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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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Editors

K.Bala, Passanna Gunasekera

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

HAI Coordinating Offices

HAI Asia-Pacific

5, Frankfurt Place,
Colombo 4, Sri Lanka
Tel: (94 11) 2554 353
Fax: (94 11) 2554 570
Email: haj@haiap.org
Website: www.haiap.org

HAI Europe

Jacob van Lennepkade 334 – T
1053 NJ Amsterdam,
The Netherlands
Tel: (31 20) 683 3684
Fax: (31 20) 685 5002
Email: info@haiweb.org
Website: www.haiweb.org

AIS Latin America

Aptdo 41 – 128,
Lima, Peru
Tel / Fax: (51 1) 346 1502
Email: ais@amauta.rcp.net.pe
Website: www.aislac.org

HAI Africa

P.O.Box 78360
Nairobi, Kenya
Tel: (254 20) 444 4835
Fax: (254 20) 440 1090
Email: info@haiafrica.org
Website: www.haiafrica.org

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A rational drug policy is possible

A Campaign launched in Belgium for rational drug policy and cheap, quality medicines

By Dirk Van Duppen and Wim De Ceukelaire*

'Doctors for the People,' a group of progressive physicians in Belgium, recently launched a campaign for another-rational-drugs policy. The Belgian healthcare system is considered chaotic with huge amounts of money being wasted and medicines becoming far too expensive in Belgium as a result of the pharmaceutical companies' super profits.

Belgium's health insurance system

With a per capita GDP of USD 27,800 and about 10 million inhabitants, Belgium is one of the 10 wealthiest countries in the world.ⁱ The country's public compulsory health insurance system (RIZIV) is integrated in the Social Security System, which is financed predominantly through salary deductions. For the majority of the insured, prescription medication is refunded at 75 per cent, while the indigent get a refund of 85 per cent on their expenses for prescribed medicines. In 2003, the total budget of RIZIV was about 15.3 billion euro, 2.7 billion euro of which was spent on reimbursements of medicines. Quite disturbingly, the expenses on medications are increasing almost twice as fast as the total budget of RIZIV an escalation of 7.8 per cent per year since 1998 for pharmaceuticals against an increase of 4 per cent of RIZIV's total budget. If this trend continues, it will inevitably lead to the collapse of the public health insurance system. The authors believe, however, that urgent measures, which are already practiced partly or in full in other countries, could stem the tide. This article summarizes the ten reasons for the present irrational drug use and cost explosion.

In comparison with its neighboring countries, medicines, including generic drugs, are far too expensive in Belgium. In the Netherlands and France, for example, Zocor has always been cheaper by 26 per cent and 35 per cent respectively - even before the expiration of the patent on this cholesterol-lowering drug. In comparison with New Zealand, the differences are extreme: branded products are some 55 per cent cheaper and for off-patent products differences are up to 90 per cent. (See table 1) Also prices of generic medicines are much higher in Belgium than in other countries. One Belgian NGO, Orbi-Pharma, sells medicines in bulk to Belgian NGOs for use in the Third World at prices which are 15 to 60 times cheaper than the same products at retail outlets. (See table 2) Perhaps, the prices of Orbi-Pharma reflect the real manufacturing costs of these medicines.

Irrational use and prescribing of drugs have led to the inappropriate use of scarce resources. The most expensive medicines are not those that are scientifically proven to provide the most benefit. For example, three of the five most expensive medicines for the health insurance system are cholesterol-lowering drugs. The two medicines that belong to the least effective in their class from a scientific point of view are the numbers one and three in the top five. (See table 3). One example is Pfizer's Lipitor (atorvastatin) which costs the Belgian health insurance more than any other medicine. In 2002, the total volume of sales reached 88.4 million euro, 70.6 million of which was paid for by RIZIV.

Since 1999, one year after its introduction to the market, it became the undisputed market leader even though the first serious clinical trial showing a clear effect on hard, clinical end-points did not see print before April 2003.ⁱⁱ While trials with other statins were able to show an effect on mortality, the ASCOT trial did not show any differences in mortality between the intervention- and the control groups, although this is the most truthful and significant clinical end-point.

A second example is Amlor (amlodipin), also a product of Pfizer and, with total sales of 53.6 million euro and a cost of 34.5 million euro for Riziv, the third most expensive medicine for

RIZIV. This is really amazing as the recent ALLHAT trial, the largest trial of anti-hypertensive drugs ever, showed that a diuretic is as good as or even better than Amlor.ⁱⁱⁱ Among patients who were treated with Amlor, the risk of heart failure was 38 per cent higher. Moreover, a simple diuretic costs less than one tenth of Amlor. The public health insurance system and the patients would save at least 20 million Euro per year if patients would be treated with a simple diuretic instead of Pfizer's blockbuster drug. Like in the case of the statins, the steep rise of Amlor's sales is not related with its clinical qualities but with the marketing prowess of the pharmaceutical multinational Pfizer.

Statins the most expensive in Belgium

In Belgium, three of the five most expensive medicines are cholesterol-lowering drugs and they are not the best in their class. It shows that medicine use is neither determined by medical needs, nor by clinical efficacy. The reason for the success of blockbuster drugs cannot be found in international medical journals such as the Lancet or the New England Journal of Medicine but in The Financial Times and The Economist. The top ten of the world's biggest pharmaceutical TNCs, which can be found in table 4, have some similarities to the top ten of the most expensive blockbuster drugs. It is the companies' economic power and marketing skills that determine the success of medicines. Look at the position of AstraZeneca at number five, for example. Five years ago this company was still number two because of its blockbuster Losec. Now it is desperately trying to climb again in the ranks through the launch of a "me too" statin in the lucrative market of cholesterol lowering drugs.

There is an anarchy of "me toos" and generic products. Often there are 10 to 15 producers of a drug with exactly the same active component and all these companies are spending for marketing and research and development. New, allegedly innovative drugs, which are outrageously overpriced and are promoted excessively, erode public health insurance budgets although after some time, scientific research often reveals that these drugs do not have any benefit at all in comparison with much cheaper, older drugs. In the therapeutic class of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), for example, the Belgian market counts 7 different basic molecules, 12 derivative molecules and 78 different branded products. Their efficacy is similar but their side-effects and prices differ widely.

AstraZeneca has invested heavily in the development of its own statin, Crestor, in order to gain a presence in this lucrative market. Even before the drug was approved, USD 1 billion was already spent on promotion worldwide. The company rushed a series of short-term trials with surrogate end points, which did not provide any data about hard, clinical end points. The company was criticized for this in the editorial of the Lancet of, October 24, 2003, titled "The statin wars: why AstraZeneca must retreat." The Lancet concluded: "Since there are no reliable data about efficacy and safety and AstraZeneca is facing unusual acute commercial pressure to force rosuvastatin into the market - which doctors should pause before prescribing. Physicians must tell their patients the truth about rosuvastatin--that, compared to its competitors, rosuvastatin has an inferior evidence base supporting its safe use. AstraZeneca has pushed its marketing machine too hard and too fast."^{iv} In the U.S., consumer organization "Public Citizen" discourages the use of Crestor because it has shown dangerous side effects in trials before it came into the market, including kidney disorders and rhabdomyolysis, the fatal muscle disease that also caused the withdrawal of Bayer's Lipobay from the market.

Drugs not covered by RIZIV

The anarchy and irrationality of drug use is even worse for medicines that are not covered by the health insurance. These drugs can be purchased over the counter at the pharmacies, their prices are very high as they are hardly regulated and, last but certainly not least, they employ direct to consumer advertising. (DTCA is only allowed for over-the-counter medication that is not covered by the health insurance.). The producers of Neurofen (Ibuprofen), Aleve (Naproxen), Daflon, Venoruton (the so-called phlebotropics) and others are making super profits with products that have no proven beneficial effect or that are available on prescription in higher doses.

Valuable and even life-saving medicines are withdrawn from the market when they become too cheap and when more expensive alternatives are available. In Belgium, the supply of the urinary disinfectant Furadantine, the first choice for the treatment of uncomplicated urinary tract infection, is erratic. Largactyl, a sedative neuroleptic that has proven its worth in palliative care, small spectrum antibiotics for the treatment of streptococcal infections and even Penidur, which is necessary in the treatment of syphilis are, if at all, very hard to come by in the Belgian market. A low dose diuretic is still the first choice anti-hypertensive treatment in the first line as confirmed by the network meta-analysis of JAMA.^v Thiazide-diuretics are at least as good as other diuretics if the effect on hard clinical end-points is measured. They are even more effective than calcium antagonists and even ACE inhibitors in the prevention of heart failure. As these “old” medicines are less than one tenth the price of the new “innovative” anti-hypertensive drugs, the societal consequences are immense. And yet the basic molecule hydrochlorthiazide is not available in the Belgian market because its production cost is too cheap.

The proliferation of “me too” products in the Belgian market reflects the fact that the pharmaceutical industry is investing large parts of its R&D budgets in the development of products without any real therapeutic added value. Out of the 1,035 new medicines approved between 1989 and 2000, only 153 (or 15 per cent) were new molecules offering a significant added value compared to existing drugs.^{vi} Much more is spent on marketing. Moreover, research that is sponsored by the pharmaceutical industry is four times more likely to produce favorable results than trials that are funded by independent sources.^{vii viii} The consequences are worrying as 80 per cent of pharmaceutical research at Flemish universities is already funded by the pharmaceutical industry.^{ix}

It is very hard to launch a “me too” product as doctors and the public have to be convinced that this particular product is any better than other similar products in the market. That is also why the marketing budgets of pharmaceutical companies are so high. According to industry sources, 31 per cent of the cost of medicines is spent on marketing—twice as much as on Research & Development (14 per cent).^x The marketing excesses towards health care providers and the broad public are worsening continuously. Belgium has about 4 to 5 times as many sales representatives as the Netherlands and this explains why prescriptions for some drugs, like quinolones for example, are much more common. Moreover, according to some studies, 69 per cent of the indications in advertisements for anti-hypertension drugs are false.^{xi} The scientific articles that were referred to in the advertisements had different conclusions, sometimes even the opposite, as the advertisements.

Although Direct To Consumer Advertising (DTCA) of prescription drugs is still not permitted in Belgium, the pharmaceutical industry is very inventive to promote its products indirectly to the public. For example, Belgium is currently flooded with so-called prevention campaigns, which are actually thinly veiled marketing drives. Usually, the government airs radio and TV programmes to make the public conscious about a certain ailment and encourage them to “talk about it with the doctor.” Scientific associations have to give the campaign a ‘neutral’ facade and the pharmaceutical industry is providing ample funding. Simultaneously, the doctors are swamped with advertising for the products of the campaign’s sponsor: AstraZeneca’ anti-androgens Casodex and Zoladex (400 euro per month) were pushed during the campaign for early detection of prostate carcinoma,

likewise Glaxo Smith Kline’s Zyban (100 euro per box) during the anti-smoking campaign, and Pfizer’s Viagra during the campaign about erectile dysfunction... The so-called screening campaign turned out to be a scaring advertising campaign.

There is a huge imbalance between the marketing power of the pharmaceutical industry and the opportunities for scientific education by independent agencies. There are only scarce resources available for the dissemination of rational and scientifically sound education of the health care providers. The independent and government-funded “Belgian Center for Pharmaceutical Information” has an annual budget of 1 million euro, which is negligible in comparison with the marketing budgets the pharmaceutical companies can mobilize to influence the prescribing patterns

of the doctors. According to estimates, marketing budgets of the pharmaceutical industry amount to 1 billion euro per year or 1,000 times the amount available for independent education!

Measures that have been implemented with good intentions, like the referential reimbursement system, have set off a perverse paradox. Under the referential reimbursement system, which is in place in Belgium for off-patent products, the 75 per cent reimbursement of medicines is calculated on the cheapest product, which serves as a reference. Patients who buy the more expensive products will have to shell out more from their own pockets. Instead of encouraging the prescription of generic drugs, this system encourages the prescription of very expensive, new medicines in the same class. Within the current legislative context, any similar system will inevitably lead to such an effect. Many patents of expensive yet valuable medicines have expired in the summer of 2001 and have led to an increase of the market share of generics to about 40 per cent of sales volume in many European countries and in the U.S. In Belgium, on the other hand, the market share of generics rose much slower to 7 per cent of sales but it stagnated when the referential reimbursement system came into force in the summer of 2001. The retail price of Pfizer's popular anti-inflammatory drug Feldene, for example, was 20 euro while the generic version cost only 15 euro. Under the referential reimbursement system, RIZIV subsidizes 75 per cent of the cheapest product, or 11.25 euro, for both the branded drug and the generic. When the consumers buy the generic, they will have to shoulder 3.75 euro themselves as against 8.75 euro for Feldene. Pfizer/Pharmacia therefore launched a new NSAID: Celebrex, which at 40 euro is twice as expensive. Efficacy and side-effects of the new COX 2 inhibitors are however comparable, to the traditional NSAIDs.^{xiii} Through an aggressive marketing campaign, doctors are encouraged to prescribe the new, expensive products instead of the old, much cheaper generics. As the patient's contribution has a ceiling of 9.5 euro, RIZIV is paying 31.5 euro more.

The antacids provide another example. As none of the new antacids has any added value compared to the traditional products, they are classic examples of "me too" products. Tabel 5 summarizes the sales figures from March 2001 to March 2002 and from March 2002 to March 2003 of AstraZeneca's Losec, its generic product omeprazole, AstraZeneca's "new" product Nexiam, and another "me too": Janssen-Cilag's Pariet. Losec used to be the most expensive drug in the market for years but as soon as its patent expired, Astra launched the "new" product Nexiam, which is in fact the isomere of the same molecule. This "new" product is covered by a patent again and therefore has no generic competitors. Because of the referential reimbursement, this new product is cheaper for the patients but much more expensive for RIZIV. Because of the aggressive marketing of Nexiam, it is not the generic omeprazole that benefits from Losec's patent expiry but Nexiam. After a few months, its sales rose from 0 to 12 million euro and they are still rising. And that for a product is not better but 50 per cent more expensive! In short, RIZIV and the public are paying 4 million euro more.

Janssen-Cilag also knows the tricks of the trade. It launched its "new" antacid, Pariet, which is not better than the others, when Losec's patent expired. Janssen negotiated with RIZIV that Pariet could

be prescribed without gastroscopic diagnosis in exchange for a price reduction of 16 per cent on its 10 mg tablets. For the patients and doctors that meant much less hassle and bureaucracy. As a result the Pariet's sales skyrocketed from 2 million euro to 13 million euro in only one year, even if it is twice as expensive as omeprazole. RIZIV and the patients are paying an extra 5 million euro.

The Belgian government always takes measures to keep the expense in check at the end of the line. The patients' own contributions are increased or the doctors have to deal with ever increasing bureaucratic requirements to ensure reimbursement of expensive medicines. Financial thresholds, however, are a blunt instrument to correct drug use and doctors' prescribing behavior. In Belgium, this has led to another perverse paradox: under consumption for those who need drugs and

Over consumption for those who don't. They encourage a two-tiered health care system instead of "evidence based" medicine (EBM) this is the reason for Archie Cochrane, the pioneer of EBM's statement: "effective treatments should be free." He advocated the complete reimbursement of effective medicines for everyone. It is the doctor who has to prescribe drugs in good conscience and according to socially and scientifically sound principles. This is only possible, however, when the government provides much more opportunities for this 'conscience' to be educated in these scientific principles. From the one side, this would entail an intensive education campaign while the pharmaceutical industry's marketing practices, which are unscientific and irrational anyway, are rigorously regulated. If government has to resort to sanctions they shouldn't be applied at the end of the line but much earlier. It is those huge marketing budgets of the pharmaceutical TNCs that have to be tapped, not the patients' contributions. France has already taken a modest step in this direction: Pharmaceutical companies have to pay 6 per cent tax on their marketing expenses and this money goes to an independent scientific education fund for doctors.

Interestingly, the principle of public tender is applied to all public expenses that are paid for with people's taxes, except for pharmaceuticals. Under the principle of public tender, the government has to choose the best out of at least three quotations. Although huge amounts of public money is spent on drugs, price setting by confidential commissions, where the pharmaceutical industry and the health care suppliers are over-represented, is not transparent. Moreover, if this commission does not reach a compromise within 180 days (a term which the European Union wants to reduce to 90 days) the latest offer of the producing company will automatically come into force.

The principle of public tender does apply for vaccines and has resulted in a price reduction of 40 per cent for the hepatitis B vaccine.

A rational drug policy is possible

In New Zealand, only the best medicine is allowed on the Pharmaceutical schedule at the lowest price and is reimbursed in full. Off-patent drugs are 80 to 90 per cent cheaper as in Belgium. Even drugs without generic competition are 50 to 60 per cent cheaper. The New Zealand government has tasked a well-equipped institute, Pharmac, to oversee the whole pharmaceutical policy. Pharmac selects the best product per therapeutic subclass. After public tender, the selected product, branded or generic, is allowed on the schedule for three years. To select the best offer, Pharmac considers all criteria: quality, effectiveness and price.^{xiii} Without Pharmac, New Zealand would have paid NZ\$ 624 Millions more in 2003 for the same volume of drugs—more than double the cost of the current system. In the past ten years, the New Zealand government has saved an accumulated NZ\$ 2.1 billion and the yearly increase of the budget for medicines has been kept in check at less than 3 per cent. More people than ever have access to free medication and 131 new drugs have been approved for reimbursement in the past 10 years.

This policy could serve as a source of inspiration for a new rational drugs policy in Europe and Belgium. We estimate that savings could reach 70 per cent if a similar system would be in place in Belgium. That means the patients would save 1 billion euro per year and the public health insurance system 1.6 billion euro. Scarce resources could be prioritized for other health care needs. Recently, the governments of Australia and British Columbia have also made the shift to a demand-driven pharmaceutical policy.^{xiv} Contrary to a supply-driven policy, which is based on the producers' market prospections, a demand-driven policy is based on a scientific needs analysis and the efficacy and safety profile of the pharmaceutical products. Public bidding ensures the best prices through free competition. Table 6 summarizes the most important differences between the two systems.

In order to match the supply of pharmaceuticals with the needs of society, nationalization of the pharmaceutical industry has been proposed in the past. However, a national drugs policy based on public tender and patterned after New Zealand's system would be already a valuable step to make the shift from a supply-driven to a demand-driven system.

Recommendations

In a country like New Zealand, on the other hand, a system of public tendering ensures that the best product is available at the lowest possible price or moreover, medicines are free for patients who need them the most. It has been estimated that the adoption of such a system in Belgium would save the Belgian patients 1 billion euro per year while the health insurance system would save another 1.6 billion every year. This money could be put into good use to support the first line of health care, upgrade the hospitals or provide better care for the elderly. “Doctors for the People” supports any bill that could help realize this dream and hence has launched a signature campaign for an alternative and rational drugs policy.

Table 1.

Comparison of retail prices of some popular pharmaceuticals in Belgium and New Zealand^{xv}

Active substance	Retail price in branded product in Belgium (28 of 30 co.)	Retail price in generic product in Belgium	Retail price in New Zealand (Branded and generic)	Comparison of retail prices in New Zealand with the cheapest product in Belgium
Ranitidine antacid Anti-ulcer	Zantac 300 mg 22.8 euro	Docraniti 300 mg 18.60 euro	Zantac 300 mg 1.56 euro	8 %
Omeprazole antacid	Losec 20 mg 53.32 euro	Docomepra 20 mg 26.39 euro	Losec 20 mg 11.70 euro	44 %
Diclofenac NSAID	Voltaren 100 mg 12.50 euro	Docdiclofenac 100 mg 10.86 euro	Generiek 100 mg 1.50 euro	14 %
Citalopram Antidepressant	Cipramil mg 31.80 euro	Citalopram 20 mg 20 euro	Celapram 20 mg 5 euro	25 %
Fluoxetine Antidepressant	Prozac 30.00 euro	Fluoxepar 15.5 euro	Fluox 2.2 euro	14 %
Lorazepam sedative	Temesta 2.5 mg 10.78 euro	Lorazetop 2.5 mg 5.4 euro	Lorapam 2.5 mg 2.1 euro	39 %
Paracetamol analgesic	15 brands (Dafalgan, Perdolan...) 4.30 euro	Paracetamol EG 3.54 euro	Paracetamol 0,15 euro	4 %
Aciclovir Anti-herpes	Zovirax 800 mg 102.62 euro	Aciclovir Bex 800 mg 24.60 euro	Aciclovir 800 mg 6,00 euro	24 %
Triphasic contraceptive	Trinordiol 15.05 euro		Trifeme 4,73 euro	31 %

Source: *New Zealand Pharmaceutical Schedule Augustus 2003.*

<http://www.pharmac.govt.nz/pdf/010803.pdf> Belgisch formularium: <http://www.bcfi.be/>

Table 2.

Comparison between retail process of branded products, retail prices of generics and wholesale prices of three popular pharmaceuticals in the Belgian market.

Generic name	Branded product	Generic product	Wholesale price (Orbipharma)	Comparison of branded product with wholesale price
Paracetamol 500 mg 20 co	3.72 euro (Perdolan)	2.06 euro (Wit Kruis)	0.06 euro	62X
Diclofenac 25 mg 100 co	14.11 euro (Voltaren)	10.42 euro (Eurogenerics)	0.30 euro	47X
Amoxycillin 500 mg 16 caps	9.39 euro (Clamoxyl)	6.02 euro (Docamoxy)	0.60 euro	15X

Source: Belgisch formularium and orbi Pharma <http://user.online.be/orbiph-arma/prijsljst-nl.html>

Table 3.

Top 5 of the most expensive medicines for RIZIV (2002)			
Name	Therapeutic class	Producer	Net cost (in million Euro)
1.Lipitor	Cholesterol lowering drug	Pfizer	70.9
2.Zocor	Cholesterol lowering drug	Merck Sharp&Dohme	44.4
3.Amlor	Anti-hypertensive drug	Pfizer	34.5
4.Cipramil	Anti-depressant	Lundbeck	33.2
5.Pravasine	Cholesterol lowering drug	Birstol-Meyers Squibb	26.8

Source: RIZIV 2003 <http://www.riziv.be/other/nt/drug/farmanet/tables/info-spot/2004-02-02/index.htm>

Table 4.

Top 10 Transnational Pharmaceutical companies Ranked by pharmaceutical sales. Miljoen USD (2001)		
Pfizer/Pharmacia	US	40,786
Pfizer	US	26,949
GlaxoSmithKline	UK	24,521
Merck Sharp & Dome	US	19,732
Bristol-Myers Squibb	US	19,423
AstraZeneca	UK	16,480
Aventis	FR	15,822
Johnson & Johnson	US	14,851
Pharmacia	US	13,837
Novartis	Swiss	11,961
Wyeth	US	11,717

Source: Financial Times, 16 July 2002

Table 5. Evolution of sales of some “me too” PPIs in the Belgian market after expiry of Losec’s patent.

	March 01 to March 02	March 02 to March 03
	Sales in euro	Sales in euro
Losec	43,412,560	40,350,060
Generic	0	5,780,238
Nexiam	262	12,076,809
Pariet	1,990,679	13,009,532

Source: “IMS Health 2003”

Table. 6. Summary of the differences between a supply-driven and a demand-driven pharmaceutical policy.

Pharmaceutical policy: Choice of registration and price-setting	
Of a supply-driven policy	Of a demand-driven policy
From the producers (marketing prospects)	From the community of patients and health care providers (scientific needs analysis)
Monopolist practices raise the prices: patents; market monopoly; monopoly or dominance in marketing, on information, on scientific research, on legal means, on lobbying nationally and internationally (Europe, WTO, TRIPS)	Maximum, free competition between the players in the market to bring the prices down.
Causes overconsumption and irrational drug use (EBM = Evidence Based Marketing instead of Evidence Based Medicine)	Chooses the best quality product for the right indication (Evidence Based Medicine: scientifically proven need for and effectiveness of the intervention)
Profit-oriented efficiency	Medical and societal efficiency

* **Dirk Van Duppen, General Practitioner, Geneeskunde voor het Volk, Doctors for the People and Wim De Ceukelaire, Regional Coordinator Philippines, INTAL**

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Belgisch formularium: <http://www.bcfi.be/>

- NETWORK NEWS -

ASIA PACIFIC - INDIA

Community Development Medicinal Unit West Bengal launches its website

Community Development Medicinal Unit (CDMU), West Bengal, India, a premier NGO engaged in the procurement and distribution of low cost essential medicines and medical supplies and a member of Health Action International Asia Pacific, launched its website <www.cdmubengal.org> at Ramakrishna Mission Seva Pratishthan Hospital, Kolkata.

The website seeks to provide a range of information on essential drugs and rational therapeutics, in addition to providing details of CDMU's activities. This is the first effort of its kind by a NGO in India and hopefully will integrate CDMU into the global village. Various Government and World Health Organization (WHO) documents are available for download from this website. CDMU's essential drugs programs, quality assurance norms, methodology of procurement from CDMU, the people behind the organization are detailed in this website. Past issues of the quarterly publication Rational Drug Bulletin are also available for download along with topical news items. An important section on adverse drug reaction with facility for online reporting of ADRs has been incorporated.

Speaking on the occasion as Chief Guest, Dr. Krisantha Weerasuriya, Head of Essential Drugs & Medicines Policy, WHO South East Asian Regional Office (WHO-SEARO), appreciated CDMU's efforts and described it as a potential one-stop source of information on rational therapeutics, drug policies and access to essential medicines globally, in general, and in India, in particular. He suggested inclusion of CDMU's pricing information, as an index to generic drug prices in India; a frequently asked question (FAQ) section to explain the terminology in this field, and various relevant public domain documents in the website to enhance its utility further. The philosophy of essential drugs being already accepted in India, the need of the hour is to enhance access and provide supporting information, a role which this website can help CDMU to perform.

Source: CDMU Press Release, March 18, 2004, Kolkata.

Thailand –USA FTA: Effects on Drug and Health Systems

The Drug Study Group (DSG), Senate Standing Committee on Social Development and Human Security, Senate Standing Committee on Public Health, the Social Pharmacy Research Unit (SPR), Faculty of Pharmaceutical Sciences, Chulalongkorn University, FTA WATCH and Social Agenda Working Committee with the support of Health Action International Asia Pacific and Medecins Sans Frontieres organized a seminar titled, “Thailand – USA FTA: Effects on Drug and Health Systems” on 27 February 2004 at the Reception Hall, Parliamentary Building 2, in Bangkok, Thailand.

The objectives of the seminar were: to analyze the up coming effects of Free Trade Agreement (FTA) on intellectual property rights regimes (on drug and health systems in particular) to brainstorm the people of Thailand and reach a consensus on the aforesaid issue at both operative and policy levels including distribution of information to public for common solution. Participants who attended the seminar comprised Senators; academics; representatives from related governmental offices, from non-governmental organizations and from the mass media. The conclusions and recommendations of the seminar include the following:

The international arena forced by globalization and liberalization create opportunities for countries with more power to rob resources from developing and under developed countries by using different forms of mechanisms at different levels, for instance, WTO at the world level, NAFTA at the regional level in the Americas and FTAs at country level.

FTAs are the strategy often applied by the US to enter into the inter-trade market of agricultural products, to gain intellectual property rights as well as investment and services for exchanges between the two countries. The profits the other party achieves from agricultural products after the completion of a FTA with the US are far less than expected because the US operates other mechanisms through its policies to prevent those imported products in the US market not to have effects on their farmers. Technically, the US sets extreme standing points during the beginning of the negotiation and gradually draws back which makes the other party to feel as if their benefits, as negotiated, are still received.

The model of US - Singapore (or US – Australia) FTA on intellectual property, reveals that the US gains benefits more than what they gain from TRIPS. The instances are extending patent protection period, providing data exclusivity rights, limiting the circumstances for compulsory licenses (CL) and parallel imports (PI), creating barriers for the development on sciences and pharmaceutical technology which obstruct people’s access to medicines causing problems on life and health. Thailand must realize that patented drugs are costly and there is no mechanism yet to control the drug prices. For example, Fluconazole, the brand form of drug to cure fungus – costs ten times higher than its generic counterpart. Moreover, in 1999, Committee on Drug Patent in Thai Patent Act was also abolished.

The network of People Living with HIV/AIDS in Thailand (TNP) comprising over 600 groups has for a long period fought for the rights of access to HIV/AIDS medicines. More than 50,000 people signed a petition to the Thai Parliament urging The Royal Thai Government (RTG) to support the National Health Security to provide provision to introduce CL in order to produce the anti-AIDS drug: didanosine (ddI), sadly to no avail whereas the US threatened this mechanism for an anti anthrax drug. By the time the correlated fighting succeeded in the abolishment of the patent over ddI tablet, the numbers of HIV/AIDS patients have plummeted.

The accomplishment of the fight resulted in improved access to medicine and urging the Government Pharmaceutical Organization (GPO) produce the off-patent anti-AIDS drug at the price of 5 per cent of patented drug. The Ministry of Public Health and Social Security Funds provides anti-AIDS drug for over 50,000 patients. If the issue on intellectual property rights of drug and

health system with the above mentioned US extreme standing point is included in the FTA between Thailand and US, our future with regard to access to medicines will be bleak.

The analysis of US Trade Representative Notifies Congress of Intent to Initiate Free Trade Agreement Negotiations with Thailand proposed to American Congress on 12th February 2004 obviously shows that USTR will gain enormous benefits from signing a FTA with Thailand. However, Thai people are made to understand otherwise. Experiences from countries that have entered into FTAs with the US evidently reveal that it reaps only short-term benefits and only among some particular groups.

Thus, dealing with the possibility of a FTA between Thailand and US, this seminar reached the consensus that the administrative authority shall comply by rules of law. It means that legal procedure with social justice shall be employed. At the same time, pharmaceuticals, medicine, life and health shall be treated more importantly than economic values. The six solutions in the respective order are as follows.

Item 1. The issues related to pharmaceuticals, medicines, life and health must be excluded in the FTA between Thailand and the US.

Item 2. In compliance with the Constitution of Thailand, the government is obliged to pay respects to sovereignty in order to lead the state to be bound with international agreements. The process in exercising the sovereignty shall recognize people's rights to participate in the decision-making process and the people participation shall involve in the negotiation process in order to reach consensus prior to/and during the negotiation on the basis of transparency and good governance. The proposed negotiation issues as well as the issues during the negotiation shall be made open to the public. Public hearing shall also be arranged to gain consensus and/or for the studies of its effects before the next negotiation starts.

The RTG should allow questioning and general debates without voting for the bill on each negotiated issue in the Parliament so that the drafted FTA will be considered. These general debates should be made before the government asks for an approval for the FTA in accordance with article 224 of the Constitution of Thailand,

The above mentioned process should be implemented and acted as a precedent for future state practice. Therefore, there shall be no obstacle, no limitation or no counter claim to refuse to proceed the proposed procedure.

Item 3. The contents in the FTA shall limit the agreement on intellectual property rights related to drug and health systems. They must not be beyond the articles in TRIPS; They should deny TRIPS Plus on the extension of terms of patenting, and data exclusivity rights on drug and chemical substances. In addition, the government shall show its intention to protect people's lives and health by applying compulsory licensing for the essential medicines as well as the parallel import so that the patients can have regular access to medicine.

Item 4. In the light of people participation for the formulation and development of public policy on the systems of pharmaceuticals, medicine, life and health, for the benefits to Thai society, different professions in public health and consumer organizations shall play important roles in exercising rights to accessing to information, giving opinions, sharing decision making as well as participation in investigation.

Item 5. Information exchange and the disclosure of information to public shall be made. It is important for Thai society to be aware of the issues of FTA between Thailand and the United States on the systems of pharmaceuticals, medicine, life and health. Therefore, the Thai government shall be obliged and shall promote the disclosure of information to public by all means for people participation via radio, television, newspaper and internet in the forms of public debates and academic fora.

Item 6. In the negotiation process leading to any international agreement, not only representatives from Department of Trade Negotiation, Department of Intellectual Property Ministry of Commerce, Ministry of Foreign Affairs and Office of Food and Drug Administration under Ministry of Public Health, but also it is most important that academics, non-governmental organizations and people networks shall also be involved in the participation process, in respects of civil rights and fair response to people life and health.

These six solutions as being consensus proposed to the RTG are for the administrative authority to proceed and to disclose to the public.

On the occasion that the Prime Minister will make the yearly announcement to the Thai Parliament, Senate Standing Committee on Social Development and Human Security, Senate Standing Committee on Public Health, Senate Standing Committee on Foreign Affairs, will bring these proposed consensus solutions to the government so these shall be integrated into the government policy on FTA between Thailand and the United States on drug and health systems and shall be conveyed to people ultimately.

The following article titled "Keep Intellectual Property Out of the [US-Thailand] FTA" appeared in The Nation newspaper on 28, February 2004 on the seminar organized by Drug Study Group.

Health advocates urged the government to exclude intellectual property rights from its negotiations on a free-trade agreement (FTA) with the United States.

Activists, senators, scholars and civil groups said that if these rights cannot be excluded, agreements on the issue should be consistent with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Anticipating that the Thai-US pact will be modelled after the one signed between the US and Singapore, intellectual-property-rights lawyer Jade Donovanik said protection under the US-Singapore model was beyond that required by TRIPS.

The US wants to restrict the use of compulsory licensing, a legal measure that authorizes private or state use of patents without the consent of patent holders.

It also wants to ban the import of patented drugs from places where they are sold cheaper, Jade added. These measures are allowed under TRIPS. Participants expressed their greatest concern over the measure known as "data exclusivity", which they said would further delay the introduction and marketing of cheaper, generic versions of essential drugs.

The government must not yield to any attempt to restrict the use of compulsory licensing and must make clear its stand on the issue of intellectual property rights, said Bangkok Senator Jon Ungpakorn. The Health Ministry must be involved in all negotiations, and the proposed agreement should be submitted to Parliament, and made public, he said.

Senior Health Ministry official Orasa Kowintha acknowledged that Thai authorities had so far no pro-active strategy in their negotiations. Another speaker, Jacques-chai Chomthongdi, of the civil group FTA Watch, said that there was little chance for Thai agricultural products to benefit from a free-trade pact with the US, as the policy of US politicians with regard to farm-sector subsidies is intact.

Source: Posted on ip-health on 28 February 2004 originally Mukdawan Sakboon, The Nation (Thailand), February 28, 2004

Papua New Guinea: Training and guidelines for the rational use of ARVs

Reported by Beverley Snell, Centre for International Health, Macfarlane Burnet Institute for Medical Research and Public Health our Australian HAI partner.

In February 2004, as part of the national comprehensive response to the HIV epidemic, the Papua New Guinea National AIDS Council Secretariat and the Papua New Guinea National Department of Health held a workshop for 44 prescribers in Madang to introduce the National Guidelines for the Use of Antiretroviral Therapy. The Guidelines, which were published in November 2003, were the basis of the training. These guidelines are designed to ensure that antiretroviral drugs are used in Papua New Guinea in a way that will benefit both individuals and the country overall.

The workshop participants included prescribers from government, NGOs, faith-based organizations and industry. The detailed evaluation of the workshop indicated a real ownership of these National protocols and a commitment to adhere to them. Provisions are in place for consultation between prescribers and review of the protocols. The prescribers course was organised and delivered by the Australian Society for HIV Medicine (ASHM) on behalf of the National HIV/AIDS Support Project, which is funded by the Australian Agency for International Development (AusAID).

Regulations are being prepared to govern the availability and use of ARV medications and to ensure that the public benefit is not eroded by the development of viral resistance. TRIPS compliant health sensitive legislation is being developed to allow import of affordable drugs for the treatment of HIV and HIV-related diseases and anti-discriminatory legislation is already in place.

People's Health Movement International Forum for Defence of People's Health

An International Forum for Defence of People's Health was held at YMCA in Mumbai, India on January 14th and 15th 2004 preceding the World Social Forum which was held in Mumbai from 16th to 21st of January 2004.

Background

At the time of the World Health Assembly in May 2003, the Steering Committee of the People's Health Movement met to chalk out a calendar of activities for the year. One such activity was the "**Third International Forum for Defence of People's Health**" to be held at the YMCA in Mumbai.

People's movements across the world are working to identify and demonstrate that the path to sustainable development and social and economic justice does not lie in neo-liberal globalization paradigm but in alternative models for people-centered and self-reliant progress. The World Social Forum developed as a response of the growing international movements questioning the neo-liberal economic policies being pursued in most countries and imperialist globalization.

The International Health Forum (IHF)

The International Health Forum brought together nearly 700 participants (comprising activists, professionals, medical students, academics, artists, journalists) from 44 countries^{xvi} from all the streams of development (both health and non-health) who actively participated in the forum held over two days. Describing the simplicity of the whole Forum Dr. Rajaratnam Abel of CHIN network says "My first observation was the simplicity of the NGO style arrangement. Basket ball court for an

International Health sounds pretty close to a basket ball light for a rural surgical theatre. In both instances this is how cost is kept low without compromising on the quality of the inputs”.

The Health Forum provided interactive dialogue opportunities for all the participants gathered. It was characterised by diverse events with plenaries, workshops and cultural events on both the days. Testimonies and Case Studies were presented at each of the sessions thereby paving the way to make the sessions more focused on actual realities and to move towards action. The case studies were not only focused on problems and situation analysis but also on actions/campaigns taken up by PHM and other activists in their regions. The events included:

Plenaries: 6 plenaries were held on the following themes

- a) Overview on Confronting the Challenge of Globalisation through Health Work:
Perspective, Struggles and Strategies
- b) Globalisation, Health Policies and Health Sector Reforms
- c) Health under War, Occupation and Militarisation
- d) HIV/AIDS; Confronting the Crisis
- e) Women, Population policies and violence
- f) Health Care and the Marginalised

Parallel Workshops: 14 parallel workshops were held (7 parallel workshops each on 14th and 15th). An Overview:

- a) Globalisation and Health Policy
- b) Promoting Synergy: Towards Joint Anti -War Action
- c) Learning from the Global Tobacco Control Campaign including FCTC
- d) Liberation Medicine
- e) Globalisation and Health Sector Reforms
- f) Health Teams for "Health for All" (Including CHW's)
- g) Traditional / Alternative Systems of Medicine (ASM) and Primary Health Care
- h) Key Issues in Women's Health
- i) Voices of the Unheard - Children, Adolescents and People with Disability
- j) HIV/AIDS and the resurgence of Communicable diseases
- k) Globalisation, Poverty, Hunger and Health
- l) New Economics and its Impact on Medical Practice in India
- m) Social Determinants of Mental Health and PHM
- n) Environmental Justice and People's Health - Confronting toxics in our communities

Closing Plenary: Reviving the Spirit of Alma Ata... the challenges before us

- At the concluding session of the Health Forum, 20 young participants who were rapporteurs of all 20 sessions presented a summary of each session
- **Release of publications:** A lot of publications were released during the Forum by PHM and their associates. Some of the publications released were
 - a) News brief 10 & 11 - Nov 2003 - The Newsletter by the PHM
 - b) Health for All Now! Revive Alma Ata, - An Alma Ata Anniversary book release by PHM and its partners
 - c) HAI News - No. 126 July - Sept. 2003 - The Newsletter from Health Action International
 - d) Health For All Now! - A book brought out by Jana Swasthya Abhiyan, PHM India

Cultural Programme: There was an enthusiastic response from all the regions of the world to participate in the cultural events. The events were as varied as music and dance from the Africans; the PHM Song being sung by the delegates from the different regions of the world; skits and dramas by a group of Activists from Tamil Nadu, India; songs and dances from the enthusiastic Bangladeshi delegation; magic shows to expose the superstitions by the Jana Vignana Vedike, Andhra Pradesh, India; A film "Health For All" by Pervez Imam was screened and the event concluded with a "Song of Resistance" from Pervez Imam, India

World Health Organization meets the Civil Society:

One of the significant features of this forum was the participation of the official delegation of the WHO delegates. During the World Health Assembly in May 2003, a PHM delegation had met the new Director General of the WHO Dr. Lee who had sought the co-operation of civil society in bringing WHO back to its focus on "Health For All". PHM assured him of a critical collaboration and extended the invitation to him to attend the forum. Accordingly WHO sent an official delegation to the Health Forum. Ian Grubb, Craig McClure, Alaka Singh, Eugenio Villar from WHO Geneva and Tej Walia from the WHO SEARO participated in the Forum on both days and heard the testimonies from the grass roots. In the plenary "HIV/AIDS; Confronting the Crisis", Craig McClure presented the new "**3X5 initiative**" to tackle the HIV/AIDS epidemic worldwide. On 16th January, the delegates of the World Health Organisation also had a meeting with a smaller group of PHM members. In a candid discussion between both the sides the apprehensions and doubts of the Civil Society and the problems with the policies of the WHO upto date including the latest **3 x 5 initiative** was shared with the WHO group. At the end of the meeting it was decided to continue the dialogue and also to identify the possible areas in which WHO and the PHM could work together to bring comprehensive Primary Health Care back into Health Policies. There has been some further collaboration between WHO and PHM in this respect.

Mumbai Declaration:

The Forum brought together all the concerns and experiences shared during the forum into a *Declaration* for action, entitled "**The Mumbai Declaration**". This Declaration is an update on the state of people's health across the globe at the beginning of 2004 and calls on People's Health Movement, Civil Society and Governments to evolve action in six key areas to achieve the goal of "Health for All Now!" dream ^{xvii}.

- **End Corporate led Globalisation**
- **End war and occupation**
- **Implement Comprehensive and sustainable Primary Health Care**
- **Confront the HIV/AIDS epidemic with Primary Health Care and Health Systems approach**
- **Reverse Environmental damage caused by unsustainable development strategies**
- **End discrimination in the Right to Health**

3. World Social Forum: Most of the participants of the Health Forum also participated in the World Social Forum, an alternative platform for the neo-liberal paradigm, to be among the nearly 123,000 people who attended the same. PHM and its associates had organised some events at the World Social Forum. The events consisted of 2 large Plenaries and 2 workshops under the PHM banner

* **Plenaries:** 2 plenaries were held on the following themes

- a) 25 years of Alma Ata: Globalisation and the "Health for All" Challenge
- b) Wars, Conflicts, Occupation and Militarisation - The Greatest Threat to Public Health

*** Workshops:**

- a) WTO and Access to Drugs
- b) Population Policies in Third World Countries - A coercive Agenda

*** Other Health Related events in World Social Forum:**

- a) Gas and Natural Resources: Corporate Powers and Challenges - PHM Bangladesh
- b) Violence as a Public Health Issue - CEHAT, FME, MFC
- c) Poverty in Germany - BUKO Pharma Kampagne, Germany
- d) Water Rights in South Asia - Options and Challenges - PHM Bangladesh
- e) Reproductive Technologies: Implication for Women's Health - WGNRR, SAMA et al
- f) "From Rights to Actions" - WGNRR
- g) Migration, Trafficking and Labour Rights - Bangladesh Perspectives - PHM Bangladesh
- h) Privatisation and Healthcare: Social Challenges in Bangladesh - GK Savar Bangladesh

Voices from the Forum:

Some of the voices that were heard during the forum were:

“WHO is reaffirming its commitment to primary health care, including in the delivery of HIV/AIDS treatment, care, support and prevention, as described in the 2003 issue of the World Health Report” *WHO delegation of Craig McClure, Ian Grubb, Alaka Singh, Eugenio Villar and Tej Walia^{xviii}* .

"Every 24 hours, 30000 children around the world die of preventable diseases. Just USD 9 billion would ensure safe drinking water and sanitation the world over. Instead, USD 900 billion is spent on military operations every year." *Dr. P V Unnikrishnan of the People's Health Movement (India)*

"**PEOPLE** need to demand from their respective governments a consistent responsibility towards healthcare so that the divide between the rich and the poor is not so glaring." - *Maria Zuniga, global coordinator, International People's Health Council*

"About 47 million people in the US have no healthcare cover at all. It's time for a global movement to make governments sit up and formulate policies that favour the people and not the pharmaceutical companies that make huge profits out of healthcare". *Sarah Shannon, executive direction, Hesperian Foundation*

"**MORE** than 50 per cent of the people in my country have virtually no access to healthcare. It's high time the public sector and the private sector focussed on jointly providing health services to all sections of society." - *Dr. Hugo Icu, Guatemala*

“**HEALTHCARE** is primarily the responsibility of the public sector. No country in the world can afford to let the private sector take over this area” - *Dr. Zafrullah Chowdhury, Bangladesh^{xix}*

"The call for legal campaign against drug patents is the part of international effort to build moral pressure on companies and force them to place the lives of people before corporate profits. We will also oppose the World Trade Organisation, Globalisation, Militarisation and poor public health policies," *Dr Ravi Narayan, the coordinator of PHM Secretariat said^{xx}*

For details of the press releases and the Media coverage please refer to the Weblink
www.phmovement.org/Media Room

References:

¹ Argentina, Australia, Bangladesh, Belgium, Brazil, Cambodia, Cameroon, Canada, Costa Rica, Cuba, Denmark, Ecuador, Egypt, France, Germany, Guatemala, Hong Kong, India, Iran, Italy, Kenya, Korea, Lebanon, Malaysia, Mauritius, Netherlands, Nicaragua, Nigeria, Norway, Pakistan, Palestine, Peru, Philippines, South Africa, Sri Lanka, Sweden, Switzerland, Tanzania, Thailand, USA, UK, Vietnam, Zambia, Zimbabwe

¹ The Mumbai Declaration – From the III International Forum for the Defence of People’s Health – www.phmovement.org/md

¹ Mumbai Report HIV-PPHP Jan 04 - Craig McClure, Ian Grubb, Alaka Singh, Eugenio Villar and Tej Walia of WHO

¹ 50 Countries meet to fight for health – The Indian Express dated January 15th 2004

¹ “Sue Drug firms” – The Asian Age dated January 16th 2004

USA - Australia Free Trade Agreement: Impact on pharmaceuticals

This agreement contains major concessions to the US pharmaceutical industry that are likely to undermine the Australian Pharmaceutical Benefits Scheme (PBS) and ultimately increase the costs of medicinal drugs to Australian consumers.

The agreement is unbalanced in that it focuses entirely on the rights of pharmaceutical manufacturers and totally neglects the rights of consumers to equitable access to affordable drugs. In particular the agreed principles on pharmaceuticals leave out the key principle of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in November 2001, namely that trade agreements should be interpreted and implemented so as to protect public health and promote access to medicines for all.

The FTA allows pharmaceutical manufacturers to ask for an independent review of a decision by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) not to list a drug because the evidence showed it not to be cost-effective. This is despite the fact that such appeals were previously rejected by a review of PBS processes held in 2000. Appeals against PBAC decision-making are likely to favour multi-national pharmaceutical companies who have large budgets and numerous lawyers; inevitably they will lead to drugs being listed at higher prices; why else would companies want such provision?

The exchange of letters between Trade Minister Vaile and US Ambassador Zoellick also shows that Australia shall provide opportunities for pharmaceutical manufacturers to apply for an adjustment to PBS prices over time. There appears no corresponding provision for price adjustment downwards when pharmaceutical manufacturers cause PBS blow-outs by excessive advertising encouraging inappropriate use, a well documented tactic in recent years.

The agreement sets up a medicines working group with the USA, a country which many people argue has the worst (most inequitable, highest priced) pharmaceutical system in the world. Yet the public health goal of equitable (affordable) access is not a consideration of this FTA or the working group. If it was, then the USA and its citizens who now go to Canada and Mexico to buy affordable drugs could learn much from the Australian PBS.

The provision about dissemination of pharmaceutical information via the Internet raises concern that this will allow Direct to Consumer Advertising (DTCA) in Australia by default. DTCA is legal in the USA but not in Australia. It has been associated with a substantial increase in usage of the products targeted (and thus health care costs) which are often not in accord with best-practice.

Finally, although not part of Annex 2-C on Pharmaceuticals, there appears to be extensive changes to Australian patent laws which are likely to delay the introduction of cost-effective generic drugs. These changes are likely to lead to increased PBS costs and increased costs of over-the-counter (OTC) medicines.

In conclusion, it is very sad that at the same time that the Australian Health Insurance Commission is successfully exporting Australian medicinal drug policy to many countries who are struggling to balance health policy with industry policy, the current Australian government has totally ignored public health considerations in a one-sided trade agreement with the USA. Beware of Free Trade Agreements with the USA!
Source: Posted on 5 March 2004 on E-Drug. The article is authored by Dr. Ken Harvey, Council Member, Australian Consumers Association; Board Member Therapeutic Guidelines Ltd.; Senior Lecturer, School of Public Health, La Trobe University; k.harvey@latrobe.edu.au

Ms Passanna Gunasekera of Health Action International Asia Pacific presented the statement to WHA on agenda item 12.1 HIV/AIDS on behalf of Consumers International. The very short statement to the assembly was based on the following presentation prepared by CI in collaboration with HAI and MSF.

Statement by Consumers International on Access to Medicines given to the Fifty-seventh World Health Assembly, 17-22 May 2004, Geneva

Consumers International (CI) is the Global Federation of consumer organisations worldwide. With 250 members in 115 countries, CI represents the world's six billion consumers. I am also speaking for Health Action International.

At the 56th World Health Assembly we welcomed the adoption of resolution 56.27 entitled Intellectual Property, Innovation and Public Health, and welcomed the establishment of the Commission on Intellectual Property, Innovation and Public Health. We are pleased to have been invited to consultations with the Commission, and look forward to continuing to provide consumer perspectives on its work. In the face of the global AIDS pandemic, we strongly advocate immediate action to create a coordinated and comprehensive response to HIV/AIDS. This includes global efforts to afford access to essential medicines – and especially quality, safe, affordable ARV medicines and medicines to treat opportunistic infections. We therefore welcome the recommendation of the Director-General for greater investment in the WHO prequalification project, which has contributed both to the availability of medicines, and the simplification of drug regimens, for example, through the prequalification of fixed dose combinations for the management of HIV. We welcomed the decision of member states in 2001 to establish the WHO Prequalification Pilot Project, and the collaboration of the specialized agencies of the UN system to support this effort. We recognise that the final authority for drug evaluation and approval rests with governments. We are also aware of the limited capacity of many member states, particularly those hardest hit by the pandemic, to undertake such activities. This is why we urge member countries to commit financial resources to expand the work of the prequalification project. The WHO Prequalification Project is an excellent illustration of rational drug policy at the international level. It uses global experts from the national drug regulatory authorities of member states to provide rapid assessment of essential drugs. It assures Good Manufacturing Practice, it contributes to national expertise in drug regulation -- through training and other means, and it provides regular information to countries on the medicines and manufacturing facilities on which they rely.

We call on member states to institutionalize the prequalification project within the WHO Essential Drugs and Medicines Programme. We urge member states to make the necessary financial, technical and human resources available to expand the work of the prequalification project.

Reliable price information and transparency are key elements in increasing access to essential medicines. Through HAI, we collaborate with WHO in its Medicines Prices project, that aims to develop a methodology for price monitoring. Other reliable sources of such information include the Untangling the Web of Price Reductions report produced by Medecins sans Frontieres, and Sources and Prices, a WHO, UNAIDS, UNICEF and MSF publication.

The efforts to provide countries with reliable price information for their treatment programmes are not helped by the production of distorted and inaccurate information. Consumers International believes it has a role to play in the co-ordinated response to the pandemic by continuing to provide accurate information to assist public understanding of health systems. We look forward to supporting and working with WHO and governments to protect consumer rights.

- JOURNAL SCAN -

The 3x5 Aids drug plan faces collapse in Africa

A United Nations plan to provide three million HIV-infected patients in Africa with anti-retroviral drugs by 2005 is in danger of collapsing owing to lack of funds, UN and World Health Organisation officials said.

Some countries, particularly the United States, are balking at supporting the project, AIDs workers say, partly because the plan intends to use a form of medicine called fixed-dose combination antiretroviral drugs whose use is opposed by large pharmaceutical companies.

Only \$2.3 billion has been secured for the \$5.5bn WHO project, dubbed 'Three by Five' because it hopes to provide drugs to three million people by 2005. Only the UK, Sweden and Spain have provided money to date, officials said.

'If Three by Five fails, as it surely will without the dollars, then there are no excuses left, no rationalizations to hide behind. There will only be the mass graves of the betrayed,' said Stephen Lewis, the UN Secretary-General's special envoy for HIV/AIDs in Africa. The WHO urgently needs \$200m in the next few months to upgrade health systems' infrastructures in 14 African states, Lewis said.

AIDs activists say money isn't forthcoming because of WHO support of the use of combination medicines. Called fixed-dose medicines, these drugs combine two or more active ingredients in one pill, thereby reducing the number of tablets an AIDS patient must swallow each day. Fixed-dose drugs are also cheaper. Taking two fixed-dose combination pills a day for a year costs \$140 per patient, compared to about \$600 per year for six pills per day.

The US, by far the largest donor with a \$15bn plan launched last year, has been reluctant to endorse the fixed-dose combination pills, saying they are not yet convinced the medicines are safe. In order to make the combination drugs, generic manufacturers use active ingredients that were discovered by different pharmaceutical companies and are under patent in wealthy countries.

'We need to have principles - standards by which the purchase decisions can be made,' said Randall Tobias, the US Global AIDs Coordinator, in recent testimony before the US Congress. Ambassador Tobias is the retired Chairman of Eli Lilly, one of the world's biggest pharmaceutical concerns. WHO and AIDs workers say the principles and guidelines are already in place because the medicines must meet extensive guidelines by the World Health Organisation before being approved for use.

The fixed-dose pills approved for use by the World Health Organization are produced by three generic drug makers in India, which does not yet recognize patent laws. Exceptions to the patent system allow local manufacturers in poor countries to produce life-saving generic medicines and export them only under certain limited circumstances to other poor nations.

This means Indian manufacturers will agree to sell their wares in the 14 poorest African nations. Mèdecins Sans Frontière's T Hoen believes the US stance is not motivated by safety. 'The US's position is to buy drugs only approved by the (Federal Drug Administration),' she said. 'The fixed dose can't be approved by the FDA because of patent problems, not because of their safety or efficacy.'

Source: Posted on E-Drug on 16 March 2004, originally by Alison Langley in Geneva Sunday March 14 2004, The Observer

Judge Upholds Ban On Chicken Antibiotic

An administrative law judge yesterday upheld the Food and Drug Administration's decision to ban an antibiotic used to treat chickens because it was making human antibiotics less effective.

The drug Baytril, manufactured by Bayer Corp., was ordered off the market in 2000 along with another poultry medication in an effort to limit the spread of antibiotic resistance that enables bacteria to become impervious to drugs they regularly encounter. The FDA targeted the two antibiotics because they are close relatives to a popular family of drugs used to treat human disease.

The drug remains on the market pending resolution of the case. Administrative Law Judge Daniel J. Davidson accepted the FDA position that chickens treated with Baytril produce resistant bacteria that cause food poisoning that could not be treated by the related human antibiotics.

The decision was hailed by public health groups but was criticized by the trade group representing the makers of veterinary drugs and by Bayer, which plans to appeal. "We don't feel that the scientific evidence that supports continued use of Baytril in poultry was fully considered," said company spokesman Bob Walker.

Baytril was once popular for treating respiratory problems in chickens, but its use in the United States has declined. The McDonald's fast-food chain has told suppliers to avoid antibiotics. The FDA's ban of Baytril and SaraFlox, made by Abbott Laboratories, was based on an assessment to determine which animal antibiotics posed the greatest threat to drugs used in human medicine.

Abbott Laboratories agreed to remove its drug from the market, but Bayer argued that its product does not cause measurable antibiotic resistance or harm.

The Animal Health Institute, which represents makers of veterinary drugs, joined the appeal. "We think a compelling scientific case was made that the absence of Baytril to treat sick chickens carries real safety risks that outweighs the theoretical risks of the transmission of resistant bacteria," Vice President Ron Phillips said yesterday.

But the group Keep Antibiotics Working, which includes environmental, consumer and farming groups, applauded the decision. Coalition member David Wallinga, with the Institute for Agriculture and Trade Policy, said the rate of drug resistance in food poisoning cases remains "disturbingly high."

Source: Posted on druginfo on 19 March 2004 but originally by Marc Kaufman Washington Post Staff Writer, March 17, 2004; Page A02

Philanthropic, Globalised Keynesianism?

At a conference held in Penang in February 2004 organized by Medecins Sans Frontieres (MSF) and the Drugs for Neglected Diseases Initiative (DNDi), John Sulston, the Nobel laureate in medicine and physiology (2002) declared that the problem of neglected diseases was not so much a market failure as the absence of a market which could bring into existence the required medical armamentarium. This remark captured quite succinctly the two strategic postures which lay dormant throughout much of the conference (in truth, a continuum rather than two polar opposites), but occasionally erupted in robust exchanges between such personalities as US-based James Love (Consumer Project on Technology) and representatives of big Pharma (most notably Novartis). The tension of course was between non-market approaches vs. reforms to "make the market work better".

Alex Matter, Founding Director of the Novartis Institute for Tropical Diseases in Singapore (est. 2002) revealed that Novartis had committed an establishment and operational budget of US\$122 million for the first five years to carry out research on neglected tropical diseases, and that "in those developing countries where these diseases are endemic, Novartis AG intends to make treatments readily available and without profit" (Novartis ITD website).

After some inconclusive discussion on the meaning of "non-profit" in relation to the accounting details of variable and fixed costs (most importantly, R&D) in the production and marketing of drugs, some participants were left wondering as to whether this was an expensive PR exercise for Novartis.

The less cynical however drew attention to the potential markets which could be created by the Global Fund for Aids, TB and Malaria (GFATM), the Bill & Melinda Gates Foundation, UK-DFID, and Advance Purchase Commitments (APC). The latter is an incentive mechanism for drug or vaccine R&D where success is uncertain and effective demand does not otherwise exist.

This APC approach, which guarantees a purchase at specified price and volume in the event that an acceptable product emerges, is currently much in vogue at the World Bank, UK-DFID and other international development and academic circles. It was also the subject of a lengthy paper and critique by Oxford economist Andrew Farlow at another session.

In the same panel, Ee Chee Ren, Deputy Director of the Genome Institute of Singapore (GIS) described a joint-venture between GIS and Roche Pharmaceuticals in developing a diagnostic test that could detect the SARS coronavirus before the onset of symptoms and furthermore provide results within one hour. Dr Ren however declined to provide details on the benefit sharing agreement between the GIS and Roche, although he did allow that the diagnostic kit to be marketed by Roche would be priced at about US\$20 per kit.

Suerie Moon (MSF) quite correctly pointed out that SARS would not count as a "neglected disease". With 10 per cent of Singapore's GDP at stake (tourism) not to mention the more distal economic effects extending as well to China and other SARS-sensitive East Asian economies, the market for SARS diagnostic kits, vaccines, and therapies is assured in East Asia. (The politically influential tourism sector in Malaysia accounts for 7 per cent of GDP and foreign exchange earnings second only to manufactured exports).

This is in contrast to the neglected diseases highlighted by MSF: of the 1,393 new drugs approved between 1975 and 1999, only 16 (or just over 1 percent) were specifically developed for tropical diseases (such as malaria, sleeping sickness, Chagas' disease, kala azar) and tuberculosis, diseases that account for 11.4 percent of the global disease burden. For 13 out of those 16 drugs, two were modifications of existing medicines, two were produced for the US military, and five came from veterinary research. Only 4 were developed by commercial pharmaceutical companies specifically for tropical diseases in humans.

These neglected diseases of course mainly affect poorer communities in countries of the South, which do not constitute a valuable enough market to stimulate adequate R&D by the multinational pharmaceutical companies.

In the event that "philanthropic" Keynesianism doesn't deliver adequate returns to the multinational pharmaceutical companies, we can anticipate that companies like Novartis will turn to the more marketable R&D in its tropical diseases research agenda, much along the lines of the publicly-funded, market-oriented Genome Institute of Singapore, which currently focuses on SARS, and perhaps avian flu, and Nipah among its tropical disease research priorities.

In short, we would be back to an intractable, fundamental dilemma: need vs. demand, in its neglected diseases-orphan drugs incarnation.

Source: Chan Chee Khoon, Citizens' Health Initiative, February 8, 2004 appeared in Malaysiakini.com (February 11, 2004).

UN HEALTH AGENCY SEEKS TO COMBAT DANGEROUS MISUSE AND OVERUSE OF MEDICINES

With misuse and overuse accounting for almost half the total global use of medicines with potential severe consequences such as drug resistance and even death, the United Nations health agency called for multilateral partnerships to set up advocacy and education programmes especially in developing countries.

"Most people see a lack of access to medicines as the main problem," the interim Director of Essential Drugs and Medicines Policy at the UN World Health Organization (WHO), Hans Hogerzeil, said in a news release in Chiang Mai, Thailand. "Unfortunately, the irrational use of available medicines is also a major threat to health and leads to considerable waste."

Irrational use of medicines includes over-treatment of a mild illness, inadequate treatment of a serious illness, misuse of anti-infective drugs, over-use of injections, self-medication of prescription drugs and premature interruption of treatment. Several country figures show that such practices are frequent, and not exclusively in developing countries.

Almost half of all medicines globally are used irrationally, with such potential consequences as adverse drug reactions, drug resistance, protracted illness and death. In addition, financial cost incurred by individuals and governments due to irrational use is often extremely high, particularly in developing countries.

"Misuse of antibiotics, overuse of injections, and under-use of life-extending drugs for illnesses such as HIV/AIDS, heart disease, and other chronic illnesses together constitute a global epidemic of irrational use of medicines," said Jonathan Quick, incoming President of Management Sciences for Health, a meeting co-sponsor. "This epidemic results in untold needless suffering and costs millions of lives each year." According to figures gathered by surveys presented to WHO, in 2000 about 60 per cent of antibiotics in Nigeria were prescribed unnecessarily. In Nepal, more than half of the antibiotics prescribed in 1996 were not needed and 40 per cent of medicine expenditures in the same year was wasted due to inappropriate prescriptions.

Overuse of most medicines contributes to drug resistance. For example, overuse of chloroquine, the traditional remedy for malaria, has led to resistance which has been recorded in over 80 countries. Resistance to penicillin, used to treat gonorrhoea, is present in as many as 98 per cent of patients in certain regions.

Irrational use of drugs due to inappropriate prescription can also lead to adverse drug events causing illness or death. In the United States, adverse drug events represent one of the six leading causes of death.

Source: Posted on PHA Exchange on 30 March 2004

- RESOURCES -

Towards a global health workforce strategy

Publisher: ITG Press, 2003
488 pp. [ISBN 90-76070-26-1]

A new book on human resources for health issues was launched in December edited by P Ferrinho, Lisbon University, M. Dal Poz of the World Health Organization & Rio de Janeiro University. A free downloadable full-text copy [PDF file] is available at:

<http://www.itg.be/itg/GeneralSite/InfServices/Downloads/shsop21.pdf>

"...The papers presented in the book cover the main dimensions of Human Resource Development in health: planning and managing the workforce, education and training, incentives and working conditions, managing the performance of personnel and policies needed to ensure that investments in human resources produce the benefits to which the investing populations are entitled.

Authors write from diverse professional, regional and cultural perspectives, and yet there is a high degree of consistency in their diagnosis of problems and proposals for strategies to address them. They all agree on the multidimensionality of problems and on the need for solutions that take into account all dimensions. They also agree that if problems tend to be similar in nature, they take forms that are time and context-determined.

This set of papers raised questions and give insights into strategies that are relevant to developed and developing countries....." Orvill Adams (World Health Organization) and Gilles Dussault (World Bank Institute)

Health and Human Rights: An International Journal

The François-Xavier Bagnoud Center for Health and Human Rights has been publishing journals on health and human rights since 1994. The journal explores the reciprocal influences of health and human rights, including the impact public health programs and policies have on human rights, the consequences human rights violations have on health, the importance of health in realizing human rights, and the ways in which human rights can be integrated into public health strategies.

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*For more details contact François-Xavier Bagnoud Center for Health and Human Rights
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WRITING FOR CHANGE

An Interactive Guide to Effective Writing, Writing for Science, and Writing for Advocacy

Alan Barker and Firoze Manji

International Development Research Centre (IDRC)

IDRC/fahamu - ISBN 0-88936-932-1

Writing for Change has been developed, designed, and published by Fahamu, the human rights organization, in collaboration with Canada's International Development Research Centre (IDRC). The lead authors were Alan Barker, a specialist in communication skills, and Firoze Manji, Project Coordinator and Director of Fahamu. Illustration and design were provided by Judith Charlton.

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DRUG BENEFITS, “PARTLY A MYTH SUSTAINED BY SECRECY, LACK OF PUBLIC ACCOUNTABILITY,” CLAIMS NEW BOOK

Published by Aksant Academic Press (Amsterdam)

Price: £19.25 (Euro 27.50).

Calls for an overhaul of the “secretive and profoundly inadequate system of medicines control”, are made in a penetrating new book launched in March 2004. The book focuses on the issues surrounding increased antidepressant use in Europe and a UK government inquiry into the “looming antidepressant drug crisis”.

Medicines out of Control? is a provocative, evidence-based case history on the safety of medicines. The book charts the promotion, regulation, prescribing and use of mood-regulating drugs, especially antidepressants – “blockbuster” drugs such as Prozac and Seroxat/Paxil. It warns how the unfolding crisis of dependency on antidepressants may prove to be a watershed in drug control. In questioning the adequacy of the UK government’s current drugs inquiry, this book raises basic questions about the competency of drug regulators and the lack of transparency in tackling user dependency and complaints in many countries. Authoured by Charles Medawar, Executive Director of Social Audit, Member of WHO’s Expert Advisory Panel on Drug Policies and Management, a leading specialist writer and lecturer on medicines policy, drug safety and corporate, governmental and professional accountability

and co-authored by Anita Hardon, Professor in Anthropology of Care and Health at the University of Amsterdam, Scientific Director of the Amsterdam School for Social Science Research, a leading expert on social and cultural aspects of consumer drug use, based on more than 20 years of research in Asia, Africa and Europe, the present chair of the Health Action International (Europe) Foundation Board

the publication was largely funded by the Joseph Rowntree Charitable Trust, with additional support from the Allen Lane Foundation and the 1970 Trust.

It also raises strong concerns about the enormous growth of antidepressant use in countries including The Netherlands, when there is little evidence of health benefit among many users. Dutch health insurers have reported a surge in the number of people using antidepressants in recent years. In fact, between 1996 and 2001, the number of Dutch consumers using antidepressant drugs (Selective Serotonin Reuptake Inhibitors (SSRIs)) jumped by 150 per cent. In 2001 alone, the Dutch spent Euro 104 million on antidepressants, 5 per cent of the total drug budget¹.

“The antidepressant crisis illustrates how drug benefit-risk assessments are increasingly made on the strength of evidence that is hugely incomplete and highly partial, using evaluation procedures that are often chaotic and misconceived,” said **Charles Medawar, principal author and Executive Director of Social Audit**. “Drug safety and effectiveness is, in part, a myth sustained by entrenched secrecy, the dominance of vested interests, misplaced optimism and an overwhelming lack of public accountability.”

The book highlights concerns including:

- How the antidepressant crisis exposes the limitations of drug regulatory systems, based on scrutiny that is often badly flawed, mainly of company-sponsored clinical trials conducted **before** drugs come to the market.
- That the medicines control authorities continue **not** to officially recognize the risks of dependency on antidepressants when user evidence suggests the contrary.
- The refusal of drug regulators to take account of valuable evidence from users.
- Failure to take stock of the extent of iatrogenic illness (harm from medical intervention), including substantial risks from the medicalization of daily life.

“The book emphasizes the urgent need to confront the disease awareness campaigns and under-the-counter, direct-to-consumer advertising [DTCA] now taking place in Europe despite the European Union consensus not to allow DTCA,” said **Anita Hardon, co-author and Scientific Director of the Amsterdam School for Social Science Research**. “This kind of promotion leads to an unsustainable demand for medicines, and overuse of drugs such as antidepressants. The EU and European governments are not sufficiently

¹ Dutch antidepressant use figures drawn from Achmea Health website,
<http://www.achmeahealth.nl/mednet/mednet.php?type=showdoc&id=10704>.

acknowledging how this huge demand for and optimistic belief in drugs' benefits undermine the sustainability of public health systems."

Medicines out of Control? states that current systems are 'fatally flawed' in their routine and 'gross overestimation' of the benefits of medicines over risk and harm. Ivan Wolffers, Professor of International Health at the Free University in Amsterdam, has also drawn attention to the overuse of SSRIs including Seroxat and Prozac in The Netherlands. "For more than ten years we have been told that antidepressants are safe," he said. "The image is quickly changing now."

"*Medicines out of Control?*" suggests that all of the actors involved in the healthcare system have been too trusting about the proclaimed positive effects of medicines. In fact, the authors argue, the results of much scientific research on medicines is tainted as most are financed by the pharmaceutical industry which is searching for products that will reap huge sales.

Secrecy about drugs' benefits and risks is another pressing problem. The authors point out that when medicines are registered by the government, much of the clinical research results remain secret. The book argues that additional post-marketing surveillance is needed to guarantee the safety of medicines once they are on the market and being used daily. In fact, to support the argument, the book reveals that based on new research results the recently revised estimated number of users affected by drug withdrawal reactions from paroxetine (Seroxat/Paxil) is not one in 500 users, but one in every four.

Consumers should demand more transparency about the details of clinical research, the authors agree. "In The Netherlands there are many commercial research organizations that carry out research for the pharmaceutical industry. We believe patients should only take part in clinical trials if the results are made public. We are now working on an informed consent procedure that would demand greater openness about this clinical data."

A number of key recommendations are made in *Medicines out of Control?* including:

- Overhauling the secretive and inadequate system of medicines control.
- Establishing a post-marketing drug surveillance system that operates independently of the licensing authorities, run by and on behalf of medicines' users.
- Obtaining a commitment from regulators to encourage transparency in drug regulation, subject only to the protection of personal privacy and commercial manufacturing knowledge.
- Moving European medicines policy under the umbrella of DG Health and Consumer Protection instead of DG Enterprise.
- Improving Europe-wide regulation of "under-the-counter" disease awareness campaigns.
- Increasing the amount of independent drug information available to physicians.
- Improving patient information so it is focused on health, not just medicines.

MEDICINES OUT OF CONTROL? could be ordered by:

Contacting Health Action International (Europe) at Jacob van Lennepkade 334-T, 1053 NJ Amsterdam, The Netherlands. Tel: (+31-20) 683 3684 / Fax: (+31-20) 685 5002 / E-mail: anita@haiweb.org and www.haiweb.org. The book price is Euro 27.50 plus shipping. Payments can be made in Euros using credit cards (MasterCard or VISA).

or

directly from the publishers, Aksant Academic Press (<http://www.iisg.nl/publications/aksant.html#aksant>) and its distributors, Transaction Publishers: <http://www.transactionpub.com/cgi-bin/transactionpublishers.storefront>

Good intentions with side-effects

Public-private partnerships have come to play an increasingly important role in development cooperation. Simultaneously, there is a lot of discussion about the concept of partnerships. Wemos contributes to this discussion through its new publication *Good intentions with side-effects*.

The booklet describes the result of a desk study at 79 international partnerships in the field of health, often including the United Nations. Wemos describes these partnerships and goes deeper into aspects such as sustainability, governance and responsibility.

***Good intentions with side-effects* can be ordered through the Wemos website: www.wemos.nl/english (publications/health and the private sector)**
