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The Network's NEWSLETTER
Association for the Rational Use of Medication in Pakistan

The Network's mission is to promote rational use of medication and essential drugs concept in Pakistan in order to optimize the usefulness of drugs and help bring equity in their access.

HEPATITIS B: Much to be desired

Hepatitis B is assuming an alarming proportion in Pakistan and the number of cases is on the rise. In various studies carried out in different parts of the country the prevalence rate of Hepatitis B carrier varies from 3 - 10%. The prevention of this potentially fatal disease should be a priority of the Government.

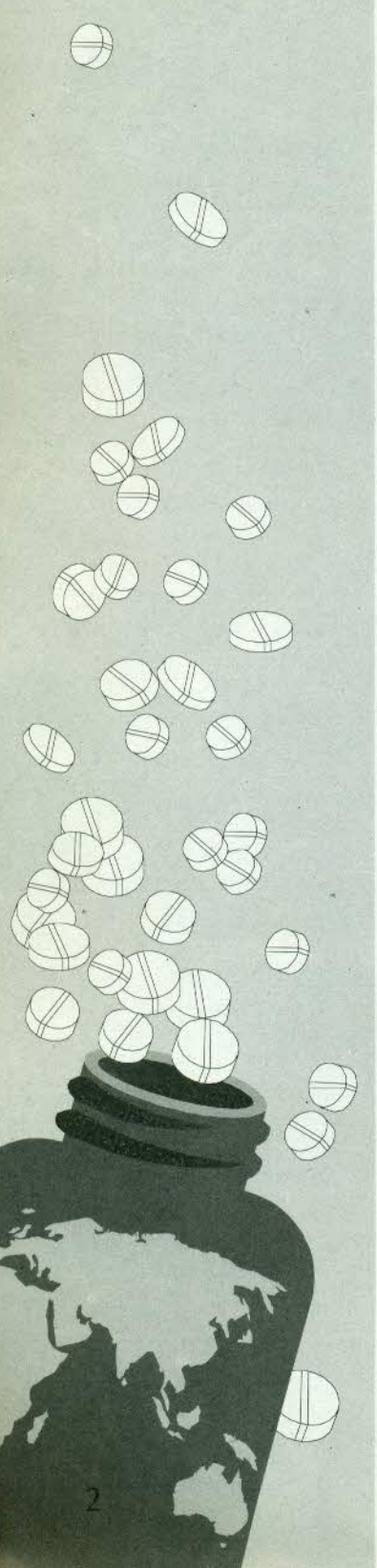
An important strategy to control Hepatitis B is screening of blood for transfusion. Although the Government of Punjab has recently started screening blood supplied in the Government hospitals but other provinces have yet to make such a provision. Most of the private blood bank services do not provide screened blood to their patients. Legislation is required to make it mandatory that no blood should be supplied unless it is screened and certified.

The second major strategy to control spread of Hepatitis B is to prevent repeated use of the same syringe to inject different patients. This is particularly important for the plastic syringes which are being indiscriminately reused for different patients without sterilization. Recent reports in the national press have brought to light another dimension of this problem arising from used disposable syringes being repacked and resold in the market by unscrupulous elements.

Although vaccine for Hepatitis B is available in the market but the present price is beyond the reach of the majority of the population. The international price of the vaccine for an adult is approximately one dollar per dose. But in Pakistan the vaccine is being marketed by the multinational companies which charge 8 to 10 dollars per dose.

The Federal Ministry of Health was approached in this regard and the Federal Secretary very graciously listened to the presentation regarding the inclusion of Hepatitis B in the EPI programme. He then called the National EPI Programme Manager and directed him to give a plan to get the Hepatitis B immunization included in the next year's EPI programme. Since then there is not much progress and we hope that the Ministry will expedite the matter to start the immunization from the next financial year to save the population from this highly dangerous but totally preventable disease.

Hepatitis B has reached scandalous dimensions in the country and needs immediate Government attention (and intervention!).



Calcium channel blockers: Warning demanded

Public Citizen, a US based consumer organization with about 90,000 members, has petitioned the Food and Drug Administration to immediately add a box warning and change the labelling on all calcium channel blocking drugs licensed in the United States to include recent evidence linking these drugs to an increased risk of heart attack and death. The petition refers to scientific evidence appearing recently in issues of medical journals like *JAMA, J Am Geriatric Soc, Arch of Intern Med, BMJ, Lancet, Eur Heart J, Br Heart J* and *Circulation* and others. The suggested warning label reads as follows:

"Emerging evidence shows a consistent association between the use of the immediate release dosage forms of calcium channel blocking drugs and an increased risk of adverse cardiovascular events including myocardial infarction and death. The evidence to date most strongly implicates the immediate release dosage form of nifedipine in moderate or high doses, but there is no evidence that an extended release dosage forms are safer as far as patient mortality is concerned. Consequently, it is prudent to consider that this warning should apply to all calcium channel blocking drugs, regardless of chemical class or dosage form (immediate or extended release).

The calcium channel blocking drugs should not be used in patients with recent myocardial infarction and congestive heart failure.

Drugs from alternative classes of agents for the initial treatment of stable or unstable angina pectoris or hypertension - diuretics and betablockers - have reduced major cardiovascular events and mortality in well controlled trials in hypertensive patients. Other agents, including the calcium channel blockers, have not been shown to reduce the incidence of stroke, myocardial infarction or death. Consequently, the Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends diuretics and beta blockers as the preferred drugs for treating hypertension."

The petition also calls for a change in the package insert.

We will keep our readers informed about the progress of this case.

The Ministry of Health is keeping up the pace. The number of drugs registered till June 1995 was 17,808, by December it has climbed up to 18,392. That means 584 new drug registrations in the last six months!

Seminar on rational use of benzodiazepines

The Department of Psychiatry and Division of Medicine, Shaikh Zayed Hospital, Lahore organized a seminar on "Rational Use of Benzodiazepines" on 13th November, 1995. The seminar was reportedly attended by a large number of doctors and was addressed by Profs Zafar Iqbal, Aijaz Haider, I.A.K. Tareen, Rashid Chaudhry and Afzal Javed.

The message to take home was: use benzodiazepines only when really needed. Many situations, particularly those associated with day to day stress, are self limiting and generally resolved simply by reassurance, support and active listening and thus do not require prescription of drugs. Particular emphasis was laid on misuse and abuse potential of these drugs and the resulting dependence and addiction.

The Network would like to congratulate the organizers of this seminar for their efforts in the promotion of rational drug use and take this opportunity to urge others to take similar initiatives in their institutions and

professional bodies.

Omeprazole has problems

The Australian Drug Reactions Advisory Committee (ADRAC) has flagged a caution on use of omeprazole because of reports of side effects including musculoskeletal and interstitial nephritis. ADRAC has received 19 reports associated with omeprazole use which included joint pain and/or swelling (including gout), muscle pain and/or atrophy, and myalgia and arthralgia occurring simultaneously.

Based on the recent reports of interstitial nephritis in Australia (where three cases have been reported) and elsewhere, ADRAC has asked the prescribers to be aware that interstitial nephritis can occur within the first few months after starting omeprazole

Quality assurance: the Ministry style

The Federal Ministry of Health held an International Seminar on Quality Assurance and Rational Use of Drugs from 12 to 14 Dec 1995 under the auspices of the WHO, PPMA and PPA. While the national press has covered most of the happenings of this seminar and the recommendations made during different sessions, we would like to comment here on the quality of recommendations in general and on one session related with drug pricing in particular.

We received the invitation to attend the seminar only two days before the seminar and the programme was not available until after reporting at the registration desk on 12 December. All other delegates whom The Network representative asked about the invitation and programme told the same story. It appeared that only those people who were to make presentations had ample advance information about the programme. Now the question arises: how can a participant make any meaningful contribution in the deliberations of a seminar without adequate preparation? Holding such an international event without seeking to get active participation of the delegates in drawing-up the recommendations seems to be a deliberate attempt at getting an already decided list endorsed. It seemed such a waste to get so many people together at great expense and not making optimal use of their combined wisdom.

Drug prices has been such a protracted issue in our country and a lot has been said and written about it in the national press. But the way our Ministry of Health chose to deal with it during this seminar speaks volumes about its ability and willingness to settle this national issue.

Added to the seminar agenda on the eleventh hour, the session on drug prices was the most ill prepared one. Presentations were to be made by representatives of the Pharma Bureau, Pakistan Pharmaceutical Manufacturer's Association, Pakistan Chemists & Druggists' Association and The Network. The Network Coordinator received a call from the Drugs Controller around midnight on the 11th December and was asked to make a presentation the next morning to give the consumers' perspective! All other speakers of this session had similar invitations. The Coordinator spent the rest of the night working in his office in his night gear and was ready the next morning. The other speakers had either to travel during the night to be in Islamabad or did not have access to their offices and could not make any formal presentation. The Chemists' representative could not even make it to the seminar.

The way this session was organized, and the short time allocated, it was just not possible to have any reasonable discussion on the issue.

Contents

GATT and third world pharmaceuticals

Intellectual property rights: a critical policy agenda

Azra Talat Sayeed gives details of the rich North's new prescription — a high dose of patent laws — for the ailing health sectors of the poor South and tells how it will prove to be the last straw on the camel's back.

What is a patent?

Intellectual property rights also known as patents are provided by the state in the form of a legal document to attest that an invention belongs to the person given the certificate. The concept of patent lies in the belief that an inventor has the right to have monopoly over the product s/he has created. Hence, at least for a limited period s/he may reap the economic benefits of the invention to be marketed. The ability of patent holders to create monopoly through patents allows market dominance and price setting which the marketer feels is justified given his/her economic investment in the innovative process.

There is a wide body of literature which debates the right of society versus the rights of the inventor; especially for inventions which serve humanity, and are tools instrumental in human development. To be amazingly simplistic, one can say those who believe in patents have their sympathies with the individual; whereas those who do not agree to patents have greater concern for the rights of society and a greater social benefit arising from creativity.

Fruit to some ...

In the nineties, of the major issues which have emerged on the policy agendas of the first and third world governments are intellectual property rights. In order to create and maintain economic superiority and subsequently political and military dominance invention and innovation are imperative. In a consumer society, it is only by creating new products and maintaining product differentiation that national economies are able to maintain economic prosperity, which then, of course, ties in with military dominance. The drive for economic superiority has led to a steep technological development in the industrialized world.

This development has largely taken place in the absence of moral and ethical considerations. There is little emphasis on researching diseases proliferating in the third world, even though the majority of the world population is suffering from these diseases. In addition, the introduction of genetic manipulation, in the face of little understanding of the science, may lead to a major irreversible crisis in the development of the human race.

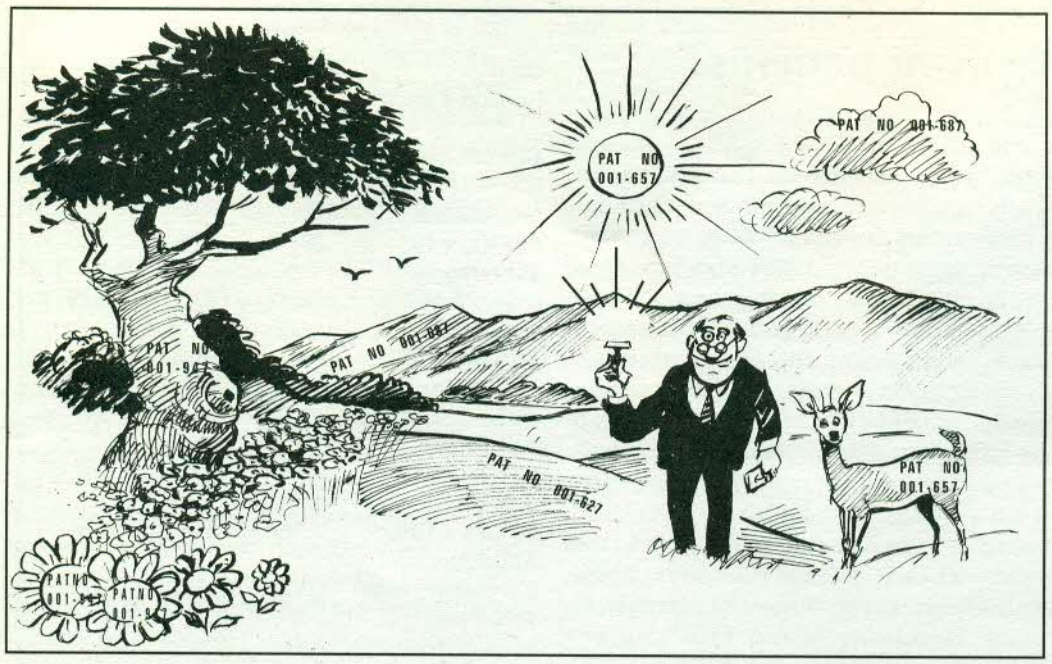
One of the major fruits of innovation are medicines which can have a critical role in reducing suffering as well as creating better life standards for human societies; the issue then is the availability and acces-

What is GATT?

General Agreement on Tariffs and Trade (GATT) is a global treaty signed intially in 1945. Its aim then was to encourage international trade through reduction of duties and other restrictions on imports. The terms of the treaty have been negotiated among its signatories eight times since then. The last round of these negotiations started in September 1986 at Punta del Este, a town of the South American country Uruguay, and continued for four years. The final draft agreement was signed by over 90 countries (including Pakistan) in April 1994.

The Uruguay Round of GATT was different from all previous ones as it expanded itself to a global regulatory body that will lay down and dictate policies to the Third World governments regarding their industry, trade, agriculture and services sector (like banks, insurance, transport, communication). All these policies, which signatories like Pakistan have to follow, heavily favour multinational companies.

The GATT '94 is the blue print of the new world economic order which is biased against the Third World. Through privatisation of public sector, indiscriminate liberalisation of economies, reduction in tariffs and strict enforcement of intellectual property right laws the rich North intends to recolonize the poor South. The GATT '94 that will be implemented through the World Trade Organisation (WTO) will cripple or eliminate the small, local industries in the Third World and will turn them into passive markets for the multinational companies.



sibility of these medicines. The availability of these drugs at prices affordable to all populations, whether they belong to the first or third world, is a basic human right. The problem, then is ultimately of profits. By limiting the access of other competitors to development and manufacturing of medicaments, the pharmaceutical industry assures a profitable market for itself; hence the introduction of universal patent protection concept.

The United States has been one of the major voices from the North demanding stringent intellectual property rights legislation at the global level and probably the most effective tool for having these demands met these days are the trade sanctions imposed by the United States against countries not agreeing to intellectual property terms of the North. These trade sanctions are enacted through the Special 301, a clause of the 1974 Trade Act of the United States.

The demand by the corporate world in the North for obedience of the Third World in following intellectual property right agreements is also reflected through the various international trade agreements and intellectual property rights treaties being formulated globally. The latest and the most potent is the Trade-Related Intellectual Property Rights (TRIPs) agenda of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).

The TRIPs agenda demands strict patent regimes in the third world. The saving grace is the ten year time period for third world countries (upto year 2004) to change their patent laws.

This will hinder the Third World from attaining self sufficiency in pharmaceutical production. Low income countries will be saddled with higher prices when they attempt to buy essential medicines. They will also discover that many life saving medicines are simply not available. This will happen because third world manufacturers will be discouraged from entering production, or forced out of business altogether, by pharmaceutical transnational corporations (TNCs).

Negotiators of GATT addressed Trade-Related Intellectual Property Rights (TRIPs) agreement in great detail, but little attention was paid to the needs of the people of the third world. The need for local firms to develop home-based expertise and capital was ignored. The Uruguay Round also shifted legal protections, further in the favor of TNCs.

... Poison to others

One of the most potent powers granted to TNCs in the Uruguay Round is the placing of the burden of proof in patent disputes on third world manufacturers. Article 34 states: "... if the subject matter of a patent is a process for obtaining a product, the

Availability of essential drugs at prices affordable to all populations, whether they belong to the first or the Third World, is a basic human right.

Protecting - patents or patients?

The Indian example

India radically changed its inherited colonial intellectual property rights system in 1970. The new law disallowed product patents altogether in food and health related areas, and in case of pharmaceuticals, it limited the duration of process patent to between five and seven years. This means that it allowed any company to manufacture a product patented by some other country if it developed a different process to produce the same patented product. This proved as a major incentive for local pharmaceutical industry to innovate and develop new processes and products. During mid 70s to late 80s Indian industry in cooperation with public research laboratories developed no fewer than a hundred energy-efficient, cost-effective processes and some new products. This weak form of patent protection discouraged multinational companies from becoming huge monopolies and provided the Indian pharmaceutical companies a solid ground to compete with them. The competition has played a major role in keeping prices of medicines in India much lower than in Pakistan which allows both process and product patent. (See table)

India being a signatory to the GATT '94 has now been under pressure to change its patent laws according to the TRIPs agreement. Any such change will cripple the local industry and the prices of the medicines will inevitably shoot up. A strong lobby of the local industry and the consumers has uptil now been succesfully resisting government moves to change patent laws.

Drug Dosage & pack	Price in India	Price in Pakistan	Times Costlier*
Ciprofloxacin			
500 mg x 4s	51.00	234.63	4.6
Norfloxacin			
400 mg x 10s	39.36	125.50	3.2
Tobramycin			
0.3% x 5ml	22.17	116.31	5.25
Diclofenic			
50 tabs x 10s	5.67	55.80	9.8
Ranitadine			
300 tabs x 10s	29.03	260.40	9.0
Panotidine			
40 tabs x 10s	26.24	260.40	9.9
Atenolol			
50 tabs x 10s	7.50	86.63	11.5
Acyclover			
5% cream x 5 gm	33.75	363.32	10.8
Aztemizol			
10 mg x 10s	6.00	120.90	20.1
Buspirone			
5mg x 10s	4.05	89.69	22.1
Fluoxetine			
2 mg x 10s	29.00	618.76	21.3

* Times costlier than Indian price
Note: Prices in Indian rupees are of 1991-92 period.
Source: Development Dialogue, Dag Hammarskjold Foundation, Uppsala, Sweden; 1995:1, p:204

judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process."

This means that if a secondary manufacturer finds an alternative process to produce the same product, the burden of proof rests with them to show that the new process is indeed unique. The accused manufacturer, and not the accuser, must demonstrate that it has not violated the process patent. This places the third world firms at a greater risk for patent suits by TNCs because they do not have the resources to defend themselves.

The burden of proof could be a deterrent to small firms. If such producers stay out of the market, monopolies already present will become more powerful in the third world pharmaceutical trade. The lack of competition will increase prices and lower customer service. To make Article 34 fair, the burden of proof should rest on the accuser and not the accused.

The TRIPs agreement protects a product patent for 20 years from the date of filing. Usually, after the expiry of the product patent, producers other than the patent holders are able to manufacture the product. But if a new process is introduced, the product is now protected through the process patent.

In many cases, TNCs will apply for a patent in a particular country but will not actually set up manufacturing facilities. This means that the drug itself is imported, but not the production process. As a result of the patent protection local firms cannot enter into production. These imported patented products are more expensive and negatively impact the balance of trade of a developing country. Article 27 of the TRIPs agreement will further extend this protection to the corporate world. The wording of the article is as follows:

"...patents shall be available and patent rights enjoyable without discrimination... whether products are imported or locally produced."

It is imperative that the above clause be re-evaluated due to its immense nega-

tive impact on the balance of trade of third world countries. By producing products within the territories of a third world country, the process would not only transfer technology (the basic premise for awarding patent protection), it would also provide a job market for the local population.

When TNCs do license their production process to Third World manufacturers, they often do not allow their licensees to export products to other countries. Such agreements are not considered "barriers to trade" under GATT, though they certainly serve to restrict access of pharmaceuticals to many markets. Moreover, if employees at a Third World plant improve the product to bring about an innovative product, they usually are required to grant all patent rights back to the parent company so that legal and commercial benefits stay in the hands of the first world corporate owners. Further, many process agreements ban the establishment of research and development facilities by the licensee, charge excessive royalties, or force the third world firm to buy inputs from the patent holder. Each of these limits the opportunity to develop indigenous industries and transfers wealth out of the Third World.

Pharmaceutical TNCs will sell products (patented and otherwise) to their subsidies at prices that are 87 to 2900% higher than found in the open market. This allows subsidiaries to show a net loss on their accounts thereby evading taxes in host countries. At the same time, subsidiaries will buy ingredients such as sugar from the parent company at excessive prices. Such manipulation of these prices has a negative impact on balance of trade for Third World countries. If patents were abolished, then indigenous firms would be free to purchase all in-puts from open markets, and hence not suffer such severe price manipulations.

Without patent protection of the TRIPs agreement, TNCs would be more willing to set up joint ventures with indigenous firms as they want to access markets even at the expense of sharing profits. This would allow indigenous firms to gain access to more sophisticated technologies and products which might not be available otherwise.

In short, it can be seen that patents in general benefit the TNCs and stifle the growth of industry in the Third World. Patent protection has never been able to provide the transfer of technology, especially to the Third World. The TRIPs agreement under GATT (WTO) creates a far more stifling arrangement. There is no reason to believe that it will generate any benefits to the developing world.

It is critically urgent that the citizens understand various dimensions of the debate and join hands to

Say **No**

to pharmaceutical patents

As said before pharmaceutical patents should not be allowed globally, and especially not in the Third World. A majority of the population here is living in poverty, with little access to critical health care facilities. Patenting of pharmaceuticals is directly tied to increase in prices, and hence for Third World populations further deterioration in the ability of individuals and governments to obtain essential medicaments.

to patenting of life forms

The most critical message which world citizens need to pass on is a ban on patenting of life forms: i.e. patenting of human genes, plant DNA material and other life forms. No human-being has the right to own another human beings' cells and withhold critical life saving information by creating a monopoly through patents. It should be remembered that the ultimate aim of patenting is profits. Of all reasons, monetary gain should never be a reason for allowing patents on life forms.

***Azra Talat Sayeed**, a social pharmacist, has recently done her doctorate on "Impact of GATT on Pharmaceutical Development in the Third World" from Minnesota University, USA. She is a member of The Network Council.*

A slightly different version of this fact sheet had been written for the Institute for Agriculture and Trade Policy, MN, USA.

MarketScan

Niclosamide & Thiazide:

Essential drugs not available, long live free market economy!

The Pakistani pharmaceutical market is full of paradoxes. While a large number of essential drugs are not available, the market is bursting at its seams with a multitude of irrational, non-essential, harmful and expensive drugs. The problem is getting worse every passing day with more and more essential drugs disappearing from the market and new registrations taking place at a breakneck speed. The situation has created all sorts of problems including irrational drug use, break down of quality assurance system, wastage of national resources, the poor being marginalized further from a healthy existence and a general deterioration and worsening of the quality of health care in the country. But who cares! The custodians of health in the country appear to be content with what is going on.

Consider that the only drug (niclosamide, brand name Yomesan - Bayer) for the treatment of tapeworm disease, common in the rural areas of NWFP and Balochistan and communities where unhygienic meat is consumed, is not available for the past many years in the country. Why? simply because the manufacturers do not find it profitable enough to market it! What happens to the patients? they get the drug through somebody travelling abroad or go with out any treatment. And the latter would be the case in the vast majority of patients.

Thiazides are effective antihypertensives and in fact the only group proven to reduce cardiovascular accidents in the old age. They are also useful in mild oedemas, hypercalciurea, primary tubular acidosis etc. Thiazides are inexpensive, do not cause hypokalemia and do not therefore need potassium supplementation. One important thiazide is bendrofluazide (Neo-Naclex - Glaxo) 1.25mg. No thiazide diuretic is available in the country for many years now. What do the doctors prescribe in the absence of these essential drugs? related drugs like Natrilix which are extremely expensive and do not have any advantage over, say, bendrofluazide.

The Network has been campaigning against the disappearance of essential drugs in general and the above two in particular, through the national media and our own publications, but nothing is being done about it either by the manufacturers or the Ministry. The best response we have so far had from the Ministry was an attempt at their part to de-register these drugs! What a way to get rid of the problem and our nagging reminders to it.

Duxil: Dubious endorsements

As has been mentioned in our previous issues some companies engage senior doctors in the country to lend credibility to their unscientific and unproven products. The product in contention here is Duxil: a combination claimed to "bring more oxygen to the brain and neurosensory tissue in intellectual, ENT and visual symptoms". Some of the very senior teachers of the art and science of medicine have been riding the Duxil band wagon and singing praises for this product all over the country recently.

The fact of the matter is that this drug has not been mentioned in any text book of repute, has not been favourably reviewed in a credible journal, is non-essential and at best an expensive placebo. Pakistan is certainly not a country where such drugs would be likely to have any positive impact on health care but would only result in unwanted side effects and loss of financial resources.

World Health Organization (WHO) has the following comments about one of Duxil's ingredients: almitrine,

"Peripheral neuropathy has been reported in a few patients receiving almitirine for longer periods. The indications for treatment have consequently been restricted in the Federal Republic of Germany. Some other countries have advised doctors to maintain patients under close supervision through out treatment and to restrict dosage to two out of every three months".

This information does not make a part of the prescribing information offered by

the company to the prescribers!

Ponstan: Jugglary of words

Ponstan's promotion in Pakistan by the manufacturer Parke-Davis has been controversial of late due to the claim that it "Provides unsurpassed efficacy compared to acetaminophen [paracetamol] in fever control" and "better tolerance". The Network pointed this out to MaLAM who challenged the trustworthiness of these claims. In their response, Parke-Davis stated that "Regarding the claim of better tolerance" our affiliate in Pakistan has agreed to remove this from future advertising pieces."

However, the company continues to endorse its claim about superior efficacy to paracetamol quoting a study of 50 children. The small study quoted does not provide scientifically valid evidence regarding the superiority of the Ponstan compared to paracetamol. A request for a copy of this study has not been responded to even after almost nine months!

Ponstan promotion violates the International Federation of Pharmaceutical Manufacturers' Association's (IFPMA) Code of Pharmaceutical Marketing Practices on at least three counts.

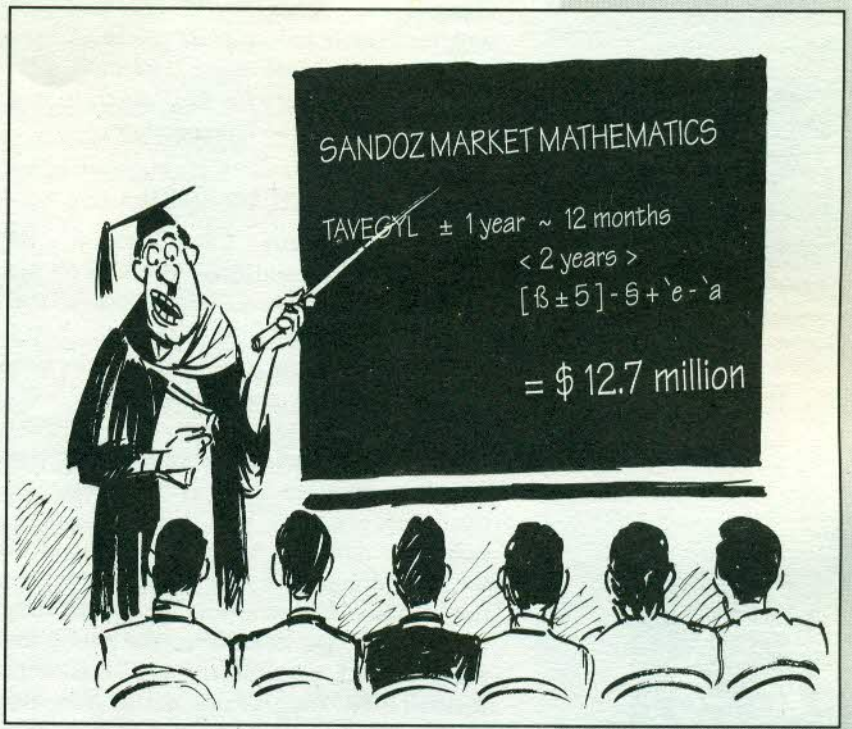
Halfan: Dear denial

Earlier this year we had pointed out to MaLAM about unethical promotion of halofantrin (Halfan) in Pakistan by its manufacturer SmithKline Beecham (SB). Three claims made in the promotional materials *"effective in all types of malaria, excellent safety profile, and convenient dosage"* were in contention. SB responded to MaLAM that *"We believe that halfan is ethically promoted in Pakistan and elsewhere"*. However, regarding its *"excellent safety profile"* claim SB responded that clearly such a statement is not acceptable, given the prior availability of data on cardiac side effects.

We are surprised that promotion accepted by the company's top brass to contain false claims is being regarded as "ethical". We were also surprised that none of the statements contained in SB's letter was supported by literature references or adequate studies. We would like to suggest to SB that denial is not the best way to respond to the company's problems.

Clemestine (Tavegyl):

The brochure currently being used by Sandoz medical representative for



clemestine (Tavegyl) promotion is indeed bizarre and misleading. The center page bold claim reads: "Tavegyl syrup can be recommended to children as young as 12 months age only, whereas syrup promethazine is contraindicated in children below 2 years of age". Both of these statements are wrong!

Promethazine is not contraindicated anywhere in the medical literature in children below two years of age. The fact of the matter is that promethazine is an essential drug and different dosage forms including syrup, tablet and injection are listed both in the WHO's Model Essential Drug List and the Pakistan National Essential Drug List. Clemestine, however, is not mentioned in either of these lists.

While the bold statement in this brochure claims clemestine to be recommendable to "children as young as 12 months" the brief prescribing information given at the last page in tiny print includes "children below one year of age" in the contraindications' sections!

We have been pointing out in the recent past about some marketing practices of Sandoz being objectionable and in violation of acceptable ethical norms. But this latest one seems to beat them all!

The Network has adopted the article published in Drugs & Therapeutics Bulletin (DTB), Vol. 33, No. 1, January 1995, (Consumers' Association, London) to suit Pakistan's specific conditions.

Drugs for the doctor's bag

General practitioners need to take medicines with them on home visits for use in an emergency or as part of acute treatment. DTB last reviewed drugs for the "doctor's bag" in 1989.[1] Here is the latest update:

Deciding what to carry

The choice of drugs for the doctor's bag depends on the conditions likely to be met, the shelf-life of the various products,[2] their costs and ultimately the size of the bag itself . In addition to drugs, many GPs carry diagnostic aids (e.g. test strips for blood or urinary glucose), instruments (e.g. thermometer, sphygmomanometer, peak flow meter), needles, syringes and swabs. Some also carry emergency kits, for example, a nebulizer with a $ß_2$ stimulants or a cardiac kit with drugs in a side bag attached to a defibrillator. In this article we list the drugs according to the conditions for which they are indicated, giving formulations in italics followed by suggestions about how they might be used.

Pain

Diamorphine (*5 or 10mg powder in vials plus an ampule of water for injection,* for reconstitution of powder before injection). For most patients in severe pain parenteral diamorphine (5-10mg, by subcutaneous or intramuscular injection) is usually effective. For the pain of myocardial infarction it should be given intravenously (5mg, as 1mg/minute, followed by a further 2.5-5mg if necessary). The addition of **cyclizine** *(50 mg/ml injection)*, 50mg by intravenous or intramuscular injection, or **prochlorperazine** *(12.5mg/ml injection)* 12.5mg by deep intramuscular injection, will reduce the likelihood of vomiting. However, intramuscular injection is not recommended for patients with suspected myocardial infarction, as it can cause haematoma in those who receive thrombolysis. Diamorphine is a controlled drug and must be kept in a locked container and its use recorded.

Naloxone *(400 ug/1ml)*-800ug-2mg should be given intravenously for opioid overdose. The dose can be repeated every 2-3 minutes upto 10mg if there is no response. If there is still no response the diagnosis of overdose should be questioned.

Diclofenac *(75mg/3ml injection)*-75mg given intramuscularly deep in the gluteal muscle is a useful non-narcotic analgesic for ureteric colic. The dose can be repeated after 30 minutes. The use of diclofenac avoids the need for pethidine in most patients with ureteric colic.[3]

Paracetamol *(500mg tablet or 120mg/5ml paediatric oral solution or suspension)* is safe and suitable for the relief of mild to moderate pain.

Vomiting

Cyclizine *(50mg/ml injection)*-50mg given intramuscularly or intravenously is the first choice for the treatment of vomiting due to vestibular disorders.

Prochlorperazine *(12.5mg/ml injection; 5mg tablets)*-12.5mg by deep intramuscular injection or 20mg orally then 10mg after 2 hours, or 5mg for labyrinthine disorders, and **metoclopramide** *(5mg/ml injection; 10mg tablets)* 10mg intramuscularly or intravenously over 1-2 minutes or 10mg orally are useful alternatives for nausea from underlying diseases. Because metoclopramide acts on the gut wall as well as centrally, it may be more useful in alimentary diseases. In high doses both of these drugs can (rarely) cause dystonic reactions.

Haloperidol *(5mg/ml injection)*-1-2mg given intramuscularly helps in patients with malignant disease where sedation is also required.

Psychiatric emergencies

Chlorpromazine *(25mg/ml injection; 25mg tablets)*-25-50mg given by deep intramuscular injection or 75mg given by mouth is widely used to calm agitated psychotic patients and also for hypertensive crisis in a patient on a monoamineoxidase inhibitor. Some doctors prefer to give **haloperidol** *(5mg/ml injection)* for emergency treatment of psychotic patients. 2-10mg should be given intramuscularly every 4-8 hours (or every hour if necessary). Severely disturbed patients may need upto 30mg initially.

Diazepam *(5mg/ml injection)* - 10mg

given by slow intravenous injection (5mg/minute) into a large vein (or intramuscularly if an intravenous route cannot be established) is useful for severe acute anxiety and panic attacks.

Asthma

The first treatment of acute asthma is now nebulized **salbutamol** *(1mg/ml solution)* 2.5-5mg or **terbutaline** *(2.5mg/ml solution)* 5-10mg. A bolus of **hydrocortisone** *(100mg powder as sodium succinate* for reconstitution with water for injection) 200mg (children 100mg) given by slow (over at least 30-60 seconds) intravenous injection or oral **prednisolone** *(5 and 20mg tablets)* 40mg (children 20mg) should also be given. Enteric coated tablets of prednisolone may be preferred by children, as they do not taste bitter.

Multiple actuations of a **salbutamol** or **terbutaline** metered dose inhaler into a large volume spacer device can be used if a nebulizer is not available. Such a device can also be used to treat patients with mild asthma who are unable to co-ordinate the use of a metered-dose inhaler (young children and the elderly).

Infection

Benzylpenicillin *(600mg vial)* should be given by intramuscular or intravenous injection in a patient with suspected meningococcal disease (infants under 1 year 300mg; children 1-9 years 600mg; older children and adults 1200mg). In a child with suspected meningococcal diseases a single dose of **dexamethasone,** 0.4mg/kg intravenously, should also be given.[4] Benzylpenicillin is also useful for the treatment of severe pneumonia in a patient with a previously healthy chest. **Amoxycillin** *(250mg vial)*, 500mg given by intramuscular or intravenous injection, is preferred for severe pneumonia in a patient with chronic respiratory disease.

The following oral preparations should be carried to start treatment where bacteria are suspected and before a prescription can be dispensed; **amoxycillin** *(250mg capsules or 125mg/1.25ml paediatric suspension)*, adults 250-500mg, children under 10 years half the adult dose, for other respiratory infections and otitis media; **phenoxymethylpencillin** *(125mg /ml oral solution)*, 62.5mg for infants upto 1 year, 125mg for 1-5 years olds and 250mg for 6-12 year old, for purulent tonsillitis; **trimethoprim** *(200mg tablets)*, 200mg in adults, for urinary tract infections; **flucloxacillin** *(250mg capsules)*, 250mg in adults, for cellulitis and acute skin infections; **erythromycin succinate** *(250mg tablets or 125mg/ml mixture)*, 250-500mg in adults and children over 8 years, 250mg in 2-8 years olds and 125mg in younger children, can be used when there is penicillin sensitivity and for suspected atypical pneumonia.

Hypoglycaemia

Glucose tablets, powder or a glucose containing drink is effective. A 50ml vial of **50% glucose solution** and a large syringe should be carried for intravenous administration. **Glucagon** *(1mg/ml)*, given subcutaneously, intramuscularly or intravenously, is an alternative to glucose.

Convulsions

Diazepam *(5mg/ml, 2ml ampoule for injection)*-For patients with convulsions, diazepam by rectal administration (10mg in adults and children over 3 years, 5mg in 1-3 years olds and the elderly, repeated after 5 minutes if necessary) is effective. Diazepam given by slow intravenous injection into a large vein (10mg over 2 minutes), or intramuscularly (10mg) if the intravenous route is not possible, can reverse the muscle spasm that occurs with acute lumbar disc prolapse.

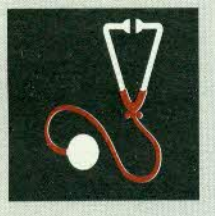
Bleeding

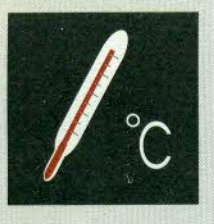
A sterile container of **saline** *(0.9%; physiological)* with a giving set and intravenous cannula should be carried to provide intravenous access and to start volume replacement.

Ergometrine maleate *(500 ug)* plus **oxytocin** *(5units/ml)* injection, 1ml given intramuscularly, will often stop the bleeding in a woman after an incomplete miscarriage or delivery. This injection should not be given intravenously.

Allergic reactions

Adrenaline *(1mg/ml ampoules)*, given intramuscularly or subcutaneously (adults, 0.5-1ml; 6-12 years olds, 0.5ml; 5 years olds, 0.4ml; 3-4 years olds, 0.3ml; 2 years





old, 0.2ml; 1 years olds, 0.1ml; under 1 year, 0.5ml) and repeated every 10 minutes if necessary, is the treatment of choice for anaphylaxis or acute angio-oedema with threatened airway obstruction. **Intravenous hydrocortisone** *(100mg powder for reconstitution with water for injection)* 100-300 mg should be given afterwards followed if necessary by **chlorpheniramine** *(10mg/ml injection)* given by intravenous injection (over 1-2 minutes to avoid the possibility of a transient fall in blood pressure), 10-20mg diluted with 10ml of the patient's blood drawn back in the syringe or with sterile sodium chloride 0.9% or water for injection.

Myocardial Infarction

Aspirin *(300mg soluble tablets)* is now part of first-line treatment for a patient with suspected myocardial infarction.[5]

Aspirin can also be used for mild to moderate pain in adults, but not in children under 12 years because of the risk of Reye's syndrome.

Some GPs may choose to carry and administer **fibrinolytic drugs** (e.g streptokinase, anistreplase, alteplase)[6] in patients with suspected acute myocardial infarction.

Atropine *(600ug/ml injection)*, 300ug increasing to 1mg as necessary intravenously, should be given if there is bradycardia and hypotension.

Glyceryl trinitrate *(as an aerosol that delivers 600ug/metered-dose)* given sublingually is useful for angina. The spray lasts longer than the tablets - 2 years compared with 8 weeks once the bottle is opened. Glyceryl trinitrate also helps relieve pulmonary oedema in acute left heart failure.[7]

Diamorphine (see PAIN)

Left heart failure

Frusemide *(10mg/ml injection)*, 20-50mg (at a maximum rate of 4mg/minute) given intravenously, relieves pulmonary oedema. It should not be given in right heart failure.[8]

Diamorphine *(5mg powder in vials for reconstitution with water for injection)*, 2.5-5mg given by slow intravenous injection, 1mg/minute, is also useful in acute left heart failure. Cyclizine may aggravate severe heart failure and counteract the haemodynamic benefits of diamorphine.

Dehyderation

Compound sodium chloride and glucose powder (ORS), in prepared sachets for dissolving in water, should be carried for immediate oral rehydration in children with diarrhoea.

Looking after the bag

It is best to store the bag in a cool place either in the clinic or at home. A maximum and minimum thermometer in the bag will record any fluctuations in temperature; most pharmaceuticals should be stored between 4 and 25°C. Bright light inactivates some drugs, such as injections of chlorpromazine and prochlorperazine, so the bag should be kept closed when not in use. Because the bag contains controlled drugs it should be lockable and during home visits not left unattented. If the bag is left in the car it should be kept out of sight and locked in the boot.

The batch numbers and expiry dates of all drugs should be recorded and drugs checked 6-monthly to see that they are still in date and usable. Expired products should be replaced immediately.

Conclusions

A well stocked doctor's bag is essential equipment for any general practitioner. The bag needs to be lockable, stored in a safe place at a medium temperature and carefully maintained. Its contents should be checked regularly to ensure that they are still usable.

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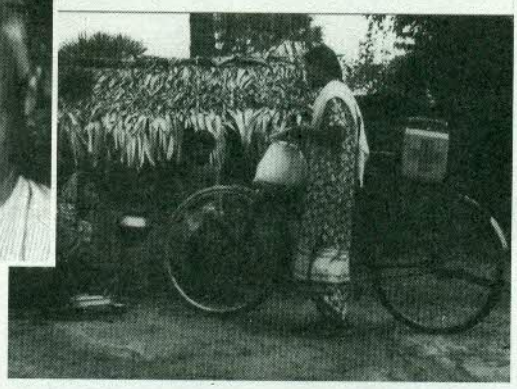
The Politics of Essential Drugs

The makings of a successful health strategy: lessons from Bangladesh

By Dr Zafarullah Chowdhury,
Zed Books Ltd, & Cynthia Street,
London NI NJF



ZAFRULLAH CHOWDHURY

The Politics of Essential Drugs

THE MAKINGS OF A SUCCESSFUL HEALTH STRATEGY: LESSONS FROM BANGLADESH

Dr Zafarullah Chowdhury is widely regarded as the father of Bangladesh National Drug Policy formulated in 1982. This policy developed an affordable health strategy based in part on the local manufacture of a relatively small number of essential generic drugs. This Bangladeshi experiment became influential in shaping health policies in many other countries. In this book Dr Chowdhury tells for the first time the complete story of this experiment, its achievements and limitations. In the words of a renowned Indian journalist and health activist: this book, "documents the effort of grassroots health initiatives to create a space in which the people's means, truthful information and rational prescription decisions prevail over corporate greed, intrigue, skulduggery, bribery and outright profiteering."

The books takes the reader on a guided tour of what transpired in the country's health sector during the years since her independence in 1971 till the formulation of NDP in 1981-82 and the storm it unleashed in the following years. While setting the context in which the saga of Bangladesh NDP was enacted, Dr Chowdhury describes how Transnational Corporations (TNCs) have flooded the market with unnecessary, ineffective and harmful drugs, use the Third World as a dumping ground, indulge in unethical and misleading marketing, syphon money out of poor economies by transfer pricing, patenting and high brand pricing in the name of research and development. Another hallmark of the situation as described by Dr Chowdhury is the general inability and apathy of doctors to discern the validity of drug company promotions making them highly prone to bad prescribing habits.

This is a fascinating account of the heroic struggle of a handful of committed people who brought about the "miracle" of Bangladesh NDP and their unflinching resolve to face up to the challenges posed by the combined power of TNCs and their allies in the government and the industrialized world in the subsequent years. Dr Chowdhury describes the events in detail which took place in the country and culminated in the formation of an Expert Committee who were to author the policy document and, later, see it through from success to success. The fury and storm unleashed in the wake of announcement of this policy by the TNCs, their omnipotent governments, and strangely, by the Bangladesh Medical Association, could have sent any policy anywhere in the world on a tail spin. Dr Chowdhury et al have been able to withstand immense pressures in protecting the policy. Until recently. But the struggle continues in round two.

The last few lines of the preface written by Susan George read: "Decent people (and I count myself self-indulgently among them) sometimes simply cannot grasp the lengths to which corporations and those who support them are prepared to go in the pursuit of power and profit. Study this exceptionally fertile case. It will stand you in good stead when you struggle for simple justice in the field of health or any other, wherever you may live."

NetworkNews

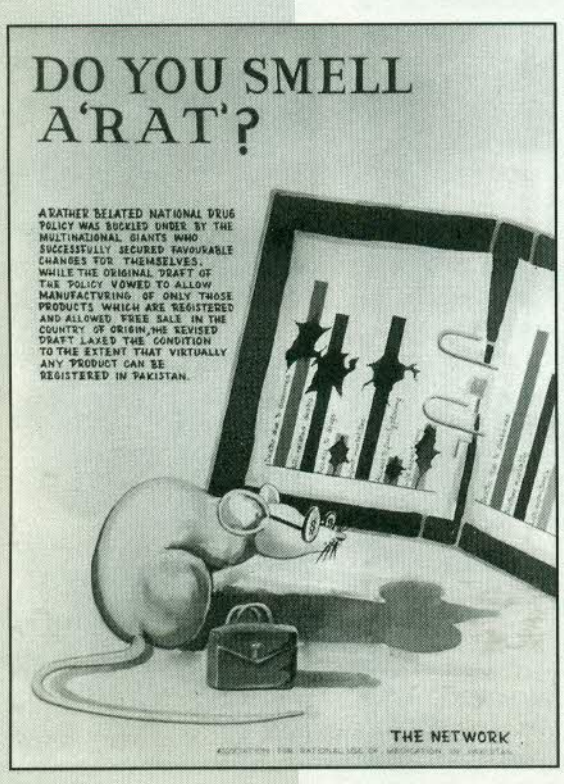
The Network Council and General Body meet

The Network Council's 7th bi-annual meeting and the Second Annual General meeting took place on the 31st August 1995 in Islamabad. The Council Members took a deep interest in the working of The Network Secretariat and expressed their satisfaction on the activities' report presented by the Coordinator. Different activities in the workplan for the next year also came under discussion and policy guidelines were finalized for them.

General Body Meeting re-elected Lt. Gen. (R) Mahmud A Akhtar as the Chairman and Prof. Tariq Iqbal Bhutta as the Vice Chairman of The Network Council.

Next (8th) CM's Meeting will take place in Islamabad on 21st March 1996.

International conference on national drug policies



The poster presented by ***The Network*** *at the exhibition accompanying the NMDP conference held in Australia*

The world wide initiative to develop national drug policies received a renewed impetus during 1995 in the International Conference on National Medicinal Drug Policies (NMDP) held in Sydney, Australia from 8 to 11 October. The conference theme was "The Way Forward". The Conference was sponsored by the WHO and Australian Government and attended by delegates from twenty two countries, mostly of the Asia Oceana regions. The Network Coordinator, Ayyaz Kiani, was invited by the Australian Government and Consumers' International, Malaysia, to attend. The Drugs Controller of the Federal Ministry of Health and a special representative of the Prime Minister, Dr Abdul Haye Saeed, were the other two delegates from Pakistan.

The Conference recommendation emphasized the need for regional consultation and mutual assistance in developing, implementing and sustaining NMDPs. The role played by consumer organizations in different countries in initiating work for development and sustenance of NMDPs was highlighted through out the Conference and it was agreed that presence of strong consumer groups have certainly been a very important contributing factor in all the countries which are leading in the field of NMDP. One message which kept resonating through out the four days of the Conference was : health is a basic right and a good investment and where presently allocated resources are inadequate and public spending in health is low, additional allocations must be made. When it comes to addressing conflicting demands made by health priorities of a nation against structural adjustments, privatization and market economy, it was a consensus decision in the conference that preference must be given to safeguarding public health. The Network delegate emphasized the need for an unequivocal demand from the national governments not to give into the pressures exerted on them by the MNCs and their collaborators like IMF and World Bank. And to not to compromise on giving top priority to equitable access to safe and effective drugs of good quality.

The Conference also recognized the presence of a strong "political will" to be an essential underlying factor for development and successful implementation of NMDPs in a country.

The Conference was very well timed as many countries of the region are at different stages of developing, initiating or implementing NMDPs and the opportunity provided by the Conference to the delegates to exchange their experiences and views will go a long way to achieve success.

Action for Rational Drugs in Asia workshop in Sydney

Since a large number of delegates representing consumer groups who came to Sydney to attend the International Conference on NMDP were also members of the ARDA initiative, this provided an excellent opportunity to hold meetings of the ARDA partners. ARDA is the Asia-Pacific arm of the global coalition of consumer groups working for promotion of rational drug use and campaign for the adoption of NMDPs. The ARDA members include health activists, academia and health ministry

officials. The Network is also an ARDA partner.

ARDA workshop preceded the NMDP Conference and was held from 4 to 7 October 1995. The workshop deliberated on four themes: NMDPs and Drug Legislation, Regional Cooperation: Sharing of Information, Drug Pricing Policies, and Economic Commercial and Technological Development of the Pharmaceutical Sector in the Asia-Pacific Region.

This workshop provided the ARDA partners with an opportunity to have a closer look at the regional context for their campaigns and they spent four working days to find ways and means to strengthening their country as well as regional campaigns.

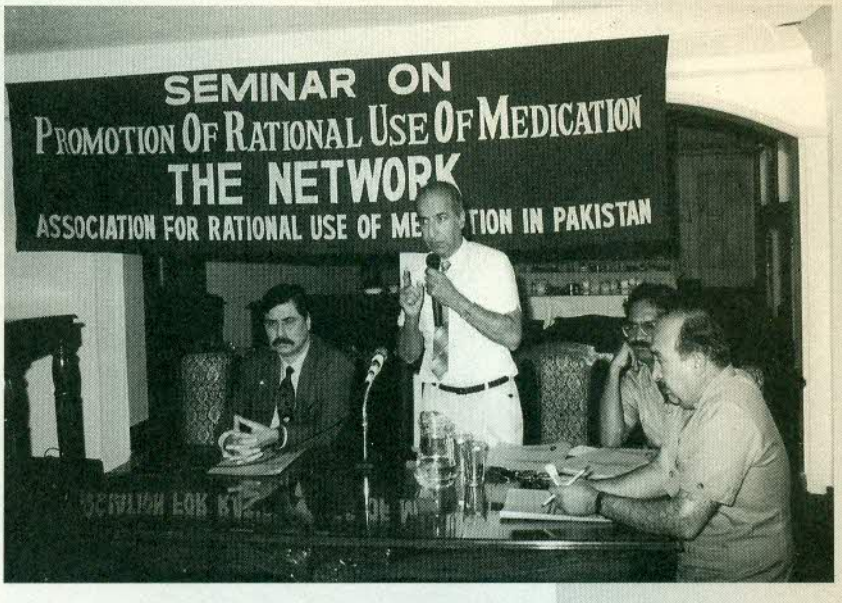
RUD seminar in Quetta

The Network held a seminar in Quetta on the rational use of drugs on 26 September 1995. The speakers included Dr Siddiqullah Khan Tareen, Dr. Ghulam Haider Khalid and Dr Arshad Mahmood. A panel of eminent medical professionals and faculty members of Bolan Medical College presided over the proceedings and consisted of Dr Arbab Sikandar, Prof and Head of Pharmacology Dept; Dr Meharullah Hashmi, Prof of Medicine; Dr A Ghaffar Nagi, Prof of Paediatrics; and Dr A Malik Achakzai, Prof of Psychiatry. Participants included doctors from different hospitals as well as general practitioners.

The presentations covered General Principles of Rational Prescribing (Dr Tareen), Cost-Effectiveness of the Treatment (Dr Khalid), and Critical Evaluation of Information Provided by the Pharmaceutical Companies (Dr Mahmood). The Network Coordinator introduced the aims and objectives of The Network, its achievements and working methods. He emphasized the need to have active collaboration between The Network and the doctors through out the country to have greater impact in the rational drug use campaign.

The presentations generated very lively discussion and questions were answered jointly by the speakers and the panel of experts. The doctors present were upset about the dismal conditions prevailing in the pharmaceutical sector in the country The Network is looking forward to having their support in future and build further on the basis of this seminar.

The Network is grateful to Dr Munir Ekbal, ENT Consultant, Quetta for his active role in making this activity possible.



Training course in community paediatrics

The Network Coordinator was invited to deliver a lecture entitled "Rational Use of Drugs" to the participants of the 8th Postgraduate Training Course in Community Paediatrics on 8th November 1995 at the Pakistan Institute of Medical Sciences. The Network Coordinator, Ayyaz Kiani, explained the basic elements of rational drug use with special reference to drugs used in paediatrics and also describe the context in which promotion of RUD concepts to the medical fraternity have become so imperative.

Wither expert drug committee?

In the aftermath of deregulation of drug prices announced by the last regime in 1993, a cascade of events followed leading to a total confusion about the pricing policy. Here we are briefly recapping the events in order to keep the reccord straight.

Drug prices rocketed after partial de-control announced on 12 June 1993 and it took Ministry of Health six months to take the right step in early January 1994 to make pharmaceutical industry announce a price freeze. This freeze was to last till 30th June 1994. (The freeze and relaxation continued alterna-tingly after 30th June in a most bizarre way and without any explanation by the MoH. The last freeze expired on 1st Nov. 1995). Immediately after, on 17th January 1994, an Expert Drug Committee, under section 10 of Drug Act 1976, was formed by the Ministry. Three Network Council Members and The Network Coordinator were included in this committee along with representatives from PPMA, Pharma Bureau and Chemists Association. The Committee was to be headed by the Federal Secretary Health with DG Health as another member and the Drug Controller serving as secretary.

This committee was assigned to design an effective system for monitoring prices, marketing, registration and deregistration, and rational use of all the drugs sold in Pakistan. The committee was to decide a drug pricing formula for those drugs whose prices were frozen and until they had given this formula the prices would remain frozen. The committee had a couple of meetings soon after its announcement, and a working group was also formed, which did some very useful work, but no meeting has been called by the Ministry in the past one year even after a very persistent demand on the part of The Network to do so.

Formation of the Expert Drug Committee was the right thing to do and if this committee had been allowed to work and take the policy making process in right earnest, there would have been no confusion as it exists today about drug prices.

Dear Reader,

We are thankful to all those who have written to us in response to our request for contributions in this Newsletter. We will start publishing these letters in coming issues.

Our observation about these letters, however, is that they tend to be generalised and patchy commentary on genuine problems related to pharmaceutical sector. What we actually need to publish here are:

** Concrete instances of abuse of medicines in hospitals and general practice.*

** Specific unethical promotional claims made by medical firms which you think are fake, vague or dubious or any other activity, commercial tricks, of the companies that you think is unethical.*

Besides this readers are most welcome to suggest ways to improve this publication.

This is an outline of our special area of interest, please feel free to improve on this as well.

If you need some helping resource material, inform us, we will do our best to arrange that.

Editor

Layout and graphics by Tahir Mehdi, Cartoons by Shujaat

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