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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.

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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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A Healthcare Financing System: a viable option for developing countries

Introduction

“The issues of healthcare financing and health equity as well as the parameters that surround them are of great significance. It is timely then that relevant discussions are taking place today” stated Professor Rahmat Awang of the WHO collaborating Centre for Drug Information at the University Sains Malaysia based National Poison Centre at the Regional Seminar on Healthcare Financing. The seminar was organized by Health Action International Asia Pacific in collaboration with the National Poison Centre of the Universiti Sains Malaysia and the South East Asia Regional Office of the World Health Organization from 17-18 April 2004. It was attended by approximately eighty participants from South East Asia and the Pacific. “The discussions that would take place during the seminar” he continued “should enable all participants to arrive at viable solutions to combat what appears to be a potentially detrimental healthcare system that is incapable of providing for the common man in the street and the poor”. Concluding his address he further stated that the questions about healthcare financing and health equity are challenging issues and perhaps the participants at the seminar would be unable to find an immediate answer or a simple solution however, it is important for everybody to work together and draw up suggestions that are feasible and practical which all can share. “And this”, he concluded “will be a good beginning”.

Healthcare Financing and Equity

“Limited resources and inequity” said Dr Balasubramaniam, Advisor and Coordinator of Health Action International Asia Pacific in his opening remarks “are the two problems related to healthcare financing which prevent developing countries from achieving their health goals”. Limited resources are due to governments’ insufficient allocation of funds on health and less spending on basic health. The key issue of equity is the manner in which health budgets are shared among users and services. Healthcare financing schemes therefore deal with how money is collected from consumers, managed and paid for services.

The four basic alternative methods for financing healthcare are direct or out-of-pocket payment by users to providers, voluntary private or commercial health insurance, general taxation and mandated social health insurance.

In the OECD countries public sector funding, either by general taxation or mandated social security pays about 70 to 80 per cent of the total health expenditure. Consumers pay less than 20 per cent out of pocket of their total health expenditure. Private insurance plays an insignificant role in healthcare financing in OECD countries. On the contrary, consumers in the developing countries represented at the seminar pay 50-90 per cent of their total health expenditure with the exception of Malaysia. The two viable options for financing healthcare would be from general taxation or mandated social health insurance. A scheme with the incorporation of these two provisions will be an efficient mechanism to pool the total risks in a country and redistribute income from the healthy high income groups to the unhealthy low income groups and share the burden collectively.

Dr Chan Chee Khoon of the Citizens’ Health Initiative Malaysia commenced his presentation by listing the components of a healthcare system which are hospitals, clinics and other treatment facilities, nursing homes and long-term care facilities, testing & diagnostic facilities, health professional services, health administration services, pharmaceuticals, medicine supplies & disposables, hospital design, construction, and equipping, hospital support (maintenance) services, insurance, managed care, HMOs, telemedicine, training, education and research and medical informatics (incl. medical registration).

* Speaking on public-private partnerships in Malaysia Dr Khoon pointed out that the Malaysian government has implemented one of the most extensive programmes in privatization. Malaysia’s receptivity to privatization is intriguing and is not simply a consequence of International Financial Institute (IFI) influence or dictates. Just as “redistribution-with-growth” in the 1960s provided a timely slogan if not ideological cover for the New Economic Policy (NEP), so did the privatization policies promoted by the IFIs provided a convenient vehicle and ethos for the divestment of accumulated public assets and lucrative concessions to well-connected private entities and individuals. Privatization under such circumstances was less about competitive, free markets than about transforming the more profitable public enterprises and lucrative concessions into private monopolies and captive markets. As these “public-private partnerships” took shape, it became

clear that healthcare and its ancillary industries had been targeted as a priority growth sector by an emerging nexus of party-family-corporate interests.

In insurance-based Healthcare Financing there is a crucial difference between social insurance, which embodies an implicit compact of cross-subsidy and social solidarity, but in commercial insurance, which assigns risk-rated premiums determined by the market's valuation of individual risk. The most objectionable consequence of for-profit risk-rated medical insurance is that those people at highest risk of falling ill and requiring treatment, will be those least able to afford premiums, and therefore treatment. Health insurers appear to have a schizophrenic attitude towards healthcare providers – deteriorating public hospitals reinforces people's felt need for private health insurance, but health insurers also complain endlessly about moral hazards and price gouging by private hospitals, so much so that they make incentive payments to policy holders to access the public hospitals when in need of care. Faced with a glut in the commercial real estate market, property developers have lately entered into joint ventures with proprietary hospital chains the property developers build and own the new hospitals, which in turn are operated and managed by the hospital management on a long-term leasehold basis.

Dr Sanguan Nitayarumphong, Secretary General, National Health Security Office in Thailand commenting on how healthcare coverage evolved in Thailand said before 1975 it was a scheme for civil servant medical benefit; in 1975 it became a scheme of free care for the poor; in 1991 a compulsory insurance for employees under the social security scheme and in 1996 a national voluntary health care scheme for the uncovered population.

Speaking on the importance of a universal coverage policy he stated that 20-30 per cent of the 62 million populations in Thailand are uninsured. The existing health insurance and welfare schemes have different benefit and payment mechanisms; therefore the quality of care provided through various insurance schemes tends to be different. The present government policy continues on a scheme for the poor and disadvantaged groups, on a scheme of social security, reform scheme of civil servant medical benefits and 30 bhat user, charge for each episode. (1US\$=41.92 bhats).

Speaking about the design of the new healthcare system in Thailand he stated that the objectives and approaches used in the 30 bhat policy were to fill the gap to cover the uninsured, reduce inequity, enhance system efficiency and promote cost containment systems. The basic essential package and payment method, the use of close end provider payment method, registration with first contact with nearby – primary care, ensuring quality of care by using accreditation, decentralizing of fund management to the province, networking of health services, consumer's choice for registration with nearby primary healthcare and planning for single administration of different fund after three years should be taken into consideration when designing the system.

The consequences were the increase of governmental budget during the first year to 10 billion and then 10-15 billions within the next 2-3 years, overall national healthcare expenditure to decrease from 10 per cent to 2 per cent after three years, private-public mix of healthcare provision in the whole country, the boom of Family Practice board examination application from 4 in 1999 to 1200 in 2002 and the redistribution of manpower in public sector as an impact from close end payment method.

Private Healthcare Insurance

Examining the challenge of rising healthcare costs and reasons for this phenomenon Dr Phua Kai Lit, of the International Medical University, Kuala Lumpur, Malaysia stated that rising healthcare costs is a worldwide problem and has therefore become a challenge for governments, employers and individuals. Some of the challenges were due to new medical technology, epidemiological transition, emerging and re-emerging diseases, population ageing, greater affluence and demand, "medicalization" of social problems and cost sharing in public facilities.

Individuals could respond to rising healthcare costs in various forms. Malaysians have a notion that private healthcare is of a higher quality than that provided by the public sector. As a result of the rising costs it is also restricted to the middle and the upper classes. However, the private sector employees could also depend on their employers to provide them with health insurance or simply buy private health insurance.

Dr Lit noted a few shortcomings that were associated with private health insurance: risk selection in which they exclude the sick and the high risk groups but cover the young and the healthy; the

market fragmented to promote cream skimming; no coverage for pre-existing conditions; unholy waiting periods; limitations on coverages; exclusions; residence requirements; higher premiums upon renewal; non guaranteed renewals; noting a maximum number of reimbursable inpatient days per year; annual and lifetime limits cost sharing and non-portability.

Dr Lit further analyzed the results of a study on nine commercial health insurance plans available in Malaysia and on analyzing the results he came across several shortcomings from the point of view of the consumer. The majority was not favourable to the consumer and had several shortcomings such as no cover for people over 60, annual lifetime or other limits, renewal not guaranteed, exclusions etc. There was also no visible difference between the hospital and surgical plans or critical illness or dread disease plans. It was noted that even with the “no coverage for pre-existing conditions” clause, many plans will not cover major conditions that develop during the first year. There were no plans available for the elderly with almost all having an allocated amount for major health conditions and other disguised caps with payment limits per disability, lifetime limits etc.

He recommended better plans that would provide adequate coverage or financial protection, better regulation of the industry with mandated benefits, price discrimination restrictions, guaranteed issue or renewals...etc and above all the establishment of a National Health Insurance scheme with protection against catastrophic illnesses.

Migration of health personnel

The latest catastrophe Asian countries are encountering is the migration of health personnel. Dr Magdalena Barcelon, Executive Director of Community Medicine Development Foundation, Phillippines drawing examples from her country commented on how migration of health workers had affected the healthcare system in the Philippines. The main reasons for these health personnel to migrate to other countries are socio-economic and political crises and low paid jobs with little benefits. Worsening the already bad doctor-patient ratio doctors, even specialists with up to 16 years experience have become nurses for easier migration while there are more taking up nursing courses with the sole intention of looking for greener pastures.

The Filipino labour export policy encourages migration of workers. It was formulated during the Marcos administration to address and facilitate intensified export of workers. Currently there are 8 million Filipinos overseas in more than 186 countries. The Department of Health claims that there is no budget for additional staff or pay hikes. Although the US\$6 billion annual remittance of the overseas Filipino workers lifts the economy, the health budget allocation is a mere 2 per cent of the national budget since debt service takes 40 per cent and the military expenses another 20 per cent.

The General Agreement on Trade in Services (GATS) has liberalized the entry of foreign investments and professionals in the service sectors. Under GATS developed countries can easily lure skilled workers from developing countries. Foreign corporations can enter other WTO member countries and can own, manage hospitals, laboratory services and other profitable services. Skilled and experienced health workers have left and therefore novice nurses now occupy responsible posts in the ICU, deteriorating the already appalling statistics of the Filipino health situation, 1 public doctor for 26,353 Filipinos, 1 public nurse for 16,170 Filipinos etc. Experienced health staff work double shifts, some hospital wards have closed down due to the lack of nurses and experienced clinical instructors.

As recommendations she stated that we needed to continue our campaign for an increased health budget, advocate that healthcare should be seen in the context of rights and services and not for trade or profit, stop the GATS attack on health and call WTO out of health and to continue the struggle for genuine economic and social development. The only solution is to change the situation in the Phillippines; to improve job opportunities and to encourage national industrialization and not those of foreign interests

Medical Tourism

Commenting on the issue of Medical Tourism, Dr Amit Sen Gupta of the National Campaign Committee for Drug Policy, India said, “the corporate culture in Medical Care has risen with the emergence of an affluent section that seeks to emulate the consumerist aspirations of its counterparts in the global North and the emergence of a private sector that thrives by servicing a small percentage of the population that has the ability to “buy” medical care. It has therefore changed the medical care sector”.

There is a merge of interest vis a vis medical care between globalization and the corporate sector, the former facilitating the flow of technology, finance and human mobility while the latter utilizes these two to globalize medical care. He defined medical tourism as “provision of cost effective private medical care in collaboration with the tourism industry for patients needing surgical and other forms of specialized treatment.” This is actively promoted by the government’s official policy. Tourism sector is seen as a major area for revenue generations and they see the area of Medical Tourism as one such avenue.

The promotion of medical tourism focuses on “key selling points”, cost effectiveness combined with the attractions of tourism. It thus, detracts from the whole concept of Primary Healthcare. It attracts an insignificant fraction of consumers who are able to pay but leaves out a bigger portion who cannot afford to pay and emphasizes on today’s notion of healthcare with technology and private enterprise.

The possible impact this could have on the future of the private and public health services are the expansion of the private health sector and luring the doctors of the public sector to the private sector.

Managed Care

Dr Chak Sri Nagara, Vice President, Association of Private Hospitals of Malaysia in his presentation mentioned managing and financing healthcare as the two important issues within healthcare delivery. They are both entwined therefore separating and dealing with each issue on its own can result in the demise of it, best plans for managed care without sufficient financing will end up being stillborn and with unlimited funds improperly managed healthcare would not reap any harvest.

Managed Care is the systems designed, structures put in place, processes developed, outcomes to the community and country and managed care organizations. To manage care he stated it was necessary to work towards a vision. One needs to understand the position they are in, project the needs towards the goal, change demography profile and epidemiology, look at the hardware and software needs, human resources, behavioural patterns of professionals and the way patients are managed. Successful managed care would be appropriate, accessible, affordable, effective, efficient and timely. Financing, on the other hand, spirals healthcare costs, increases patients demands and the cost of medication and disposables, medio legal dimension.

To manage care properly at national level one needs to address problems of financing and try to control cost of care. The funding for managed healthcare is allocated a bigger portion from the budget even more than education. However if it shrinks from the national coffers new sources of funds should be looked into. Funding could be acquired from individual out of pocket, insurance funds, lotteries, employer contribution, sin tax and from charity. These funds could be disbursed through what is known as the present “mixed bag”, fully nationalized, fully subsidized model, the USA model and the non privatized national universal compulsory insurance model.

Commenting on the National Healthcare Insurance (NHI) model that is in consideration in Malaysia he stated that it covers the civil servants and armed forces, hard core poor, the old, the unemployed, the handicapped, the self employed and the employed. The NHI structure should be drawn to have a statutory body, owned by the government, compulsory health insurance, provide primary, secondary, tertiary care, all citizens included, identical care for identical needs and different social/economic groups pay different premiums.

A few consensus points which were thought to be essential for a properly run and financed health delivery system were non marginalization, core provided, supply chain, transparency, solidarity, responsibility of one’s own health, not for profit system of financing, changing role of the Ministry of Health and public/private divide. He concluded by stating that the compulsory health insurance system should carry options of paying higher premiums during working years to store for the future, the scheme remains viable for the long term without disappearing leaving hundreds of customers in the lurch.

Viable options for healthcare financing

Sharing some pearls of wisdom on optional healthcare financing mechanisms for countries in the Asia Pacific region: what is viable Dr Claudio Schuftan of the People’s Health Movement of Vietnam stated that equity in health meant equal access for equal need. Government intervention

in the inequitable workings of the free market is required to bring about equity in health. The problem of resource shortages in the health sector cannot thus be seen as a mere sectoral problem.

Health fees are little more than an additional form of direct taxation. Even if efforts are made to base fees at affordable levels, the poor will accumulate debt when faced with major illness. Protecting the poor from charges depends on setting up cumbersome administrative procedures for waiving fees. A question that also arises is, does willingness to pay reflect the ability to pay? This means that we need to address the ethical issues of the impact of charges on equity. From the World Bank's perspective, efficiency is the key concern to pursue in healthcare financing and equity takes second place to efficiency. The bank supports a market-based allocation of health resources and envisions a limited role of government in the distribution of societal resources. But ultimately, it is the relative utilization of health resources and facilities by the different socio-economic groups which will tell us about how equitable the allocation of these resources has been. Increasing efficiency is therefore, not a good enough reason to raise fees.

The basic justification for assessing equity does not change with the level of resources available in a society. With equity in mind, the assessment of the likely impacts of paying fees on users has to be disaggregated by income distribution and these characteristics of users need to be assessed before and after implementing the change. The challenge definitely is finding a just balance between efficiency and equity. From the perspective of the poor, social and economic considerations are too often forgotten in the politics of healthcare allocations.

Payment exemption and mechanisms and retention of revenue arrangements remain grossly unaddressed in healthcare financing plans and most of the power still remains centralized. Increasing access to healthcare is not impossible if fee revenues are retained by the facilities themselves. But barriers still exist for peripheral facilities to retain fee revenues and using them effectively and equitably at local level community inputs. Public expenditure is more important than taxation in the overall distribution of income, healthcare expenditures should be biased in favour of the poor. Therefore need for healthcare should be defined along the lines of the socio economic status of households. Income per capita is associated with demand for healthcare. A more deliberate, broadly-based, pro-poor socio-economic development is thus prerequisite for an improved status that is sustainable. Worldwide the distribution of healthcare is already inequitable in socio economic terms. Increasing the cost of care will become more inequitable and aggravate poverty. Prices are important determinants in healthcare demand, lower income would bring a low demand in response to price changes. Healthcare financing reforms alone cannot bring about sustained better health. The promotion of wider structural changes in society is also required. Health is only a part of total care.

We should continue to struggle for pre payment schemes preferred over fee for service schemes, if a fee for service system; is chosen, under five care, maternal services, preventive care, chronic diseases treatment, mental health and STD/AIDS/epidemic diseases, services should remain free of charge. A system for certifying indigency needs to be determined before launching a cost sharing system; a cost sharing system cannot be denied: it has to start nationwide from the beginning, ad-hoc security measures must be taken to collect and safeguard the money, accounting/auditing systems need to be set up so that administrative personnel is trained accordingly, payments for inpatient services need to be capped for the poor, referrals to higher levels of care have to be capped not to penalize the sick, cost sharing on laboratory, X ray services and on expensive essential drugs could be incorporated in the system; assessing the ability to pay by users has to precede even the planning of cost sharing interventions; assessing the users/payers socio economic and other characteristics before and after launching is also a must; assessing the impact of the new system on the demand for services after launching is a must as well; alerting the mission hospitals/clinics to expect an increase in demand for services after government begin to charge is highly recommended; retention of fees by the Ministry of Health is non negotiable. Studies are needed to assess users' perceived of care shortcomings in government facilities so as to concentrate expenditures on closing these qualities of care gaps first. District health management teams, with community participation have to have control over expenditures of fee revenues and the Treasury must give assurances to the MOH that no further cuts in the MOH budget will be attempted later when cost sharing revenue is collected.

Reports of working groups

In the latter phase of the seminar participants were divided into small working groups to find responses to some of the questions posed by the speakers themselves. All the groups agreed that private Health Insurance (HI) may have a role to play in the event a National Health Financing Scheme is put in place. Nevertheless, some argued that strict regulation and accountability should be taken into consideration while others stated that private HI has to be country specific e.g. Belgium, Canada do not allow any private HI for essential services. Consensus was that private HI was acceptable but should not compete with national systems for a defined basic package that should be available to all. People With higher purchasing power would have the freedom to opt for additional coverage from private HI providers. Therefore, clear-cut guidelines must be formulated to ensure that the private sector functioned in a responsible and consumer-friendly manner. Practically all countries in the region are working on some form of social Health Insurance scheme that is being promoted by the government

Expressing their views on developing a third sector (public sector, private sector) and a cooperative sector in the provision of Health Care some participants stated that the word cooperative was rather confusing however, if it means community based health insurance (CBHI) it must be subsidized by the government. The concept of CBHI is difficult to implement for instance in Sri Lanka because the government is already taking money in the form of taxes. Cooperative schemes are already in operation in some countries of the region. There may be schemes for defined population groups for instance factory workers, railway employees, armed forces. There is place for a cooperative sector to bridge the gap wherever the public sector services are not up to the mark and the private sector is too expensive. Viability of a cooperative sector would come into question because whenever the other sectors improve or the private sector adopts a 'poaching' mentality. Probably a third sector is not a viable alternative for a nationwide system.

Speaking on the ongoing debates and discussions on viable optional health care financing mechanisms in the countries represented, the participants stated that Malaysia had a difference of opinion, both positive and negative. India and Sri Lanka were not transparent and Pakistan came out with a negative response. For Thailand it was a question of foreign debt. However, discussions and debates are ongoing in all the countries represented regarding

- Optimum level of Government spending on healthcare as opposed to other sectors.
- Role of the private sector.
- Strengths & weaknesses of existing health financing schemes and suitable alternatives to them.
- User fees.
- Health insurance

Analyzing the strengths and weaknesses in the health care financing schemes in the countries represented the groups commented that the public sector budget is inadequate, suffers from overcrowding, poor reimbursement of providers, poor management and has to share almost the entire burden of preventive services. Private sector is expensive, concentrates on specialized and curative services, avid and uncritical user of new technology. In Australia waiting period in public schemes is sometimes too long and doctors are reluctant to serve in rural and interior areas. In Sudan access to health facilities is in itself a major problem and the private sector concentrates on tertiary care, though officially this should not be the case. In Malaysia the health care sector would not reform only with NHFS.

A question that was posed by many present at the seminar was whether a community based health insurance was viable in all the countries. Participants agreed that political will/choice matters a lot and that community based options have been eroded because of intervention by international agencies e.g. IMF, World Bank. Local governments have limited freedom to formulate programs of public health. They were also of the view that community based is needed, viable or not depends upon governments. There was no consensus on the issue of CBHI, ideologically would be a good experiment. However it would tend to encourage the state to abrogate from its duty of reaching essential health care to all. Speaking about how bad the fee for service system has been for the poorest 20 per cent income in the countries represented the participants stated that the groups could not state exact figures but the general consensus was that the user fee system badly impacted the poorest 20 per cent of the population – to the extent that they avoided the formal healthcare system and tended to rely on self-medication and unqualified practitioners, sometimes with disastrous consequences. It was definitely regressive and detrimental for all countries.

The extent of the problem of migration /movement of health personnel in Asian countries was also discussed. In the Philippines it was a very serious problem, while in India it was important and a much debated problem. In Indonesia it was a sure problem while in Thailand and Sudan although it did not appear to be a threat, intersectoral migration posed a problem. In Pakistan there was brain drain of health professional such as doctors, nurses and pharmacists taking place. In Sri Lanka it had not become a problem as yet. On the other hand Australia and Malaysia were two countries that attracted doctors from overseas. On the viable intermediate and short term solutions to the problem the groups suggested increasing salaries and incentives. However, in the case of India, the scenario is different since the doctors already had high salaries. Some participants also stated that a period of compulsory service to the Government should be imposed although other participants felt that this solution alone was inadequate. Another solution that was mentioned was to request non-residents to contribute to the national Government but besides the logistics, this would be unfair if doctors at home cannot be properly paid. Build up more capable nursing and paramedical personnel who can share some of the routine workload of doctors. Best solution in the long-term is to understand the reasons for migration and address them.

Dealing with the question of striking a balance between engagement with activism/agitation all the participants said it was necessary. Nevertheless for them these terms carried different connotations. Engaging in meaningful dialogue and activities without being too radical and dismantling the existing structure was essential. Integrating in popular health movements with broader social movements (for instance at a global level-PHM and WSF replicate at national level and regional levels). Two views on this matter were put down by the groups. People involved in health movements tend to stick to them as the field itself is vast and there is so much to do. However, awareness of broader social issues and movements is essential. Health movements alone cannot be successful without integrating with other social movements at the national and regional levels

** Anwar Fazal, a HAI board member from Malaysia, reports that recent developments under the leadership of the new Prime Minister of Malaysia suggest that there are now some positive concerns about privatization in Malaysia. Among these developments is the Malaysia Integrity Plan and encouraging announcements that privatization contracts will be reviewed and be more transparent. Whether these recent developments will materialize into some fundamental change is not yet certain but the situation will be watched carefully by civil society groups, some skeptical and others optimistic.*

- Network News -

HAI Europe

Four projects underway for HAI Europe

HAI Europe currently has four major projects underway focusing on Drug Promotion, Essential Innovations, Medicine Prices and Public Private Interactions. A short synopsis of the work involved is given below.

Medicine Prices project Tackling the challenges of price, affordability and availability

One-third of the world's population lacks reliable access to the medicines they need – primarily because they cannot afford to buy them. In the poorest countries of Africa and Asia this figure rises to 50 per cent. People in industrialized countries generally have social insurance covering most of the price of the medicines they need, but people in poorer countries typically pay the full cost. For them price is a huge problem.

HAI and WHO have developed a method to survey the prices people pay for a selection of needed medicines, assess the affordability of some standard treatments and assess price components (mark-ups, taxes etc). The tool is published in the manual "Medicine Prices: a new approach to measurement" (working draft). In addition to offering guidance on how to collect and analyze price information and make international price comparisons, the manual sketches broad policy options to

achieve more affordable prices. The manual and accompanying software are a result of the widely felt need for greater transparency on prices in the global medicines marketplace. Price data collected using the methodology is lodged on HAI's web site – www.haiweb.org/medicineprices

In 2004/5 a number of regional workshops will be held to assist investigators to use the survey tool. In addition, country-specific in-depth analyses of the reasons for high medicine prices will be undertaken e.g. a multi-country assessment of the manufacturers' selling price and an assessment of the impact of negotiations and pooled procurement on prices. A number of validation studies are also planned and in 2005 the manual will be finalised.

Drug Promotion

Educating to improve critical appraisal skills

Unethical drug promotion can result in irrational, wasteful and even dangerous use of medicines by health professionals and consumers alike. Unethical drug promotion takes many forms, including: provision of information that is scientifically inaccurate or lacking in balance; inappropriate inducements to prescribers; failure to provide full product information; misleading presentation by medical representatives and promotional activities disguised as educational symposia and clinical trials. New marketing trends include the promotion of prescription drugs directly to the public (which is illegal in Europe). This is often done covertly through means such as patient help lines, and support to and relationship building with patient groups.

One of the reasons why unethical drug promotion occurs is due to the lack of awareness. Health personnel have insufficient training to see promotion for what it is and to critically appraise it. Consumers also lack access to reliable and objective medicine information, and to education to critically evaluate drug promotion and basic principles of rational drug use.

HAI Europe will continue to advocate for good quality, independent, objective, and comparative information about prescription medicines and other treatments (rather than drug promotion whose purpose is to sell the product).

The HAI/WHO drug promotion database (www.drugpromo.info) currently contains 2700 entries on material that describes, analyses, reports on or comments on any aspect of drug promotion. This database will be updated and further developed in 2004/5. A review of database material found that only a few papers have been published describing programmes to teach health professionals or students to critically assess drug promotion. Therefore, HAI Europe and WHO are working together to develop a global inventory of educational initiatives to teach medical and pharmacy students about drug promotion.

Public Private Interactions

Enhancing equitable access to HIV/AIDS medicines: benefits and risks of public private interactions

Growing recognition of the depths and costs of the AIDS crisis have produced, at the transnational level, a shift away from a largely public production of health care policy to an institutional framework involving a mix of actors.

Private Public Interactions (PPIs) are proposed as win-win solutions to the AIDS pandemic. With an outcome orientation and efficient 'lean' governance structure, PPIs are expected to move fast in making medicines available to people living with HIV/AIDS. In practice, fast and effective action is proving to be difficult: funds for implementation of projects are often constrained, with implications for their functioning and the communities they are intended to serve. Other risks have been recognized including strain on existing health infrastructure, inequity in delivery, and questions about accountability and responsiveness to the public.

Through working with academic institutions and NGOs providing care and support and community based organizations of people living with AIDS, HAI is developing a methodology to conduct country situation analyses in a number of pilot study countries. The resulting information will be used to assess the impact of PPIs on access to medicines at the community and country levels, and to contribute to global data collection and policy.

This project is conducted as a collaboration between the four HAI regions - Africa, Asia/Pacific, Latin America and Europe. The project is co-ordinated by HAI Europe.

Essential Innovations:

R&D to meet public health needs

The pharmaceutical sector is failing the public. It is widely recognized that in pharmaceuticals, private sector research and development (R&D) is market-driven. In rich countries a market-driven pharmaceutical industry does not sufficiently respond to the needs of particular patient groups, such as women and children. Across the world, it excludes those population groups who represent commercially non-viable medical needs, despite the fact that their illnesses constitute 90 per cent of the global health burden.

The commercial power and influence of the pharmaceutical industry in national and global policy has thrown up a visible divide between trade competitiveness and health. Increasingly health appears to be sacrificed in the race between regions for trade superiority. Health care systems are under enormous strain, and costs continue to spiral, without clear signs of benefits for the public. Yet the public pays for innovation in health through a number of mechanisms such as taxes, tax breaks and credits, insurance, and through legal framework

As a network working to protect the interests of consumers in medicines policy, HAI will be assessing the suitability and sustainability of current strategies to stimulate innovation that responds to public needs. The public deserves fair returns and fair accounting of its investments in health financing, taking into account both social and economic criteria. It deserves efficient production and delivery of medicines it finances.

The Essential Innovations project will involve a series of consultations with consumers, health care providers, regulators, and policy makers, to examine the evidence of the success of the current global framework of financing R&D as a mechanism for delivery of drugs, diagnostic tools and other instruments to meet public needs. The project will explore policy adjustments necessary to improve R&D, and it will document best practices for achieving essential innovation. The project also intends to develop tools for measuring the returns to the public from R&D, and test this methodology in a number of contexts.

Contact HAI Europe on info@haiweb.org if you would like more detailed information on any of these projects.

Baby food companies exposed as IBFAN presents evidence at UK Parliament

The International Baby Food Action Network (IBFAN) launched its latest monitoring report documenting how baby food companies idealize their products, ignoring the negative health impact of artificial feeding. Evidence gathered through monitoring of baby food companies in 69 countries was presented at the House of Commons in May 2004.

The meeting was hosted by UK Member of Parliament, Lynne Jones MP, who has tabled an Early Day Motion (a petition for MPs) calling for the UK Government to support action to end baby food marketing malpractice in the UK and in other countries. This is already receiving significant support across political parties.

The IBFAN experts discussed current concerns in infant and young child nutrition, such as bacterial contamination of powdered formula and the increased use of bogus health claims to promote artificial feeding at the World Health Assembly 2004.

The "Breaking the Rules, Stretching the Rules 2004" monitoring report analyses the promotional practices of 16 transnational baby food companies and 14 bottle and teat companies between January 2002 and April 2004. The benchmark standards used for measuring marketing practices are the International Code of Marketing of Breast milk Substitutes and subsequent, relevant World Health Assembly (WHA) Resolutions. The marketing requirements aim to defend breastfeeding and to ensure that breast milk substitutes are used safely, if necessary, on the basis of adequate information and appropriate marketing.

Some 3,000 complaints were received from monitors in 69 countries around the world. After legal checking about 2,000 violations were reported in Breaking the Rules and many of these came with

photos. Yeong Joo Kean, IBFAN's Legal Advisor said: "We have 712 pictures of actual violations in the report. There is no way that the companies can deny that they were found in flagrant violation of the Code and Resolutions."

An overview of the report is available on the site. It highlights the following trends in violations:

- * 'Functional' claims. Companies try to differentiate their formulas by adding a string of additives and then claiming performance benefits for these.
- * Free and low-cost supplies continue.
- * Exclusive breastfeeding for 6 months continues to be undermined by most companies.
- * Information to health professionals. Companies violate the requirement that this is restricted to scientific and factual matters.
- * Health facilities and health workers continue to be targeted.
- * Sponsorship of medical seminars, conferences and associations of medical professionals is becoming more widespread.

It also contains profiles of the big 16 baby food companies. The major bottle and teat companies are also evaluated. Country summary reports with the title "Look What They're Doing" have been prepared for several countries including China, Egypt, Indonesia, United Kingdom, Zimbabwe, Tanzania, Ghana, Latin America and the Caribbean.

Source: IBFAN Press Release - 14th May 2004. For more details see on-line version for reports and links at <http://www.ibfan.org/english/news/press/press13may04.html>

International conference in Moldova about professional and consumer reporting

"Safety of medicines" is a hot topic among physicians, pharmacists, nurses and economists from Non Governmental Organizations and Governmental Organizations in the Newly Independent States (NIS). This was a conclusion drawn by DrugInfo Moldova and KILEN Sweden, the organizers of the three-day-conference titled, "Quality and Safety of Medicines - Patient Safety" in May 2004. It was supported by the Swedish International Development Agency. The participants came from 6 NIS-countries - Kazakhstan, Kyrgyzstan, Moldova including Transnistria, Tajikistan, Ukraine and Uzbekistan.

The venue for the conference was a small city in the northern part of Moldova, Bricheni where the chief of the hospital, Claudia Veltman, was the local host. The host and the organizers had also involved the local administration and the Mayor of Bricheni and the representative of the President from the north in the conference, which was very successful. During the opening ceremony, the City Mayor, the collaborating parties and the international guests spoke about safety of medicines, a topic of paramount importance to all of us. Especially in the conference hall of Bricheni such words had never been pronounced before!

During several "small groups" the participants explored the problems around safety of medicines, pharmacovigilance and their needs and possibilities for establishing systems for a medicine safety programme. The participants also made a personal plan for their safety of medicine programme in the respective countries - how to establish reporting facilities for professionals and consumers - and how to collaborate with each other. The huge interest among the participants and the great delight to have the possibility to exchange experiences about working conditions, medicine problems were striking.

One of the problems expressed by many of the participants was the huge lack of equipment, like computers and Internet access. Sweden, as one of the collaborators in this conference and project, will start a subscription in aid of computers in Sweden and donate them to organizations which need them.

At the end of the conference a statement of these discussions was adopted titled, "the Bricheni Declaration". Although it is originally in Russian it will also be translated into English. The Bricheni

Declaration will work as a platform for future engagement and work in the region. This is a start of a three year project which has as its aim involving professionals and consumers in "safety thinking" when it comes to medicines and encouraging organizations to start work in the field of pharmacovigilance. Some of these NIS-countries are not members of (UMC) yet, while others are already members. Conferences like this would be ideal preparatory venues for a future membership in UMC, but most of all, good for thinking of safety in medicines - would mean nothing less than a life saver!

Source: KILEN

For more information, please contact Dr. Natalia Cebotarenco, DrugInfo Moldova, druginfo@mtc.md or Jan Albinson, Lena Westin, KILEN, kilen@kilen.org

World Health Assembly in a nutshell

The adoption of a global strategy on diet, physical activity and health was one of the highlights of this year's World Health Assembly. The strategy addresses two of the major risk factors responsible for the heavy and growing burden of noncommunicable disease, emphasizing the need to limit the intake of certain fats, sugars and salt, and increase consumption of fruit and vegetables, and levels of physical activity. Another issue that was dealt with broadly was Reproductive health. Reproductive and sexual ill-health accounts for 20 per cent of the global burden of ill-health for women, and 14 per cent for men. Demonstrating a unified commitment to improve this situation, the World Health Assembly adopted WHO's first global strategy on reproductive health. The strategy targets five priority areas including antenatal care, family planning, and sexually transmitted infections. On HIV/AIDS the WHA welcomed the Director-General's "3 by 5" strategy to support developing countries in their response to HIV/AIDS, by increasing access to prevention, care, treatment and securing access to antiretroviral treatment for three million people living with HIV/AIDS by the end of 2005. The Health Assembly also urged the Director-General to improve the access of antiretroviral medicines and other products used in the diagnosis, treatment and care of HIV/AIDS to developing countries. Another highlight of this year's World Health Assembly was the unanimous adoption of a resolution on road safety and health. The resolution, the first on this topic to be adopted by the body since 1974, seeks to address the lack of safety on the world's roads, responsible for 1.2 million deaths and as many as 50 million injuries annually. The resolution follows the widely celebrated World Health Day 2004, dedicated to road safety.

Mycobacterium ulcerans disease, or Buruli ulcer, is a poorly understood disease that affects the skin, causing deforming ulcers that can lead to serious disabilities. By adopting a resolution on increasing surveillance and control of Buruli ulcer, the World Health Assembly called for intensified research to develop tools to diagnose, treat and prevent the disease. While Dracunculiasis, or guinea-worm disease, is a painful and disabling parasitic disease found in poor, rural communities lacking access to safe water. The number of cases has decreased dramatically over the last two decades. In a bid to finally eradicate guinea-worm disease, the WHA adopted a resolution urging endemic countries to intensify eradication efforts, and calling on the global community to continue its cooperation and commitment for these efforts.

In his speech to the World Health Assembly, Mr Jimmy Carter, former President of the United States of America, stressed the importance of access to treatment for people with mental illnesses. The message was reinforced during a technical briefing on mental health and substance abuse by former First Lady Rosalynn Carter, who urged ministers and delegates to implement an earlier resolution (WHA55.10) aimed at improving people's mental health.

Source: For more information please access www.who.int

Asia-Pacific

Neglected Diseases Group & Medecins Sans Frontieres Annual General Meeting report

The annual meeting of the Médecins Sans Frontières (MSF) Neglected Diseases Group (NDG), which was co-hosted by the National Centre for Drug Research at the Universiti Sains Malaysia, took place from 6-7 February 2004 in Penang, Malaysia. The NDG is a multidisciplinary, global network of committed experts who share their ideas and analyses on ways to promote the

development of medical innovations adapted to the needs of neglected patients, and to ensure access to new and existing health tools. The meeting brought together about 100 participants, including representatives from academia, the scientific research community, governments (including drug regulatory agencies and policymakers), intergovernmental and non-governmental organizations, the pharmaceutical industry, and other members of civil society. The broad goals of the meeting were to review progress since the last gathering in Rio de Janeiro in December 2002, share and discuss new findings and engage concerned experts on the issue of neglected diseases.

The Crisis in Health R&D

The meeting opened with the affirmation that there is a global crisis in health Research & Development (R&D) that could be felt in both developing and industrialized countries. "Most scientists will say, 'Crisis? What crisis?' There are more scientists than ever before, more progress, and more patents," observed Nobel laureate Sir John Sulston in his keynote address. "But I think there is a crisis about applying R&D to necessary targets..., will the benefits extend to everyone, or only to the rich?"

The failings of the R&D system are clearly reflected in the shortage of new drugs developed for the diseases that most heavily impact populations in developing countries: out of 1393 new drugs approved between 1975 and 1999, just over 1 per cent was specifically developed for tropical diseases and tuberculosis. It is estimated that only 5 per cent of total R&D funds are being spent on the health problems of 93 per cent of the world's population. "About a third of all deaths are from infectious and parasitic disease.

The Art, Science and Politics of Priority Setting in R&D

Priority setting is not a straightforward process, as Dr Vasantha Muthuswamy of the Indian Council of Medical Research pointed out; rather, it is sometimes conducted in a haphazard way, according to the whims of decision makers or scientific trends that are far removed from real human needs. However, Dr Tikki Pangestu of the World Health Organization (WHO) asserted that the process has become more systematic in the past decade, with perhaps even too great a reliance on "scientific autonomy" that was "detached from the public interest." Dr Pangestu continued that scientific input was a "necessary but not sufficient" factor for setting priorities, and emphasized the importance of political commitment. Dr Bernard Pécoul stressed that the Drugs for Neglected Diseases Initiative—a brainchild of the NDG—would set its research priorities based on patients' needs and the principle of "going where others are unable or unwilling to go."

Another oft-cited challenge for agenda-setting was the frequent lack of reliable data on those most affected by neglected diseases, who are—almost by definition—politically and/or geographically marginalized. As Dr Nick White put it, "The quality of our data is inversely proportional to the severity of the problem." "In certain aspects AIDS is a neglected disease," said Ellen 't Hoen, Interim Director of MSF's Campaign for Access to Essential Medicines. "The R&D agenda for AIDS is set in America and Europe with those markets in mind, and very few tools are being developed for the majority affected by the disease. Paediatric formulations of badly needed fixed dose combinations do not exist— this is not acceptable. We have to do more to improve the quality of care for patients in the developing world".

The Role of Asia in Neglected Disease Research

Dr Visweswaran Navaratnam presented the long history and future potential of natural products, pointing out that 11 per cent of 252 drugs on the WHO essential drugs list come exclusively from flowering-plants. There has been a recent upsurge in interest in natural products in Malaysia, where the number of herbal products registered with the National Pharmaceutical Control Bureau leapt from just 339 in 1995 to 8570 by 1999. Dr Navaratnam argued that new technologies could enable a more rapid and scientifically-rigorous exploration of the potential of natural products, possibly yielding results for neglected diseases. The development last year of a SARS diagnostic test shows what can be achieved when there is significant motivation by the scientific and political community. Dr Ren Ee Chee, who led the team that developed the primer-based assay at the Genome Institute of Singapore together with Roche in just three months, said such a kit would normally take 18-months to develop. "This development was more needs-based than money-motivated. Everybody was screaming for assays, we really had to push ourselves."

Also based in Singapore, Dr Alex Matter presented the recently-launched Novartis Institute of Tropical Diseases (NITD), a partnership of the pharmaceutical company Novartis and the

Economic Development Board of Singapore. With a budget of \$US 122 million over ten years, the NITD plans to discover new treatment and prevention methods for dengue fever and tuberculosis, with a commitment to making the resulting products “readily available and without profit.”

Patents and Neglected Diseases

Professor Sudip Chaudhuri of the Indian Institute of Management Calcutta contended that, for multiple reasons, the Indian pharmaceutical industry was unlikely to conduct significant research into neglected diseases in the coming years. One key reason is the business model that Indian firms have chosen: to engage in upstream research, and then try to license out promising molecules to larger multinationals, which have much greater capacity to complete the drug development process and market a new drug. Consequently, Indian firms are targeting their R&D towards molecules that will appeal to major pharmaceutical firms, whose priorities lie in wealthy Western countries. Professor Chaudhuri concluded that the arguments made during negotiations for the World Trade Organization’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)—that patent protection would lead to research that was more relevant for developing countries—have yet to be proven true.

Dr Hanna Nohynek and Dr Veronica Tallo pointed out another challenge to conducting R&D in the area of neglected diseases, when they related the difficulties they faced continuing their clinical trials for a pneumococcal vaccine in the Philippines; the manufacturer for the future vaccine did not want to continue the Phase III trials when it was found that the vaccine might be useful in developing countries, but was not likely to be licensed in Europe or the US.

Mobilizing the Scientific Research Community

There is no lack of basic research on tropical diseases. But most of this is done in the West, and little translates into benefits for patients. visceral leishmaniasis, a disease that kills around 50,000 people every year is a good example of this disjunction. It was generally agreed that both cultural and structural reasons prevented scientists from engaging in neglected disease research. Speakers offered a number of concrete suggestions to address both, including: increasing the stature associated with neglected diseases through establishment of a prestigious prize; restructuring public funding requirements; rewarding multidisciplinary approaches to global public health problems; establishing regional networks of research centers, universities, and local pharmaceutical firms focused on neglected diseases; and setting up an international information system to connect concerned researchers. Dr Pierre Druilhe of the Institut Pasteur cautioned against “exporting to the south our own mistakes about research.” He said “we should try to think about how to increase the capacity of excellent research units in the south, so that they are not dependent on a system which is totally impotent.”

Regulatory Capacities and Challenges

Dr Kris Weerasuriya of the WHO/South-East Asia Region explained that drug regulatory agencies (DRAs) in developing countries have widely varying levels of capacity, and many rely on the assessments of Northern agencies regarding the safety and efficacy of new drugs. Thus, it may be problematic for developing countries to assess the safety and efficacy of new drugs for neglected diseases if established DRAs, such as those in the US, UK and Scandinavia, have not first registered them.

A related concern is that the globalization of the International Conference on Harmonization (ICH) may impose inappropriate and overly stringent regulatory standards on developing countries. The ICH is an effort by DRAs and pharmaceutical companies based in the US, EU and Japan to harmonize their regulatory requirements; however, since 1997, the ICH has been trying to expand its guidelines beyond these 17 countries and promote them as global standards.

Dr Wilbert Bannenberg presented the findings of an expert meeting which the NDG convened in July 2003, expressing concerns that ICH implementation might increase the price of generic drugs without any discernible benefit, is driven by market concerns—not public health, and is not transparently governed. Given that ICH countries represent only 15 per cent of the world’s population, he also raised questions about the legitimacy of ICH to set de facto standards for the remaining 85 per cent of the globe. Multiple participants called on the WHO to get more actively involved in regulatory issues by defining “essential standards” for safety and efficacy, strengthening DRA capacities, and expanding its pre-qualification activities.

Paying for New Medicines

The meeting also considered how R&D for new medicines is financed. Recuperating R&D costs through drug prices means that medicines are often unaffordable to the majority of those who need them; in order to achieve “equity prices” for essential medicines, which can be defined as 'being fair, equitable, and affordable from the point of view of the individual and the community,' it may be necessary either to reduce the costs of R&D and/or to separate the financing of R&D from the price of medicines. Professor David Henry of the University of Newcastle argued that drug prices should not, in fact, blindly reflect R&D costs, but rather, should be scaled according to the therapeutic value of a medicine. Furthermore, in a system he calls “therapeutic value equity pricing,” Professor Henry proposed that drug prices reflect different income levels between and within countries. But if R&D is to be de-linked from prices, how else should it be financed? One possible alternative that has recently gained in popularity is the 'advance purchase commitment (APC),' which major funders such as the Gates Foundation, World Bank, and the UK Global Fund for Health are currently exploring. In general terms, an APC requires a donor to commit to buying a certain quantity of a drug at a certain price if it is successfully developed. However, economist Andrew Farlow of Oxford University was skeptical that APCs would be effective or efficient. Because of the changing nature of technology, information asymmetries, and the strategic incentives of various competitors, among other factors, he argued that APCs are likely to cost far more than currently estimated and may reward the first, but not the best, inventor of a drug.

Alternative Models for R&D

Alternatives for financing R&D, such as major public-private partnerships (PPPs) to address neglected diseases, have been road-tested now for several years; the moment was ripe to take another look at the potential and problems these partnerships face. Dr Anthony So of Duke University proposed the development of a widely-accepted set of criteria by which PPPs should be evaluated. He suggested criteria such as transparency of governance, capacity building in developing countries, and track record developing affordable products as possible yardsticks. He also argued that civil society watchdogs should monitor PPPs to ensure that they do in fact serve the public interest. For instance, Novartis has set up a drug discovery institute for Dengue and TB in Singapore. Dr PV Venugopal of the Medicines for Malaria Venture pointed out some operational challenges that PPPs face, including: competition among PPPs for the same funders, difficulty attracting the pharmaceutical company partner with the right mix of motivation and capacity and attracting top scientists despite relatively low salaries.

Sir Sulton expressed concern that patent protection is cutting off exploitative routes for scientific discovery. “The R&D effort is private, and data which is not used to create a profitable product will be lost.” Tim Hubbard, was also critical of the social worth of patents. “The patent system is based on the idea that you have to pay for R&D commercially. But patents prevent access to medicines by making prices very high, and you end up with only the drugs which industry wants to develop.” Dr Hubbard proposed an alternative that is completely different from the PPP paradigm: an open-source research model. Applying lessons learned from the Human Genome Project, the 'open-source' software movement, and an emerging trend of “open-source” publishing in the sciences, Dr Hubbard argued for moving away from the existing monopoly-based drug R&D model to a new business model that emphasizes collaboration and sharing of information. Not only would greater openness be more efficient, he said, but it would also allow for independent evaluation and greater accountability for findings. In such a system, most drugs would not be patented. Rather, an R&D 'market' would exist separately from the sales of medicines, and include its own internal systems for rewarding researchers, thus allowing drugs to be sold at near production costs.

Time for a New International R&D Framework?

The market-based intellectual property system, which promises patent monopolies to drug developers, drives much of the world's pharmaceutical R&D today. However, numerous ethical and efficiency concerns arise with this model, including unaffordable drug prices, drugs that do not meet major human needs, a proliferation of “me-too” drugs, duplication of research efforts when findings are not made public, and concealment of unfavorable scientific findings, among others. WHO will begin exploring some of these issues this year through its Commission on Intellectual Property Rights, Innovation and Public Health. The Commission is charged to produce “an analysis of intellectual property rights, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries.” In the closing session, the NDG meeting turned its attention to these issues as well by focusing on alternative R&D frameworks.

One concrete proposal for an R&D treaty that would serve as an alternative to TRIPS came from James Love of the Consumer Project on Technology. In part, the rationale for international agreements like TRIPS was to prevent “free-riding” by some countries on the R&D done by others, according to Mr. Love. By finding alternate ways for countries to contribute their fair share to R&D he said, states could be released from their obligation to provide patent protection on medicines.

Conclusion

The NDG gathering made it clear that the issue of neglected diseases—and more broadly, the health needs of neglected populations—remains high on the public agenda. In addition, recognition is growing that the existing R&D system, dominated by market priorities and patent protection, is failing societies both rich and poor. Various members of the NDG are engaged in efforts to change the system: at the micro level, the focus is on improving priority-setting practices, harnessing the abilities of disease-endemic countries, strengthening national regulatory capacities, mobilizing scientists, and making disease-specific public-private partnerships work. At the macro level, work is underway on how to structure an international system for health R&D that is fair and effective, and serves the needs of all.

The NDG meeting agenda, all presentations, and available copies of speeches are available at <http://www.accessmed-msf.org/ndg/index.asp>. Comments are welcome and can be sent to access@geneva.msf.org

Latin America Round table on generics and bioequivalence

The roundtable on generics and bioequivalence held in Lima, Peru from 15-16 April, 2004 was organized by Acción Internacional para la Salud. Experts from Argentina, Brazil, Chile and Ecuador were invited to review the status of generics products facing bioequivalence. The findings are as follows.

Argentina has established a system to classify drugs according to their “sanitarian risk”, “therapeutic range” and “adverse reactions” of the drug. Under this system, Argentina has three types of generics:

a) high sanitarian risk; b) medium sanitarian risk; and c) low sanitarian risk. They also take in to account the regulations regarding generics in countries like Canada, Germany, and the United States. This has been useful to set up a priority list of those drugs that should have bioequivalence tests in the country. In Brazil, drugs have been categorized into three categories: a) innovator/brand name; b) generics, that have to demonstrate bioequivalence; and c) “brand name copies”, which do not have to demonstrate bioequivalence.

While in México, the medicines in the market are classified into two categories: a) brand name drugs (innovator and copies); and b) generics. The latter use the term “interchangeable” and they need to go through the following tests: a) compliance of GMP; b) GMP+dissolution profile and c) GMP+dissolution profile + bioequivalence test. 67 per cent of generics are approved without bioequivalence tests. In fact, to demonstrate that a generic drug is “interchangeable” with other drugs it is not always necessary to have bioequivalence tests.

Colombia has stressed the compliance of GMP to assure the quality of medicines. All producers should fulfill the norms of GMP. In Chile the “generic drug” is regarded as “interchangeable” and should demonstrate pharmaceutical and therapeutic equivalence. However, they classify the drugs according to their solubility and permeability characteristics and decide which should go through a bioequivalence test to prove therapeutic equivalence. For many drugs, dissolution profile test is a valid alternative to prove interchangeability, without going through bioequivalence tests.

In Ecuador, there is a proposal to reform the drug registration where quality of drugs is considered: strengthening specific pharmacokinetics tests (e.g. dissolution profiles), biopharmaceutical classification of drugs, and the adoption of a restricted list of substances which required bioequivalencia by bioavailability. In Perú, regulations do not require bioequivalence test for generic drugs and there exists a law allowing the “generic substitution”. Recently, the governmental laboratory of quality control has being equipped to run bioavailability and bioequivalence tests.

As a result of the debate, the compliance of GMP is considered the most important mechanism to assure the quality of drugs, be brand names or generics. Consequently, bioequivalence test should be regarded as an

additional proof of quality for those substances with a given "sanitarian risk". Bioequivalence should not be shifted from an evaluation technique to a barrier to the introduction of generic products to the market, and therefore the use of costly medicines.

Source: AIS LAC

- *Journal Scan* -

Is GSK guilty of fraud?

Whether paroxetine, a selective serotonin reuptake inhibitor made by GlaxoSmithKline, should be prescribed to depressed children and adolescents has been the subject of recent clinical controversy. Debate over the drug's efficacy and safety has been mostly confined to the academic medical and drug-regulatory communities. The issue was catapulted into a much wider arena, with the filing of a lawsuit against GSK in New York by the state's Attorney General, Eliot Spitzer. The state accuses the company of fraud, by depriving consumers of the information they and their doctors need to make informed decisions about treatment, and seeks the return of all profits obtained through fraudulent means.

The stakes are high, for all concerned. GSK's net income in 2002 was more than US\$6.9 billion, and in the first quarter of 2004, sales of paroxetine were \$533 million. 2.1 million paroxetine prescriptions for children were written in the USA in 2002.

Paroxetine is approved for the treatment of various psychiatric disorders in adults but is not approved, either in Europe or North America, for use in patients younger than 18. But not uncommonly, doctors can prescribe drugs for unapproved indications, if they believe this is in the best interest of the patient. "Off-label" prescribing in the USA is governed not by the Food and Drug Administration (FDA) but by individual states, which regulate the practice of medicine. So the state of New York can claim a fiduciary duty to protect patients.

Paroxetine's safety and efficacy in children have been tested in at least five studies sponsored by GSK, only one of which has been published. Although that trial's results were mixed, they were heralded in a memorandum entitled "Paxil demonstrates REMARKABLE Efficacy and Safety in the treatment of adolescent depression". The other studies showed either mixed or negative results; paroxetine was no better than placebo at treating depression in children, and was associated with a possibly increased risk of suicidal thinking and acts. What constituted suicidal behaviour was eventually coded as "emotional lability". Doctors were able to obtain some, though not all, of this information, only by specific request. An internal memorandum issued at GSK in 1998, now disavowed, was aimed at managing "the dissemination of these data in order to minimize any potential negative commercial impact".

The lawsuit alleges that GSK suppressed the results of these studies, failing to make them available to doctors, in a demonstration of "repeated and persistent fraud". By providing only partial information about safety and efficacy, GSK caused doctors to have a biased and misleading picture of the drug. Doctors were thus unable to assess the balance of its risks and benefits and could not discharge their professional duties to their patients.

GSK maintains that it has "acted responsibly" in undertaking studies and in disseminating their results. Disclosure of the results, however, by GSK's own admission, has been limited to the FDA and other regulatory agencies. The company claims to "have publicly communicated data from all pediatric studies", apparently in abstract form at conferences attended almost exclusively by specialists.

People enrolled in GSK's studies; people bought the drug; people gave consent to participate in trials, presumably believing the results would be made public. Many researchers and journals have argued strongly that all clinical trials should be registered and all their results published. But as the lawsuit pointedly demonstrates, the time has come for these matters to be revealed in a bright and public light. By moving the issue into the public sphere, the pharmaceutical industry may be forced to acknowledge that all its results, whether positive or negative, are obtained only by virtue of the voluntary cooperation of the public.

This contest ought to follow the example set by recent tobacco-company litigation. GSK must create a public archive of all documents relating to paroxetine in under-18s. If GSK has nothing to hide, as it claims, it should open its files before being ordered to do so by a court--and do so right now.

Source: Posted on E-Drug on 15 June 2004

WHO to promote proper use of alternative medicines

Since traditional, complementary and alternative medicines remain largely unregulated, consumers worldwide need to be informed and given the tools to access appropriate, safe and effective treatment. To help address these issues, the World Health Organization (WHO) released a new set of guidelines for national health authorities to develop context specific and reliable information for consumer use of alternative medicines.

Up to 80 per cent of developing country populations rely on traditional medicine for their primary health care, due to cultural tradition or lack of alternatives. In wealthy countries, many people seek out various types of natural remedies on the assumption that natural means safe.

However, as the use of traditional or alternative medicines increases, so do reports of adverse reactions to these medicines. In China, a country where traditional therapies and products are widely used in parallel with conventional medicine, there were 9, 854 reported cases of adverse drug reactions to traditional medicines in 2002 alone, up from 4 000 between 1990 and 1999.

Many traditional/alternative medicine products are sold over the counter. In a WHO survey of 142 countries, 99 responded that most of these products could be bought without prescription. In 39 countries, many traditional remedies were used for self-medication, bought or prepared by friends, acquaintances or the patient. These trends raise concerns over the quality of the products used, their therapeutic appropriateness for a given condition, and the lack of medical follow-up.

"WHO supports traditional and alternative medicines when these have demonstrated benefits for the patient and minimal risks," said Dr Lee Jong-wook, Director-General of WHO. "But as more people use these medicines, governments should have the tools to ensure all stakeholders have the best information about their benefits and their risks."

Accessible, easy to understand information is key to guiding consumers in their choices. The guidelines provide simple, easy to follow tips on issues to look out for and a brief checklist of basic questions which may be used to help facilitate proper use of traditional and alternative medicine.

Advice is provided to government authorities on preparing easy-to-access information and on working with the mass media to sensitize and educate the population. In addition, suggestions are given for several health system structures and processes needed to promote proper use of traditional and alternative medicines.

While the guidelines cannot compensate for poor products or inappropriate practices, they can help governments educate consumers on how to maximize the benefits and minimize the risks of

traditional medicines.

Empirical and scientific evidence exists to support the benefits of acupuncture, manual therapies and several medicinal plants for chronic or mild conditions. For instance, the effectiveness of acupuncture, a popular treatment for relieving pain, has been demonstrated both through numerous clinical trials and laboratory experiments. As a result, 90 per cent of pain clinics in the United Kingdom and 70 per cent in Germany include acupuncture as a form of treatment. Equally, some medicinal plants have shown efficacy for life-threatening conditions; medicine combinations containing the Chinese herb *Artemisia annua* are now considered amongst the most effective remedies against malaria.

However, there have been many cases of consumers unknowingly using suspect or counterfeit products; choosing inappropriate therapies in self-care; as well as several reports of unintentional overdose.

Similarly, there have been reports of consumers being injured by unqualified practitioners. For example, a study performed by the National Research Institute on Complementary and Alternative Medicine in Norway reported cases of pneumothorax caused by unqualified acupuncturists. In addition, there have been reports of paralysis caused by unqualified manual therapists.

Another potential risk is that patients do not inform their doctors about their use of traditional and complementary medicines. For instance, Ginkgo biloba is a popularly used herbal medicine worldwide whose main function is to prevent vascular disease and to increase blood circulation. The WHO Uppsala Monitoring Centre reported some cases of excess bleeding during a surgical operation. If the patient had informed the doctor about the use of the medicine this could have been avoided.

The development of the guidelines was carried out with the financial and technical support of the Regional Government of Lombardy, in collaboration with the State University of Milan. The guidelines are based on evidence and experiences collected from 102 countries representing all WHO regions.

Policies governments could put in place:

- Make sure that sufficient information is provided to consumers on the efficacy and safety of products as well as contraindications
- Set up the right channels for consumers to report adverse drug reactions and make those channels known
- Organize communication campaigns to equip consumers with the ability to discern the quality of the service they receive
- Ensure that practitioners are appropriately qualified and registered
- Encourage interaction between traditional and conventional practitioners and,
- Provide insurance for non-conventional therapies and products whose evidence base is sound.

Health system structures and processes that would help promote better quality and safety:

- Development of quality standards and treatment guidelines to ensure uniformity within a particular health system
- Standardization of training and knowledge requirements for practitioners to promote the credibility of traditional or alternative practices and enhance consumer trust
- Collaboration between conventional and traditional or complementary care providers to improve results of treatment but also promote health sector reform
- Organization of traditional or alternative medicine practitioners to provide better structures for self-control mechanisms

Questions consumers should ask:

- Is the therapy suitable for his/her disease or condition?
- Does the therapy have the potential to prevent, alleviate and/or cure symptoms or in other ways contribute to improved health and well-being for the consumer?
- Is the therapy or herbal medicines provided by a qualified traditional medicine/ complementary and alternative medicine practitioner (TM/CAM) or health care practitioner with adequate training, background, good skills and knowledge, preferably registered and certified?

- Are the herbal medicinal products or materials of assured quality and what are the contraindications and precautions of the products or materials?
- Are the therapies or herbal medicinal products available at a competitive price?

**Source: Posted on druginfo on 23 June 2004. For more information contact: Daniela Bagozzi
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Studies Show Drug Prices Rising Rapidly

Changes in Medicare will do little to shield older Americans from drug prices that are going up much faster than inflation, say two groups pressing for lower drug prices.

American Association of Retired Persons (AARP) and the consumer group Families USA released separate studies that show prices for brand-name prescription medicines rose at more than three times the rate of overall inflation last year and that the rate of increase has accelerated in recent years.

They said the widening gap between drug prices and general inflation is diminishing the purchasing power of older Americans who receive increases in Social Security based on the Consumer Price Index. The index is the government's most closely watched inflation measure.

Families USA fought Medicare legislation last year that created a drug discount card which was to go into effect in May and prescription drug insurance that starts in 2006. The group argued the bill shortchanged consumers and rewarded insurers and drug makers. The 35 million-member AARP gave the bill its blessing, widely viewed as a key reason it was approved.

Now, both groups assert that the new law lacks provisions to alter the trend of rising pharmaceutical prices. They want drug imports legalized and the government to have the authority to negotiate Medicare prices with drug makers.

"If the price of drugs keeps going up faster than inflation, it will become more and more difficult for consumers, especially older consumers, to be able to afford them," said John Rother, AARP's Policy Director. AARP also has asked pharmaceutical companies to limit price increases to inflation, but the responses have not been encouraging, AARP spokesman Steve Hahn said.

The average price increase for the top 30 brand-name drugs used by older Americans was 6.5 percent last year, the Families USA report said. AARP's study showed an average 6.9 percent price increase for nearly 200 drugs. Inflation in general was 1.9 percent.

Since 2000, the drug prices have risen 27.6 percent, AARP said. General inflation was 9.3 percent for the same period. Prices increased between 6.9 percent and 9.9 percent last year for the five leading drugs in terms of sales -- cholesterol-reducing Lipitor, the blood thinner Plavix, Fosamax for osteoporosis, the blood pressure drug Norvasc and Celebrex, a pain reliever -- the Families USA study said.

The Bureau of Labor Statistics, which compiles the Consumer Price Index, said prescription prices rose by only 2.5 per cent last year, but that measure also includes generic drugs. Stephen Schondelmeyer, a University of Minnesota Professor of Pharmaceutical Economics and an author of the AARP report, said the index was changed in the mid-1990s to minimize drug price increases.

The reports excluded generic drugs, which make up roughly half of all prescriptions written in the United States, but only about 10 per cent of the dollar value, said Schondelmeyer.

Both studies examined wholesale prices, reasoning that fluctuations in those were reflected in costs at the retail level. Jeff Trewhitt, a spokesman for the Pharmaceutical Research and Manufacturers of America, an industry group, said the studies overstated the inflation rate for prescription drugs and did not account for the industry's substantial research and development costs.

Prices of prescription medicines have risen 4.4 per cent on average in each of the past three years, slightly slower than medical inflation, Trewhitt said. "That's a more accurate basis for comparison," he said.

Ron Pollack, President of Families USA, said the increases undermine the discounts available through Medicare's new drug cards. "Over time, base prices have increased by a higher percentage than the discounts the administration is claiming," he said. The Bush administration has said the Medicare drug cards offer savings of 10 per cent to 17 per cent on brand-name drugs.

Mark McClellan, Administrator of the Federal Centers for Medicare and Medicaid Services, said the cards and the requirement for drug prices to be posted will help reduce Americans' drug costs. McClellan urges Medicare beneficiaries to consider using cheaper generics when they fill prescriptions.

Source: Posted on Druginfo on 26 May 2004. Original article extracted from the Associated Press May 26, 2004

- Resources -

World Health Report 2004: Changing history

Published by the World Health Organization, Geneva, Switzerland

192 pages

Swiss francs 30/US 27

In developing countries Swiss francs 10

HIV/AIDS is currently the world's leading cause of death. Three million people lost their lives to this killer disease while another five million became infected in 2003. Among six million people who needed treatment it was a mere four hundred thousand who were fortunate to receive it. At a crucial moment in the history of the pandemic, the World Health Organization not only dedicates its annual world report titled, "Changing History" but also calls for a comprehensive HIV/AIDS strategy that links prevention, treatment, care and long term support to save the lives of millions of people in poor countries.

The report shows how a partnership linking international organizations, national governments, the private sector and communities is working simultaneously to expand access to HIV/AIDS treatment and strengthen health systems in the countries where they are currently weakest. In his message Dr Jong Wook Lee, Director General of the WHO states, "Most of the increased funding is for the fight against HIV/AIDS. ..The responsibility of WHO and its partners in this effort is to ensure that the increased funding is used in such a way as to enable countries to fight HIV/AIDS and at the same time strengthen their health systems". The report in its opening pages carries two photographs; of a HIV/AIDS infected farmer from Lacahobas in a dying state, the other of the same person taken several months after receiving treatment looking quite healthy. He is symbolic of what can be achieved when HIV/AIDS programmes are properly implemented with 'antiretroviral therapy as an entry point' and 'building up primary healthcare in communities'. The report reports in the overview, " It does so through improved drug procurement and management, the expansion of HIV counselling and testing, increased salaries for local health care personnel and the training of numerous community healthcare workers. Primary care clinics have been refurbished, restocked with essential medicines and provided with new staff". The photos signify the changing history of HIV/AIDS.

The report is divided into an overview, five chapters and a conclusion. Chapter one describes the current epidemiological state of HIV/AIDS epidemics around the world and examines the daunting challenges that lie ahead while the second chapter emphasizes the need for a comprehensive HIV/AIDS strategy that links prevention, treatment, care and long term support to save the lives of millions of people in poor countries and points out that treatment has been the most neglected component of this approach in much of the developing world. Chapter three deals with the background of community participation as a dimension of public health work and recalls key achievements of civil society HIV/AIDS activism. Well functioning of the health sector is one of the priorities when speaking about HIV/AIDS in chapter four. The participation of both public and

private providers are taken note of and consideration of the health systems context in resource poor settings is dealt with. The final chapter records the remarkable research achievements related to the disease by many scientists ever since it was first detected in 1983. However it would be several more years before a safe and effective vaccine becomes widely available. The chapter also identifies four broad categories of challenges envisaged by the researchers. They are prevention research, slowing down the growth and geographical expansion of the epidemic; vaccine research, designing a safe and effective prevention vaccine; treatment research, generating new antiretroviral drugs and designing new therapeutic strategies that would be active on "wild" and resistant strains of viruses, easy to take and better tolerated than currently available drugs and delivery system research making care and antiretroviral treatment available to all of those who need it worldwide. The chapter also examines important matters such as the prevention of HIV transmission from mother to child, the development and use of microbicides, the need to sustain long term adherence to treatment, toxicities, drug resistance, joint approaches to HIV/AIDS and collaboration. The conclusion gives a very optimistic view of the future.

To order contact the WHO Marketing and Dissemination, CH 1211 Geneva 27, Switzerland. Tel: +41 22 791 24 76, Fax: +41 22 791 48 57 or email at bookorders@who.int. Please quote order number 1242004.

Hepatitis-B Vaccination: Misleading Policy and Promotion

Published by Drug Action Forum Karnataka and TEST Foundation

Drug Action Forum-Karnataka (DAF-K) is a committed group of citizens voluntarily involved in bringing awareness among consumers in India regarding Rational Drugs Promotion and Policy. DAF-K along with the TEST Foundation, Chennai published a book titled "Hepatitis-B Vaccination: Misleading Policy and Promotion". The book outlines the Government of India's plan to implement hepatitis B vaccination as a part of its Universal Vaccination Programme in a phased manner in all parts of India. The authors express grave concern on this issue because of two reasons.

Lack of resources: To vaccinate all newborns with hepatitis B vaccine and to implement would cost Rupees 1250 million annually for the hepatitis-B vaccine alone, at the rate of Rupees 50 per new born for the 25 million annual births in India if this is compared with the budget in the year 2000-2001 of Rupees 1250 million allotted to the National Tuberculosis Programme and Rupees 1050 million for Malaria control. Tuberculosis & Malaria are obviously major killers in India. It is necessary to address these questions in a developing country like India, where financial resources are always constraints. Secondly, in any case, modern health care management should consider cost efficacy and effectiveness of any healthcare intervention paid through public money.

Absence of epidemiological basis: the quoted study, by medical bodies has been that of S.P.Thyagaran et al, which puts the carrier state in India at 4.7 per cent. This is not acceptable, as it suffers from errors as pointed per Phadke Anant & Kale Ashok. Actually the epidemiological HBsAg carrier rate works out to be 1.42 per cent. Based on low carrier rate alone, it is clear that the Universal Vaccine Strategy is not a priority in India.

Therefore to suggest that the Government of India take up the Selective Vaccination Strategy, in which the pregnant women be screened for HBsAg and vaccinate such newborn only if the mother is positive. It has been observed that the cost efficacy of this Selective Vaccination Strategy, (around Rupees 5227), is much greater, than Universal Vaccination Strategy, (around Rupees 9260) for protection from HBeAg (hepatitis B e antigen). Secondly, to cover all the pregnant women and their newborn in a year, the total annual cost of the programme for Universal and Selective vaccination for a cohort of 10,000 would be Rupees 5,00,000 and Rupees 1,15,000 respectively. This publication records the misleading promotion of the drug by the company GSK. DAF-K records in the book the correspondence it had with the drug company.

To order please contact: Drug Action Forum Karnataka, 57, Tejaswinagar, Dharwad 580002, India. Tel: +91 (0) 836-241554. Email: drdabade@sancharnet.in

Development at Risk: Rethinking UN-Business Partnerships

Published by UNRISD in collaboration with the South Centre

In recent years there has been an upsurge of initiatives that engage private sector companies and the United Nations in collaborative ventures that are commonly called partnerships. Under the umbrella of "UN-business partnerships" are a variety of initiatives, involving, for example, specific projects, global health programmes and multi-stakeholder initiatives such as the Global Compact.

These new relationships have attracted considerable attention and controversy. For some, they constitute a pragmatic way of sensitizing the business community to development issues and improving the developmental impacts of transnational corporations and other business enterprises. Partnerships are part and parcel of contemporary policy trends associated with corporate social responsibility and good governance. For others, partnerships constitute a mechanism through which large corporations can gain undue influence over the public policy process and enhance their image and competitive advantage. In the case of the Global Compact, there are concerns that such gains are being achieved in return for relatively little, given the weak mechanisms that exist to ensure that companies actually adhere to the nine human rights, labour and environmental principles promoted by this initiative.

In view of these debates, UNRISD commissioned this report by Ann Zammit. It forms part of a broader UNRISD inquiry into the developmental and regulatory implications of corporate social responsibility and the potential and limits of so-called voluntary initiatives for improving the social and environmental performance of large corporations.

Contents

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- 8: Public-Private Partnerships: A Holy Alliance
- 9: A New Development Strategy and True Test of Corporate Responsibility

The book can be ordered for free at UNRISD or the South Centre (as long as stock lasts).

For more details, see

[http://www.unrisd.org/80256B3C005BCCF9/\(search\)/43B9651A57149A14C1256E2400317557?Opendocument&highlight=2,zammit&fromsearch=yes&query=Zammit](http://www.unrisd.org/80256B3C005BCCF9/(search)/43B9651A57149A14C1256E2400317557?Opendocument&highlight=2,zammit&fromsearch=yes&query=Zammit)

The Chronic Poverty Report 2004-5

Published by the Chronic Poverty Research Centre - Institute for Development Policy & Management

University of Manchester, UK

"Between 300 and 420 million people are trapped in chronic poverty. They experience deprivation over many years, often over their entire lives, and commonly pass poverty on to their children. Many chronically poor people die prematurely from health problems that are easily preventable. For them poverty is not simply about having a low income: it is about multidimensional deprivation - hunger, malnutrition, dirty drinking water, illiteracy, having no access to health services, social isolation and exploitation. Such deprivation and suffering exists in a world that has the knowledge and resources to eradicate it.

This Report's concern about chronic poverty leads to a focus on poverty dynamics - the changes in well-being or ill-being that individuals and households experience over time. Understanding such dynamics provides a sounder basis for formulating poverty eradication policies than the conventional analysis of national poverty trends.

The chronically poor are not a distinct group. Many different people suffer such deprivation; people who are discriminated against, stigmatised or 'invisible': socially-marginalised ethnic, religious, indigenous, nomadic and caste groups; migrants and bonded labourers; refugees and internal displacees; disabled people or those with ill-health (especially HIV/AIDS). In many contexts poor women and girls, children and older people (especially widows) are likely to be trapped in poverty.

While chronically poor people are found in all parts of the world the largest numbers live in South Asia (135 to 190 million). The highest incidence is in sub-Saharan Africa, where 30-40 per cent of all present day 'US\$1/day' poor people are trapped in poverty - an estimated 90 to 120 million people. East Asia has significant numbers of chronically poor people, between 55 to 85 million, living mainly in China.

Within countries there are often distinct geographies of chronic poverty, with concentrations in remote and low-potential rural areas, politically-marginalised regions and areas that are not well connected to markets, ports or urban centres. There are also concentrations of chronically poor people in particular slum areas in towns and cities as well as the millions of homeless people sleeping in streets, stations, parks and burial grounds.

The causes of chronic poverty are complex and usually involve sets of overlaying factors. Sometimes they are the same as the causes of poverty, only more intense, widespread and lasting. In other cases, there is a qualitative difference between the causes of transitory and chronic poverty. Rarely is there a single, clear cause. Most chronic poverty is a result of multiple interacting factors operating at levels from the intra-household to the global.

Some of these factors are maintainers of chronic poverty: they operate so as to keep poor people poor. Others are drivers of chronic poverty: they push vulnerable non-poor and transitory poor people into poverty that they cannot find a way out of...."

To access online click on http://www.chronicpoverty.org/chronic_poverty_report_2004.htm