Quarterly

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The Network's NEWSLETTER Rx

Association for Rational Use of Medication in Pakistan

National Drug Policy

Back to square one?

The draft of the country's first ever National Drug Policy has been revised. The act followed six months of hectic lobbying by the stake-holders in the country's health sector. In the revised draft ironically all the sections of the policy which were being supported by the consumer interest groups but opposed by the multinational pharmaceutical companies have been omitted, diluted or distorted.

Most of the health activists and concerned professionals were encouraged by the Ministry of Health's maiden initiative late last year to formulate a drug policy along the World Health Organization's guidelines. Though, judging by international standards, the Ministry was late by no less than two decades in discharging its duty of setting things right in the chaotic pharmaceutical sector, many lent it credence saying better late than never. The first draft circulated in February this year evoked mostly a positive response despite the fact that it failed to address certain important issues like drug pricing.

We had hoped that the policy would lead to significant improvement in people's access to medicines as it envisaged steps to promote the essential drug concept by asking all the companies to supply a percentage of their turnover as essential drugs. However, the new draft has simply omitted this section to the satisfaction of the multinationals. The policy also would have gone a long way in making the country self-reliant in drug manufacturing as it wanted the foreign companies to form joint ventures with local ones and thus facilitate transfer of technology. But this point has also been dropped to give the powerful multinationals a free hand to manipulate our highly under-developed health sector for making a quick buck.

Another section of the policy would have prevented Pakistan from becoming a dumping ground of useless, obsolete and even dangerous preparations as it had attempted to tighten laws regarding registration of new drugs. But the no-hold-barred pharma giants also managed to get rid of this section. In the last six months a very large number of drugs have been registered by the Ministry of Health without fulfilling all the requirements given in the Drug Act 1976. This could be a harbinger of another flood of irrational medicines which, propelled by marketing gimmicks, could sweep our health sector to new lows.

This revision by the Ministry has reduced the policy to a piece of paper meaning nothing. The alterations have killed the basic objective of having a national drug policy and made it a bureaucratic exercise in futility. As the draft policy still awaits approval by the Cabinet we urge the Ministry to review these changes which will adversely affect the objectives laid down in the policy and restore the provisions made in the first draft. Otherwise a very good opportunity for improving the pharmaceutical scenario will be lost. Perhaps forever!

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

DrugNews

WHO Alert

Cyproterone acetate (Diane®, Androcur®), indications restricted

The Committee for Proprietary Medicinal Products (CPMP) of the European Commission has evaluated toxicology data on cyproterone acetate and has concluded that there was evidence of significant hepatotoxicity, seen mainly in patients being treated for prostatic cancer, which appeared to be dose and duration related.

It was agreed that an additional warning statement on hepatotoxicity should be included in the prescribing information of all medicinal products containing cyproterone acetate (50mg or more).

Subsequently, the German Federal Institute for Drugs and Medicinal Devices (BfArM) has restricted the indications for medicinal products containing cyproterone acetate (Diane®, Androcur®) with effect from July 1, 1995. The BfArM, however, acknowledges that the currently available findings are neither qualitatively nor quantitatively sufficient for a final assessment of the carcinogenic potential of cyproterone in man.

Complete information in this regard can be requested either directly from WHO DRS Information Exchange Service, re. Alert No. 49, or from The Network.

NSAIDs: relative safety

The United Kingdom Committee on Safety of Medicines has reviewed 10 published epidemiological studies of the gastrointestinal risks associated with individual nonsteroidal anti-inflammatory drugs (NSAIDs). It has then compared the results of these studies with the frequencies with which these events have been notified for the most widely prescribed NSAIDs in the UK.

Within the published surveys, ibuprofen, which was included in seven of the studies, was consistently associated with the lowest risk. Conversely, azapropazone was included in only two studies, but in both of these it was associated with the highest risk. Among the other

Sandoz concedes on Parlodel, worldwide

The Swiss multinational company Sandoz has announced that Parlodel (bromocriptin) will not be promoted any more for the inhibition of post-partum lactation.

The parent company's newly appointed Chief Executive Officer (CEO) has acknowledged the "mistakes" made in Pakistan in promotion of Parlodel and has regretted it. The previous CEO had also acknowledged that in Pakistan the company had infringed the established code of ethics in promotion of Parlodel and had apologized for it.

Now even Sandoz's Pakistani subsidiary which has remained adamant through out and kept on using scientifically lame arguments to defend themselves has seen the daylight. They have withdrawn inhibition of lactation as an indication for Parlodel. Sandoz Pakistan has informed the Ministry of Health about their withdrawal but they are yet to announce it to the medical profession.

This concession comes after pharmaceutical activists throughout the world acted in unison to have this indication removed. We would like to acknowledge the efforts put into this campaign by our supporters on our request and extend our gratitude for it. There are many more such pharmaceutical products out there in our markets which deserve similar campaigning.

The best and lasting measure against such dangerous drugs and marketing practices would, however, be a rearguard action from our doctors and allied medical professionals by being more stringent and scrupulous in their appraisal and acceptance of drugs for prescription and recommendation.

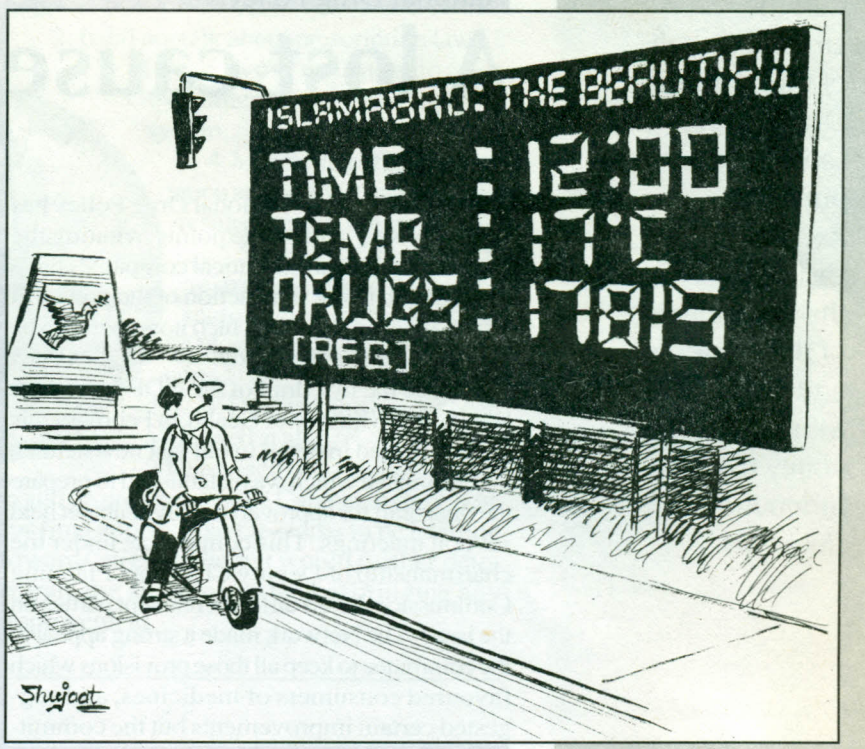
Sandoz Pakistan is somehow still hesitant about announcing the withdrawal to the medical profession. We suggest to our supporters to inquire from the Sandoz representative about the withdrawal of the Parlodel indication and inform us about the representative's response.

5.5 new drugs per day!

If Guinness Book of Records had some interest in how fast a country could throw new drugs into its market, Pakistan probably would have the honor of winning the slot. Registering new drugs is one thing our Ministry of Health loves to do.

In April 1994 a total of 15,188 drugs were registered with the ministry, the number jumped to 17,808 by June, 1995. That makes a total of 2,620 drugs registered in 15 months which comes out to be 165 drug registerations per month or 5.5 everyday (holidays, weekoffs inclusive).

How could a Ministry always complaining of resource crunch and staff shortage 'successfully' handle such a large number of registration applications is anybody's guess.



drugs included in these studies, diclofenac, indomethacin, ketoprofen, naproxen and piroxicam were consistently intermediate in the rank order of risk.

The same ranking has been demonstrated in the frequencies with which these reactions have been reported (as per 100,000 prescriptions) in UK between 1989 and 1993. Spontaneous reporting of other serious reactions to these drugs - including renal and hepatic damage, blood disorders, anaphylaxis and other allergies - conforms to the same general pattern.

In the light of these findings the Committee has recommended that NSAIDs associated with low risk should generally be preferred; treatment should be started at the lowest recommended dose; concurrent use of two or more such drugs is discouraged and all NSAIDs are contra-indicated in patients with peptic ulceration.

Azapropazone, it is proposed, should be reserved for patients with rheumatoid arthritis, ankylosing spondylitis and acute gout who have not responded to other NSAIDs. It should never be prescribed for patients with a history of peptic ulceration. Patients over 60 years of age requiring treatment over extended periods should not take more than 600 mg daily.

Source: Committee on Safety of Medicines. Current Problems in Pharmacovigilance, Vol. 20. August 1994.

Move to ban free drug samples

A bill intended to prohibit the distribution of drug samples to doctors has been introduced in the US Senate.

It is estimated that many hundreds of millions of drug samples are distributed by US drug manufacturers each year. The practice has long been regarded within the US as a controversial promotional practice, but it is also sometimes used to assist low-income and uninsured patients to obtain supplies of essential drugs that they could otherwise not afford. The bill provides for exemptions in such cases.

The practice has been portrayed in Congress as an inappropriate influence in prescribing, and as a threat to public health. Notwithstanding strict regulation, samples continue to be illegally repackaged and sold and, in some cases, they have been deliberately adulterated during the course of diversion.

Source: US Congress. Prescription Drug Marketing Reform Act, 1994 (S 2168).

Contents

Can the amended draft of the National Drug Policy serve any purpose? Recent events cast doubts over the usefulness of the exercise and the Ministry's ability to make independent decisions.

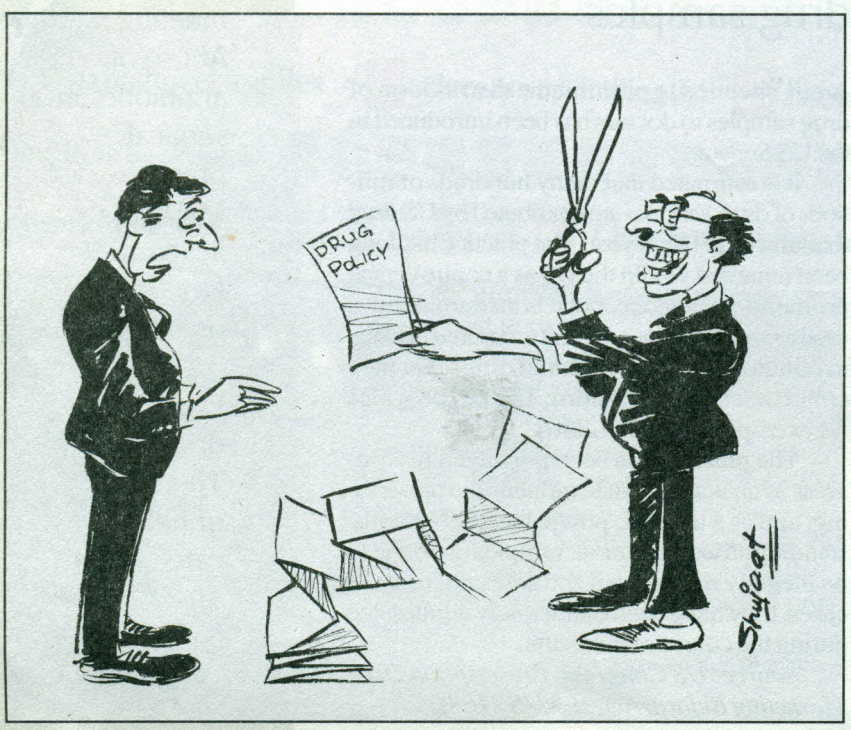
National Drug Policy

A lost cause?

The first draft of the National Drug Policy has been 'revised' and all the points irritating the multinational pharmaceutical companies have been altered to the satisfaction of the powerful lobby, Pharma Bureau, which now seems to be dictating our health agenda.

Since the first draft of the NDP was circulated by the Ministry of Health in February this year (reported in detail in our last newsletter), the committee which was established to prepare the final draft for approval from the Cabinet held several meetings. This committee, under the chairmanship of Deputy Chairman Planning Commission, heard different relevent parties on the issue. The Network made a strong appeal to the committee to keep all those provisions which favoured consumers of medicines, and suggested certain improvements but the committee preferred to be more concerned about the objections raised by the Pharma Bureau representing the 31 multinationals working in our country. Consequently, the second draft of the NDP circulated in June this year, had all the ingredients to please the Pharma Bureau.

The revision has rendered the policy impotent on all the important aspects which according to the WHO Guidelines should be the objectives of such a policy.

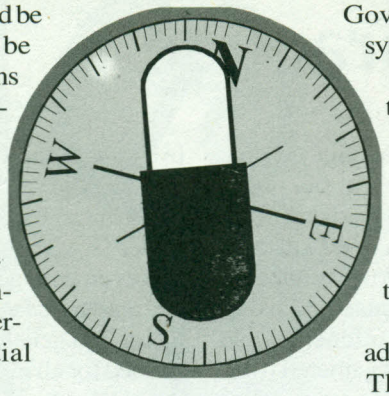


The most important point in the original draft of the NDP was that it laid proper emphasis on the promotion of essential drugs concept and supplemented the commitment by requiring all the pharmaceutical companies in Pakistan to supply a certain percentage of their turn over as the essential drugs. This would have changed our pharmaceutical senario substantially as of now 80 drugs of the Ministry's National Essential Drug List are not available and many are not even registered. But the June draft of the NDP has dropped this section altogether without giving any alternative how the policy will ensure the availability of essential drugs and gradual deletion of the non-essential drugs which at present have flooded the market.

Another major objective of the policy was to lead the country towards self sufficiency in pharmaceutical production and to achieve that the original draft provided that new foreign companies shall be allowed joint venture only with the national units. In the June draft this condition has been withdrawn in a very absurd way. Forgoing its earlier role of encouraging formation of joint ventures, the second draft has assumed the job of policing the splits in joint ventures. The related section in February draft said: "New foreign companies shall be allowed joint ventures only with the national units." The section now reads: "Where an MNC and a national collaborator partnership splits up, the former shall be permitted either to set up an independent unit or to enter into a joint venture project."

A large number of products are imported from the developed countries which are not available either in the country of origin or severely restricted due to their non-effectiveness, side effects and toxicity etc. In the February draft it was explicitly mentioned that the foreign companies shall be allowed to manufacture only those products which are registered, and their free sale is allowed, in the country of origin. This is the only way available to the developing countries to stop the import, registration and production of obsolete and dangerous drugs. In the recent draft this condition has been relaxed. It now says: "For the registra-

tion of a new drug the fact that a drug is registered in one of certain specified countries (e.g. USA, UK, European Union, Switzerland, Japan, Germany, China) would be necessary for registration to be allowed." This virtually means that any pharmaceutical product on earth can be registered in Pakistan. This makes even the present requirement of having free sale certificate from the country of origin redundant. This will lead to import and production of dangerous, toxic and non-essential drugs in Pakistan.



Not very surprisingly, the new draft retains almost all the weaknesses of the original draft which are:

1: The policy is non binding for the industry to follow a code of conduct in drug promotion.

2: It did not talk about prescription law.

3: There was no mention of Government's position on patent system.

4: Monitoring of implementation and periodic evaluation of results was not mentioned.

5: Scope of the policy is restricted only to the public sector which at best is only 20% of national drug consumption.

6: Drug pricing has not been addressed at all.

The revised draft policy which could be presented to the Cabinet anytime now for final approval so far seems to be heading towards an end where it would further deteriorate the situation instead of bringing any improvement.

National Essential Drug List

Review committee meeting

The Ministry moves to make the National Essential Drugs List less embarrassing!

The WHO guidelines for making essential drug lists highlight the importance of periodic review and revision of these lists. Such revisions are envisaged to make the lists dynamic and responsive to the changing disease patterns and/or changes in our understanding about them. However when our Ministry of Health summoned a meeting of experts to review its National Essential Drug List, it had some thing different in mind. The Ministry is sick of the criticism over its failure to get the NEDL implemented and through this revision it wanted to make the list less prone to criticism.

The Pakistan NEDL was prepared in May last year and had problems right from the day one. A significant number of drugs included in this list are either in a chronic short supply or are just not available in the market. And some are not even registered with the Ministry of Health! As if having made the list alone would achieve the objectives, the Ministry did not institute a system to implement the concept and ensure achievement of the objectives (if there were any).

The review meeting held on June 25 this year also turned out to be a bureaucratic maneuver of the Ministry to get rid of those drugs from the list which were either chronically in short supply or were not available at all or were not registered, and press coverage about the issue was continously embarrassing the Ministry. The move however was frustrated as Chairman of the review committee, Lt. Gen. (R) Mehmud Ahmed Akhtar, who is also chairman of The Network's council, strongly opposed it.

This was a most poorly attended meeting and had only three doctors (only one of them was a specialist) as compared to 45 odd doctors present in the committee which had originally formulated the list. Even these three doctors came to attend at a very short notice and there was absolutely no way they could have prepared themselves properly to make a meaningful input. Perhaps that was the purpose of this review?

Moreover, instead of forming a statutory review committee (say, a National Committee for NEDL Review), and officially notifying it, with proper representation of all the concerned medical specialities, the Ministry prefers to keep the process adhoc and whimsical. Constituting such a body of experts that could continously review the list by meeting periodically should have been an integral part of this nationally important essential drugs list. Whatever has happened in the formulation of the list, since then and during this first review is enough to convince a neutral observer that the whole exercise is a farce.

Abuse of antibiotics in surgical practice

Dr. Azam Yusuf and **Dr. Mohammad Ishaq** point out at the massive abuse of antibiotics in surgery and present a study to suggest that it is not necessary to use antibiotics in each and every case.

Abuse of antibiotics is common in the present day surgical practice in Pakistan. Millions of doses of all kinds of antibiotics, mostly unnecessary, are dispensed each day by the ignorant, gullible practitioner whose knowledge of pharmacology is gathered from bits of information doled out by uncanny salesmen of national and multinational companies.

The two cardinal hazards of hospital practice abuse of antibiotics and presence of cross infection, tend to reinforce each other and set up a vicious circle. The practice is responsible for a host of problems becoming more and more serious day by day.

In Pakistan persons unfamiliar with the basics of microbiology and pharmacology prescribe antibiotics. These includes many doctors, quacks, chemists, shop dispensers and friends/family of the patients.

To give you an example of how irrationally drugs are being used, I would quote a letter from a pharmacist. The letter was received in response to my letter to the editor of the Network's Newsletter written last year about the same subject. I will not mention the name of the hospital the pharmacist works with but I shall call it a busy hospital of adequate standard in a fairly large city. The letter goes as follows.

"Sir, We have a very well equipped O.T. with all necessary facilities. There are two senior and two junior qualified General Surgeons. You can imagine the work load of the surgeons by the fact that more than 2000 operations were done under G.A. in the year 1993. The problem is that even with good sterilization, disinfection and antiseptic facilities, antibiotics not less than 3rd or 2nd generation cephalosporins are prescribed for all minor and major surgical procedure like hernia repair, thyroidectomy, appendicectomy, laparotomy, prostatectomy, open, or closed reduction of fractures and C-sections etc.

The regime remains 1 gm, 3 times a day for not less than 7 days and then are switched over to a quinoline group injection or orally for further 5 days and then quinolines for further 7 days after discharge as out patients..

All this consumes over 3/4 of local purchase budget. Being a pharmacist I have to manage the procurements of medicine. You are requested for a detailed guidelines in respect of use of antibiotics in all surgical procedures."

This letter clearly shows how much antibiotics are being abused by some surgeons and this is more so by those working in the peripheral hospitals. Most of the surgeons who used too much antibiotics justify their use by saying that they are not sure about the sterilization in their operation theaters and about the uncleanliness prevalent in their wards. "What they are most concerned about is their own reputation."

Surgeons make such excuses to use antibi-

Dangers of antibiotic abuse

1. Development of drug resistance. Bacterial resistance may cause break down of suture lines, collection of pus and even death from septicemia, thus increasing both morbidity and mortality.

2. Change in normal flora of body leading to super infection due to over growth of drug resistant organisms.

3. Masking of serious infections without eradicating them.

4. All too often continued use of an antibiotic can itself be the cause of fever.

5. Widespread sensitization of population leading to hypersensitivity, anaphylaxis, rashes, blood dyscrasias, cholestatic hepatitis.

6. Minor side effects like diarrhoea, vomiting, skin rashes.

7. Serious toxic effects due to drugs, like: aplastic anaemia with chloramphenicol, ototoxicity and nephrotoxicity with aminoglycosides, pseudomembranous colitis with lincosamines, blood dyscrasias with co-trimoxazole, pancytopenia due to cephalosporins.

Dr. Azam Yusuf (FCPS, FRCS) is Assistant Professor of Surgery at Rawalpindi Medical College, Rawalpindi and Dr. Mohammad Ishaq (MBBS) is House Surgeon at D.H.Q. Hospital, Rawalpindi.

otics: There is improper sterilization in O.T. Our aseptic measures are poor, nurses and paramedical staff are not properly trained, wards are dirty, patients are unhealthy, environment is unclean. There is cow, buffalo and horse dung on the road sides and dust, dirt, garbage, flies and cockroaches everywhere.

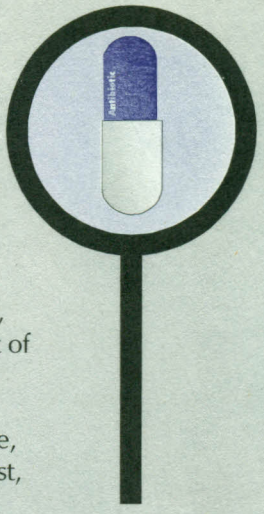
None of these excuses justify the use of antibiotics indiscriminately for as we all know: "Antibiotics are not a substitute for sound surgical technique and proper aseptic measures". (Surgical Infection, Surgery 1988)

Let me recount my own experience. After working in a hospital abroad, where I had seen minimal use of antibiotics, I was posted in D.H.Q. Hospital, Rawalpindi. It is not a posh hospital and certainly less well equipped than most other standard hospitals in Pakistan, with a very high patient turn over.

THE WAY TO RATIONALITY

NO antibiotic used in 85 clean cases, wound infection developed in only 5 cases.

Perioperative antibiotic used in 92 clean cases, wound infection developed in only 5 cases.



These operations of clean catagory were performed
From Sept. 1992 to Nov.1994, by the same surgeon i.e. me, under general anesthesia, on elective list, in the department of surgery at D.H.Q. Hospital Rawalpindi.
Operations like inguinal herniotomies and repairs, orchidopexies, repair of paraumbilical and epigastric herniae, operation of hydrocoeles, soft tissue swellings, lump in breast, varicose veins, lymph node biopsies, thyroid operations etc.

Against the routine of the hospital I decided one day not to give even a single dose of antibiotics to a patient after hernia repair. I just wanted to see what would happen. I kept a close watch on the patients wound, his pulse rate and temperature. There was no complication. I kept the patient admitted in the ward for seven days. Wound healed up nicely, stitches were removed and he went home without any problem. Encouraged I stopped giving antibiotics in selected cases of clean category. At the same time for the purpose of comparison I used perioperative antibiotics also in the same category of cases. I am carrying on with my study and want to complete it on a substantial number of patients in both the groups. As of now the results of the study are shown in the figure above.

Although the infection rate is twice that of hospital in advanced countries in clean cases. It is almost similar in both groups for the moment without any significant difference. Those patients who did get infection in both the groups were minor and easily controlled.

Recommending routine use of antibiotic prophylaxis in all clean surgical operations does not appear to be justified even for a country like Pakistan. (JCPSP, June 1994)

However there is a place of prophylactic antibiotics in potentially contaminated cases. We use selected antibiotics perioperatively i.e. one dose just before operation and two doses postop or at the most for 48 hours.

Principles of surgical antibiotic prophylaxis

When an antibiotics is to be used for surgical prophylaxis

- It is usually administered parenterally.
- Antimicrobial activity must be present at the wound site at the time of its closure. For this purpose the antibiotics is to be given immediately preoperatively and, in case of prolonged operations, it may be repeated once intraoperatively.
- The continued use of antibiotics after the completion of surgical procedure is unwarranted. If continued beyond 24 hours of surgery, the use of antibiotics may in fact be harmful as it increases

Antibiotic prophylaxis during surgical procedure cannot reduce the need for sterile and skilled surgical techniques. These drugs should never be used as an excuse for poor surgical technique

the chances of overgrowth of resistant micro organisms.

- The antibiotics selected must be active against the most likely contaminated microorganism. It need not necessarily include antibiotics that are active against every potential pathogen.

- It may be emphasized that the antibiotic prophylaxis during surgical procedure cannot reduce the need for sterile and skilled surgical techniques. (Editorial, JCPSP June, 1994).

- Majority of infections in surgery in the clean and contaminated groups can be controlled by narrow spectrum antibiotics.

- No doubt broad spectrum antibiotics do have very important role as Life Saving Drugs in serious mixed infection and septicaemia.

However giving broad spectrum antibiotics for prolonged periods in minor infections and clean cases is illogical. It is like trying to kill a tiny innocent bird with a cannon ball.

Principles of surgical infection therapy

Long established surgical principles should not be forgotten e.g.

1. Pus requires drainage and unless this is established, the patient's condition is unlikely to improve whatever antibiotics are given. (Principles of Antibiotics Therapy, Surgery, 1988). Inadequate drainage of an abscess prolongs morbidity and no amount of antibiotics or antiseptics will effect the outcome.

2. Likewise necrotic tissue requires removal to achieve resolution of associated infection. Antibiotics are often prescribed in apparent ignorance of these unassailable facts. (Principles of Antibiotics Therapy in Surgery, 1988).

3. Antibiotics should never be used as an excuse for poor surgical technique

- Long operations
- Inadequate hemostasis
- Presence of dead space
- Large non absorbable sutures
- Over enthusiastic use of diathermy
- Ischemic tissues and if operation has compromised, the blood supply to an organ.
- Presence of open drains

All these situations are conducive to wound infections. Antibiotics will not help in these situations.

4. In the prevention of post operative sepsis, there is no substitute for meticulous operative technique. The surgeon who traumatizes the tissues, leaves foreign bodies, hematomas in the wound, uses far too many ligatures, exposes the wound to drying, pressure from retraction exposes the patient to needless risk of infection

To summarise the main aspects of prevention of surgical infections are,

1. Careful, gentle, clean surgery
2. Reduction of contamination
3. Proper aseptic measures
4. Ancillary measures like restoration of normal immune mechanism, nutritional replenishment improving of local tissues perfusion.
5. Support of patient defence with judicious use of antibiotics.

The isolation of a microbe is seldom in itself an absolute indication for prescribing an antibiotic, although for example isolation of streptococcus pyogenes is virtually synonymous with the need for antibiotic treatment, this is not the case for many other organisms.

The urge to treat what is infected, a laboratory result should be resisted. Many clinicians become un-nerved by laboratory reports of microbe (particularly those with unfamiliar names) and turn immediately to antibiotic treatment. such a practice may actually do more harm. (Principle of Antibiotic Therapy, Surgery 1988)

Length of treatment

Most antibiotics are given for too long, the length of treatment required for the majority of infections is unknown, and many estimates of treatment are based on anecdote.

Duration of therapy must be finite, depending upon severity of disease and clinical responses. Generally most infections are to be treated for 3-5 days after full clinical response, but many times the duration has to be individualized. Many common infections are satisfactorily treated with only a few days of antibiotics and some such as lower U.T.I. can be cured with a single dose.

Under treatment results in drug resistance and relapse, while over treatment will result in side effects and super infection. A much more critical approach to the length of treatment is needed. Many side effects could be avoided, and a great deal of money saved.

Combinations

Similarly use of broad spectrum combination of two, three or even more antibiotics should seldom be necessary for more than a few days. Prolonged courses of combinations of antibiotics have become all too common place. Such a practice is seldom justified and results in colonization with resistant microbes or yeasts. The claim that antibiotics give "psychological benefits" is the argument of the feeble minded. All drugs including antibiotics are chemical poisons. Use them with utmost caution.

Ponstan for children:
A case of double standards

Prescribing information for Ponstan in the USA and Australia states that "safety and effectiveness in children below the age of 14 have not been established", but the company, Parke-Davis (an American multinational), would still choose to promote it for fever in Pakistani children. When the Pakistani Parke-Davis was asked by MaLAM (Medical Lobby for Appropriate Marketing Inc) to provide their evidence for their promotional claims they said: It "provides unsurpassed efficacy compared to acetominophen in fever control" and "better tolerance", but the company could not provide even the unpublished study referred to in the promotional material.

This is yet another case of double standards by MNCs.

Noscapine cough syrups:
Who will bell the cat?

The Committee on Safety of Medicines in UK announced in June 1991 that noscapine had been shown to be genotoxic on testing in vitro. Manufacturers of products containing noscapine were asked to issue warnings that they should not be prescribed for women of child bearing potential. To avoid this restriction Roche-UK reformulated their product Omnopon to exclude noscapine from it.

In our country there are at least four such products containing noscapine namely Noscapine syrup of AD Marker, Abenol syrup of PCM, Triad plusof NH Shahni and Dolocough of Progressive. These products are being sold here without any such warning. Will some body in the Ministry please bell the cat?

Lindane: Toxic marketing

Public Citizen, a US nation wide consumer organization with nearly 110,000 members, has petitioned the FDA to remove the drug lindane (indicated for treatment of scabies and pediculosis or lice) from the market due to high degree of neurotoxicity. Public Ctitzen has asked the FDA to immediately remove it from the market due to toxicity, the fact that it is carcinogen, and availability of safer and equally effective alternatives. According to data from IMS, 2.3 million prescriptions of this drug were filled in the US alone. This drug, which is registered in Pakistan by the brand names Lorexan (ICI) and Scabene (Stiefel), has 88 reported cases of neurotoxicity including 50 people with convulsions and two deaths. The WHO has also recommended since at least 1992 that lindane is not to be used for scabies or lice "because of its persistence in environment and its toxic degradation".

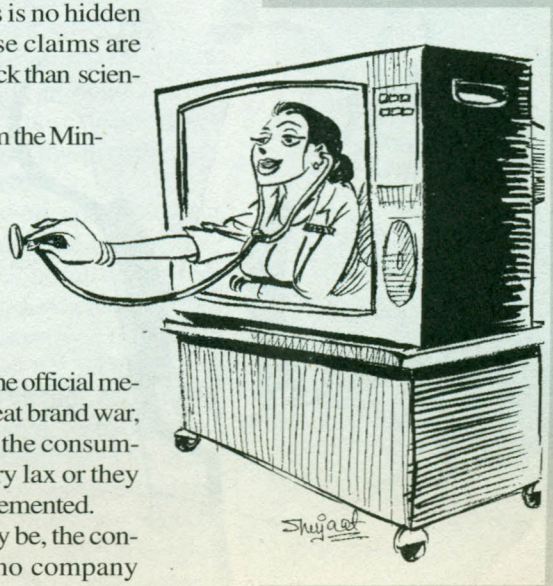
Health stunts for consumer goods promotion

Health has suddenly become a best seller. The most active ingredients in the advertising campaigns of a host of consumer goods these days are claims of having a medicinal value.

From the cholestrol free edible oils to plaque fighting tooth pastes and magical shampoos and skin whiteners to milk in paper cartoons all build their marketing strategies around fake or vague health claims. Their TV ads use images of doctors and scientists, to sound even more scientific they mention mysterious names of chemicals which their products contain and show exaggerated computer graphics to exhibit how their product will say for example penetrate the user's skin and do the claimed good.

A cosmetic product claims to be 'The solution of pollution'. A baby food ad asks mothers not to feed their babies natural food as they do not know what are the 'scientific food requirements' of children, it's the company that has the real recipe for health! This is no hidden fact that almost all of these claims are more of a marketing gimmick than scientific research.

PTV gets approval from the Ministry of Health for such ads and the Ministry in turn has a committee of experts that scrutinises these claims. There are laws to regulate the ad campaigns. Despite all this the official media is playing host to the great brand war, whose only casualties are the consumers. Either the laws are very lax or they are not being properly implemented.



Whatever the case may be, the consumers' concern is that no company should be allowed to distort science for quick profits.

Every visitor to a clinic or a hospital should not leave with a drug. **Tahir Mehdi** of The Network says that doctors should exercise their right to prescribe a no-drug therapy.

Drugs or no drugs

Freedom of prescribing

Remarkable developments in the field of medicine over the last half century or so have improved the lot of humanity to unprecedented and previously inconceivable levels. Fatal diseases which once threatened the existence of entire societies are now curable with a few doses of a drug.

This miraculous impact of drugs on the general health , however, gave birth to certain misbeliefs. It laid unjustified emphasis on the use of drugs and people at large started equating drugs with health. Since these beliefs lead to an unrealistic increase in the consumption of drugs, these are supported, fueled and at times generated by profit-oriented drug companies.

The indiscriminate use of drugs helped small pharmacies of mostly western countries pocket colossal sums in profits and become all-powerful global drug companies. It, however, has taken its toll on human health and resources. Massive negative impacts of irrational prescribing are today more than visible. It would be best to quote the example of antibiotics. Though antibiotics have saved and improved more lives than any other class of drugs, experts today are worried that the golden age of antibiotics might be over. The dramatic increase in antibiotic resistant strains of bacteria is alarming. "We have never been much more than one step ahead (of bacteria), and now it seems that this slender lead is in danger of being lost."

A study carried out in Pakistan in 1986-89 on children with acute lower respiratory tract infection found that 97% of *Streptococcus pneumoniae* isolates were resistant to at least one antimicrobial drug. 62% had decreased susceptibility to co-trimaxazol, 31% were resistant to it and 39% were resistant to chloramphenicol.

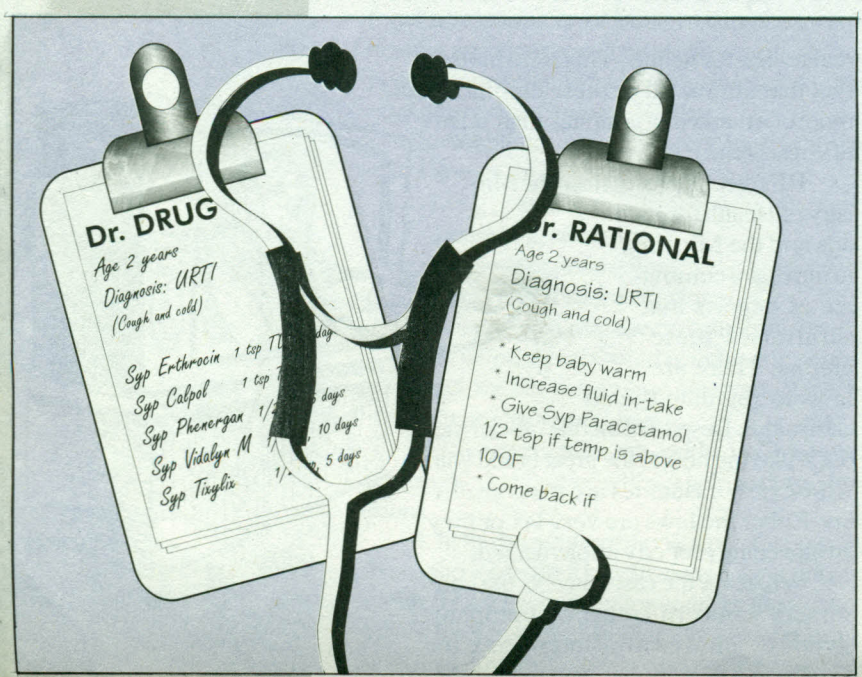
An inquiry into prescription patterns of general physicians in Karachi in 1994 showed that two out of every three patients (62.1%) were prescribed at least one antibiotic. Another survey of Peshawar GPs carried in 1990-91 showed that antibiotics were present on 89% prescriptions for childern with diarrhoea.

At the core of the misbeliefs which triggered this mad rush for medicines is the concept that drugs are the easiest and the best way to health. "Parents exert pressures on doctors to prescribe (drugs), expecting quick relief. In rural areas in India, parents insist on injections for even minor self-limiting illnesses in childern." (Balasubramaniam, K. 1987)

In a 1990 survey of pediatric prescribing in Karachi 19% of the doctors who prescribed appetite stimulants to their young patients said they did so on the request or demand of patients' parents. States of unwellness are seen by the people as disease, and for every disease there must be a cure, preferably by a course of pills.

But is there really a pill for every ill? Drug manufacturers love to say yes and patients wish it could be so while most doctors find themselves trapped between the expectations of their patients and pressures of the manufacturers and hence fail to formulate an objective answer to such a basic question. Doctors today are not free to assess and analyze the condition of their patient in the light of their knowledge of disease and medicine and make independent decisions. They are pressed into handing over a drug to everybody who walks into their clinic.

The 1994 inquiry into prescription patterns of general physicians in Karachi found that the average number of drugs prescribed to a patient was 4.86. The range was one to 14 drugs per



patient. According to the WHO number of drugs per prescription varies from 1.5 to 4 around the word. Pakistan falls on the higher side of the range.

Vital in generating this drug fetishism are however not the popularly held cliches about drugs, these are rather the concerted efforts of the pharmaceutical manufacturers that result in the unjustified bulk consumption of drugs. The manufacturers have basic differences in conception of drugs with health professionals. For them drugs are not primarily therapeutic agents, these are just a type of product whose sales mean making profits. The more the sales, the more the profits. David Jones, a former executive at both Abbott and Ciba-Geigy, provided a clear description of the industry's approach: "Prescription drugs are marketed as if they are cosmetics or candy. Claims are made beyond what the product will do. Demand is inflated beyond the medical need. Uses are promoted that are neither healthy nor wise."[7]

Overwhelmed by the pressures of the companies and partly in an attempt to not to 'disappoint' the patients, doctors have foregone their first and foremost choice - whether to prescribe any drug or not.

There are many situations where drug therapy is not required or treating patient means giving them no drug. "Many of the diseases encountered in general practice are self limiting or functional i.e. have no organic causes. Such disorders generally resolve with time and reassurances or superficial psychotherapy."[9]

Similarly infants and children have frequent but not usually serious illnesses. A child's frequent illnesses in early years are part of a natural process which develops his or her immature immune system. They do not need to take a drug in most of these cases.

In Scandinavian countries about 45% of the patients leave clinics without drug prescriptions while the figure in US is about 25%.

If our doctors have to play a role in saving the people from the catastrophic affects of excessive drug use, they will have to fight for the freedom of choosing between drug therapy and no-drug therapy. The first question that a doctor should ask himself after examining a patient should be: Does the patient need a drug or not? They should be as free in deciding in favor of a no-drug therapy as they are in choosing from among the different brands of a drug. There could be a pill for every ill but there shouldn't be a pill for every person who walks into a clinic or a hospital. Doctors should rather take time to explain to the patient why drugs should not be

used. A patient should be taught what can be done to get over the sickness on their own. They should be told that it is never risk free to take a medicine and that their 'disease' is not worth the risk.

Prescribing a no-drug therapy definitely is not an easy choice. When confronted with this question many doctors quote from their experience instances of a patient rejecting their prescription which had no drug or cheap, common drugs only. These examples are not untrue. But these should not be used as excuses as it does not absolve doctors from their prime professional responsibilty - curing ailments and not pushing drugs. More so because doctors have been instrumental in shaping this particular attitude in people towards drugs.

The problems may be big and varied but they are surely not insurmountable. We have examples of many countries, not all of them belong to the developed world, where concerted efforts of doctors have improved the health scene a lot.

To make the no-drug therapy acceptable, needs patients to be educated, restrictions on the activities of drug companies and a lot more. But to initiate the whole process is a doctors' historical responsibility. Clinics must not become sales out-lets of pharma barons lest history will call doctors silent and docile partners in crime.

In Scandinavian countries about 45% of the patients leave clinics without drug prescriptions while the figure in US is about 25%

Essential drugs concept has the potential of improving access to modern medicine. **Ayyaz Kiani** of The Network warns that words be put to action before it is too late.

Essential drugs:

Long awaited solution

In the early seventies, policy makers, managers, and activists in the pharmaceutical sector started realizing the emerging health problems due to inaccessibility of modern medicine to a large population of the world.

While in the third world countries both individual as well as public sector supply system were running out of drugs, the wealthy nations also were finding it increasingly difficult to pay the burgeoning costs of drug bills. Prices were escalating and purchasing power of the common man was being eroded fast.

To further complicate the situation, roars of a flood of new and expensive patented drugs could be heard just over the horizon of a booming pharmaceutical research brought in by a phenomenal technological advancement. Prospects of any improvement in this inequitable situation were bleak.

The WHO responded to this situation in 1976 by introducing the idea of "essential drugs" and offering it as a solution to the problem of dwindling access. An essential drug is understood to be one which has proven efficacy, is acceptably safe, relatively cheap, and can satisfy the health needs of the largest number of people. A very large number of drugs would certainly fall way short of this standard. Out of a total of around 6,000 active substances, the WHO has a total of 275 essential drugs now in its 1995 "Model List" which has had seven revisions since its first edition in 1976. This concept has simple logic and aims at bridging the gap by bringing in cost efficiency. For optimal use of limited financial resources in a health care system, the number of drugs available is suggested to be limited only to the essential drugs. These drugs are almost always no longer protected by a patent and are available in generic form.

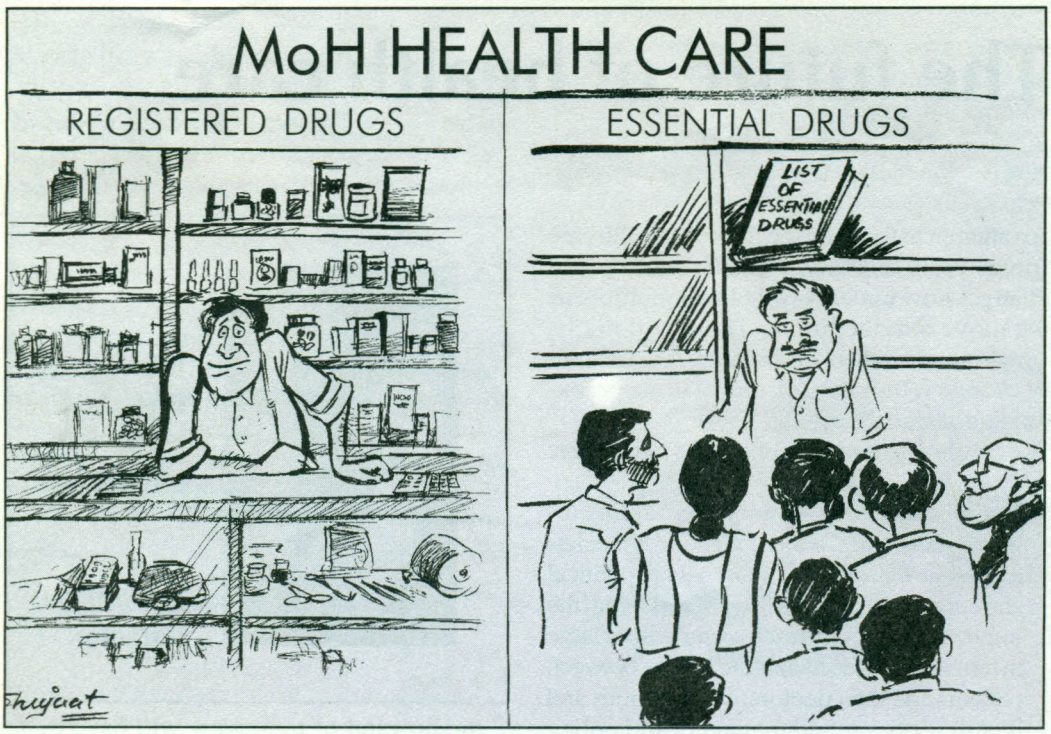
The idea was pioneered in 1977 by a South Asian country Sri Lanka, which was joined during the later years by many developing and developed countries. In order to assist countries in drawing up and implementing essential drugs concept as a part of their national drug policy, the WHO launched its Action Programme on Essential Drugs (APED) in 1981. APED took on two critical functions. The first was to provide conceptual leadership and advocacy in mobilizing and coordinating a global collaborative effort to improve the world drug situation. The second was to cooperate with the member states of the WHO and international, bilateral and non-governmental organizations in the formulation and implementation of the programme.

Designed to serve as a template, the WHO's Model List offers itself for countries to develop their own lists which are specific to their requirements based on disease prevalence and financial resources. The concept is not limited to developing countries alone. Many developed countries are taking advantage of its logic to develop drug formularies used widely by both public and private health providers and insurance companies. Australia provides an example of a developed country applying this concept in both public as well private levels to develop formularies and treatment guidelines. Applicability of the essential drug concept is such that more than 110 countries have adopted it to suit their disease situation and available financial resources.

During the last almost two decades of the essential drug concept existing in varying degrees of practice in the countries subscribing to it, the difference made in bridging the gaps has been quite significant; more so in some countries like Zimbabwe, Bangladesh, Sri Lanka (until around 1992-93 when essential drug policy had a set back there), Sudan and Australia. However, the limited results borne by the idea are not because of some inherent and intrinsic problem with the idea itself but due perhaps to its partial understanding, adaptation and implementation. A thorough evaluation of the concept and its ability to solve the problem of access to drugs at country and global level is in order.

The first effort by the Ministry of Health in Pakistan to formulate a drug list in line with the WHO's concept started in 1987 and the first list which had WHO input came in the following year. This list was called "List of Essential Drugs for Pakistan" and it proved only to be an academic exercise as it was poorly propagated and never implemented. (Provincial health authorities were engaged in the meanwhile in making their own lists parallel to the federal authorities and the whole concept was confused.) This list was followed by three more lists in 1989, 1990

Applicability of the essential drug concept is such that more than 110 countries have adopted it to suit their disease situation and available financial resources



and 1991. While the names of the subsequent lists kept changing, dissemination and implementation did not. In 1994 the exercise was started all over again and "National Essential Drugs List of Pakistan" came into being. Regrettably, this list has also met a fate similar to the previous ones. Besides that, a large number of drugs included in this list are not available (or not freely available) in the country! Some are not even registered! In the meantime, instead of any improvement, the situation of access to medication deteriorates even further.

Lack of political will, an overwhelming dominance of the transnational pharmaceutical companies, lack of support from the medical profession, corruption, and inadequate human and material resources are stumbling blocks in effective development and implementation of Essential Drug Policies in Pakistan, and elsewhere.

While these problems relate more to the environment in which this concept has to work, there has been criticism intrinsically at the concept itself. Such criticism came mainly from the pharmaceutical industry which feared that essential drug policies would impose a ceiling on the range of drugs available in the market and would limit their markets. Gradually however, the notions that basic needs must be met before expenditures on other matters can be considered gained ground, and such criticism shifted from the concept to more specific issues related to implementation.

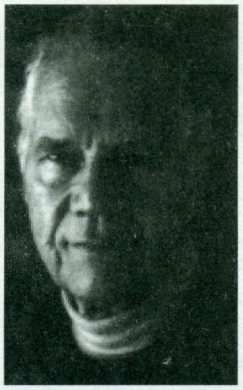
In order to widen its scope and prepare the ground for realization of its broader drug accessibility goals, the essential drug concept must also be actively applied and promoted at a micro level besides the macro policy level. And that is what we now intend to do on these pages of our Newsletter. From the next issue, we are starting a series of articles to create space for a discussion about the application of the essential drugs concept at, say, individual doctor's level, the speciality level and in the private sector institutions etc. How can a general medical practitioner make a formulary of drugs according to the concept to suit his/her own specific needs? What benefits such a formulary can be expected to allow in general practice? and likewise to specialists, by formulating such a list according to his/her speciality? What financial benefits can a hospital of any size derive from a formulary specific to their needs? etc. We believe that the problems listed above in the way of proper implementation of essential drugs policy at national level can be helped if the concept is popularized amongst the medical fraternity in the country. However insurmountable they may seem, these problems can be overcome if the medical fraternity sets its self to adopt it in letter and spirit and create a conducive environment for implementation of the Essential Drugs Concept.

Our readers are most welcome to write to us in this regard with ideas, suggestions and thoughts.

Lack of political will, an overwhelming dominance of the MNCs, lack of support from the medical profession, corruption, and inadequate human and material resources are stumbling blocks in effective development and implementation of Essential Drug Policies in Pakistan

This write-up by **John H. Byrant** was published as the editorial in the September-October, 1994 issue of World Health, the magazine of the World Health Organisation.

The future of health care



John H. Bryant, M.D., Emeritus Professor, Aga Khan University, Karachi

An attempt to focus on the future of health care forces us to acknowledge the widespread changes now under way that will multiply as we move into the future. These will not be simple trends with modest impact. A maelstrom of change is buliding up, global in scope, extending across all sectors.

Seven major streams of change can be seen.

Democratization. History is unfolding towards increasing democratization of societies. While there will be many social, political and economical expressions of this trend, the implications for the health sector will be large in terms of how decisions are made - between patients and their doctors; communities and health services; and managers and policy makers. Democratization, decentralization, and empowerment will be pervasive.

Equity. If there is one word that defines the values that will underline the future health care, it is equity. Two key concepts must be kept in view: universal coverage and care according to need. They require defining a population, assessing its needs, and ensuring that all receive care according to need, in keeping with available resources.

Ethics. Interest in ethics in relation to health care in rapidly expanding, appearing virtually in every corner of the education of health personnel, research involoving human subjects, and the care of patients and communities and increasingly guiding policies.

Science and technology. Health care finds its roots in science, and much of its growth in technology. The challenge is to use both well for the benefit of those who are in need.

Health care reform is global in its spread, and entails more than fine tuning of health systems - it is integral to large social and political transformations. Health care systems cannot avoid reforms, but neither can they be reformed independently of other social movements.

Hospitals. Are they part of the answer or part of the problem? Possibly both. Either way, the hospital of tomorrow will have to be closely integrated with the larger health care system, supportive of the community-based services with both outreach and referral, linked into collaborative networks of regional sharing of information and resources, with balanced responsiveness to both technological advances and social need.

Roles and education of health personnel. Health workers are inevitably at the centre of change of the health sector. Will they lead those changes, or impede them? The universities will play important roles in answering that question. The key lies largely in the perspective of the university on its role in society - cloistered behind academic walls, or grappling with societal problems.

We face large unanswered questions about health care for the future. Given the enlarging capacities of sciences, technology, information system and health care, will we be able to bridge over the inequities that afflict the global society? Or will these exciting advances simply add to the list of unshared gains? I have a clear and undiluted view on that question:

The sweep of change towards democratization and equity is too strong and too pervasive to allow technologies to remain unapplied to the needs of the underserved. There will be uncertainties and failures along the road, to be sure, but the direction and urgency of movement will be towards responding to these needs on a global scale.

Workshop at Shirkat Gah

In order to reach out to the ultimate consumers of medicines, The Network has started forming alliances and coalitions with NGOs working at grass roots level and have "health" on their agenda of work. Besides exchanging information and know-how at the managerial level with these NGOs, The Network is also looking at the possibilities of providing training in rational drug use to their health workers at community level. This training will aim at sensitising and informing the workers and helping them develop Rational Drug Use campaigns/messages and disseminate them to the communities.

Shirkat Gah is a Lahore based NGO working for women development and has a community based operational network. The Network was invited to conduct a one day workshop at their Lahore office on 6th July. This workshop was designed for their programme officers and office staff.

Dr. Zafar Mirza and Ayyaz Kiani conducted the workshop along with Cassandra Balchin of Shirkat Gah as the resource person. During this day long workshop basic concepts of rational drug use and essential drugs were discussed at some length. Participants showed keen interest in the subject.

Book 'Rational Therapeutics' awarded

The book titled "Rational Therapeutics - A Cost-Effective Approach" has been selected for the 3rd award, by the National Book Foundation.

The book has been written by Lt. Gen. (Retd) Mahmud Ahmad Akhtar, HI(M), MBBS, MD, DPH, FPAMS, FCPS, FCCP, Professor Emeritus in Medicine and Clinical Pharmacology/Therapeutics and formerly, Surgeon General/DGMS/(IS), Pakistan Army, Principal, Army Medical College, Rawalpindi and Dean Faculty of Medicine, Quaid-i-Azam University, Islamabad and Director General Medicine, Pakistan Armed Forces. He is also the Chairman of the Network's council.

The scenario of the health and pharmaceutical sector in Pakistan is characterized by inadequacies, irrationalities, imbalances and a lack of direction and implementation of operational guidelines. These are the bitter facts which provoked the author to write a book of this nature.

It has been the enthusiastic reception of the book by the readers and the dire need of cost effective therapeutics in the developing world which has inspired the author to write the third edition of this publication within a short period (since January, 1990). It is hoped that the message of "logic in prescribing" would be borne in mind to avoid biochemical effects of the drugs and to reduce the pressure on national exchequer.

Network's Newsletter becomes ISDB member

The International Society of Drug Bulletins has awarded the The Network's Newsletter full membership.

The ISDB formed in August 1986 is an international network which encourages the development of independent drug bulletins and promotes the international exchange of good quality information on drugs and therapeutics. The activities of the ISDB include exchange of information on new drugs, discussions on editorial procedures, sources of information, financial support of bulletins, organisation of training seminars by experienced bulletins for less experienced ones, collective support of bulletins which have difficulties etc.

Network Council member honored

Prof. Akhlaque-un-Nabi, ex-principal Sindh Medical College, Karachi and Liaquat Medical College, Jamshoro, has been awarded honorary Fellowship (FRCP) of the Royal College of Physicians of Edinburgh in recognition of his services in the fields of medical education and pharmacology. He is currently working as Professor of Clinical Pharmacology at the College of Physicians and Surgeons, Pakistan and is member of the Network's council.

The professor who set up the department of clinical pharmacology at the CPSP about a year ago has been instrumental in recently getting started the programme of Fellowship (FCPS) in Clinical Pharmacology and Therapeutics.

National ADR Center starts working

In pursuance of the plan of Government of Pakistan, Ministry of Health, the National Adverse Drug Reaction Monitoring Center has been established in the department of Clinical Pharmacology at the College of Physicians and Surgeons Pakistan, Karachi.

Having completed the preliminary work the center is now ready to receive and process the reports of suspected ADRs from the members of medical profession.

All doctors working in public and private sector (hospitals/clinics) are requested to send reports on the ADR Monitoring Center forms (Available with the ADR Center, Karachi and The Network) whenever it is suspected that a reaction has been caused by a drug, particularly following the use of newly introduced drugs. However, reports of adverse reactions to any drug, new or old, may also be sent to the Center, if considered interesting/important.

The reports received will be processed and analyzed by a team of experts and will form the basis for initiating timely intervention, whenever considered necessary, to minimize the damage caused by them. The reporting doctors will be kept informed of our findings and of other reports of reactions to the same drug received from any where in Pakistan or from other countries received through the WHO Collaborating Center for International Drug Monitoring in Upsala, Sweden, of which our center is an associate member.

The names of the reporting doctors and the patients will remain confidential and they will not be involved in any controversy or confrontation with any party because it is purely an academic activity aimed at protecting our patients from drug related morbidity/mortality.

The ADR Center hopes that members of the medical profession will actively participate in the programme by sending drug reaction reports to the center which will help in promoting safe use of drugs in our country.

HANDS: A Brief Profile

HANDS is a nongovernment, nonprofit, nonsectarian organization established in 1979 in Karachi by its present Chairman Prof. A.G. Billoo. It is a group of volunteers, dedicated and committed health and management professionals. HANDS is working to improve health and education status in the rural Sindh with special focus on women and children and aims at over all development of the rural communities. Research and training at all levels is their preferred strategy to achieve these goals.

HANDS has started a series of seminars in Sindh and has so far conducted seminars on Rational Use of Drugs in Children for family physicians in Dadu, Mirpurkhas and Larkana during the months of Dec. '94, Jan. and Aug.'95 respectively.

Dear Reader,

We are continuing our efforts to make this newsletter more readable, comprehensive and responsive. We have added some new sections to it and have reshaped others.
We want to further improve it but for that we need your input.
Besides suggesting ways to improve this publication you can also write for us.
You can write about:

- *Instances and patterns of abuse of medicines in hospitals and general practice.*
- *Any practice, circumstances or activity you find responsible for irrational use of drugs.*
- *Promotional claims made by medical firms which you think are fake, vague or doubtful or any other activity of the companies that you think is unethical.*

These are just broad outlines 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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