



Final Report of

**Health Action International Asia-Pacific's
8TH REVIEW AND
PLANNING MEETING**

29th and 30th, The Tamarind Tree Hotel, Minuwangoda, Sri Lanka.

DAY ONE

Book Launch- Where There Are No Pharmacists

The proceedings of the meeting began with the national anthem and lighting of the traditional oil lamp.

Ms. Beverly Snell presented the first book to Prof. Qassem Chowdhury, Chairperson of the HAIAP Governing Council.

In developing countries health workers who are not pharmacists are doing the work of managing medicines in formal and informal settings. Managing medicines includes ensuring a supply of the right medicines, storing and caring for them and helping people to use them well. There are so many aspects of managing medicines. HAIAP initiated the project "Where there are no pharmacists" to draw the knowledge of the members together into a book that could be used as a resource for health workers or for teaching. Sarah Andersson, a younger pharmacist with experience and enough time, was entrusted with making the story. She communicated with contributors all over the world who are listed in the front of the book. HAIAP coordinated the process and developed a final product. Ms. Snell extended her gratitude to Dr Bala for his patient and caring support and to Dr Jayabalan, Professor Izham, Mr Rajamoorthy, Shila Kaur and the Third World Network Team in Penang who made the final production possible.

Dr. Bala shared a few words about the process of compiling the publication and introduced Mr K G Jayasuriya representing the Pharmaceutical Association of Sri Lanka to the audience.

Mr. K G Jayasuriya shared an overview of the book and its importance in using the publication in Sri Lanka, especially in the rural areas where there no trained pharmacists.

Initiation and evaluation of a University Based Pharmacovigilance program involving consumers in Malaysia- Prof M. Izham M. Ibrahim

Medicines treat illness but could also cause harmful effects. Medicines safety is a concern for healthcare professionals, regulatory authorities, drug companies, consumers and others. Consumers are often neglected in both developed and developing countries. The National pharmacovigilance program has existed in Malaysia for the past 20 years. There is also mandatory reporting for pharmaceutical industries and voluntary reporting for professionals. However, consumers play a minimal role in adverse drug reaction reporting in Malaysia.

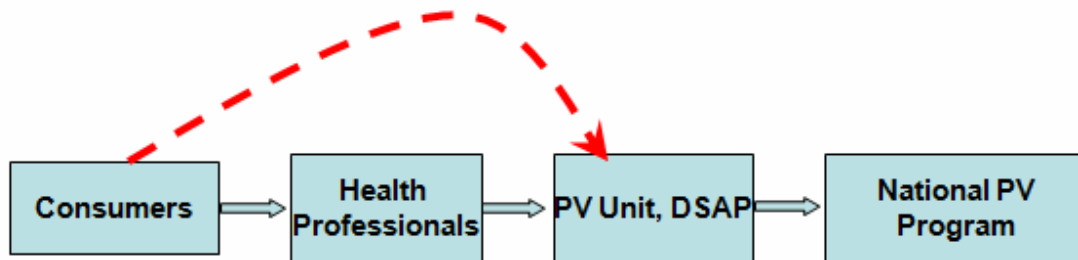
Initiation of consumer reporting program in USM, Penang

Universiti Sains Malaysia (main campus) has a Wellness Center, with four doctors, one pharmacist and approximately thirty health staff. The center treats around 1800 employees around, 20,000 students, retirees + dependants. The center also collaborates with the National

Poison Center, Medical School (Health Campus) and Pharmacy School. The consumer reporting program was initiated at USM to achieve the following objectives:

- To involve consumers in medicine safety program of Malaysia
- Enrich consumers with the importance of medicine safety
- To link consumer reports to National program

The proposed model for the Consumer Pharmcovigilance program



The following preliminary steps were followed to establish the Consumer Pharmcovigilance program-

- Baseline KAP of consumers
- Baseline KAP of Health professionals
- Intervention for HCP
- Intervention for consumers

Patient education material such as a brochure for patients, a poster titled, 'Advantages and disadvantages of medicine and poster titled, 'know your Medicine' were published to initiate the program. This program was established due to the existence of a multicultural community, considerable volume of patients, Manpower, experts, financial & other resources.

Networking and collaborations

The center is planning to collaborate with consumer groups, Ministry of Health and HAIAP member countries in the future.

Future plans

- To establish a panel of experts to review the cases.
- To develop a Standard Operation Procedure.
- Intensive research on related areas e.g. consumer willingness, consumer empowerment, economic impact, barriers in ADR reporting by consumers
- Development of novel education modules for consumers in developing countries on ADR reporting
- Strengthening the National PV program in Malaysia through consumer reporting (University-based PV Program for Consumer Reporting)

National Workshop on Pharmaceutical Policy and Access to Essential Medicines- Sulagna Dutta, CDMU West Bengal

The workshop has been organized to discuss the following points:

- The important factors which affect access to medicines in India, where resources are limited, market are flooded with irrational medicines.
- Policy changes in India during the past two and a half decades have far reaching consequences for issues related to access, availability, affordability and quality of essential medicines.
- The Government proposed changes to the pharmaceutical policy in 2005 which was shelved due to strong pressure from Industry lobbying.
- Prices of medicines, promotional practices of the pharmaceutical industry also have an impact on affordability in India.
- Issues affecting people working in the field of healthcare both in urban and rural areas with special focus on poor and marginalized living in un-served and underserved areas facing problems related to availability and affordability.
- Lobbying and advocacy for people-friendly pharmaceutical policy is essential.

Objectives of the workshop:

- Discuss multiple chapters relating to policy for developing definite conclusions.
- Develop recommendations towards formulation of a comprehensive Pharmaceutical Policy
- Use the recommendations as campaign tools through the participating organizations
- Pursue the recommendations with Ministries concerned with Pharmaceutical policy
- Publish papers presented in the workshop

Workshop Summary:

Five years after the Kolkata Declaration was adopted, some of the recommendations in the declaration were adopted in principle by the Government of India, but they had not been implemented in earnest. As much as 65% of the country's population still did not have access to essential medicine, although India is the fourth largest producer of pharmaceuticals in the world, exporting to over 200 countries.

The need to address this irony, inculcating changes over the five years, and contribute to making good drugs regularly available especially to the low-income majority, became the focus of a "National workshop towards a pharmaceutical policy in India in the changed perspective". It was held in Kolkata on February 19-20 and attended by 108 delegates from all over India. Papers were presented by eminent scientists, economists, health activists and representatives from the government and drug industry.

Organized by Community Development Medicinal Unit, West Bengal, in association with Health Action International –Asia Pacific [HAI- AP] and Jan Swasthya Abhiyan (People's Health Movement, India), the workshop sought answers on how the impoverished mother, already bogged by making ends meet, could cope with the additional burden of providing medicine to her ailing child.

With disease continuing to be a part and parcel of life, preventive and curative medication is of essence, more so in an affliction-prone developing country like India. In the face of rising drug prices, the impact of Patent Act amendment on research and production, the ignoring of ethics connected with medicine promotion by companies as well as clinical drug trials and other important issues, the participants presented the latest scenarios in their respective fields and discussed threadbare ways to ameliorate the more weighted problems. Even the effectiveness and viability of costly new vaccines and the limitations of fixed drug combinations were taken up. In addition to pursuing the proposals of the Kolkata Declaration, the National Workshop concluded with the consensus to take up a further set of solutions towards essential drug availability in terms of cost, quality and regularity. In the light of recent trends witnessed over the country, rational prescription and consumption of medication was also stressed on. A new look at drug pricing vis a vis recent and improved formulations was called for.

It was suggested that the think-tanks and lobbies concerned focused on the government in a bid to hone national pharmaceutical policy, making it more practicable and efficient towards the common objective. On the other hand, the lobbies and pressure groups would also be activated to get the pharmaceutical industry be more involved in maintaining and increasing social commitments while toning down profit motives. A major thrust was emphasized on the proper implementation of existing rules and regulations relating to drug pricing, production and distribution, where it was seen that even a 30 per cent extra push would mean a lot. The need to curb the growth of irrational medications was also proposed, while keeping a watch on emerging commercialization of Indian System of Medicines. All the recommendations were reached keeping in mind recent available data on need and consumption trends.

Conclusion & recommendations:

Prices of Medicines – all essential medicines should be under price control so that it can be available at affordable price to the people. The Jan Ausudhi is an important step by the government but it may be complimentary steps for making free medicines available.

Irrational Medicines – these medicines should identify and banned without delay. To understand the problem government should make a mechanism of prescription audit of both public and private healthcare facility.

Provision of Medicines to Universalize Access - We demand that a plan be set in motion immediately, which ensures that all essential medicines be made available in public health facilities. The central should promote the effective system in Tamil Nadu and others states in procurement process across the countries.

Issues Related to Intellectual Property –

- Public health safeguards such as the use of compulsory license should be used liberally to safeguard public health No TRIPS Plus measures to further strengthen IP protection - either as autonomous measures or through FTAs The Government needs to defend its own Patent law and resolutely fight the legal challenges being mounted by MNCs
- The Drug Registration mechanism should not be allowed to act as the Patent “police” safeguarding interests of private companies
- The Indian Govt. should reject the attempts of WHO to criminalize generic drug production through WHO’s initiative on “counterfeit” medical products.
- Government should establish institutional mechanism to monitor impact of access on patented medicines and ensure access to those medicines.
- Patent office should take steps to ensure transparency in its process of granting and maintenance of patents

Promotion of Medicines – the recent move by the government was welcomed. We also propose that we shall develop a model Code for ethical marketing practice, as an advocacy and campaign tool.

Medical and Pharmacy Education – the curriculum should address issues related rational use of medicines. Pharmacy curriculum should include medical stores management

Quality Control Standards – the regulation for implementing GLP and GMP should be there but that should not add burdens on small and medium scale manufacturers. While not compromising with quality, judicious use of GMP and GLP guidelines need to be ensured

Vaccines Use in the Public Health System – We welcome the recent government notification of restoring manufacturing licenses to the three PSUs, who had been asked to discontinue production. Several new vaccines are now sought to be introduced into the public health system. Their introduction needs to be supported by robust scientific evidence and detailed evaluation regarding costs and benefits. We demand an enquiry into the ongoing HPV vaccine administration program, being conducted among poor adolescent girls in Gujarat and AP.

Public Funding of Research - There is need to harmonize public sector research with national priorities; to harness private sector capabilities within the framework of such priorities; and to

monitor FDI flows in R&D. To address these concerns we demand of the Government to introduce legislation on health research in Parliament.

Promotion of Nutraceuticals – The pharmaceutical companies promote nutraceuticals as wide-spread problem of malnutrition which is unethical and harmful. We demand the following in this context. Drugs should not be; literally and figuratively, mixed up with food products. Standards need to be set to ensure that production of therapeutic food allows the maximum possible community participation and decentralization. There should be zero tolerance for conflicts of interest in policy making on technological interventions in malnutrition that involve manufacture through companies.

Unethical Clinical Trials - The Government has encouraged clinical trials by allowing concurrent same phase trials in India. There is extensive evidence that regulatory measures are being circumvented in the conduct of many such trials. Many of these trials also target women, especially poor women who are vulnerable. We demand that the regulatory mechanism on clinical trials be strengthened and all clinical trials be monitored by an authority with statutory powers.

Indian Systems of Medicines - There is evidence of creeping commercialization in the manufacture, marketing and promotion of products of Indian Medical systems. There are very few regulatory controls on this growing industry. It is necessary that medicines of ISM, which are being promoted in the same manner as modern medicine, be the subject of similar kinds of scrutiny and control as is the case for modern medicine.

Issues in Biotechnology - The workshop notes the tremendous developments taking place in genomic research and the possible positive implications on public health and the possibilities opened up for the generation of biomedicines that can tackle many health problems more effectively and efficiently. Peoples Science and Health Movement groups and socially committed experts and scientists need to discuss both the positive and negative impacts of the ethical, social, political and economic implications of the genomic revolution. We also demand the following:

- Patenting of life forms including all forms of genetic materials should not be permitted.
- The government should take all efforts to control the prices of new generation biomedicines
- The National Biotechnology Regulatory Authority Act should not be finalized in haste, and should be preceded by a public debate to address diverse concerns. Such an Act, by no means, should include provisions to muffle genuine voices of concerns as regards biotechnological products.

Conflict of Interest - There are several instances where regulatory bodies related to various aspects of the pharmaceutical sector, include people with clear conflict of interest. We demand that all regulatory bodies be purged of people with conflict of interest, and further that in future all members of such bodies be scrutinized for conflict of interest before inclusion in such bodies.

Medicines Financing mechanisms & some relevant Socio Economic factors of Sri Lanka: Sandunika Peiris, Research Intern

Health is a state of optimal physical, mental and social well being and not merely the absence of disease or infirmity. Health is a fundamental human right; we should ensure that everyone receives equal access to health care. At present, almost 2 billion people, 1/3 of the global population, do not have access to essential medicines. The main reason for this is the lack of affordability and availability.

Health Expenditure

The total health expenditure refers to the;

- Expenditure on health goods and services –this includes expenditure on health services (medical treatments and diagnosis), health goods medications, aids and appliances), and other health services such as expenditure on public health, research and administration, and
- Health-related investments.

In 2006, the total expenditure on health goods and services and capital formation in Sri Lanka was estimated to be Rs.117.9 billion. This showed an increase of Rs.21.4 billion over the preceding year, which is a 22% increase in nominal terms. Only 1.8% of GDP is diverted to the health sector by the government of Sri Lanka. Even after adding the contribution of the private sector, it is about 4.2% in 2006. It shows an increase from the level of 3.6% of the GDP in 1990. even in 1990 private sector was included. This shows an increase of 0.7% of GDP in a period of 16 years.

Overall, total health expenditure more than doubled in between 1990 and 2006. With just 1.8% of GDP allocated for public health, it will be impossible for the Government of Sri Lanka to provide health services for all. WHO has recommended that the public sector health budget should be a minimum of 5% of the Gross Domestic Product.

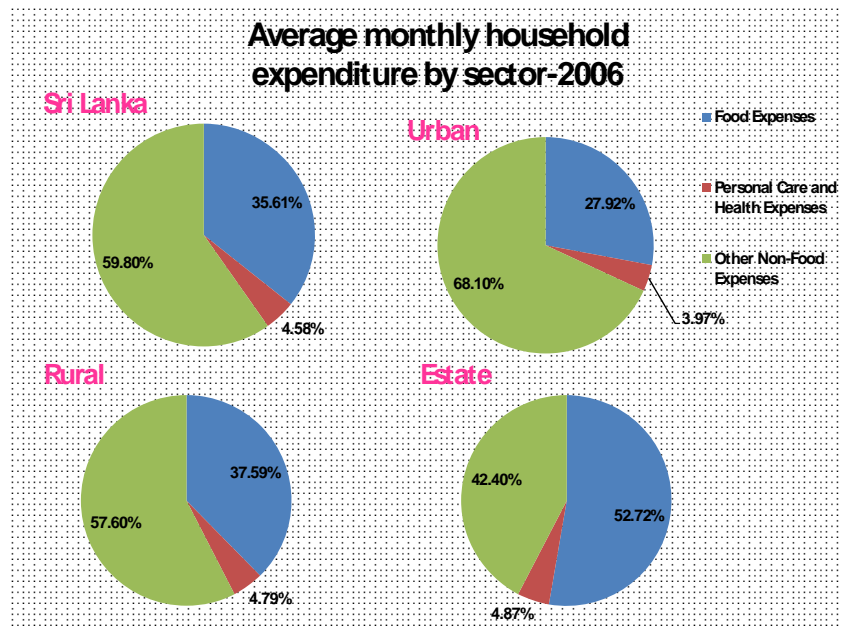
Average Monthly Household Expenditure by Sector-2006

Average monthly household expense	Sri Lanka(Rs.)	Urban(Rs.)	Rural(Rs.)	Estate(Rs.)
Food (major food groups)	8106	10,604	7753	6790
Personal care and health expenses	1044	1510	989	628
Other non food expenses	13521	25865	11879	5461

Source: Household income and expenditure survey-2006/07

According to the Household Income and Expenditure Survey, in 2006 an average Sri Lankan household spent Rs.1044 per month for their personal care and health. The urban, rural and estate sectors spent Rs.1510, Rs.989, and Rs.628 respectively.

The urban sector spends almost double the cost on personal health care compared to the estate sector due to the heavy usage of private healthcare services.

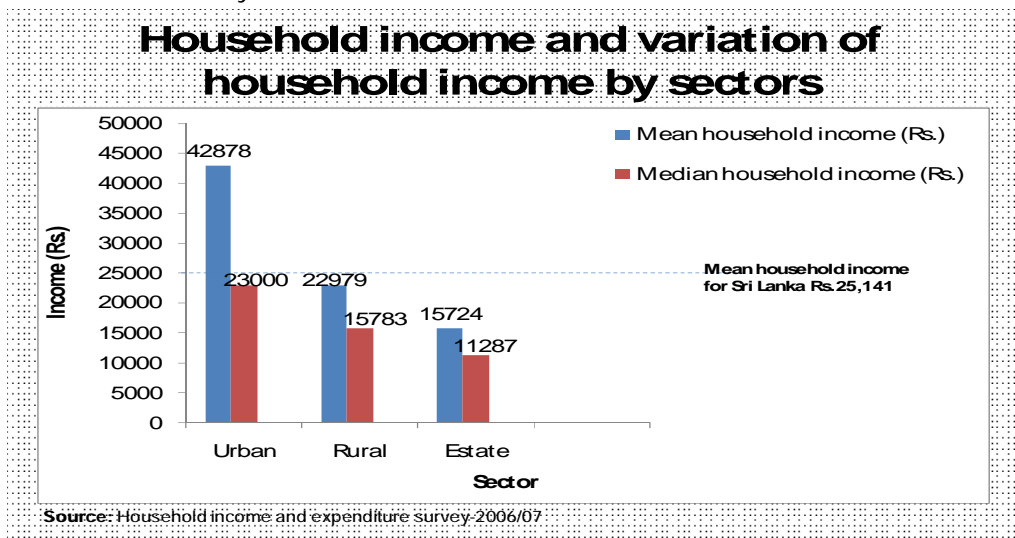


Food expenses vary greatly among urban, rural and estate sectors. The estate sector spends a higher percentage (53%) on food expenses compared to the other two sectors.

Both rural and estate sectors spend less on personal health care (rural-Rs.989 and estate-Rs.628 per month) due to their relatively low household income and high expenses on food consumption.

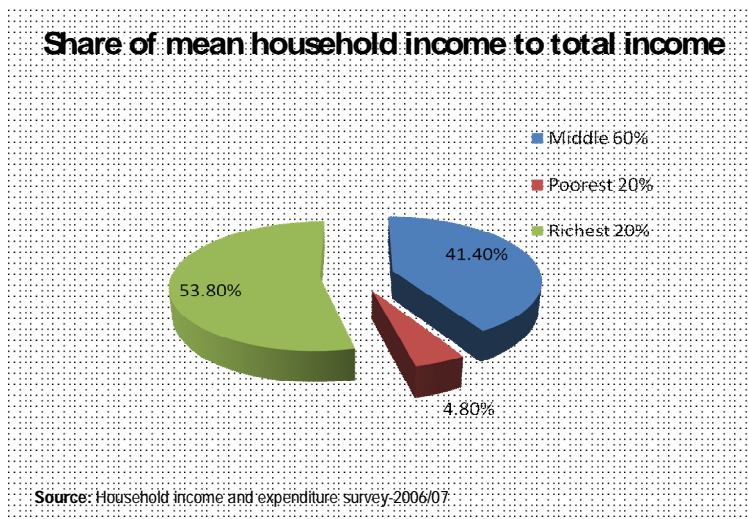
The high percentage of expenditure on food in the rural and estate sectors is also observed in other developing countries.

Next is an analysis of the household income distribution of Sri Lanka to show that in order to eliminate health disparities among sectors, we need to focus on developing the public health care services in the country.



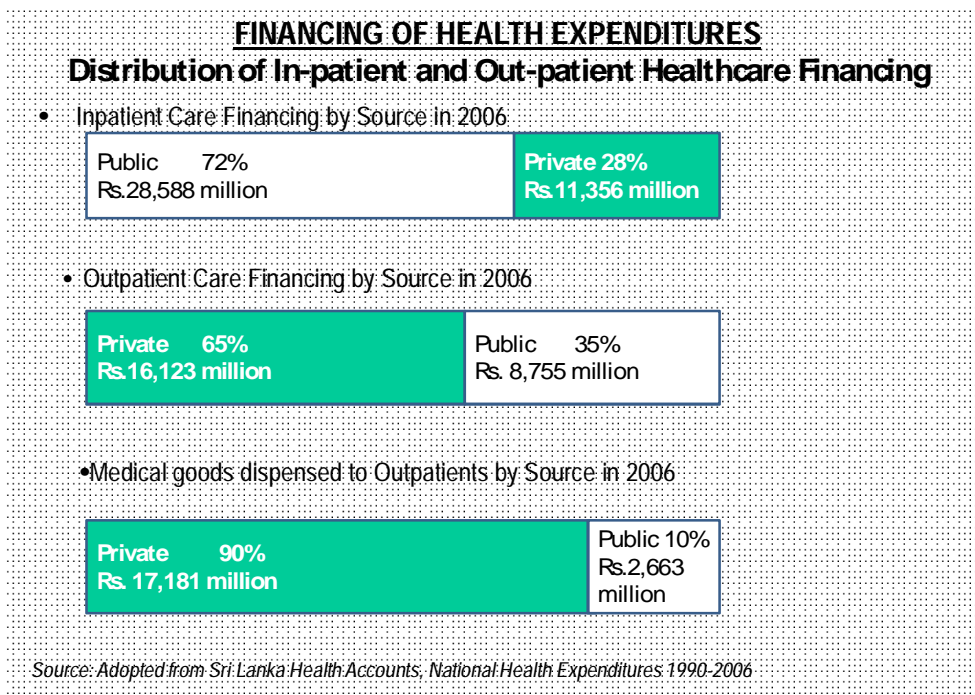
Household income is defined as the income received by all members of the household from various sources, either in cash (monetary income) or in kind (nonmonetary income). This figure illustrates the variation of the mean & median household income reported for the urban, rural and estate sectors. The mean household income reported for the urban sector is markedly above the national average. The mean household income reported for the estate sector is markedly below the national average.

There is a market disparity in incomes between sectors. Published data shows that 52.9% of the urban sector, 71.6% of the rural sector and 90.5% of the estate sector receive less than the mean household income. This suggests that there is a wide urban- rural disparity in the country. The urban household contribution to the national average is more compared to rural and estate household contributions combined. Therefore inadvertently this disparity also indicates that the mean household income for the country is not representative of the entire population.



This figure further elaborates the distribution disparity of the share of mean household income to total income among the population. The richest 20% of the country receive nearly 53.8% of the total income, while the poorest 20% receive only 4.8% of the total income. This pattern has remained unchanged during the last 20-year period.

The inequity of income distribution is reflected at the inter-district and inter-sectoral level health status of the country. IMR is a very sensitive index of the health status of a nation. The correlation coefficient for mean household income and IMR was calculated to be -0.40. This indicates that there is negative correlation between the two variables. However, the correlation is poor due to impact of other factors influencing the IMRs including literacy of the mothers, drinking water.



The distribution of in-patient and out-patient health care financing in Sri Lanka:

In-patient expenditures are mostly financed by public sources; this was 72% of the total by 2006. Private sector financing increased from 15% in 1990 to 28% in 2006 due to increases in the turnover in private hospitals. Out-patient expenditures are mostly financed by private sources; this was 65% of the total by 2006. Overall about 90% of medical goods dispensed were privately financed, and mostly by household out-of pocket spending. Privatization of health and making health a marketable commodity should be examined in relation to the purchasing power of Sri Lankans and the systems of health care financing in the country. At present Sri Lankans pay out-of-pocket for healthcare financing in the private sector. The World Bank Poverty Reduction Strategy Papers have proposed insurance schemes to pay for private healthcare.

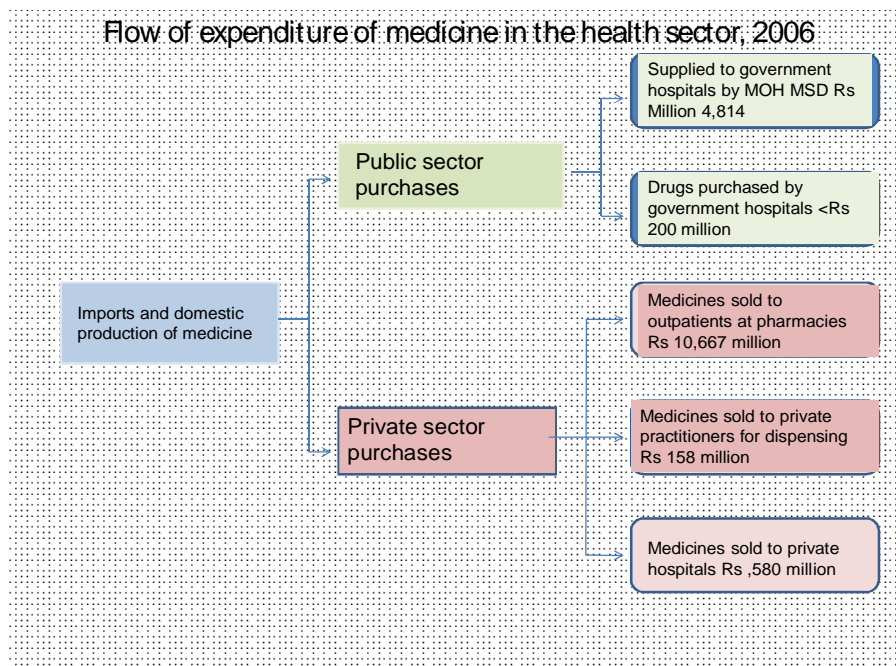
In 2006, the central government share of public sector financing was 67%, while the provincial government financed 36%. Local government financing was 1% and the Employees Trust Fund, which is a form of Social security, contributed 0.1%. The Ministry of Health accounts for almost all central government expenditures, with only small additional contributions from other government departments and agencies. Of these other central government financing sources, the President's Fund is the most substantial. Its share in total government financing increased significantly from less than 1% of government financing before 1996 to almost 3% in 2004. But it has declined to 1% in 2006. The bulk of the private sector financing is by household out-of-pocket expenditure, which has been Rs.47.36 billion and 88.9% of the total private expenditure on health. According to the World Health Organization (WHO) out-of-pocket payment is the most regressive form of financing health care and it's not sustainable. Eventually people become pauperized due to high healthcare expenses. Access to healthcare and namely equity, can never be achieved by this form of financing.

Countries such as Denmark, Norway, Sweden, UK, Ireland and Canada finance the health serve through general taxation, where as France, Germany and Netherlands finance through mandated social health insurance. Another important feature is the very low contribution private health insurance to health financing in capitalist countries. This is an important lesson for policy makers in Asia Pacific.

Comparison of out of pocket payment as a percentage of the total healthcare expenditure in 16 OECD countries and 11 countries in the Asia Pacific region

Countries	Range
OECD (165)	08-24.0
Asia Pacific (11)	42.4 – 87.0

In 16 OECD countries out of pocket payment as a percentage of total health expenditure range between 8-24% where as in 11 Asia Pacific countries it varied between 42.4% and 87%.



As illustrated in the flow chart above the expenses for public sector purchases in 2006 totaled to Rs. Million 5014 as opposed to Rs. Million 12,104 out-of-pocket purchases in the private sector. Medicines and medical supplies used for in-patient care in public and private hospitals are not included in this category. Public financing dominates the financing of medicines used in in-patient care. The expenditure by government on supplying medicines to in-patients is far greater than it spends on out-patient medicines and greater than the amount spent on in-patients in the private sector.

Expenditures on medicines in the private sector can be valued in different ways depending on whether the cost is taken at the point of importation or at the wholesalers or at the point of sale to patients. SPC procurements are known to be cheaper due to the bulk procurement process called through worldwide tenders.

Medicine financing mechanisms are ways in which money from consumers is collected, managed and paid for medicines. There are four basic alternative methods for financing medicines. They are General Taxation, Social Mandatory insurance, Out-of-pocket payments and private health insurance. A comparison of the four financing mechanisms were presented and shown that general taxation and social insurance mechanisms are the most beneficial for a given population.

Conclusions

Sri Lanka has one of the lowest infant mortality rates among all developing countries. The Sri Lankan health system has, therefore, achieved one of the objectives namely goodness. But has the Sri Lanka health system achieved fairness? The distribution of infant mortality rates with household income clearly shows inequality of the distribution of the health status among the population.

Achieving high average levels in health outcome alone is therefore, not good enough if there are inequalities among population groups.

Even though Sri Lanka has attempted to eliminate the inequalities and the deprivations by the Governments assumption of the role of provider of health service as a public good/service, this has far from being achieved owing to several constraints, such as (1) inadequacy of resources, (2) dearth and misdistribution of health personnel (3) lack of proper procedure for admission and referral, (4) poor management, (5) undue labor unrest, (6) politicization of administration and (7) corruption.

Health care expenditure is closely related to national income: health spending tends to rise proportionately with economic growth. Health systems are under great obligation to respond to people's concerns about quality & access to health services. Resource constraints, rising costs put great strain on government budgets. Policy makers should pay attention to this.

Recommendations

To improve coverage of the poor and to improve financial risk protection, we must shift financing from out- of- pocket payments toward reliance on public financing, involving tax financing and/or social health insurance. Increased external assistance can help, but its effectiveness depends on better pooling and integration with domestic sources of financing and better design.

DAY TWO

Establishing a baseline to monitor public health implications of new Intellectual Property Rights regime on pharmaceuticals in Sri Lanka- Dr. Manuj Weerasinghe, Faculty of Medicine, University of Colombo

Introduction

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed in Marrakesh, Morocco on 15 April 1994. This agreement claims to maintain a balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and

creations. But the benefits of TRIPS agreement on developing countries are still debatable. As a developing country new Intellectual Property Rights (IPR) regime is applicable in Sri Lanka from the year 2005. The impact of new IPR regime on Sri Lanka has not been studied. There have been no systematic research studies found in this area, in Sri Lanka up to now. It is crucial to establish a baseline to follow and predict the implications of TRIPs provisions to public health in the country as real effects of new IPR regime is to be expected within the next decade in the pharmaceutical market.

Objectives

- To determine the patent status of new chemical entities registered in Sri Lanka during 2005-2009.
- To describe the price fluctuation in the market in new chemical entities/ patent drugs registered during the period.
- To determine the proportion of new chemical entities/ patented drugs of selected therapeutic groups appear in prescriptions received at a selected state owned pharmaceutical retail outlet.
- To determine the perception of personnel involved in pharmaceutical regulation on public health implications of new IPR regime.

Methodology

First component consists of secondary data analysis. The potential sources of data are:

- Drug Regulatory Authority
- Sri Lanka patent office
- State Pharmaceutical Corporation
- Sri Lanka Customs
- Medical Suppliers Division of Ministry of health pharmaceutical importers

The data will include:

- The new chemical entities registered during the five year period of 2005-2009.
- Patents obtained in Sri Lanka for new chemical entities during period of 2005-2009.
- Price information of these drugs in the domestic market during the study period.
- Patent drugs imported by the state sector and unit cost during the five year period.
- Volume of the patented drugs imported during the study period.

Component two will consist of a prescription survey in a selected state owned pharmaceutical retail outlet within a period of one month (April/ May 2010).

The data will include,

- New chemical entities/ patented drugs of selected therapeutic groups appearing in the prescription
- Price breakdown on the prescriptions in relation to new chemical entities/ patented drugs
- Appearance of innovator brand names, branded generics and generic substitutes on new chemical entities on prescriptions

Component three will consist of a cross sectional survey to be conducted on knowledge and perceptions of personnel involved in pharmaceutical regulation in Sri Lanka on implication of new IPR regime on the public health.

- Data collection procedure:
 - A self administered questionnaire
 - Brief qualitative interviews
- Ethical consideration - Informed written consent

Results

During the past 5 years 70 new chemical entities (NCEs) have been registered at the Drug Regulatory Authority by 19 pharmaceutical companies. The NCEs belonged to 35 therapeutic groups according to ATC classification Level 3. 2 NCEs had no ATC codes. Except for 4 therapeutic groups (bile therapy, other respiratory system products, parathyroid hormones and analogues, low-ceiling diuretics, excl. thiazides) all other groups had alternatives in the Sri Lankan market.

Drugs which are included in the Essential drug lists of WHO and Sri Lanka

Out of the 70 NCEs, 7 drugs (10%) were included in Sri Lankan essential drug list (2009), while 2 drugs (2.8%) were in the WHO essential drug list (2010 March). Out of the 86 alternatives for the NCEs that were already available in Sri Lankan Market, 63 (73%) and 47 (54%) drugs were included in Sri Lankan and WHO essential drug lists respectively.

Data from the National Intellectual Property Office of Sri Lanka

527 entries in the database of patent applications in the National Intellectual Property Office from 2006 up to date were chemical compounds and claims that were compatible with medicinal drugs. The patent office is unable to provide the information whether a drug is patented or not. They only rely on the PTC code given by the WIPO. The WIPO data base only states what the chemical compounds are, but not the exact drugs produced using those compounds.

Remarks

NCE registered after 2005 will consist of a major portion of drugs which will be prescribed in the next decade. Blanket patent rights given to chemical compounds are likely to create a major public health issue. The need clause to consider that the medicines are registered to be patented is not there. The drugs which were registered were looked at first and then the patented statuses were observed. Out of 70 prescriptions at least 10% will have patented chemical entities. It was suggested to compare the prices of the prescriptions with the new chemical entities. We need to consider that patent laws were applicable from 1995, even though the survey is conducted from 2005 onwards. It was suggested that this project can be adopted in other countries. It may be useful to take a look at the local patent laws as it may be useful at the policy level to introduce public health safeguards against detrimental effects of patent laws. A chemical technologist may come useful to identify the patented new chemical entities.

The orange book of the US FDA and the EU has more information to identify new chemical entities registered in the country. In Sri Lanka the product patents were not allowed earlier not both product and process patents are allowed. Patent office in Sri Lanka is more industry oriented, the compulsory licensing clause was not even available in the original law, but later on it was appealed to Supreme Court and included. It was suggested that we look at the laws more closely.

Development and evaluation of pharmacovigilance education modules for medical, pharmacy and nursing students in Nepal- Country Study by Dr. Pranaya Mishra.

Introduction

Irrational use of medicines is a common problem worldwide, which causes various unwanted outcomes and it is under-focused in the curriculum. Pharmacovigilance is important in minimizing harmful effects of medicines and every healthcare professional needs to be sensitized including: doctors, Pharmacists, Nurses. They need to play a central role. Pharmacovigilance education is a very much overlooked topic in curricula. Developed countries are partially successful in launching pharmacovigilance programs however, for developing countries it is still a new concept. Pharmacology teaching at Manipal College of Medical Sciences, Pokhara, Nepal is based on problem-simulated learning, developing communication skills and is different from traditional pharmacology teaching. However, Pharmacovigilance education in Nepal is less focused, whereas adverse drug reactions are being covered as a lecture topic. Manipal College of Medical Sciences is the first to initiate pharmacovigilance teaching to medical students and students were regularly taken to the pharmacovigilance center.

Although the importance of ADR monitoring is well understood, the emphasis on and discussion about the topic in the curriculum of doctors, nurses and pharmacists in Nepal is very limited. Study about ADRs only covered as a topic in the theory course. Curriculum of pharmacists, nurses and doctors do not lay adequate emphasis on medicine safety.

Two universities and one autonomous institution in Nepal conduct the undergraduate medical course and pharmacology is taught using a combination of didactic lectures and problem-stimulated learning sessions. Although all the existing regional pharmacovigilance centers in Nepal are attached to medical schools, the medical students are not exposed to the existing pharmacovigilance program of the country.

Similarly, nursing education does not provide adequate insights about the existing pharmacovigilance programs. Curriculum of the Diploma in nursing program is focused towards practice in hospital settings but, rational pharmacotherapy is not stressed. Although pharmacology is being taught, there is only a very limited coverage in the curriculum regarding ADRs and pharmacovigilance. Undergraduate pharmacy curriculum in Nepal is more 'product oriented' and less emphasis on pharmacoepidemiology and other aspects of medicine use. Curriculum prepares the students for a job in the pharmaceutical industry rather than in a hospital or community pharmacy. Topic on ADRs is covered in one-hour lecture consisting of the basic aspects on ADRs like definition, types of ADRs and examples; Emphasis on pharmacovigilance is lacking.

Objective of the present study

- To design education modules for pharmacy, medical and nursing students
- To test it with students
- Obtain students' feedback on the modules
- Arrive at a pharmacovigilance education module acceptable by the students

Setting

- School of pharmaceutical and biomedical sciences, Pokhara University, Pokhara
- Manipal College of medical Sciences, Affiliated to Kathmandu University
- Manipal School of Nursing, Pokhara, affiliated to Council of Technical Education and Vocational Training (CTEVT), Nepal.

The content of the training sessions conducted for pharmacy, nursing and medical students were described extensively by Dr. Mishra. The study revealed the following major findings in each category:

Major findings (Pharmacy students):

- Almost all of them found the sessions useful in understanding the concept of pharmacovigilance
- A considerable amount of students felt that herbal drugs are relatively safe
- A high percentage felt that Pharmacovigilance program in Nepal is not successful
- A good number of students felt that the sessions may be useful for their future job
- Most of them were willing for similar sessions in the future.

Major findings (Medical students):

- Similar to the pharmacy students, a considerable number of Medical students also felt that herbal drugs are relatively safer than that that of modern medicines
- There was some level of reluctance among the students in accepting that adverse drug reactions are one of the major causes for death in the world
- A high percentage felt that Pharmacovigilance program in Nepal is not successful
- Most of them had a positive opinion on the sessions and were willing for similar sessions in the future

Major findings (Nursing students):

- All nursing students felt that pharmacovigilance is very much essential to developing countries like Nepal
- Similarly, all of them felt that pharmaceutical industry should report adverse drug reactions
- A high percentage of them felt that dosage adjustment is an important strategy to prevent the occurrence of ADRs
- There was a slightly less acceptance among the nursing students on the sessions, as reflected by a poor score.

Based on the findings the following curriculum changes have been recommended for each program:

Recommended curriculum content (Pharmacy students):

Objectives: To familiarize the pharmacy students on the existing national pharmacovigilance program and filling ADR reporting forms, carrying out causality and severity assessments.

Key areas to be covered:

- ✓ Definitions of adverse drug reactions
- ✓ Terminologies in pharmacovigilance
- ✓ Existing system of adverse drug reaction reporting in the world and Nepal
- ✓ Role of pharmacists in pharmacovigilance

Activities (The following activities may be planned):

- ✓ Schematic presentation of the national pharmacovigilance programs
- ✓ Designing of ADR reporting forms
- ✓ Filling ADR reporting forms
- ✓ Causality assessments
- ✓ Severity assessments
- ✓ Preventability assessments
- ✓ Visit to the pharmacovigilance center

Time duration: 4-6 hours divided into 2-3 sessions.

Recommended curriculum content (Medical students):

Objectives: To familiarize the medical students on the existing national pharmacovigilance program and filling ADR reporting forms

Key areas to be covered:

- ✓ Definitions of adverse drug reactions
- ✓ Terminologies in pharmacovigilance
- ✓ Existing system of adverse drug reaction reporting in the world and Nepal
- ✓ Role of doctors in pharmacovigilance

Activities (The following activities may be planned):

- ✓ Schematic presentation of the national pharmacovigilance programs
- ✓ Designing of ADR reporting forms
- ✓ Filling ADR reporting forms
- ✓ Causality assessments
- ✓ Severity assessments
- ✓ Preventability assessments
- ✓ Visit to the pharmacovigilance center

Time duration: 3-4 hours divided into 1-2 sessions.

Recommended curriculum content (Nursing students):

Objectives: To familiarize the nursing students on the existing national pharmacovigilance program and filling ADR reporting forms

Key areas to be covered:

- ✓ Definitions of adverse drug reactions
- ✓ Terminologies in pharmacovigilance
- ✓ Existing system of adverse drug reaction reporting in the world and Nepal
- ✓ Role of nurses in pharmacovigilance

Activities:

- ✓ Schematic presentation of the national pharmacovigilance programs
- ✓ Designing of ADR reporting forms
- ✓ Filling ADR reporting forms
- ✓ Visit to the pharmacovigilance center

Time duration: 3-4 hours divided into 1-2 sessions.

It is the first study conducted in a developing country. It focused on evaluating the feasibility of an education module for pharmacovigilance in a developing country. The study shows that curriculum change/modification is necessary. The changes suggested could be accepted depending upon universities. Advocacy through the councils is also necessary to strengthen pharmacovigilance program around the country.

National Medicines and Health Polices to ensure regular access to essential medicines and basic health care- Dr. Amit Sen Gupta

There has been a growth of the "for profit sector" and its relation to the decline of the public sector. This has gone hand in hand with the introduction of market principles in the public sector viz. user fees, contracting out and insurance schemes with private sector participation. Between 1980 and 2004, public facilities doubled whereas the private sector grew eight fold!

State of Public Health Systems

Growth of infrastructure has lagged behind demand. Creation of new infrastructure has lagged well behind targets set in the Tenth Plan period. Achievement of targets is 76% in the case of sub-centers but just 13% and 37% in the case of PHCs and CHCs. Even where sub-centers, PHCs and CHCs exist, their conditions are often abysmally poor --50% of sub-centers, 24% of PHCs and 16% of CHCs function in rented or temporary premises.

Public Health Expenditure

Real increase has been 12.6% in 2007-8 and 11.2% in 2008-9, which has barely been above the annual growth of GDP. As a consequence total public expenditure on health has remained around 1% of GDP.

Health Care Expenditure

60% of expenditure goes on primary care services, 85% (almost 50%of total spending) for primary Curative care services. Government expenditures account for 24% of inpatient treatment expenditures.

Although fees in government hospitals are low, households still report sizable out-of-pocket expenditures on drugs and supplies for hospitalized patients. It is estimated that private health expenditure has grown at 12.5% per annum, since 1960-61. The income elasticity is 1.47, which means that for each 1% increase in per capita income, the private expenditure on health increased by 1.47%.

State of Public Sector encourages Growth of Private Sector

State of the public health system forces people to access the unregulated private sector. As a consequence in excess of 80% of medical care costs are borne by people through "out of pocket" expenses. Survey shows that, in the case of ailments considered serious by respondents, 40 percent cited financial reasons for not taking recourse to treatment.

Public Private Partnerships

Endorsement by multilateral agencies of Public Private Partnerships has influenced policy. At the secondary level, PPPs are involved in contracting out of non-clinical services like laundry, diet, drug stores, diagnostics and ambulance. Selective contracting out of services to the private sector is often a component of reform packages promoted by bilateral and multilateral agencies for low-and middle-income countries. PPPs now also extend to contracting out clinical services.

Health Insurance

There has been a penetration of health insurance is low: estimated 3-5% covered under any form of health insurance. Commercial insurance is <1% of total expenditure.

Existing schemes can be categorized as:

- Voluntary health insurance schemes or private-for-profit schemes;
- Employer-based schemes;
- Insurance offered by NGOs / community based health insurance,
- Mandatory health insurance schemes or government run schemes (namely ESIS, CGHS)

Rashtriya Swasthya Bima Yojana(National Health Insurance Scheme)

Rashtriya Swasthya Bima Yojana (RSBY), launched in 2007-08, aims to transform the way public provision of health services have been designed -moving away from the model of direct provision of health services Govt. Every BPL household will be covered against hospitalization cost of Rs.30,000 per annum. The Union Government is committed to pay a premium of up to Rs.750 per family (the Central government would bear 75 percent of the total premium); households need to pay Rs.30 annually to register. 6.5 million Below Poverty Line (BPL) families in India -- to enroll all need to spend around Rs. 4,875 crore annually while current allocation is only Rs.308 crore in 2009-10 –enough to cover just 0.46 million. Scheme does not cover outpatient treatment, thus living a major source of expenditure (more than 2/3rd of total health

costs) out of its ambit. It involves harnessing of Private Sector --health insurance schemes based on private provision leads to huge cost escalation due to over consumption esp. in the context of weak regulation of private health sector. According to a Government Committee around 40% of the population in India is BPL.

Access to Medicines

It has been estimated by different sources --50% to 80% not able to access all the medicines they need. The World Medicine Report (2004) of the World Health Organization -India has largest number of people (649 million) without access to essential medicines. Given India is the 4th largest producer of drugs in the world and exports medicines to over 200 countries, local production/availability not major constraints. Studies indicate that poorer populations spend a larger proportion of health care expenditure on medicines. World Bank Study shows that out-of-pocket medical costs alone may push 2.2% of the population below the poverty line in one year. It is also estimated that total expenditure on medicines in India is in excess of Rs.300 billion per annum --Rs.1,500 for every family in the country.

Factors that determine access to medicines include:

1. rational selection and use
2. affordable prices
3. sustainable financing
4. responsive health system
5. reliable supply system

While affordability is only one dimension of access, it continues to be a critical factor in India's Health system.

Special Features of Indian Pharmaceutical Market

Most prominent in very large proportion of drugs consumed in India are through retail sales (85%). Retail sales: US\$ 6.2 billion Institutional sales: US\$ 1.1 billion. This pattern is different from most markets, where a bulk of drug consumption is through supplies from large institutional mechanisms (hospitals, health insurance, etc., both in public and private sector). Given this, major issues related to drug prices are related to those that impact on retail prices

Ensuring Access to Medicines

Present situation, where in excess of 80% of drugs consumed are paid for through out of pocket contribution by the consumer, is unacceptable. There is a need to ensure is availability of a majority of drugs through the Public Sector. There are no alternatives to instituting price controls -- market mechanisms do not help to stabilize drug prices. Revival of Public Sector Units needs to be a priority. Pooled Purchasing will minimise Costs in the Public Sector.

There is a need to weed out Irrational Drugs and revive Public Sector Units. Pooled Purchasing will minimise costs in the Public Sector. It is necessary for price control on all Drugs in EDL: All Essential drugs should be under price control. There should be an independent mechanism of Data Collection and the necessity to weed out Irrational Drugs. The survey results will be presented as a report and it will be available on the HAIAP website.

Strategic Session convened by Dr. Ken Harvey

1) Where there are no Pharmacists

Set rules for extracting excerpts of WTANP to be translated for different settings.

The members discussed the need to acknowledge HAIAP and TWN in one sentence. Bangladesh wants to translate the entire book, where as India wants only a part of it. The book will also be available on the website.

Marketing:

It was suggested that all the member countries could get their pharmacists to distribute together with the marketing carried out by TWN. It was noted that TWN charges USD12 per book where as HAIAP only 6 USD. The postage will have to be borne by the person who orders it. The offer of HAIAP is only for the members. Dr. Bala asked the members to write to HAIAP to order the number of books required by them. There will be complementary copies available to be distributed to WHO offices and Ministries of Health.

2) ERDU Web group

Dr. Ken Harvey presented the progress of the ERDU web group. In recent times the discussion in the group has been slow. The members requested the continuation of the list serv for another 12 months. Dr Harvey reminded members to continue to use them to share resources.

3) HAI Global projects on Drug Promotion

Project was to measure the impact of the regulation and the other one was to develop a model regulation or code for the implementation of the WHO ethical Criteria. The members requested more information from HAIAP secretariat to take part in the project.

4) Gender parity in the HAIAP Governing Council

Dr. Bala suggested that to address this issue that we need to ensure among the members that there is fair representation of males and females in the HAIAP Governing Council. Dr. Tariq requested that we create an enabling environment.

5) Next meeting: When and Where

It was agreed that the next meeting to be in Penang if the office is transferred to Penang. If not the other countries willing to host are: India, Pakistan and Nepal.

List of Participants for the HAIAP Meetings 26th - 30th April 2010.

Name	Tel/Fax/E-mail	Address
Amit Sen Gupta (Dr)	+91 9810611425 (mobile) 91-11-26524323 (work) 91-11-26862716 E-mail: ctdsf@vsnl.com	National Campaign Committee for Drug Policy D 158, LGF, Saket, New Delhi 110 017 India
Amitava Guha (Mr)	Tel: 91 33 24242862 Fax: 9133 2424 4943 E-mail: amitava45@gmail.com	Federation of Medical & Sales Representatives Association of India (FMRAI) 60A Charu Avenue, Kolkata 700 033 India
Berverley Snell (Ms)	Tel: 61 3 9282 2115 Fax: 61 3 928 22144 E-mail: bev@burnet.edu.au	Essentials Drugs & Community Health Specialist & Senior Fellow Centre for International Health Macfarlane Burnet Institute for Medical Research & Public Health GPO Box 2284, Melbourne 3001, Australia
Chan Chee Khoo	Tel: 604-653 4537 Fax: 604-658 5820 E-mail: ckchan50@yahoo.com	Center for Policy Research and International Studies Universiti Sains Malaysia, 11800 USM, Pulau Pinang, Malaysia
Edelina P de la Paz (Dr)	HAIN Tel 63-2-9526312 Fax 63-2-9526409 e mail: hain@hain.org Dept. of Family and Community Medicine, Social Medicine Unit College of Medicine Tel/Fax 63-2-4006658 E mail: smucm@cm.upm.edu.ph delen27@yahoo.com	Dr.Edelina P. de la Paz Executive Director Health Action Information Network 26 Sampaguita Avenue Mapayapa Village II Barangay Holy Spirit Quezon City 1127, PHILIPPINES <i>UP College of Medicine :</i> Dr. Edelina P. de la Paz Associate Professor Dept of Family and Community Medicine Vice Chief, Social Medicine Unit College of Medicine University of the Philippines 547 Pedro Gil St. Ermita, Manila 1000, PHILIPPINES

Name	Tel/Fax/E-mail	Address
Gopal Dabade (Dr)	Tel: +91 836 2461722 Mob: +91 9448862270 drdabade@gmail.com	Drug Action forum – Karnataka (DAF-K) 57, Sony, Tejaswinagar, DHARWAD, Karnataka 580002 India
Jayabalan T (Dr)	Tel: +604 657 0099 Fax: +604 656 8417 Mobile: +6012 402 7445 E-mail: drjayabalan@gmail.com	National Poison Centre Universiti Sains Malaysia 11800 Penang Malaysia
Joel Fernando (Dr)	Tel: 9411 2502449 E-mail: joelfdo@gmail.com	45/1 Jawatta Road, Colombo 5 Sri Lanka
Ken Harvey (Dr)	614 1918 1910 (M) & 613 9818 1910 (O) 613 9818 1875 k.harvey@latrobe.edu.au k.harvey@medreach.com.au	35 A Mary Street Hawthorn Victoria 3122 Australia
Marlene R Bermejo (Dr)	Tel: 63 2 952 6312 Fax: 63 2 952 6409 E-mail: marlene.rillera@gmail.com	Health Action Information Network 26 Sampaguita Ave, Mapayapa Village II Barangay Holy Spirit Quezon City 1127 Philippines
Manuj Chrishantha Weerasinghe (Dr)	Tel: 9411 2856772/112677765 Fax: 9411 2691581/ 9411 2677765 E-mail: manujchir@yahoo.com	21/5 Sunethradevi Road, Kohuwala, Nugegoda Sri Lanka
Mira Shiva (Dr)	++ 98-10- 582028 ++91-11-2685 5010 ++91-11-2651 2385 91-11-2685 6795, 2696 2589 mirashiva@yahoo.com mirashiva@gmail.com	Initiative for Health Equity and Society Co - coordinator, AIDAN A-60, Hauz Khas, New Delhi 110 016, India
Mohamed Izham Mohamed Ibrahim, PhD	Tel #: +604-653 2579 Fax #: +604-657 0017 E-mail: mohamedizham@yahoo.com	Prof. of Social & Administrative Pharmacy School of Pharmaceutical Sciences Universiti Sains Malaysia 11800 Penang Malaysia

Name	Tel/Fax/E-mail	Address
Niyada Kiatying-Angsulee (Dr)	Tel: 662 412 3507-8 Fax: 662 4123508 Niyada.K@chula.ac.th Niyada_k@yahoo.com Niyada.k@gmail.com	Drug Study Group 695 Charansanitwong 12 rd., Bangkokyai Bangkok, 10600 Thailand
Pranaya Mishra (Dr)	Ph: 00 599 416 34 56 Ext 243 (Work) 00 599 416 74 87 (Mobile) Fax: 00 599 416 34 58 E-mail: mishrapranay@hotmail.com	Course Director and Associate Professor Department of Pharmacology Saba University School of Medicine P.O. Box 1000, The Bottom Saba, Netherlands-Antilles
Qasem Chowdhury (Dr)	Tel: 8802 8617383 / 8617 208 / 9673512 / 9673507 Res: 8802 836 0255 Fax: 8802 8613567 qsemchowdhury@yahoo.com	Gonoshasthaya Kendra House 14e, Road 6, Dhanmondi, Dhaka 1205 Bangladesh
Rajitha Wickremasinghe (Prof)	Tel: 9411 2953411 e-mail: arwicks@slnet.lk	Department of Community and Family Medicine, University of Kelaniya P O Box 06, Thalagolla Road Ragama, Sri Lanka
Ramon P Taterno (Dr)	E-mail: rppaterno@yahoo.com Mobile: 0920 960 4947	UPM – NIH Institute of Health Policy and Development Studies P. gie, Malate Metro Manila, Philippines
Razak Lajis (Mr)	604 657 0099 / 2924 604 656 8417 razaklajis123@yahoo.com	National Poison Centre Universiti SAINS Malaysia 11800 Penang, Malaysia
P K Sarkar (Prof)	Tel: + 91 03242 203210 Bodhi_fha@dataone.in Drpksarkar2010@gmail.com	Foundation for Health Action P254, Block B Lake Town, Calcutta 700 089 India Amader Haspatal Phoolberia, Nischintapur Bankura 722 136, WB, India
Peter R Mansfield (Dr)	Tel & Fax: +61 88557 1040 peter.mansfield@adelaide.edu.au peter@healthyskepticism.org Website: www.healthyskepticism.org	34 Methodist St Willunga Sa 5172 Australia

Name	Tel/Fax/E-mail	Address
Sulagna Dutta (Mrs)	Tel: +91 2265 2363 Fax: +91 2265 4758 Mobile: 9433 485761 E-mail: cdmuwb@dataone.in	Community Development Medicinal Unit (CDMU) 47/1B, Garcha Road Kolkata 700 019 India
Shaikh Tanveer Ahmed (Dr) –	Ph : 92-021-4532804 Fx : 92-021-4527698 Email : tanveer.ahmed@hands.org.pk Web : www.hands.org.pk Mobile: 0300 8200 507	Dr. Shaikh Tanveer Ahmed Executive Coordinator Health And Nutrition Development Society(HANDS) C-140, Block II, PECHS Karachi Pakistan
Shila Kaur (Ms)	Tel: 604 890 2669/014 254 0191 E-mail: kaur_shila@yahoo.com	Till further notice: 42A Lebuah Lembah Permai 3 11200 Tanjung Bunga Penang Malaysia
Tarak Das Banerjee	Tel: 0099379-62110 cdmuorissa@satyam.net.in	Administrative Officer 97, Forest Park Bhubaneswar- 751009 Orissa India.
Tariq Bhutta (Prof)	Tel: 92 42 3572 0101 92 42 3572 0101 Fax: 92 42 357 2045 tbhutta51@hotmail.com	Chairman, National Immunization Advisory Group 240 – W, DHA, Lahore, Pakistan
Zafrullah Chowdhury (Dr)	Tel: 8802 8617383 / 208 Res: 8802 8111495 Fax: 8802 8613567 E-mail: zaf.chowdhury@gmail.com	Gonoshasthaya Kendra (GK) House 14e, Road 6, Dhanmondi R/A Dhaka 1205 Bangladesh