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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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Bubbling business: German drugs in Third World countries
 BUKO Pharma-Kampagne presents new study on German pharmaceuticals, sold
 in Africa, Asia and Latin America

The following is an extract from a brochure published by BUKO Pharma-Kampagne, Bielefeld providing comprehensive insight into the quality of German drugs in 46 countries of Africa, Asia and Latin America. The expert publication outlines the concept and the methodology of the study. It contains numerous tables and graphs as well as explanatory texts. The pharmaceuticals examined including their appraisals are listed according to the companies in the Annex.

German pharmaceutical companies are among the biggest providers of pharmaceuticals to the Third World and are proud of their reputation. A new drug study on German pharmaceuticals in 46 Third World countries by BUKO Pharma-Kampagne, a German health NGO, however dents this positive image. BUKO studied the sales of German pharmaceutical companies in the countries of the South for the fourth time. The conclusion of the new study: in 2003, over 39 per cent of the German preparations sold were irrational or even dangerous. Moreover, lack of adequate product information of German manufacturers shows evidence of negligence.

Pharmaceuticals offer no solution to a great many health problems in countries where the living conditions of large parts of the population are characterized by hunger, miserable housing conditions and unsafe drinking water. Nevertheless, do people all over the world have an equal access to effective medicines? The answer is simple. Pharmaceutical companies which sell unsafe drugs or medicines without therapeutic benefit seriously restrict people's right to health. BUKO Pharma-Kampagne evaluated more than 2,500 pharmaceuticals in these countries sold by German companies in 46 countries of Africa, Asia and Latin America. Thirty nine per cent, that means almost one thousand preparations continue to be marketed without any medical justification. These drugs must be considered irrational according to clinico-pharmacological criteria. BUKO's drug-study is based on a total of eleven drug compendia which were available in the 46 countries in 2003.

German pharmaceuticals put to the test

For the first time, the share of sales of rational and irrational drugs marketed by 33 German drug companies was assessed in 1984/85. Table 1 gives periodic assessments of the shares of rational and irrational drugs sold in 46 countries.

Table 1

Share	1984/85	1988	1991/92	1997/98	2003
Percentage of rational drugs	33	39	47	58	61
Percentage of irrational drugs	67	61	53	42	39

Table 2 shows the increase in share of sales of rational drugs expressed as a percentage of the share of sales in the preceding assessment period and decrease in share of sales of irrational drugs expressed as a percentage of the share of sales in the preceding assessment period.

Table 2

	1984/85	1988	1991/92	1997/1998	2003
Increase in the share of sales of rational drugs expressed as a percentage of sales of rational drugs in the preceding assessment period	-	18	20	25	05
Decrease in the share of sales of irrational drugs	-	09	13	17	07

expressed as a percentage of sales of irrational drugs in the preceding assessment period					
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This table shows a marked and steady improvement between 1984/85 and 1997/98 but the improvement between 1997/1998 and 2003 was lower compared to the previous period.

There are considerable differences between the 33 evaluated companies: Large suppliers like Aventis or E. Merck offer more than 400 pharmaceuticals each; some companies offer only single preparation each. The quality of the offer also differs: Three manufacturers market more than half of all pharmaceuticals which were assessed as irrational. With almost 200 irrational medicines, E.Merck ranks first, closely followed by Hoechst/Aventis and Boehringer Ingelheim. While every second preparation of Byk Gulden, Boehringer Ingelheim or E. Merck is irrational, it is every third of Aventis and only every eighth of Fresenius as shown in Table 3. Boehringer Ingelheim and Byk Gulden have made themselves particularly unpleasantly conspicuous by even increasing their share of irrational medicines

Table 3: The ten biggest German suppliers and their percentage of irrational drugs

German pharmaceutical supplier	Percentage of irrational drugs
Byk Gulden / Altana	58
Boehringer Ingelheim	57
E.Merck	48
Degussa / Asta Medica	45
Grünenthal	42
Hoechst/Aventis	30
Bayer	28
Hexal	28
Schering	27
Fresenius	13

A considerable amount of the irrational preparations are dangerous and quite a few are banned in Germany. The therapeutic benefit of many of these drugs is only insufficiently proven. People in the Third World suffer avoidable damage to their health owing to such pharmaceuticals. They frequently do not receive the best possible and safest treatment. Irrational medicines are not only detrimental to the individual patient only but to society as a whole. They waste scarce resources and undermine rational drug treatment. The consequences are particularly tragic in these countries since less than five US-dollars per capita is spent on medicines a year.

Missing drug information

Public health care systems in many poor countries present large deficits. Regulatory authorities to supervise the pharmaceutical market do not exist or are understaffed. In many countries, highly effective and prescription-only medicines are freely available and are even sold individually and without a package leaflet even by street dealers. Under such circumstances, pharmaceuticals - especially irrational preparations - are apt to produce disastrous consequences. Independent information on the risks involved in these pharmaceuticals is often not available to the doctors in the Third World. The fact that a pharmaceutical is banned or its use strictly restricted in the manufacturer's home country is usually not known in the countries of the South, where even the drug compendia often lack important details. Aventis, for example, kept offering its lipid-lowering drug Lesterol[®] (active substance probucol) in Brazil until May 2004 although the drug had been withdrawn from the market in Germany ever since 1998. Hoechst took the drug out of the US market "for commercial reasons" already in 1995 before the relevant FDA expert committee convened to assess the efficacy and safety of the lipid-lowering agent. The drug is considered obsolete and may, among other things, produce severe cardiac arrhythmia. The entry on Lesterol[®] in the 2003 index for Brazilian doctors

withholds such information. The two and a half lines long text mentions neither undesired effects nor contraindications.

Only few essential medicines from German manufacturers

Only 27 per cent of the German preparations were counted among the "essential medicines" according to the World Health Organization (WHO). This implies that only every fourth preparation can be classified as essential to meet the health needs in these countries. In certain therapeutic groups the study found hardly any or no useful medicines. The majority of vitamin preparations, for instance, are irrational combinations, which people spend a lot of money on, instead of buying healthy food. Seventy out of 80 vitamin preparations had to be assessed as irrational. All 19 liver preparations studied were irrational, as were all 11 slimming preparations. The picture for cough and cold preparations looks similar. In this area, German companies - without any justification - benefit from the good reputation which products from industrialised countries often have in the Third World. On the other hand German companies have only little to offer with regard to the major diseases in the 46 countries. Out of the 2500 pharmaceuticals marketed by German companies only 26 amoebicides, 11 antimalarial agents, two antiretrovirals and 11 anthelmintics or less than two per cent of the total were available in the South although these pharmaceuticals are urgently required in poor countries.

Huge differences between countries

Marked differences exist between the various countries and regions: Brazilians are, for instance, confronted with 333 different dubious German pharmaceuticals. Bearing in mind that approximately 300 essential medicines are sufficient to treat the majority of diseases and that German companies are not the only suppliers, the amount of irrational medicines becomes oppressive. Africans get off comparatively lightly with "only" 47 irrational medicines as shown in Table 4.

Table 4: Number of irrational drugs in certain countries and regions

Country/Region	Number of rational German drugs	Number of irrational German drugs
Brazil	510	333
Mexico	425	258
South Africa	437	153
Colombia	251	134
Central America	165	123
Pakistan	261	121
Middle East	138	90
Philippines	151	86
India	108	79
Thailand	167	70
Africa	130	47

Business without any ethics

Many business practices of German companies pose unnecessary risks to the lives and health of people in the Third World. As far as the common drug compendia, the indexes for doctors, are concerned, the manufacturers often provide partial or only meagre information on ingredients, risks and dosages of their preparations. This practice is compounded by irresponsible advertising campaigns opposing rational use of medicines. The frequently misleading antibiotic advertising in Third World countries serves as a particularly severe and grave example of this risk to health. In this context, over-prescription of antibiotics is to be considered critical not only under cost aspects but mainly because of the risk of resistance development. According to the WHO, more than 70 percent of all patients in Indonesia, Pakistan and India are treated with antibiotics although they are frequently not indicated.

At present, Bayer is promoting its expensive pharmaceutical Avelox[®] among African doctors using the highly dubious slogan "Don't waste time when treating adult RTI's [respiratory tract infections]. Avelox[®] wipes out RTI bugs in no time. Avelox[®] works rapidly when every day counts" (Fig 1). However, the active substance, moxifloxacin, is regarded as a reserve antibiotic rather than a drug of first choice for respiratory tract infections, where standard and much cheaper antibiotics are just as effective. With such irresponsible advertising practices, Bayer not only forces up the cost of treatment but also considerably makes drugs like moxifloxacin being massively prescribed without necessity thereby becoming worthless as reserve antibiotics due to over prescription.

This is an example of irresponsible antibiotic advertising from Africa.

Figure 1



Don't think twice - prescribe a reserve antibiotic at once. (MIMS Africa 4/2004)

Another scandal is the massive public advertising for dipyron-containing preparations which have been going on for decades in the countries of Latin America. Boehringer Ingelheim markets, for instance in Brazil, the dipyron drug Anador[®] for use in adults and children (Fig 2).

Figure 2



"Ping Ping against pain - No Ping Ping in your purse," states Boehringer Ingelheim in Brazil". Current advertising for the high-risk painkiller Anador[®].

Dipyrone-containing painkillers may trigger the life-threatening blood disorder agranulocytosis (a loss of white blood cells which protect against infection) and shock. Since pharmaceuticals are often sold without prescription and adequate warnings in the Third World,

patients are prone much more to potential risks. What is more, the treatment options in case of undesired effects are significantly worse. There is often no chance to save a patient's life through intensive treatment.

Unhealthy double standards

Grave double standards are nothing unusual in the global marketing of pharmaceuticals: While Buscopan compositum[®] of Boehringer Ingelheim, for example, continues to contain dipyrone in Brazil, Mexico, Pakistan, South Africa and Central America, the company has long since replaced this active substance by paracetamol in Buscopan compositum[®] in industrialized countries. In Brazil, the much riskier, dipyrone-containing variant ranks among the five best-selling pharmaceuticals. Aspirin should not be used to treat feverish illnesses in children and youngsters without doctor's advice. Because of the risk of Reye's syndrome, experts warn against giving Aspirin[®] to children below the age of 12. Such restrictions do not bother the Bayer company. In Brazil, it specifically promotes its Aspirina Infantil[®] (Aspirin[®] for children) with the slogan: "*Live each moment. Without pain*".

Such examples from the everyday marketing routine of the German pharmaceutical industry illustrate ever so clearly what is behind the figures, data and graphs in the brochure published by Buko Pharma Kampagne. They should be a cause for alarm for doctors, pharmacists and workers in healthcare areas in rich countries as well. For irrational drugs are not only a problem of the so called Third World. German companies offer every fourth of their dubious preparations in Germany as well. Problems, that remain unsolved in the European countries, directly affect people's health in the South. When we talk about pharmaceuticals, we particularly talk about ethics too, because pharmaceuticals are highly sensitive goods which may directly protect or harm people's lives and health. The German pharmaceutical industry must be bound to withdraw its irrational products without delay - not only in the South, but in the north as well.

Methodology and the System of Evaluation

The drugs under study had to undergo two separate assessment procedures in order to answer the questions: Do the products meet the WHO criteria for essential drugs? Do the medicines comply with the clinical-pharmacological standards for rational drugs according to the latest international scientific discussion?

Essential medicines:

For more than 25 years the WHO Model List of Essential Medicines¹ has proven to be an invaluable tool for saving lives and improving health care by promoting a more rational use of drugs, wider access to drugs, containing costs and improved drug quality. The first WHO Model List published in 1977 showed that 95 per cent of treatable diseases can be treated with about 250 medicines. The WHO Model List of 2002 used in this study contains about three hundred active substances in 450 dosage forms. The drugs are listed by their international non-proprietary names (INN). The drugs of the Model List are selected by specific criteria such as efficacy, safety, quality, stability, availability and price in order to ensure good basic health care for the majority of people under varying medical conditions and settings. Essential drugs should be the drugs of first choice, not only in cases of limited financial resources but in all health systems. All drugs included in our study were checked to see if they were included in the WHO's 2002 Model List of Essential Medicines. Some drugs on the WHO list represent only one example for a therapeutic group. In this case other substances with comparable actions and properties meeting the criteria set by WHO had to be classified as essential medicines. Therefore, one will not find every drug listed in the study as an essential drug explicitly mentioned on the WHO Model List. Not every drug classified as "non-essential" is a bad drug. "Non-essential" drugs can be rational but they are not first-choice drugs according to WHO criteria. If a drug is classified as non-essential, nothing is said about its efficacy, safety or general usefulness. This information had to be decided with the help of the clinical-pharmacological criteria used in our second assessment procedure.

Rational drugs:

This second classification partly overlaps with the first one. While the first assessment leads to the simple answers whether the drugs are essential or not, the second assessment procedure is more elaborate. The drugs were classified according to the criteria of a rational pharmacotherapy which is based on scientific evidence. Pharmaceuticals corresponding to these principles are supposed to be rational, that is, tested for efficacy and safety as far as present science permits, produced under good manufacturing practices and marketed. The use of medicines which do not meet these criteria is pharmacologically and clinically irrational.

Pharmaceuticals are rational:

* If their efficacy is clinically proven, and if their therapeutic benefit outweighs the risks. In this study rational pharmaceuticals are classified as positive.

Pharmaceuticals are irrational:

* If there is no good clinical-pharmacological evidence of their therapeutic benefit and safety. From a public health point of view, the use of irrational drugs is not acceptable and has to be rejected. This is not only true for Third World countries, but for every pharmaceutical market. In this study, irrational pharmaceuticals are classified as negative. In this study we applied the criteria of rational pharmacotherapy, based on clinical evidence. This is the same theoretical framework which the companies studied claim to follow. All medicines were checked with clinical-pharmacological criteria to determine if they are useful for a rational therapy.

For the assessment process we used a system of evaluation which divides the examined drugs into two main groups and several sub-groups. The two main groups separate positive medicines from negative ones. Three sub-sections of rational drugs and eight sub-sections of irrational drugs document the essential reasons why the drug was assigned to one or the other main groups.

We tried to establish clear evidence for each judgement, using renowned scientific literature that gives reliable, evaluated information on substances and drugs on the international market and reflects the latest state of international scientific discussion. We are aware that an assessment is always influenced both by objective facts and subjective values. Nevertheless, the clearly defined assessment criteria provide good evidence on the quality of the drugs under study.

The process of classification and the ratings into positive and negative pharmaceuticals were carried out by asking whether all the active ingredients are effective, whether the combination makes sense, whether they were sufficiently tested, as effective as other drugs for the same therapeutic use, the dosage and form were appropriate. The criteria for classification were checked in consecutive order. As soon as one criterion applied to a drug led to the assessment negative, the drug was classified into the corresponding sub-group and not checked for subsequent criteria. All rational pharmaceuticals were qualified as positive, all irrational ones as negative. This procedure ensures a consistent process of evaluation and can be easily applied to any medicine.

To order the original brochure in German please refer information below:

Jenkes, Schaaber, Velbinger: Sprudelnde Geschäfte: Deutsche Medikamente in der 3. Welt.

Editor: BUKO Pharma-Kampagne, Bielefeld 2004, 20 pages

ISBN 3-928879-23-5

Price: EUR 5 plus postage

This brochure (in German only) **is an easy-to-read introduction to the problem also outlining the basic prerequisites of health care systems in poorer countries. Numerous photographs, colour illustrations and many examples guarantee an exciting read.**

Jenkes, Schaaber, Velbinger, Zettler: Data and facts 2004: German drugs in the Third World.

Editor: BUKO Pharma-Kampagne, Bielefeld 2004, 56 pages, English language

ISBN 3-928879-25-1

Price: EUR 10 plus postage

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- Network News -

EUROPE

Solution or Disillusion: Can we make Global Public Private Partnerships work for health?

'Solution or Disillusion: Can we make Global Public Private Partnerships work for health?' was the title of the seminar organized by Wemos in November 2004 at Café Dudok, The Hague, Netherlands.

In the introduction delivered by Jose Utrera, Project Leader of Wemos it was noted that Global Public Private Partnerships (GPPPs) bring along collaboration between public bodies such as governments, the United Nations, and private bodies such as industry (mainly the pharmaceutical industry).

The industry is becoming more and more involved in GPPPs. Currently 80 to 90 GPPPs exist worldwide. This trend did not remain unnoticed. There has been discussion about:

- a. The consequences for the World Health Organization by participating in these partnerships: its impact on credibility, reliability etc.
- b. Conflicts of interest that may lead to problems
- c. The fact that GPPPs generally are too much supply-driven; just giving medicines/drugs seem to be the main input from industry

Wemos decided that it is important to look at the effects of the GPPPs on the health situation of the receiving countries. Therefore, Wemos and partner organizations initiated several case studies in 2004 to obtain information and build knowledge on:

- 1) How often the GPPPs are implemented locally?
- 2) Are they a good instrument to help governments fulfill the Right to Health? Are they also improving the basic determinants to health including: poverty reduction, water and sanitation, education etc.?
- 3) What is the effect on the local health system?
- 4) Are they really effective in improving health in developing countries?

Speaking about Roll Back Malaria in Tanzania - does it work for the poor? Ms. Mwajuma S. Masaiganah, from the People's Health Movement (PHM), East Africa stated that Roll Back Malaria should be incorporated into the Health Sector Reform that is going on in the country. Roll Back Malaria has so far encountered some problems in Tanzania. These include:

- Health care is more and more in the hands of the private sector
- There is insufficient feedback to policy makers
- Understaffing of health care institutions
- Insufficient quality of care/cure (is also related to shortage of staff and education)
- Malaria prevalence is still increasing
- Basic awareness (and knowledge) of the population on malaria is declining
- Medicines are usually available but expensive

Priorities of the poor usually do not include spending money on mosquito nets. Often people can't afford to buy the proper dosage of malaria medication therefore they often purchase half a course of treatment. This is not sufficient to treat the disease and it will eventually lead to resistance to the drugs, which is a serious problem. The training of health workers and

pharmacists is not always adequate. This causes problems with drug provision (e.g. the provision of half a course of treatment).

The role of the Tanzanian government in shaping the health system is diminishing - their control function is problematic. Incorporating the work of a GPPP into the national health system is still difficult. For example, some drugs are still unaffordable for the poor. The provision of drugs in regional hospitals is not yet properly linked to the provision of drugs through the GPPP operating in the country since GPPP is a vertical programme not integrated with the normal health system.

More than just medicine and netting are required to combat malaria. Socio-cultural aspects should be taken into account in the battle against malaria. Also environmental sanitation and educational activities are necessary. The community should definitely be involved. Therefore, Ms. Mwajuma Masaiganah recommended not to tackle a single health problem in a vertical fashion but place it in its context and embed it in the public health system. Integration is essential.

Daisy Dharmaraj, from PREPARE and Test Foundation, India talking on Lymphatic Filariasis in India stated "The strategy to fight Lymphatic Filariasis should be mass drug administration, vector control and morbidity management, in combination with poverty reduction. But within the Global Alliance to eliminate Lymphatic Filariasis (GAELF), according to me, the wrong drug is used-Albendazole. GAELF introduced Albendazole in combination with diethylcarbamazine (DEC), whereas we used to have a successful program that only used the locally produced DEC. Albendazole is given free by GlaxoSmithKline but has many negative side-effects".

"Vector control was not carried out within GAELF. Furthermore the volunteers used for the distribution of the drugs received insufficient training. This has led to problematic situations - for example drugs were given to one person in the family and not to all. Also the doses to be given were unclear to the health personnel and the compliance rate was low".

"Considering the fact that there was already a program in place which used the locally produced DEC, why was GAELF introduced? India wants to eliminate Lymphatic Filariasis and accepted GAELF. When India had already agreed to start GAELF, suddenly the introduction of Albendazole appeared to be part of GAELF. Fortunately, India accepted the programme on the condition that clinical trials had to be started in order to assess the actual need to add Albendazole. This trial is going on right now".

"There are some critical aspects. Albendazole is given free. But what will happen if the contracts end? Also, the pharmaceutical industry decides primarily how their money should be used. And still there remain operational costs for India, such as costs related to distribution. Furthermore, since the generic version of Albendazole is manufactured in India, GAELF is wiping out the local production of this drug".

"We at Test Foundation think that the primary health care system as a whole should be supported and strengthened simultaneously. This should be an integral part of a programme such as GAELF. And instead of providing medicines only, one should look at structural aspects related to the prevalence of the disease, such as improving water supply. Otherwise there will be no long term effects of these GPPPs. India has the knowledge to eliminate Lymphatic Filariasis itself, and the industry to produce the necessary drugs. What we need is health education and better water supply. Plus, vector control is needed, as mosquitoes spread many diseases. These aspects should be taken care of; we should not focus on this kind of specific program against one disease only. We do not need foreign pharmaceutical industry for this! The industry should encourage the production of generics and contribute to poverty reduction programmes."

Speaking on WHO and Partnerships, Dr. Descarpentris from WHO Department 'Government, Civil Society and Private Sector Relations' stated that different definitions of PPPs (public private partnerships) are being used. The definition of PPPs is not universal, but comes down to: PPPs are collaborations with a voluntary agreement signed by all partners, whereby all agree to work together to attain a common goal. Every partner in a PPP should have the same goal and share the same risks. The characteristic is that the public and private sectors are working together, on a global scale, to reach a common goal.

The phenomenon of GPPPs started around 1970. In the end of the 1990s GPPPs explosively increased. Between 1999 and 2003, 56 new GPPPs were formed. Currently, the WHO plays a role in 72 of these partnerships. For the United Nations, GPPPs are a development wanted by Kofi Annan and by the former Director General of the WHO, Dr. Brundtland, as well as the current Director-General Dr. Lee.

There are several reasons for WHO to participate in GPPPs:

- 1.. 75 percent of the money in health (worldwide) comes already from the private sector.
2. Funding from WHO comes from Member States. The WHO was urged to adapt and to find private partners. The level of funding from Member States has remained the same over the past year, so WHO is in need of finding additional funding. GPPPs can help to achieve a better dynamism and push from the private sector in the changing and globalizing world.
3. New and additional funds are needed for WHO to extend its work.
4. To promote sustainable development, private sector involvement is needed and not only public sector involvement. All sectors are needed to achieve this - synergy is required. It is also a pragmatic decision of WHO to be involved in partnerships: expertise is needed for WHO to continue its work, and moreover, dynamism is available in the private sector.

The impact of GPPPs on public health is not yet clear, since there is no sufficient research available yet, especially at the level of the population/beneficiaries. Evaluations are ongoing. It is especially interesting to assess the implications of their functioning in relation to the objectives they have set.

What do GPPPs bring? What are their advantages?

- Neglected diseases have been put higher on the agenda and treatment is made possible
- The programmes have a potential to lobby strongly to combat the diseases
- The introduction of flexibility and innovation in the public health systems. GPPPs have a certain flexibility which is not always possible in the public sector alone
- It will encourage the collaboration between different kinds of people

But also, the risks are very real and should be considered carefully:

- 1- Disorganization of the public health mechanism/system. The mandate of WHO moves to the sidelines, while the management is taking place at local level. The political priority can change and can be abused. Decisions now take place outside of WHO. The legal institutions are sometimes marginalized which also bring along the risk of disorganization and destabilization of the existing health system.
- 2- Proliferation of GPPPs drives the responsibility now more and more towards private entities. The public sector has lost or remains with less possibilities to control. This brings along a process of less responsibility and accountability mechanisms change. New mechanisms are developing but not yet well defined. The responsibility of politics is also changing. The power of the public sector might decrease which could easily lead to disengagement.

The WHO sees two essential points for the future:

* public power should remain included in GPPPs and it should profit from this collaboration; the public health sector should not be excluded. An official mandate for the public sector is important and should be clearly defined.

* In line with the above-mentioned issues, GPPPs should be organised very well and be carefully set up. Governance should be very strictly defined. What we need is synergy and not all actors need the same responsibility; each one can have a different responsibility and task.

Francis Weyzig of SOMO, a Dutch foundation devoted to research on multinational companies speaking on the role of pharmaceutical companies in partnerships stated that they have expressed that they wish to make a contribution to health in developing countries because of their commitment to public health. A less ethical motivation could be business interests, lobbying or promotion of their own drugs.

Pharmaceutical companies are involved in partnerships in different ways:

- Provide drugs free or make them more affordable
- Play a role in lobbying - focus on a certain disease and bring in resources
- Technical expertise
- Research and development for diseases related to poverty

They play a very different role in each GPPP. For TB, they play almost no role. In GAELF, they donate drugs. In Roll Back Malaria, they have a representative in the board. Also in Roll Back Malaria they have a very large business interest to distribute new drugs and/or bed nets.

Different industries in the private sector have distinct interests. Involving industry in decision making is sometimes tricky. The board of a GPPP, which may or may not include a representative from the industry, generally decides where the money goes, which countries are benefiting from donations, etc. One can say that conflicts of interest may occur when profit-making companies participate in a GPPP. In Roll Back Malaria, pharmaceutical companies promote their own drugs. In GAELF, industry gives only free donations of drugs and is not selling the drugs. But they have a different motive: Albendazole for example, is being sold in certain regions in India in a different package and with a different prescription (de-worming) as the Albendazole being donated free within GAELF. But it is in fact the same drug. The drug donated free is only for specific use to treat Lymphatic Filariasis. The local manufacturer of Albendazole could be pushed out of the market as a result of the donations of this drug by GlaxoSmithKline (GSK). GSK would then obtain a monopoly position when it comes to the sale of this de-worming drug.

What are the positive consequences of the involvement of pharmaceutical companies in GPPPs?

- technical expertise
- availability of increased financial resources
- lobbying power for prioritizing a certain disease and public awareness

But there are also critical issues:

- A partnership might be created for the sake of creating a partnership; thereby making it a goal in itself and not a means to an end, namely health for all
- Pharmaceutical companies might be involved in partnerships for better access to health care for people in developing countries, but at the same time they support the lobby for stronger patent rules. This shows that they use GPPPs especially to look good to achieve their private interests.

Debating on the subject of "Can GPPPs only make a sustainable contribution to access to drugs if they invest in the local production of drugs in poor countries," Ms. Spring Gombe of Health Action International Europe said the emphasis is on the role of private companies. We also have to look at the role played by governments and at the power relationship between the two. We should be cautious when allowing too much power to the private sector. Responsibilities of all actors are important. Transferring technology is also part of it, by way of opening a factory for example or investing in capacity to set up good laboratories. As signatories to several international treaties all states have the responsibility to guarantee the Right to Health and thus transfer technology.

Mr Martin van der Graaff of Nefarma in his comments added that he supported the concept of the transfer of technology, but not the means. "We should not build the roof of the house before the foundation is completed. What is needed now is an adequate infrastructure before you can think about locally producing drugs. Industry has helped to reduce barriers and not created them. Industry wants to do their bit, for instance by donating drugs free or at low prices. In the end producing locally would probably be a good idea but we should first invest in the foundation of the 'house'. Further into the development of this path, we can start with the transfer of knowledge. This is where industry can contribute" he concluded.

Ms. Mwajuma Masaiganah explained that drugs should be produced in the South. We have well trained human resources for health but they move to the North. That must stop! Artisanate should be produced in the South instead of in the North! We need it here, and production in the South is cheaper. In response to this Martin van der Graaf stated that human resources migrate to the North as a result of the wealth differences. It is not a problem that can just be put on the doorstep of the pharmaceutical industry. At present we are working on a sustainable solution by supporting the build up of clinical trial capacity in the South.

Saskia Bakker from Humanist Committee on Human Rights (HOM) added that local production may take away the focus from the long term solution which should be directed towards making drugs available for everybody at reasonable prices. Local production is not always the best solution to achieve this in the long run. Organon's Mr. Jan Peter van Suchtelen debated that the economy of scale is also important. It might be more efficient to produce drugs in a few places in the world. It is not realistic to set up factories everywhere in the world.

Adding to this Spring Gombe questioned whether the interests of the countries can be met? Production is moving to China, India, etc - but the skill resides here! The interest of the different actors is not the same. Marjan Stoffers of Wemos stated that the scope of local production with the ultimate goal of access to drugs for all should be broadened.

If GPPPs are to support the achievement of the Millennium Development Goals (MDGs) they have to invest in health systems. How then are we going to achieve this? Responding to this Rob de Vos, Deputy Director General, International Cooperation of the Dutch Ministry of Foreign Affairs (DGIS) stated that they aim for the MDGs to be achieved by 2015. Investment in health systems is important but we need to broaden our perspective and look at economical, social and cultural factors. We have to take gender perspectives into consideration and look at agriculture as well. In the past one size fitted all but that is no longer true. Governments should become more accountable to the people. Furthermore a multi-actor approach is needed. We have to work together! Bridges between macro, meso and micro levels are required. Local leadership is a very important issue in order to reach the MDGs.

Dr. Daisy Darmaraj from India described the faith of an Indian woman with HIV/AIDS who died while giving birth to a child; an everyday reality in India. What is needed is investment in women's education, the health system and access and affordability of services and drugs. Privatization in India is increasing but it is not helping in overcoming the problems mentioned above. Health system improvement is extremely important. GPPPs need to be integrated in general, horizontal programmes instead of vertical ones.

Rob de Vos commenting once again stated that for a more integrated response it is required that 15 per cent of government's budget is spent on health. The dynamics of the PPPs should be used to attract global funds a multi-actor approach is needed. Not always direct investment but via the local systems - concerted actions are needed.

Rosien Herweijer of PSO, a Dutch foundation working on capacity building of civil society organizations in developing countries stated that capacity building is needed; donations skew the system! We need to invest in people, the workers and the leaders. We have to convince Bill and Melinda Gates that sending volunteers is not the best way.

Can we make GPPPs work for health? - What is the role of the WHO in making GPPPs work for health? Mr. Descarpentris answered that for the moment there is no clear position of WHO. Several problems have been identified, stumbling blocks that need to be improved. For the future I see that a clear-cut constitution should be set up; clear rules have to be formulated for the governance of the GPPPs. Important is that everybody finds their place and their own interests with the GPPPs.

Reacting to what is the role of the international NGOs? Ms. Spring Gombe from HAI stated that we should be very critical as NGOs. For example in October there was a global conference on Health Systems Research and what did we see? Not one single country sent its health, Finance or Trade Ministers!

Speaking on the role of the industry Martin van der Graaff of Nefarma outlined three points to draw lessons from what works and what doesn't, we need to continue to develop drugs - that is what we are good at and conduct research; enhance the potential for improved drugs.

What is the role of donors? Rob de Vos responding to this stated that we can be a broker. WHO is a key player; we can ask WHO to take up its role. Encourage NGOs to be critical. Require governments to be open and accountable. But, control of the industry is not possible. That is not our duty! But what can be the role of Southern NGOs? He said that we needed to negotiate for equal power relations, a sustainable framework, transparency, accountability, evaluation of programs and very importantly the participation of our people.

Source: Wemos, Netherlands

ASIA PACIFIC

Sub Regional Workshop on Pharmaceutical for Indo China

Approximately fifty local and foreign (Bangladesh, Cambodia, Indonesia, Laos PDR, Myanmar, Sri Lanka and Vietnam) participants representing Ministries of Health, Non Governmental Organizations and Universities gathered at the Twin Towers Hotel in Bangkok to formulate strategies and action plans to improve and strengthen pharmaceutical supply systems thereby making safe and effective medicines of good quality available regularly at affordable prices to all those who need them. Health Action International Asia Pacific (HAI AP) jointly with Social Pharmacy Research Unit (SPR), Faculty of Pharmaceutical Sciences Chulalongkorn University and Drug Study Group, Thailand organized the workshop from 23-25 October 2004; DGIS and SIDA provided financial support. Issues that were presented at the workshop included promoting concepts of Essential Drugs and Rational Drug Use, Drug Registration and Quality Assurance, National Drug Policies, International Experiences, Free Trade Agreements and their impact on pharmaceuticals and health, Communication & Information, Ethical Drug Promotion, Interaction between NGOs' health workers and Health Ministries – Experience of Thai NGOs and Country Papers of Cambodia, Laos PDR, Myanmar and Vietnam were also presented.

The plenary sessions were followed by panel discussions; panellists and participants presented ideas and action plans for sub-regional co-operation and identified issues that could be taken up during small working group discussions.

The participants were divided into three groups of about fifteen each. Guidelines were given to each working group to facilitate them to discuss in depth the following issues: explore possibilities of setting up national groups on pharmaceuticals in the four countries Cambodia, Laos, Myanmar and Vietnam; assistance required from organizers to set up national groups and prepare plans of action; the strengths and weaknesses of access to medicines in each of the four countries; what to expect from sub-regional co-operation, membership in WTO and finally whether it would be useful to have a mechanism to share information on relevant aspects of pharmaceuticals.

Presentations of the working groups to the plenary included the following: all groups agreed that setting up of national groups on health and pharmaceuticals in Cambodia, Laos PDR, Myanmar and Vietnam was possible some noting that special initiative should be taken by the NGOs participating at this workshop to assist setting up these. They also required the assistance of the organizers in terms of technical support, advisory, consultancy services and seed grants to set up the above groups.

Strengths and weaknesses

1. (a) Cambodia - strengths

Public sector } *Essential Drug List *central medical management *standard management tools
*low price pharmaceutical products
*introducing regulations to manage private sector

(b) weaknesses } *late procurement system *availability of unregistered drugs *quality and price control at the drug outlet

2. (a) Laos PDR – strengths } *decentralized drug procurement *Essential Drug List *Drug revolving fund *free healthcare services *an effective healthcare control system *an accessible “medicine box”

(b) Laos PDR – weaknesses } * mismanagement of the drug store *black market drugs *self-medication *poor procurement system and drug management *quality of drugs *counterfeit drugs

3. (a) Vietnam – strengths } *government paying for healthcare of the poor *fixed price of drug in every drug store *having a pharmacist in every drug store *drug stores regulated by the government

(b) Vietnam – weaknesses } *Self medication without prescription *the coverage of health card *unhealthy drug marketing and competition *weak registration system *high prices *quality control at the drug outlet *doctors prescribing high cost drugs instead of generics

4. (a) Myanmar – strengths } *registration of drugs *free healthcare services *a good healthcare control system *improve accessibility to a medicine box

(b) Myanmar – weaknesses } *self medication without prescription *partial decentralized drug procurement system *black market drugs * mismanagement of drug store

The working group sessions also enabled the participants to discuss and analyze expectations from sub regional co-operation. They outlined the setting up of an inter country network to share information on post marketing surveillance, quality drugs, drug price control system, situation and control of promotional practice and advertisement, quality of raw material, treatment guidelines, drug suppliers, manufacturer, GMP; price and supply monitoring network, regular meeting of the network; strengthen collaboration with other countries for access to essential drugs, share experiences with other local and international NGOs and training on rational prescribing practices.

Strategies for cooperation in strengthening access to medicines included:

- extending the implementation of patent protection to 2016 by convincing the governments of Least Developed countries
- giving information to all stakeholders on access to drugs
- sharing information between government and NGOs

- strengthening women's associations by health professional associations
- looking for new resources to run the project
- internet conferencing between the countries
- public sector to provide information to consumers i.e. side effects of medicines
- encourage people to consult health professionals and avoid self medication and promote concepts of rational use of medicine to doctors and consumers
- essential drug use, availability of essential drugs, regulation on advertising warning them on side effects, available generics, educating consumers through health workers on the adverse effects.

Conclusions and Recommendations:

- collection of morbidity data
- selection of essential drugs according to the respective level of healthcare facilities
- quantification of drug requirements; procurement, storage and distribution of drugs
- essential drugs concept introduced starting from medical curricula to consumer medical education, promotion of essential drugs concept to the community by NGOs through media,
- upgrading traditional medicines
- formulation, development and implementation of health insurance system
- introducing rational prescribing practice starting from medical curricula, training of health personnel, publication of standard treatment guidelines to all levels of health
- workshops and programmes concerning rational prescribing practice
- The audience added a few points the working groups had missed such as doing away with poly pharmacy and concentrating on treatment with one drug, going into access to medicines at a national level, working closely with the two regional offices of the WHO etc
- As concluding words one cited Mahatma Gandhi's words of wisdom when he said before you implement or write a new policy see what it would do to the poorest of the poor.

For presentations and more information on the workshop please write to hai@haiap.org or passanna@haiap.org

Strengthening the pharmaceutical situation in the Pacific Island Countries

In November 2004, the WHO Western Pacific Regional Office (WPRO) organized a meeting on the Pharmaceuticals Sector in 21 Pacific Island Countries (PICs) in Nadi, Fiji. During the first two days the group discussed Human Resources Development (HRD) and during the following three days, they discussed "Implementation of the new European Community - WHO Partnership on Pharmaceutical Policies and the Regional Strategy for Improving Access to Essential Medicines".

Human resources

At a similar WHO/WPRO meeting in 2003 participants expressed the need for more trained staff. The problems associated with maintaining an adequate workforce were associated with a shortage of appropriately trained pharmacists and locally trained technicians or assistants. In some cases trained pharmacists from other countries were recruited for varying periods. This practice was not ideal because Pharmacy courses in countries like Australia, New Zealand and other 'developed' countries did not cover the concepts and skills needed in the Pacific Island countries.

The objectives of the HRD meeting during the first two days were:

- to review current pharmaceutical workforce in Pacific Island Countries, to estimate the optimum need for pharmaceutical workforce in Pacific Island Countries training needs and to review pre- and post service training needs
- to review curricula in the current pharmacy programmes at Fiji School of Medicine (FSM) and University of Papua New Guinea (UNPNG) and to identify and compare other existing post-graduate training schemes (internship programmes)

- to identify and compare existing local training and training material for pharmacy assistants and technicians, and see what commonality exists.

Based on the above objectives, short- and long-term plans were made for human resource development covering the following:

- Curriculum development/harmonization
- Common training for pharmacy technicians/assistants
- Distance learning
- Needs for in-service training

The group considered that, as a basis for the practice of pharmacy at different levels of care in the health service system, it is important that PIC governments review, create or update legislation and regulations to cover all aspects and levels of the practice of pharmacy.

The working groups agreed that it was important to look at consistency among the PIC pharmacy technician curricula. A combination of on-the-job training in the national setting with distance supervision and additional training from the Fiji School of Medicine Pharmacy Training program was considered worth pursuing. It was accepted that specific management training for pharmaceutical services and medicines supplies is essential as part of all levels of any pharmacy training.

In addition, recognizing that nurses perform various pharmaceutical roles, particularly in remote health care facilities, it was considered appropriate that introduction of a short medicine supply management and rational drug use course for practising nurses, as well as inclusion of subjects in nursing curricula, should be explored. The curricula of the courses available at the University of PNG and the Fiji School of Medicine were shared. The representatives from both institutions were pleased to know that their programs were considered appropriate and stressed the importance of maintaining enrolments so the courses could be continued. The value of input from the HRD working group was recognised.

The group recommended that each individual country pursue estimation of their pharmacy work force needs using appropriate methodologies; a population based, patient based, service based and a function based table was devised to facilitate the estimation.

The EC WHO Partnership on Pharmaceutical Policies and the Implementation of the Regional Strategy for Improving Access to Essential Medicines

Following the HRD Working group meeting delegates from the 21 PICs met for 3 days to discuss the general pharmaceutical situation in their countries. The scene was set with presentations explaining the role of the EC WHO Partnership on Pharmaceutical Policies and the Implementation of the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region of the World Health Organization: Dr Daisy Carandang, Geneva; Mr Truls Eriksen, Suva and Dr. Budiono Santoso, Manila made the presentations.

Each PIC delegate presented a summary of their national situation to the group. Technical assistance needs were identified across National Medicines Policies development, implementation and monitoring; intellectual property and trade-related issues; affordability and financing; drug supply management; effective drug regulation; and rational use of medicines. In many cases interventions were already taking place or would be undertaken during the next year with the technical assistance of WHO or other sources.

Small group discussions provided opportunities to consolidate recommendations for future plans and by the end of the meeting the delegates recorded achievements to date, prepared action plans for the future and identified priority areas and the need for technical assistance from EC WHO partnership funds or from other sources. Priority needs that were common to most PICs were the need for major training in all aspects of drug quantification and procurement including analysis of disease patterns, record keeping, communications between all levels of the health services, as well as warehouse maintenance and stock control and all

aspects of procurement from international sources. Strategies to assist monitoring of suppliers' performance were sought.

Development or refinement of registration procedures was also an expressed priority. Issues included the possible restriction of Registration to products that have been registered in countries with well-developed regulatory systems and how to evaluate certificates and other documents submitted with applications for registration, Sharing of intelligence might be helpful. How can that be facilitated? Plans were made for continued communication between the PICs to encourage cooperation to strengthen the pharmaceutical situation across the region.

Source: Reported by Beverley Snell, Centre for International Health, Macfarlane Burnet Institute for Medical Research and Public Health, HAIAP member

Rational drug use - A growing concept in Western Nepal

In November 2003, a Drug Information Center (DIC) was started at Manipal Teaching Hospital, a multi speciality teaching hospital located in the Pokhara, the western region of Nepal. The main objective of the center was to promote the practice of evidence based medicine. At the outset the center focused only on providing drug information but later extended its services to medication counselling and pharmacovigilance related activities. This center was the only one of its kind in Western Nepal.

Drug Information Center - A tool for appropriate drug use

The queries are placed at the center either through telephone or through drug information request forms that are available in all the wards and out patient departments. One can also directly visit the center for their advice. These queries are mainly related to drug dose, indication, adverse drug reactions, dosage adjustment in renal failure etc. In a few instances, the patients themselves visit the center to get their queries answered and doubts cleared. Up to October 2004, the center has received more that 300 queries from various healthcare professionals as well as from patients.

In addition, the center has been publishing drug information bulletins quarterly for health care providers. The bulletins are circulated to all the doctors of Manipal Teaching Hospital, medical colleges throughout the country, drug regulatory authority of Nepal and to a few other educational and health care institutions abroad. So far the center has published 4 issues of the bulletin.

Medication counselling – A step ahead to ensure patient compliance

In February 2004, a Medication Counselling Center (MCC) was inaugurated at the Manipal teaching Hospital, with the objective of educating and counselling out patients regarding safe and effective use of drugs. The center has been opened as a unit of the DIC. The main focus of the center was to provide counselling to specialized patient population such as illiterate patients, patients with specialized dosage forms (inhalers, rotahalers, spacers, suppositories, pessaries, insulin injections, insulin pens etc), Patients with drugs of narrow therapeutic index (lithium, digoxin, carbamazepine, valproate etc), Patients on drugs which require special precautions (oral contraceptives, low dose methotrexate, corticosteroids etc), patients on drugs known to cause side effects frequently (Antibiotics), pediatric patients, psychiatric patients, non intentional non-compliers and the patients more prone to OTC drugs. While counselling the pharmacists stress on the following aspects of drug use: name and description of the medication, the dosage form, the dosage, routes of administration, duration of therapy, special direction, common side effects and methods to prevent, detect and manage them, techniques of self monitoring of drug therapy, storage, prescription refill information, action to be taken in case of missed dose etc. Since its inception, the center has counselled more than 500 patients.

Drugs and Therapeutics Committee (DTC) - an approach towards rational use of drugs in the hospital

The Drugs and Therapeutics Committee (DTC) was reorganized in the hospital in May 2004. The main objective of the committee was to ensure rational drug use in the hospital. The committee is headed by a Chairman (Professor of Medicine department) and a member Secretary (Chief, Pharmaceutical Services). The committee consists of members from all the clinical specialties of the hospital. The committee meets once in every two months. The agenda for the discussion is prepared by the member secretary and are circulated to the members well in advance. The committee decides on the inclusion and exclusion of drugs in the hospital. A total of only three brands of a particular drug will be approved by the committee for use in hospital. The committee decides on inclusion and exclusion as per the following criteria: Safety, efficacy, availability, suitability and cost.

Pharmacovigilance- A specific mechanism to ensure consumer safety

The DIC has started pharmacovigilance activity from September 2004 to ensure consumer safety as far as drug users are concerned. The center has started a spontaneous reporting program. The Adverse Drug Reactions (ADRs) reporting forms are placed in all the wards and outpatient departments of Manipal Teaching Hospital. All healthcare workers are requested to fill the ADR reporting forms whenever they detect ADRs and send them to the Pharmacovigilance cell of the hospital. Upon receiving the reporting forms, the pharmacovigilance cell personnel provide drug and related information to the concerned clinician or other healthcare professional regarding the management of the same. The spontaneous reporting program is expected to be expanded to a fully fledged pharmacovigilance program by January 2005. Up to October 2004, the center has reviewed and documented 15 adverse drug reactions.

The DIC has also organized lectures on drug regulatory situation and rational use of drugs in Nepal for consultants, medical officers, nurses, pharmacists and interns of Manipal Teaching Hospital and interviews over the electronic media on proper use of drugs, its storage and general precautions to be taken before administering the drugs.

Source: Reported by Dr Pranay Mishra of the Department of Pharmacology, Manipal College of Medical Sciences, Pokhara, Nepal

A study of pain killers (analgesics and antipyretics and nsoids) listed in a commercial publication for doctor's use

Why this study?

Pain is perhaps the most common symptom for which patients seek guidance and help from doctors. Pain killers are a group of drugs that are extensively used both by general practitioners and consultants.

Drug Action Forum – Karnataka (an independent, non-profit non – governmental organization campaigning for rational drugs and policies) took up this study, with an attempt to bring to the notice of the consumer, the type of the pain killers that are commonly promoted to doctors. A commercial publication used exclusively by doctors was referred to get the common pain killers that are promoted by various drug manufacturers.

The study is mainly aimed for consumer groups that are actively involved in building awareness among consumers by involving them in campaigning and lobbying for rational drugs. It is hoped that the consumer groups would be better equipped to lobby for rational drugs, when dealing with drug policy makers, with studies of such nature.

The study is relevant because in India, doctors after graduating from the medical colleges have no access to unbiased and scientific information regarding drugs. They are often

compelled to depend upon the information that is given to them by drug companies or by information that is supplied to them through company sponsored seminars. Often drug companies promote irrational drugs to doctors. Using the case study of pain killers, this study confirms the above statements.

The study is mainly under two heads:

* Rationality: - Does the drug listed in the commercial publication (MIMS), match with the Essential Drug list by WHO? And are the drugs rational?

* Drug prices: - Comparing the Essential Drug prices set by different companies.

Is the drug Essential and Rational?

For this study three publications have been employed. One is a commercial publication used by doctors extensively all over India and the other two are scientific publications. The commercial publication is “Monthly Index of Medical Specialities” known popularly by its acronym MIMS. Among the scientific publications one is the well known “WHO model list of Essential Drugs”, first published in 1977 and regularly updated ever since every two years and the other “The Pharmacological Basis of Therapeutics”, 10th edition by Goodman & Gilman, a standard text book which is used for reference and study by academic medical professionals all over the globe.

MIMS :-

In June 2004, volume 24, number 6 issue of MIMS lists in its index, 90 groups of drugs under different categories. But for the present study only two categories were selected. Firstly, analgesics & antipyretics and secondly NSAIDs. (Analgesics is a term used for all categories of pain killers. Antipyretics are drugs that reduce fever. NSAIDs is an acronym for Non Steroidal Anti-Inflammatory Drugs, a term used for all categories of drugs that reduce inflammation and do not belong to the steroid group of drugs). All these analgesics, antipyretics and NSAIDs are available in various forms (like tablets and syrups etc) and also different dosage forms. Altogether 235 formulations, manufactured by 49 drug companies and sold under 120 brands were systematically scrutinized with reference to World Health Organization (WHO) Model List and a standard text book of Pharmacology.

WHO Model List of Essential Drugs :-

The WHO Model List of Essential Drugs 2003 referred to in this study contains about 375 drugs in 500 formulations (or dosage forms). These could provide safe effective treatment for the vast majority of communicable and non-communicable diseases. Essential Drugs should be the drugs of first choice, more so in a situation where financial resources are a crunch. The list was first published in 1977 by WHO and has proven that most diseases can be managed with few medicines. All 235 drugs in our study were checked to see whether they are included as Essential Drugs or not.

Of the total 235 formulations listed for this study only 23 (9 percent) were listed in the 2003 WHO model list.

Rationality:-

To assess whether the drug is rational or not, Goodman & Gilman's “The Pharmacological basis of Therapeutics” was referred.

The term “rational” is used for drugs that are referred, recommended or mentioned in standard text books. Irrational drugs on the other hand are those that are not referred, recommended or mentioned in standard text books. With the help of the text book the following two criteria were evolved:-

1. Firstly if the formulation is not mentioned in the book (for example combination like paracetamol with Ibuprofen) then this was considered irrational
2. Secondly if the formulation is described but the text book does not advocate it, the formulation was considered as irrational (for example Analgin or Nimesulide).

If a certain formulation does not fall under both the above mentioned criteria, it was labelled as a Rational drug

What are Rational drugs? If their efficacy is clinically proven and the therapeutic benefits outweigh the risks, they are called rational drugs. **What are irrational drugs?** If there is no good clinical pharmacological evidence of their therapeutic benefit and safety then, such drugs are considered irrational drugs.

The presence of irrational drugs is not only an economic burden but also harmful to the community.

Summary of the study

Of the total 235 formulations that were screened only 22 (9%) conformed to the Essential Drug list of the WHO, 140 were (60%) rational drugs and remaining 95 (40%) were irrational.

Only one out of every ten drugs that are promoted to doctors confirm to WHO's Essential Drugs. And out of every ten drugs, six drugs are rational. From this it is obvious that if a doctor prescribes a drug, there is only one in ten chances of prescribing the drug of first choice. This is not an acceptable situation where financial resources are always a major crunch.

Some interesting observations:-

Following were some of the interesting observations after the study.

1. A multinational company (Aventis) manufactures and sells the drug Analgin. This drug is obsolete as several safer alternatives exist.
2. Another hazardous drug is Nimesulide. It is manufactured by 5 companies, and amongst them 4 companies manufacture the drug for use in children too. This drug has never been allowed in the US and banned in several European countries.
3. Diclofenac – a pain killer often used by both specialists and general practitioners is also manufactured in the form of injectable. The injectable form of this drug is not mentioned in the standard text book (The Pharmacological Basis of Therapeutics, 10th edition by Goodman & Gilman), that has been referred for this study.
4. Aspirin – a popular and most commonly needed pain killer is not manufactured by any drug company. Aspirin is listed in WHO's list of Essential Drugs. Only one drug company i.e. Nicholas Piramol manufactures an irrational combination of aspirin (acetyl salicylic acid) 350 mg with caffeine 20 mg under the trade name Micropyrin. This study therefore, shows that some drugs which are on the WHO's Essential Drugs list are not promoted to the doctors by any drug company. In fact aspirin should have been made available for the doctors' to prescribe.
5. A combination of the drug ibuprofen with paracetamol is perhaps the most widely used irrational combination. In this study 6 drug companies manufacture this drug combination and most of them even have the preparation for use in children (in the form of syrup). A question often raised by the consumer is that, why do doctors prescribe such irrational combinations? As mentioned above one factor is that such drugs are heavily promoted by the drug companies to the doctors. During medical education students are taught by teachers that such combinations are irrational and that they can be harmful to the patients, but as they start prescribing drugs to patients, the flood of misinformation by companies overshadows the scientific information.

Cost analysis of Essential Drugs :-

The second part of the study analyses the cost of the Essential Drugs listed in MIMS. This part of the study is important as it gives a picture to the consumer regarding the cost of the drugs that should have been of top priority for a doctor to prescribe.

WHO's Essential Drugs list has only three NSAIDs viz. paracetamol, ibuprofen and aspirin. As aspirin is not manufactured by any drug company we studied the pricing of only two drugs i.e. paracetamol and ibuprofen

Following are the highlights:-

- a. Paracetamol 500 mg is manufactured by 6 drug companies. Amongst them 2 drug companies (SKF and Nicholas Piramol, the former being a multinational) manufacture and sell the same drug paracetamol under two different brand names with different pricing Table 1. There can be no scientific justification for this.

Table 1 – Comparisons of retail prices of eight dosage forms of Paracetamol by six manufacturers

Sn	Trade name	Generic name	Price of the drug for 10 tablets.	Manufacturer
1	Calpol	Paracetamol 500 mg	Rs. 8.78 / 10 Tablets	GSK
2	Crocin	Paracetamol 500 mg	Rs. 7.98 / 10 Tablets	
3	Disprin Paracetamol	Paracetamol 500 mg	Rs. 9.40 / 10 Tablets	Reckitts
4	Doliprane	Paracetamol 500 mg	Rs. 4.88 / 10 Tablets	Nicholas Piramol
5	Molidens	Paracetamol 500 mg	Rs. 4.21 / 10 Tablets	
6	Pacimol	Paracetamol 500 mg	Rs. 6.30 / 10 Tablets	IPCA
7	Ultragin	Paracetamol 500 mg	Rs. 8.80 / 10 Tablets	Wyeth
8	Pyrigesic	Paracetamol 500 mg	Rs. 13.50 / 10 Tablets	East India

Source: MIMS

- b. The lowest priced paracetamol cost Rs 4.21 per 10mg tablet and the highest priced is Rs 13.50 a high price difference of 69 per cent. How does one explain such a huge price difference? Drug companies spend a lot of money in promoting a drug to the doctor and this cost is recovered by hiking the price of the drug. Doctors are neither taught during their student days nor do the drug companies mention its price when they promote the drug to doctors. So doctors tend to prescribe the most expensive drug. Unfortunately the consumer also believes that a costly drug is better. The consumer is not aware that one could buy the same drug of another company at a much lower rate. Medicines are the only commodities in the market where the buyer is not the chooser.

Drug pricing of Diclofenac 50 mg: - Diclofenac is another common pain killer used though not in the list of Essential Drugs by WHO. The prices of the innovators' brand and a branded generic shows a very wide difference in Table 2.

Table 2: Comparisons of retail prices of two brands of Diclofenac

sn	Trade name	Generic name	Price of the drug for 10 tablets	Manufacturer
1	Voveran	Diclofenac 50mg	Rs 15 / 10 Tablets.	Novartis
2	Tromagesic	Diclofenac 50 mg	Rs. 3.15 / 10 Tablets	Themis Chemicals

This table shows that Voveran manufactured and marketed by Knoll is almost five times more expensive than Tromagesic manufactured and marketed by CIPLA.

Summary of the study :-

This study shows:

- Of the 235 drugs studied only 22 or nine percent were listed in the 2003 WHO Medicines List
- Of the 235 drugs, 60 percent were classified as rational and 40 per cent irrational
- Essential Drug process show wide variation

This study underscores the urgent need for all concerned including health professionals, medical and pharmacy educators, NGOs and peoples' organizations to lobby the government to formulate and implement national drug policies based on the concept of essential drugs and rational economic use of these drugs.

Source: Reported by our network partner Dr Gopal Dabade, from Drug Action Forum, Karnataka, India.

LATIN AMERICA

Latin American activists declare policies and practices used in the negotiation of Free Trade Agreement between the United States and Latin American countries wrong

In October 2004, Ecuadorian police, following the orders of the Ecuadorian Minister of Trade, withdrew the credentials of Mr. Roberto Lopez Linares, Coordinator of Health Action International Latin America (HAI-LA), and expelled him from participating as a representative of Accion Internacional para la Salud, during the fifth Round of Negotiations of the Free Trade Agreement (FTA) between the United States and Colombia, Peru and Ecuador, in the city of Guayaquil, Ecuador.

Mr. Lopez Linares, a specialist on the subject of intellectual property and a relentless defender of health rights, was accused of distributing an informative pamphlet during the negotiations drawing attention to the possible medicine access problems that could arise from the FTA if the conditions demanded by the United States are complied with. The document distributed was a public document, massively distributed by a Peruvian newspaper, and which was given by Mr. Lopez to a journalist in one of the hotel corridors, not to any medical delegate or to any participant at the meeting.

Further, at the meeting the Peruvian Trade Minister told Roberto that the police, under orders from the Ecuadorian Trade Minister, was looking for him for allegedly "distributing a pamphlet against the FTA". Immediately after Roberto's credentials were taken away, he went

to give statements to the Andean press, which created a stir. During the intervention of the police against Mr Lopez, he was told that this decision was an agreement between the Ecuadorian Ministry of Commerce and the Peruvian Consulate in Guayaquil. It is likely that the Peruvian negotiators were directly involved in the incident, as that government is under a lot of pressure from the US and has been doing its utmost to silence those promoting alternatives to the FTA.

The same night, the Peruvian negotiating team returned Roberto Lopez his credential to participate in the side room, saying that the intervention against Mr Lopez was a "misunderstanding", but he decided not to continue participating unless conditions improved.

He and his colleagues in Guayaquil developed a media strategy to get more coverage of the issue and emphasize the double standards of the negotiators: on the one hand they punish those defending public health, and on the other, they reward those defending private interests (as in the case of the former member of the Peruvian IP negotiating team who went to work for Pfizer, but who suffered no consequences as a result).

Source: AIS Latin America

- *Journal Scan* -

A hopeful Malaria vaccine by 2010?

An effective vaccine against malaria has been developed and could be licensed by 2010, scientists say.

Many other candidate vaccines are in development, but experts say trial results of this one, published in the Lancet, are the most promising yet. The vaccine was used to protect 2,022 children in Mozambique and cut the risk of developing severe malaria by 58 per cent.

The team, led by a Spanish expert from the University of Barcelona, is working with drug company GlaxoSmithKline. Lead researcher Professor Pedro Alonso said: "These are clearly the best results we have ever seen with a candidate malaria vaccine. "We are quite certain not only that the vaccine is safe...but that we have seen a clear efficacy."

The team tested the trial vaccine, called RTS,S/AS02A, on children aged between one and four years old in Mozambique, where malaria is widespread. Globally, over one million people, many of them children under the age of five, die from malaria each year.

Preventing infection is especially important because resistance to anti-malarial drugs is a growing problem. The healthy children in the study were randomly allocated to receive three injections of the malaria vaccine or a vaccine against a common childhood disease, such as Hib, which acted as a control.

At six months, the malaria vaccine had reduced a child's risk of developing one episode of malaria by 30 per cent. The risk of developing severe malaria was reduced by 58 per cent. The team followed up 400 of the children for longer and found the vaccine extended the time to first infection by 45 cent.

Professor Alonso said it would have been unrealistic to have expected the vaccine to prevent 100 per cent of infections and that the results were really encouraging. "It's difficult to imagine that we will have in the near future a magic bullet that by itself can sort out the problem of malaria," he said.

"Control will rely on using a combination of other malaria control tools." "We believe a malaria vaccine, even of moderate efficacy, could make a huge impact." Among the under two year olds in the study, the vaccine was 77per cent effective against severe malaria. The scientists said these young children would be the ultimate target group.

Further trials will be needed to prove the vaccine is safe before a licence can be granted, but the researchers are hopeful this will happen by 2010. It was well-tolerated by the children in the study, with few serious side-effects. Allan Shapira, of Roll Back Malaria, said: "The research is very high quality and the findings are very encouraging." He said there would always be concerns about the possible cost and availability of vaccines and treatments for malaria.

The vaccine is directed against the form of the malaria parasite that is injected by mosquitoes. This form is known as the sporozoite. After immunization, antibodies and white blood cells are produced which can prevent the sporozoite from surviving or from further development in the liver. The research was funded by GSK Biologicals and a global project, created through a grant from the Bill & Melinda Gates Foundation, to overcome barriers to malaria vaccine development - the PATH Malaria Vaccine Initiative. Mozambique's Minister of Health, Dr Francisco Songane, who approved the trial, said: "Malaria is the number one killer of African children. "We did this not only for the people of Mozambique, but for the people all over Africa whose health and development suffer greatly from this terrible disease."

Source: E-Drug October 17 2004 originally from BBC News

Ethnobotanical research: Progress with profit-sharing agreements between Samoa and US research institutions

The December issue of the Australian Public Health Association newsletter InTouch² carried a report on a possible 'new AIDS drug' from botanical sources in Samoa, citing Harvey Black in The Scientist.³

According to the Medical Research Agencies of America, Antonio Pisig of AIDS Research Alliance of America reported in 'The Prostratin Story', that Samoan healer Epenesa Mauigoa told ethnobotanist Paul Cox, when asked if she knew anything about traditional herbal medicine, 'I know a little.'⁴ According to Pisig's report, 'she described boiling the bark from the mamala tree and giving the liquid to those suffering from fiva sama sama -- viral hepatitis'. Samples of this remedy were sent to the National Cancer Institute in the USA, and in 1992 the institute isolated a part of the plant that demonstrated powerful effects against HIV in laboratory settings.

Prostratin, a protein kinase C activator, was isolated from the stems of the small Samoan tree *Homalanthus nutans*. *H. nutans* plays an important role in Samoan ethnopharmacology: the leaves are used to treat back pain, the root is used to treat diarrhoea and the stem wood to treat yellow fever. In contrast to many other phorbol derivatives, prostratin does not appear to be a tumor promoter, and in fact, suppressed the growth of several T-cell lines at anti-viral concentrations.⁵

² Samoa to benefit from AIDS drug. *In Touch* December 2004, 2.

³ Harvey Black: <http://www.biomedcentral.com/news/20041001/02/>

⁴ 2002, Medical Research Agencies of America <http://www.mraa.org/stories2.htm>

⁵ Gustafson KR, Cardellina JH, Mcmohon JB, Gulakowski RJ, Ishitoya J, Szallasi Z, Lewin NE, Blumberg PM, Weislow OS, Beutler JA, Buckheit RW, Cragg GM, Cox PA, Bader, JP, Boyd MR. A nonpromoting phorbol from the Samoan medicinal plant *Homalanthus nutans* inhibits cell killing by HIV-1. *J Med Chem* **35(11)** :1978-1986 (1992).

Lab studies at the AIDS Research Alliance of America have shown that prostratin not only prevents HIV from infecting human cells, but can also purge HIV from 'viral reservoirs' in the body – places that HIV can hide from even the most powerful drugs approved to fight AIDS. Scientists at AIDS Research Alliance of America hope that prostratin has the potential to help eradicate HIV from infected individuals.

Harvey Black in *The Scientist*, October 1, 2004, reported that an agreement between the University of California at Berkeley and Samoa will result in equal share of royalties from the sales of drugs derived from the genes of the Samoa native mamala tree. The agreement was hailed by Irl Barefield, Executive Director of the AIDS Research Alliance (ARA), which has sponsored research on plant-derived prostratin in the United States and abroad since 2001 under a license from the National Cancer Institute, and which holds the patent for prostratin. Under the terms of the agreement, money from commercialization of prostratin would go to the Samoan government, the village where the compound was found, and each of the families of the healers who helped discover it. ARA will use any revenues it derives from prostratin for additional HIV/AIDS research.⁶

'I think it is another step in redressing past wrongs that have been part and parcel of first-world dealings with third world countries when it comes to dealing with plant medicines and native cultures,' Barefield said.⁷ 'Ethnobotanical research in Samoa helped us to learn about this important natural resource and its potential for treating HIV,' 'It is only right that the people of Samoa share in any potential reward and we hope that this agreement will set a standard on ethical dealings with medicines derived from indigenous cultures.'

- Resources -

Public-Private Partnerships and International Health Policy-Making: How can public interests be safeguarded?

Author : Judith Richter

Public-private partnerships (PPPs) are promoted as the innovative policy model of the new millennium. Should we be concerned about the rush into closer relationships with business? What are the effects of this policy on the decision-making powers of nation states and the UN system? Will transnational corporations use these new channels to exert more influence in public affairs? What safeguards are in place to protect democratic and participatory decision-making?

The publication summarises the findings of a new review of the development of public interest safeguards in the health arena with a focus on the World Health Organization. It explores challenges to the establishment of an effective system to enable WHO to deal with conflicts of interest and other risks linked to the relationships between public and business-interest actors. A lack of space for open discussion about the new policy paradigm is identified as a key obstacle.

This publication makes a contribution to candid public debate. It argues for a re-examination of safeguards of other UN institutions, such as UNICEF. It proposes another look at such high-level arrangements as the legally-independent global health PPPs and the UN Secretary-

⁶ Prostratin Press Release December 13, 2001. **Contact:** Irl S. Barefield, Executive Director, AIDS Research Alliance, 621-A North San Vicente Boulevard., West Hollywood, CA 90069, 310.358.2423, ext. 190, info@aidresearch.org
<http://www.aidsresearch.org/prostratin.html>

⁷ Black, H. Agreement hailed as a model for ethnobotany projects *The Scientist* October 1, 2004
<http://www.biomedcentral.com/news/20041001/02/>

General's Global Compact initiative. It presents suggestions of ways to strengthen the UN system's integrity and independence to fulfil its role in international health policy making and public interest advocacy.

Published in the Elements for Discussion Series, Ministry for Foreign Affairs of Finland Development Policy Information Unit it is also available on-line http://global.finland.fi/julkaisut/pdf/public_private2004.pdf"http://global.finland.fi/julkaisut/pdf/public_private2004.pdf

A hard copy can be ordered free of charge by e-mail to <mailto:keotilaus@formin.fi> or by visiting <http://www.global.finland.fi> and on English, publications, and the publication title (or on 'order publications')

Therapeutic Guidelines: Endocrinology – Version 3 : a helpful resource for a challenging clinical area

Published by Therapeutic Guidelines, Melbourne, Australia
Number of Pages: 312

Therapeutic Guidelines Endocrinology Version 3 is published and distributed by Therapeutic Guidelines Ltd, a not-for-profit independent organization in Australia and it is one in a series of many publications covering almost all common disorders seen in general practice such as Therapeutic Guidelines on Analgesic, Antibiotic, Cardiovascular, Dermatology, Gastrointestinal, Neurology, Palliative Care, Psychotropic and Respiratory. These guidelines have been designed to assist prescribers' in ensuring that patients receive optimum treatment since the first publication of Therapeutic Guidelines on Antibiotics in 1978. Endocrinology version 3 released after three years of the last edition on Endocrinology. The publications very rightly opens with the lines below regarding its aim, "The aim of Therapeutic Guidelines Ltd is to provide clear, practical, authoritative and succinct therapeutic information for busy health practitioners for the management of patients with specific conditions." The publication from the very outset provides key information about the process of preparing the Therapeutic Guidelines, choosing topics, forming expert groups, management of the guidelines, inaugural meeting, formulating and revising of the guidelines, basis of recommendations, external preview and endorsement and post publication evaluation.

Endocrinology Version 3 comes with a whole new range of discussions, topics, tables and wherever possible clinical trial evidence has been used as the basis of the recommendations. "The publication has also considered a number of new medications that have appeared on the market in the last three years both in relation to publishes information and the decisions of the Pharmaceutical Benefits Advisory Committee" states the preface to the publication. All chapters according to the preface has been revised and accordingly amended to suit the 21 century. For instance the chapters on diabetes have an emphasis on metabolic syndrome and the associated risk of cardiovascular problems and the chapters on overweight and obesity have been extended to include detailed guidelines on dietary modifications and exercise needed for weight loss and to limit weight regain. Endocrinology version 3 also comes with complete new chapter dealing with common causes of high and low blood levels on magnesium, sodium and potassium.

The content page reveals that this publication greatly deals with most of the common diseases prevalent all over the world such as Diabetes, Overweight and obesity, thyroid disorders, osteoporosis, menstrual disorders, infertility, Ovarian hormone replacement therapy running into twenty odd chapters. However, a skim through this easy-to-comprehend publication reveals that although it is designed to advice medical professionals a lay person could enlighten herself/himself by reading it since it employs simple diction and style.

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

Update your WHO/EDM Bookshelf

The latest version of the WHO Medicines Bookshelf CD-ROM, containing over 350 medicines-related publications, in English, French and Spanish, taken primarily from materials published by the Department of Essential Drugs and Medicines Policy (EDM). The Bookshelf covers the Department's entire field of interest, including:

- access to essential medicines
- rational use of medicines
- national drug policy
- quality and safety issues
- traditional medicine.

Core publications from other sources are also included on the CD-ROM, with the kind permission of the organizations concerned.

For those in areas where Internet access is particularly slow or is unavailable, we have designed the Bookshelf to serve as a self-contained medicines information resource. For this reason, a version of the Essential Medicines Library (totalling 20 MB) has been included on the CD-ROM. The Library includes the WHO Model Formulary, and the Library interface serves as a seamless gateway to a wide range of useful web sites, such as WHO clinical guidelines and United Nations price information resources, among many others.

The Bookshelf is available free of charge. Write to: EDM Documentation Centre, e-mail: edmdoccentre@who.int