestige by admitting someone else wrote their article. Professional ghostwriters won't embarrass their clients. People like Peter won't embarrass their colleagues. Ghost writing is a big enough business, though, to sustain companies focused on medical writing. Medical editors recognize ghostwriting as a widespread practice and have tried to tighten up their rules. Still, there is no protection against misleading or dishonest representations, and authorities suggest that up to 50 per cent of articles reporting results of pharmaceutical trials are ghostwritten. Lead authors of major drug studies may not only have done little of the writing, but their participation in the research itself may have been minimal. Company personnel may have developed the research plan, supervised the collection of the data, conducted the analyses, and written the first draft of the article.

The companies then go to prominent researchers. "Would you like to be an author, or even the leading author, on the article?" they ask. The higher the profile of the author, the better for the company. The author's prestige helps to establish the credibility of the study, and contributes to the attention that the article receives. While these extreme situations are not the most common way drug studies are reported, they merge into a grey area that is very common. Academic researchers may participate in planning the study and carrying it out, but they may never see the actual data. The company conducts the analysis, and presents the academic authors with tables that summarize the results.

A McMaster University researcher, P.J. Devereaux, has just completed a study comparing how medical scientists report their research, and what actually happens in their studies. To carry out his research, Devereaux interviewed authors over the phone, asking them detailed questions about the conduct of their studies. One lead author of a study published in a top journal had little idea what happened. He informed Devereaux that the company had completed the study, analyzed the data and

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wrote the first draft of the article. He advised Devereaux to contact the company for further information about the trial. On other occasions, Devereaux found that authors' knowledge was sketchy because their role in the planning, conduct and particularly the analysis of their studies was limited. Such situations mean that academic authors may never see important information, or that the company may present results in a misleading way. That helps to explain the findings of a recent study showing that the odds of industry-funded trials enthusiastically recommending treatment are more than five times as great as non-industry funded studies.

Biased presentations affect not on how individual doctors understand research results, but how experts who create guidelines understand the results. Worse yet, the industry exerts direct influence on those experts.

Investigators at the University of Toronto conducted a survey that included 44 guidelines designed to help doctors make decisions about diagnosis and treatment for their patients. The Toronto researchers found that 58 per cent of guideline developers had received research funding from the industry, and 38 per cent had served as employees or consultants. Fifty-nine per cent had relationships with companies whose drugs were considered in the guideline they authored.

Whether they are recruiting ghost writers, giving credit to academic authors while controlling the conduct and analysis of research studies, or providing generous funding to researchers, the industry's goal is the same. Having researchers and experts carry their sales pitch to the practising doctor enhances the credibility of the company's message.

The result is often poorer and less efficient patient care. Industry bias leads to overuse of medication, and particularly overuse of new drugs. Drugs that are recently developed and released are far more expensive. About 25 per cent of the time, these new drugs turn out to have serious side effects that are not suspected at the time they were released. On occasion, these side effects are fatal.

Doctors expect objectivity in the research reports and expert recommendations that guide their practice. Too often the drug industry ensures that bias, rather than objectivity, is what doctors receive.

*Source: Reproduced with the permission of the author and MEDICAL REFORM, Issue No 130, Volume 24, Number 1, Summer 2004. First published Tuesday, April 13, 2004 as one of Dr. Gordon Guyatt's biweekly columns in the Winnipeg Free Press.*

## **WHO Wants to Start Drug Trial Registry: Proposal to Be Made in November**

The World Health Organization wants to establish an international registry of drug trials to ensure that the public finds out when medications do not work, as well as when they do.

Pressure has been growing on pharmaceutical companies to fully disclose details of all clinical trials, not just those that support the use of their products. WHO officials said an international database, which would be modelled on registries in the United States and other countries will be proposed to National Health Ministers at a meeting in November.

Full disclosure has gained momentum with the recent report that drug companies had not published the results of tests of antidepressant drugs that showed they were ineffective in treating children. Authorities say there is a similar bias against publishing negative results across all of medicine, with the result that the medical literature presents too rosy a picture about many drugs.

"When you go to do a systematic review, not all the data is out there in published form," said Kay Dickersin, Director of the U.S. Cochrane Center, which periodically reviews the evidence for various medical treatments. "If what is unpublished is systematically negative, we have a problem with our knowledge base," she said.

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Metin Gulmezoglu, a Scientist at WHO's special program for research in human reproduction, said officials have not yet worked out how to enforce compliance with a global registry.

Individual governments have struggled for years to create registries. A recent report by the U.S. Food and Drug Administration found that many privately funded trials were not being registered as required with the U.S. registry created by a 1997 federal law, ClinicalTrials.gov.

The information that can be gleaned from registries is limited because none includes results of the trials or details of drug side effects. But experts say knowing the total number of trials can help researchers evaluate the merits of published studies.

"You look up all the trials, and say numbers one, eight, nine, seven were not published," said Drummond Rennie, a Deputy Editor at the Journal of the American Medical Association. "You can say every [published] trial we have shown that it works, but in 112 trials we have no answer, so we know it does not work."

Editors of several medical journals recently called for a trials registry.

Some companies have said they are amenable to disclosing the existence of trials. A registry could help avoid duplicating failed efforts and reduce the risk to volunteers and the cost of developing new drugs. But companies are also concerned that disclosure could endanger trade secrets.

Critics say drug makers want to keep doctors and patients from getting the true picture about some medications because sales and profits could be affected.

While the current proposals call only for the registration of tests of a drug's effectiveness, Connie Ojile of Arlington said registries ought also to list safety studies -- known as Phase 1 trials -- to help desperate patients such as herself. Ojile, 53, has a form of leukemia that has no current treatments. By chance, a doctor in New York recently told her about a Phase 1 trial in Texas that even Ojile's regular oncologist did not know about.

"I want to get the drug as soon as possible" even if its effectiveness has not been shown, she said, explaining that her cancer could quickly escalate and kill her. "Phase 1 can last six months, a year or 18 months. It's in my best interests as a patient with death on her shoulder to say, 'I'll try that.' What are my options?"

*Source: Posted on Druginfo on July 8 2004. Originally by Shankar Vedantam, Washington Post Staff Writer, July 8, 2004; Page A03. You could also access it on <http://www.washingtonpost.com/wp-dyn/articles/A35253-2004Jul7.html>*

## **New molecule offers hope for faster TB cure**

Indian researchers have discovered a new molecule that they say could lead to a faster cure for tuberculosis (TB). They have applied for clearance to perform human clinical trials on the potential drug and for patents both in India and in the United States.

The molecule has been tested in rats and in guinea pigs, where it reduced the normal treatment time of six to eight months to just two months. In addition, it was found to be effective against all known drug-resistant strains of the bacterium that causes TB.

Indian Science Minister Kapil Sibal announced the results in September 2004. Raghunath Mashelkar, Director General of the Council of Scientific and Industrial Research (CSIR), who participated in the study, says this is the first time in 40 years that a TB drug candidate has shown

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promising results in animal studies.

Mumbai-based Lupin Laboratories identified the new molecule in 2001. In subsequent cell-based and animal studies, researchers found that it significantly reduced numbers of TB bacteria. When given in combination with other TB drugs, it cleared TB bacteria in animal lungs and spleens within two months.

Over the course of six months, the scientists found no evidence that the bacteria developed resistance to the drug. The researchers observed no adverse effects on tested animals whether the molecule was given in single or multiple doses, and a single oral dose given daily was effective.

The proposed human trials would study whether the molecule could work as a stand-alone drug, or substitute one or two components of the present four-drug cocktail, says Sudarshan Arora, of Lupin Laboratories.

The current anti-TB treatment lasts six to eight months and is effective only in an uninterrupted schedule. In many resource poor countries, patients often skip their doses, which makes multiple drug resistance more likely.

Some 1.6 billion people (almost one-third of the world population) are infected with TB, with eight million new cases occurring each year. The current global market for TB drugs is estimated at US\$600 million.

A consortium of 12 government research institutes and universities joined Lupin Laboratories to develop the molecule. They included three CSIR laboratories: the Central Drug Research Institute in Lucknow, the Indian Institute of Chemical Technology in Hyderabad, the National Chemical Laboratory in Pune, and the University of Hyderabad.

*Source: SciDev.NET. To access this article please click on SCIDEVNET*

<http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1596&language=1>

## **GLAXOSMITHKLINE grants a fourth voluntary licence for the manufacture and sale of hiv/aids medicines in AFRICA**

GlaxoSmithKline (GSK) announced further action to help tackle the HIV/AIDS pandemic in Africa. GSK has granted a voluntary licence under its patents to Cosmos Limited, a Kenyan pharmaceutical company, for the manufacture and sale of antiretrovirals (ARVs) containing zidovudine and/or lamivudine in the public and private sectors in Kenya and other countries in East Africa. GlaxoSmithKline currently sells zidovudine (sold as Retrovir®), lamivudine (sold as Epivir®) and the combination of the two molecules (sold as Combivir®) across the region.

GSK is one of the world's leading manufacturers of ARV medicines and has been instrumental in efforts over the past few years to improve access to ARV medication through its preferential pricing programme which is in operation around Africa and in the other developing countries. Furthermore GSK is the industry leader in HIV Research & Development, bringing to market newer and more effective medications for treating HIV disease.

Cosmos produces quality drugs on the WHO essential drugs list to meet the healthcare challenges in Kenya and throughout the region. Under the terms of the agreement Cosmos is granted the right to manufacture and distribute ARVs in Kenya, Uganda, Tanzania, Burundi and Rwanda. Cosmos will obtain all appropriate health registrations, permissions, consent and regulatory authorizations relating to the manufacture and sale of the product. As a major supplier of essential drugs to various medical institutions, Cosmos is well placed to provide ARVs in the region.

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“This announcement amplifies GSK’s long-standing and continuing commitment to improve access to medicines in developing countries – a commitment the company is very proud of and will maintain far into the future,” says Andrew Bulloch, General Manager: Pharmaceuticals, GSK East Africa. “We are pleased that another local healthcare company will play a significant role in addressing the HIV/AIDS crisis.”

To facilitate the distribution of reduced-price product in relation to this voluntary licence, Shire Pharmaceuticals Group plc, which has a Master Licence agreement with GSK, has agreed to waive or reduce its rights to royalty payments from GSK for products containing lamivudine.

The above licence is GlaxoSmithKline’s fourth voluntary licence granted to African generics companies for the sale of some of its antiretrovirals in Africa. The other three licences which cover Sub-Saharan Africa were granted to Feza Pharmaceuticals, Aspen Pharmacare and Thembalami Pharmaceuticals (Pty) Limited.

*Source: Press Release Galxo Smithkline, 22 September 2004 posted on IP healthon 23 September 2004*

## - Resources -

### **Therapeutic Guidelines: Dermatology – Version 2 to manage skin diseases successfully**

**Published by Therapeutic Guidelines, Melbourne, Australia**

**Number of Pages: 410**

Therapeutic Guidelines Dermatology Version 2 is published and distributed by Therapeutic Guidelines Ltd, a not-for-profit independent organization in Australia and it is one in a series of many publications covering almost all common disorders seen in general practice such as Therapeutic Guidelines on Analgesic, Antibiotic, Cardiovascular, Endocrinology, Gastrointestinal, Neurology, Palliative Care, Psychotropic and Respiratory. These guidelines have been designed to assist prescribers’ in ensuring that patients receive optimum treatment since the first publication of Therapeutic Guidelines on Antibiotics in 1978. Dermatology version 2 of these guidelines very rightly opens with the lines below regarding its aim, “The aim of Therapeutic Guidelines Ltd is to provide clear, practical, authoritative and succinct therapeutic information for busy health practitioners for the management of patients with specific conditions.” The publication from the very outset provides key information about the process of preparing the Therapeutic Guidelines, choosing topics, forming expert groups, management of the guidelines, inaugural meeting, formulating and revising of the guidelines, basis of recommendations, external preview and endorsement and post publication evaluation.

The preface to Dermatology Version 2 opens with, “the skin is the biggest organ in the body and the most visible.....skin diseases cause patients considerable physical, psychological and social distress”. In an age where skin diseases are more than banal the two volumes of Therapeutic Guidelines - Dermatology are more than timely and resourceful. Undoubtedly, they provide important, practical guidelines for management of common skin conditions for these guidelines are thoroughly reviewed and updated by an expert writing group and with specialist input on burns, cosmetic dermatology, leg ulcers, wound healing and oral lesions. The preface also states that “assisted by these guidelines, many skin diseases can be successfully managed by the general practitioner”. However, at instances where complex dermatology diseases that do not respond to standard treatment one must seek the attention of a dermatologist and the above publication could then serve as a second opinion for the doctor.

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The content page reveals that this publication strikes a good balance between hair, skin and nail diseases that have been covered so far. Blistering disorders, acne, burns cosmetic dermatology, hair disorders, infestations and bites, pigmentation disorders, nail disorders, oral lesions, pregnancy rashes are some chapters from the thirty two chapter publication. However, a skim through this easy-to-comprehend publication reveals that although it is designed to advice medical professionals a lay person could enlighten herself/himself by reading it since it employs simple diction and style.

*The publication is available from Therapeutic Guidelines Limited, Ground Floor, 23-47 Villiers Street, North Melbourne 3051, Australia. Telephone: +61 3 9329 1566, Facsimile +61 3 9326 5632*

## **Dealing with International Migration, Health and Human Rights**

**Published by the World Health Organization**

**Number of pages: 36**

**Price: 10 Swiss francs (9USD) AND 7 Swiss Francs in developing countries**

“The work of the World Health Organization is guided by the principle that health is a fundamental human right to be enjoyed by every human being without discrimination. Vulnerable and marginalized population groups require priority attention. In the context of migration, these range from forced and undocumented migrants lacking access to basic health services to poor populations left behind by the “brain drain” as health professionals in poor countries migrate to richer ones” states Dr Lee Jong Wook, Director General of the World Health Organization in the preface of “International Migration, Health and Human Rights”. In an age where people are increasingly moving from one country to another for political, humanitarian, economic and environmental reasons this timely publication draws attention to important health and human rights issues that migration poses for health policymakers.

We note that migrants envisage several obstacles to health as a result of socio economic factors, cultural and language barriers, legal status and other discriminatory circumstances. Simultaneously, migration policies could result in adverse public health consequences.

The publication is divided into four chapters. Chapter one titled, “Introduction to migration, health and human rights” explains the motive behind addressing the issue of migration and health through a human rights framework and discusses the magnitude of and reasons for migration. The second chapter on “Health implications for those left behind” focuses on “brain drain” and at this instance draws special attention on migrating of health professionals. “Health implications for those on the move” which is chapter three refers to both public health as well as the health of the individual and takes into consideration the various ways in which migration is managed. The fourth and final chapter “Health and human rights of migrants in the host country” gives considerable amount of thought to health and human rights issues of migrants once they are in the host country addressing some of the vulnerable categories of migrants and highlighting some key challenges by promoting and protecting their health. The conclusion ends with the following statement, “We are far from the required paradigm shift towards treating migrants as ‘global citizens’ and ‘rights-holders’ regardless of where they are coming from and where they are going. Such a paradigm shift will take time, dialogue, accurate information, good will and above all political will. This report represents only a small step in this direction”.

The final outcome of this “small step” in the direction of treating migrants as global citizens and rights holders undoubtedly serves to emphasize important human rights principles by which

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governments, policy-makers and other actors can design and implement health policies and programmes in the context of migration.

**To obtain a copy please contact WHO Marketing and Dissemination, 1211 Geneva 27, Switzerland. Tel: +41 22 791 24 76/ Fax: + 41 22 791 48 57/ Email: [publications@who.int](mailto:publications@who.int)**

## **The World Medicines Situation**

When WHO released its landmark "World Drug Situation" report in 1988, it caused an uproar. Now, 16 years later, its successor, the "World Medicines Situation", has silently been released on the WHO/EDM website: [http://www.who.int/medicines/library/theme/theme\\_sup.shtml](http://www.who.int/medicines/library/theme/theme_sup.shtml)

The World Medicines Situation (available as pdf download - 1052KB – see [http://www.who.int/medicines/organization/par/World\\_Medicines\\_Situation.pdf](http://www.who.int/medicines/organization/par/World_Medicines_Situation.pdf)) provides an accessible source of information on the pharmaceutical situation at global and national levels. It assembles the available evidence regarding the production and consumption of medicines, and a range of issues in national medicines policies, including the level of people's access, patterns of use, the challenges of medicines regulation and promoting rational use. Numerous different sources of data are used. A 32-page annex of statistics is included.

The introduction of the 145-page report states:

"This second review of the world medicines situation (first published in 1988 as The World Drug Situation) presents the available evidence on global production, research and development, international trade and consumption of pharmaceuticals. In addition, it draws on the most recent surveys and studies in WHO Member States to examine the state of national medicines policy. The aim is to provide an easily accessible source of information on the pharmaceutical situation at global and national levels.

Although the text is based on and around the available data, these data pose several challenges. For example, reliable data on the large pharmaceutical markets in the world's most populous countries, the People's Republic of China and India, are in short supply. Trade, production, expenditure and consumption data all come from different sources.

In addition, the use of monetary values, rather than an indicator of volume, gives a distorted picture of production and consumption since it fails to reflect the scale of global consumption of traditional medicines and low-priced generics (both branded and non-branded).

Another problem is that certain key terms, such as "generic" medicines, are used differently by different parties, and usage is also changing. While 10 years ago the term "drugs" was widely used by WHO and other agencies, in today's usage this seems too vague and inclusive, and is increasingly understood to refer to illicit substances. As a result, the term "pharmaceuticals" is now increasingly used (meaning both medicines and vaccines) or alternatively "medicines". All three terms are used in this report, with explanations given when needed, and this is reflected in the change in title from the 1988 report.

Meanwhile, the pharmaceutical industry itself is difficult to define. Its products extend from first aid and cough remedies which are on sale to all, to highly specialized medicines for use only by hospital specialists. Some definitions bundle veterinary medicines and vaccines, bulk ingredients, medical devices and diagnostic products with finished pharmaceutical products. The Standard International Trade Classification (SITC Rev 3) distinguishes pharmaceuticals from medicaments and itemizes 57 four- and five-digit sub-items of these two commodities. Within these classifications the main focus of this report is medicines for human consumption, including those available only on prescription and those which can be purchased over the counter. However, in Chapters 1 and 3, the broader industrial and trade classifications are used.

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The manufacturers of pharmaceuticals are numerous and diverse. At one end of the spectrum are the many firms of all sizes which collect and process herbs and medicinal plants for use in traditional medicine. No data are available on the volume of products involved. At the other end of the spectrum are large, 'integrated' transnational corporations, with the capacity to develop new molecular entities and to manufacture, market and distribute medicines to most parts of the globe. Situated in between is a wide range of manufacturers differing in size, the kind of pharmaceuticals produced and in manufacturing and marketing techniques. In India, for example, 20 000 pharmaceutical manufacturers have been inventoried, but only 250 of these are in the 'organized' sector, and they account for 70 per cent of the country's total output of branded generics. Elsewhere, China's rapidly growing pharmaceutical industry has an estimated 7500 manufacturers but, according to one source, only 87 of these have internationally accepted Good Manufacturing Practice certification.

Finally, the pharmaceutical markets of the high-income countries differ widely from those in developing countries. Not only is per capita spending on health and medicines many times higher in high-income countries, but a much greater share of the medicines bill is publicly subsidized. In the lowest-income countries, spending on medicines comes largely from household resources and has to be paid for out of pocket at the time the person is ill. Markets also differ in the extent and effectiveness of regulation in areas such as medicine prices and safety. This report therefore covers a wide range of different products from multiple and varied sources, prescribed, purchased and consumed in very different domestic contexts.

The report does not attempt to deal in a comprehensive way with a number of key policy issues in medicines policy, such as parallel trade, intellectual property rights, counterfeiting, or corporate pricing strategy, around which vigorous debate continues at both the national and international level. Whilst WHO's concerns and policy positions are made clear at relevant points in the text, our primary aim is to provide an up-to-date set of basic information on the global medicines situation and on the current status of national medicines policies. It is hoped that these data will serve as a useful set of reference material for analysts, researchers and others concerned with the global pharmaceutical situation."

*Hard copies of the "World Medicines Situation may be obtained from [edmdoccentre@who.int](mailto:edmdoccentre@who.int) (quote WHO/EDM/PAR/2004.5)*

### **HAI Europe gives its website a newlook**

On September 17, 2004 HAI Europe launched its new website at the Annual General Meeting. The new website is user friendly, contains up to date information and is a useful tool for sharing information about HAI's major projects and current issues. You can check out the new site at [www.haiweb.org](http://www.haiweb.org).