'Singing About the Dark Times'

Bangladesh Drug Policy

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The Politics of Essential Drugs – The Makings of a Successful Health Strategy: Lessons from Bangladesh by Zafrullah Chowdhury; Vistaar Publications, New Delhi, 1996; pp 192, Rs 195 (HB). First published in 1995 by Zed Books, London and Dag Hammarskjold Foundation, Uppsala.

THIS book is an excellent primer about the trials and tribulations of Bangladesh's radical drug policy of 1982, what was the historical build up to it, what happened when, who tried to – and are still trying to – derail it, and what is the upshot of it a decade and a half after. The author, Zafrullah Chowdhury, has had an unique vantage point in that he was a prime mover, if not the father, of the National Drug Policy (NDP) of 1982 and has been willy-nilly a focus of controversies that continue to be raked up almost every year since.

Drugs form an important part of the modern health care system; and in terms of costs, drugs form a significant percentage of costs of health care. It is therefore necessary that prescription costs be minimised; and in turn doctors ought to take care to make the correct diagnosis and to see that the prescription matches the disease of the consumer. It also means that medicines be low-priced in, especially, a poor country; and only the lower-priced medicine be prescribed when confronted with a choice of equally effective medicines.

But unfortunately this has not happened in reality. A study of Dhaka Medical College (1992) found that 79 per cent of prescriptions contained at least one error, resulting in overdose, undertreatment or adverse reactions. Aggressive promotion by drug companies was identified as the main cause of bad prescriptions [Anwar 1992]. An extensive study of prescribing habits of GPs and paediatricians in Indonesia found that GPs wrote fewer drugs per prescription than paediatricians [YLKI/ARDA 1989]. Paediatricians often wrote two or more antibiotics in the same prescriptions. A 1994 Pakistan survey in Karachi among leading GPs showed that the average number of drugs prescribed per consultation was 4.86; 73.3 per cent of children were prescribed at least one antibiotic; 40 per cent prescribed dipyrone (brand name Novalgin); 85 per cent prescribed kaolin-pectin in syrup form; and 60 per cent prescribed Lomotil in diarrhoea [Ahmed 1994].

A more recent study in India on the study and use of pharmaceuticals in Satara district in Maharashtra found that the overall quality of prescriptions of doctors both in public and private sector was low. "Due to irrational prescriptions, 69 per cent and 55 per cent of the money spent on prescriptions in the private and public sector, respectively, is a waste, with an average of 63 per cent. Projected to the Satara district level, this wastage amounts to Rs 17.7 crore out of the total drug supply (in the district) of Rs 22 crore" [Phadke 1995].

Why do these occur? Are not doctors expected to be scientific professionals? Can even senior doctors be prescribing wrongly? In reality, most doctors are anything but scientific in their prescriptions. Your typical doctor sees himself/herself as a profit-maximiser. In attempts to rationalise pharmaceutical operations, the opposition therefore comes mostly from national medical associations and other vested interests within the medical profession. Indeed, with such doctors as healers, who needs enemies?

The pharmaceutical industry throughout the world has been found to be both corrupt and powerful. It corrupts the medical profession, the policy-makers, and, as the Lentin Commission so amply documented, the Food and Drug Authority (FDA) too. Internationally, the top 20 companies had more than 50 per cent of the global sales (1992-93). Profits over sales varied from 25 per cent to over 37 per cent with Glaxo at 34 per cent, Merck at 37.1 per cent and so on. Sales of top companies varied anything from 55 to 89 per cent, and in case of the Swiss companies Ciba-Geigy, Roche and Sandoz over 95 per cent of the sales of were to foreign markets.

In spite of a thriving global (and national) pharmaceutical industry, drugs are out of the reach of the majority of the people. They are costly and overpriced. Other concomitant factors which make it difficult to reach affordable essential medicines to people have been: drug production of individual companies not matching the disease patterns prevalent; proliferation of unnecessary, ineffective and harmful drugs; exaggerated and misleading claims of drug companies; the dumping of drugs of doubtful efficacy by TNCs (and in case of India, 'national' companies too) in the third world; promotion of brand name drugs over generic drugs; transfer pricing by which a drug company imports raw material from its parent company or subsidiaries at inflated prices; and research and development as an excuse for high pricing. The situation is made worse by lack of knowledge and awareness in doctors about the motivating commercial interests of drug companies. And when aware, they tend to become willing accomplices for the quid pro quo of a few mundane gifts, a foreign trip, a seminar sponsored or even a Maruti car thrown in.

Internationally, and nationally, the 1970s symbolised some bold, if chequered, attempts to rationalise the drug industry starting with India's reform of its Patents Act (1970); the pioneering Sri Lankan attempts at regulation of its pharmaceutical sector (1971); the introduction of generic names in Pakistan (1971); and the Allende government's attempts to introduce a rational drug policy in Chile and the discovery of Pfizer's involvement in drug smuggling both of which actions contributed to the murder of Allende on September 11, 1973. Other landmarks of the decade include the Generic Drug Law of Afghanistan (1976); the Hathi Committee in India (1974-75) that made extremely sensible recommendations only to be shelved by and large; and even a call by the Non-Aligned Meeting (NAM) held in Colombo in 1976 to regulate the pharmaceutical industry and in particular the passing of resolutions calling for a limited, essential list of drugs affordable and available to all. Even Canada (1977) and the Montana State Assembly (1977) of the US took actions to encourage the prescription of generic drugs while several pioneer NGOs demonstrated the viability and feasibility of village-based community health programmes using a select list of essential drugs.

Among all these initiatives, arguably the most important and influential globally, has been the WHO Expert Committee's report titled *The Selection of Essential Drugs* (WHO, TRS 615, 1977). The little 36-page booklet was a bolt from the blue for the international pharmaceutical lobbies like International Federation of Pharmaceutical Associations (IFPMAs) and the US Pharmaceutical Manufacturers Association (PMA), both of which strongly opposed it. This booklet advocated a model limited list of essential drugs defining essential drugs as those that were 'indispensable for the health needs of the population' and also available at a reasonable cost. Its tentative identification of an essential drugs list was to be considered a 'common core' of basic

needs which had 'universal relevance and applicability'. This was one of the few acts which has somewhat salvaged WHO's disappointing reputation as one that is bothered about poor people's needs.

Things were back to normal however with the next edition of *The Selection of Essential Drugs* (1979). Catapulting to the criticism of the pharmaceutical industry lobby, the report shed its teeth. The second edition made it 'crystal clear that essential drugs were for third world countries only and made no reference to the universal relevance and applicability of a model list'. The expert committee no longer called WHO and member states to 'widely disseminate' the book. Concomitantly, WHO's Action Programme on Essential Drugs, initiated by the World Health Assembly of 1978, never took off as it did not get the necessary backing from within WHO. Also, by the end of the 1970s, several of the attempts by third world governments to rationalise and regulate the pharmaceutical industry had fallen by the wayside.

Key Events

Thus when in the 1980s, Bangladesh attempted to clean up its drug industry, it did not have many encouraging examples to go by, except the confidence coming from the pristine glow of a freedom just wrested after a heroic struggle. India's own Hathi Committee was an encouragement of sorts. But Bangladesh, unlike India, depended heavily on imports of basic raw material bulk drugs, and therefore MNCs, a few local companies, indenting agents and assorted rentiers ruled the roost.

The key events to the Bangladesh National Drug Policy (NDP) of 1982 – the theme of this book – were the taking over of general Ershad as president on March 24, 1982 and the appointment by him, just a month later on April 27, of an expert committee to review the drug situation in the country and make recommendations for a National Drug Policy consistent with the health needs of Bangladesh. What happened subsequently, is history but bears repetition.

The expert committee came out with 16 criteria to be met by all pharmaceutical products imported into or manufactured in Bangladesh. These criteria, much of which the government of India could adopt for the good of India, resulted in a basic list of 150 drugs plus a supplementary list of 100 specialised drugs. The old British Drugs Act of 1940 (still current in India) was to be revised and replaced even as a series of measures to ensure manufacture of quality drugs were to be undertaken. Unani and Ayurvedic drugs were also to be critically scrutinised. Most important was a proposed pricing policy that put ceilings on tablets, capsules and liquids.

The impact of these measures was to be seen a decade later (1992):

- Essential drugs increased from 30 per cent to 80 per cent of local production.
- Drug prices stabilised, increasing by only 20 per cent, compared with an increase of 178.8 per cent in the consumer price index. The drop in price in real terms made drugs more affordable.
- Bangladesh companies increased their share of local production from 35 per cent to over 60 per cent – overall, local production increased by 217 per cent.
- Less dependence on imports and prioritisation of useful products saved the country approximately US dollars 600 million.
- The quality of products improved – the proportion of drugs found to be substandard fell from 36 per cent to 9 per cent [Chetley 1994].

All these are amply illustrated by figures in the book. One of the most important outcomes was the abolition of transfer pricing especially by TNCs which were resorting to over-invoicing of imports of capital machinery, raw material and packaging materials.

Even the contentious generics issue was somewhat circumvented by devising a strategy to achieve the main benefits of generic drugs without making the marketing of drugs under generic names compulsory: manufacturers were free to market their drugs under brand names, provided the generic name was printed underneath the brand name in the same size of type; and drugs with same ingredients were to be sold at the same prices "irrespective of whether they were brand name drugs, branded generics or commodity generics".[1]

Misleading drug promotions however continue to be a problem in Bangladesh. Deceitful promotion by Ciba-Geigy of the anti-TB drug rimactane (Rifampicin) in 1988-89 and of maprotiline (brand name Ludiomil) in 1991 are some of the many instances cited by the author. Roche, the 'champion bribe-giver', continued its 'outstanding record of unethical drug promotion, leading to irrational prescription.' To illustrate his point, the author details the marketing of Ceftriaxone (brand name Rocephin) advocated by Roche for the use of certain serious bacterial infections like meningitis. The drug, apart from being very costly results in abnormalities to plug which the resulting treatment turns out to be even costlier. Roche introduced Rocephin as a magic drug to doctors in Bangladesh. The dosage was announced as a single daily injection for serious infections. It later changed it to 'thrice a day works better and faster'. Roche, according to the author, bribed, feted and dined a number of consultants in Bangladesh resulting in the piquant tragegy that every second prescription of many senior surgeons and paediatricians in Bangladesh has Rocephin in it.

Bad prescriptions thus have continued to plague Bangladesh despite a rational drug policy, although studies have given evidence of improved prescription patterns. Prescription patterns in Bangladesh continue to reflect the frequency of medical representatives' visits, particularly among medical teachers and consultants. Elsewhere, a study by Bero et al, on the number of ('medical', 'scientific') symposia proceedings published in medical journals suggests that such company-sponsored 'scientific' symposia do alter the prescribing patterns of physicians often resulting in inappropriate and expensive drugs even for unapproved indications. [Bero et al 1992]

Back in 1982, when the NDP of Bangladesh was announced, there was considerable storm and fury. The US ambassador to Bangladesh, Jane Coon, thought it against her country's interests, conflating, as is usual among elite diplomats, interests of American people with American capital. She got together ambassadors of other leading pharmaceutical exporting countries to delay the implementation of the NDP, with overtones of withdrawal of aid. Lobbies within the Bangladesh press were mobilised by the US embassy in Dhaka to make bleak forecasts about the future of Bangladeshi health under NDP. This behaviour of the US towards Bangladesh would be repeated five years later with the Philippines government in 1987. When the latter announced the Philippines National Drug Policy, two influential US senators and authors of a mini-Marshall aid-like plan to Philippines wrote to president Aquino that the task of stimulating the US investments would become 'more difficult' if a national drug policy were implemented. The upshot of such pressure was the collapse of the Philippines Generic Drug Policy.

Pressure from vested interests among medical and business elite within Bangladesh led to the appointment in June 1982 of a Review Committee to review the NDP. About the same time, ambassador Coon also informed that a four-member 'independent, scientific committee' was to arrive to examine the drug policy and advise the Bangladesh. Both these so-called review committees were exercises in advocacy of business and partisan interests. And in the case of the US government's 'scientific' committee, independent scientists were conspicuous by their absence, the committee being composed of a quality control manager, two marketing managers, and a public relations officer. Such pressure was however withstood by Bangladesh, and by president Ershad, surprising sceptics. NGOs and health activists in Europe, the US and India came

out in support of the NDP. In the midst of this arm-twisting and muscle-flexing folly of his country's government, the American public health activist, Sydney Wolfe, put things in perspective: "Imagine the outrage of the US public if a foreign government asked us to delay implementing a health-protecting decision of our Food and Drug Administration or the Environmental Protection Agency. Moreover, it is rather naive to ignore that Bangladesh is a US aid recipient and that a hope expressed by our state department is perceived as a threat, veiled or unexpressed though it may be."[2] He and a colleague, Gordon, also wrote to the Bangladesh health minister, Shamsul Huq, "The .... measures you have adopted to encourage the development of a viable domestic drug manufacturing industry have been adopted by most if not all industrialised countries in the form of tariffs, quotas and subsidies."[3]

Within Bangladesh, there was a courtroom drama of sorts, with president Ershad presiding, between the review committee of the NDP and the expert committee who originally proposed the NDP. The meeting was a crucial one and president Ershad was "convinced of the scientific validity of the NDP" (p 84).

There was, and appears to be still, no let-up in the battle since. This book goes into enormous detailing of the moves and countermoves. This exercise of the author is very instructive for those who undergo similar battles for similar causes. In a crooked world, straightforward things which benefit all the people all the time are opposed by a few dominant interests and often by so-called educated professionals, succumbing to the propaganda and allurements of the business class. The orchestrated and uninformed opposition to the Bangladesh NDP is a classic example.

National Health Policy

A pricing policy in 1987, subsequently modified in 1989, tried to put brakes on the prices. Also, realising that a National Drug Policy is not enough, a four-member presidential committee was appointed – on March 18, 1987 – to formulate a National Health Policy (NHP), of which the author was again a member. The NHP is again something India could profit by emulating.

The winter session of the Bangladesh parliament in January 1990, saw the announcement of the NHP by president Ershad. The NHP called for, among other things, abolition of private practice by all doctors employed in government medical colleges. At the same time their salaries and perks were to be hiked upwards of 150 per cent with full housing, transport, etc. A system of medical audit was to be introduced. The health budget of the government was to be increased from 2.5 per cent to 10 per cent. Medical negligence was to be severely punished. And many unhealthy practices like smoking, narcotics additives, etc, were to be severely curbed even as sale of harmful pesticides were to be banned. Health and family planning activities were to be decentralised and powers handed over for health administration to local leaders, doctors, consumers, freedom fighters, women's organisations, etc. When a bill in parliament was later introduced in October 1990 so that the NHP became law, events erupted and saw to it that the NHP never became the law of the land.

A perfectly sincere policy aimed at promoting people's health, was termed by the Bangladesh Medical Association (BMA) as anti-people. This was par for the course. On October 17, 1990, the BMA called for a 72-hour strike to protest against "the anti-people health policy". The author and two other active colleagues were expelled from the BMA. Later on October 27, 1990, the Gonoshasthaya Pharmaceuticals (GPL), the pioneering manufacturing unit set up under the author's leadership, was attacked and its offices, vehicles and stores burnt. The scene became complicated by a bullet that killed Shamsul Alam Khan Milon, the joint secretary of the BMA in October 1990. What happened subsequently is best quoted from the book (pp 147-48):

> Politicians immediately seized the opportunity offered by the doctors' strike and Dr Milon's death to mobilise protests which continued to escalate and ultimately led to the fall of the Ershad government on December 6, 1990. President Ershad handed over power to the Chief Justice of the Bangladesh Supreme Court, Shahabuddin Ahmed, who then formed an interim government. The president of the BMA, Professor M A Majed, was appointed Health Advisor (Minister) in the interim government.
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> On the very first day of the interim government, parliament was dissolved and the NHP bill was cancelled by the acting president.
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> The loss of the health policy was highly regrettable. However, in the political turmoil that ensued, it began to look as if the NDP would also be lost as it, and many of its strongest proponents, came under renewed attack. The BMA called for the cancellation of the NDP (which it also termed an anti-people policy), an investigation into GK (Gonoshasthaya Kendra)[4] and a government takeover of both GK and GPL. It also demanded the arrest of Zafrullah Chowdhury of GK and Rahman, the erstwhile health minister who had introduced the NHP bill. BASS (the Bangladesh Association of Pharmaceutical Industries) supported the BMA's demand for an investigation into GK and GPL.
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> The NDP was not withdrawn, but a six-member committee under the chairmanship of major general Anis Waiz was announced by the health minister on February 9, 1991 to carry out an investigation into GK, GPL and the Bangladesh Association of Voluntary Sterilisation, a non-government organisation (NGO) of which Dr Azizur Rahman was president. Major General Anis Waiz was known for his virulent opposition to the NDP. Dr Majed ordered the cancellation of Dr Zafrullah Chowdhury's membership of the Drug Control Committee and the Drug Pricing Committee.

Political stability returned to Bangladesh after elections in February 1991. Begum Khaleda Zia was sworn in as prime minister in March 1991. On April 30, 1991, a disastrous cyclone struck Bangladesh. At a consultative meeting of NGOs and foreign diplomats on disaster relief for the cyclone affected, Begum Khaleda was offered, among other things, plane loads of medicine and baby food. Begum Khaleda Zia promptly thanked the ambassadors and participants present but said any medicine brought into Bangladesh must conform with the essential drugs list. The NDP had finally arrived. It was now good politics to support the NDP, at least to pay lip-service to it by politicians who had otherwise stood on the sidelines in the last 10 years lest they be seen to be endorsing president Ershad.

Attacks on NDP did not stop however. Opponents of NDP led by the Bangladeshi managing director of Pfizer as also the Bangladesh Medical Association demanded withdrawal of the "anti-people drug policy". A new review committee of 15 members was appointed in March 1992 with the mandate to formulate a revised drug policy. The demands of the Foreign Investors Chamber of Commerce and Industry (FICCI) bordered on the absurd: easier registration of new medicines, full importation of raw material without drug administration's approval; withdrawal of price control and advocacy of market competition; protection of TNC's product patents, etc. Your own countrymen could be your worst opponents.

The FICCI was merely echoing the World Bank's recommendations, with the exception that the FICCI did not bother to ask for removal of restrictions on advertisement as already irrational information was being purveyed by drug companies with impunity. The first major push towards dilution of the NDP of 1982 came in the form of recommendations of the new review committee. It recommended creation of a Drug Registration Advisory Committee (DRAC) instead of the Drug Control Committee (DCC). The constitution of DRAC effectively shut out consumer groups but opened itself to a number of lobbies of vested interests including professional pharmacologists, pharmacists, manufacturers and even traders. The DRAC busied itself with preparing a list of OTC drugs, of all

things! Self-prescription and self-medication was back on the agenda or so it would seem. Other recommendations of the review committee, that formed the core of the new NDP (1992), echoed World Bank's recommendations to Bangladesh:

- promotion of under-licence manufacturing and special incentives to foreign companies to set up manufacturing plants to encourage production of their 'research-based' new products;
- protection of intellectual property rights;
- removal of the requirement of prior approval for the importation of raw and packaging materials;
- the setting of their own MRP (maximum retail price) by manufacturers;
- separate administration of traditional medicines 'which should not be amalgamated with allopathic drugs at any level be it manufacturers or dispensaries'.

The NDP 92 could not however go through: a legal petition from representatives of traditional medical systems contended that the review committee recommendations were invalid. The court issued a stay order and the government was prevented from proceeding on the report. But the erosion of the National Drug Policy (1982) however continued thanks to the newly reconstituted DCC and an ambivalent finance minister who believed the NDP 82 discouraged foreign investment.

The DCC for its part set about doing what the finance minister could not do. It proceeded to unban a series of drugs, starting with a non-essential, vaporub. The month of June 1992 saw Pfizer winning two banned drugs that had been banned under NDP 1982. The banned drugs Unasyn (ampicillin plus salbactum) and Daricon (oxyphencydamine) were back in the market. In late 1992, the DCC allowed back antacids with simethicone, multivitamins with minerals, and even vitamin B-complex syrup.

Later in January 1994, the recommendations of the Nurun Nabi Committee report said only 117 drugs (referred to as tested drugs to bypass court restrictions on amending the essential drugs list) were to be subjected to price control. High selling common drugs like ranitidine, diclofenac as well as vitamins and minerals were not part of this arbitrary list. Drugs belonging to the same therapeutic group were subject to differential pricing policies. Expectedly prices of unlisted drugs like Volteran (diclofenac) and Glaxo's Zantac (ranitidine) shot up four to six times higher than other brands of the same drugs. (Glaxo's Zantac is a notorious example of arbitrariness in multinational drug pricing: a few years back it sold Zantac at US $3 per 100 in India and for US $150 per 100 in Indonesia.)

A great experiment, the NDP 82 of Bangladesh, is struggling to survive. It deserves support of all right-thinking people from everywhere. Within Bangladesh itself, the Health for All, a people's organisation, filed, in early 1995, a public interest case against the government for violation of various provisions of NDP 82. (A crucial lacunae now being felt by activists is that the schedule of banned drugs and lists of essential and supplementary drugs were not made part of the 1982 Drug Control Ordinance; thus the provisions of the 1982 ordinance are at best administrative orders not legislative requirements.)

Much of the spotlight on the NDP 82 has been on banned drugs and the essential drug list. The NDP 82 also recommended abolition of product patents, several measures to reduce substandard drugs in the market, provision of inspection of retail pharmacies and traders by existing upazila health administrators, measures for quality assurance during production and so on. There is still a lot to be done on transparency of registration decisions.

The Bangladesh example is an inspiring and salutary reminder of the perils of mindless opening up of the country to all and sundry, of the effect of price controls and the lack of it, and the feasibility of serving people's needs with drug companies being viable even under a regime of relevant price and production controls. On the flip side, it reminds us that an uncontrolled drug industry – as is again being felt now in Bangladesh, thanks to the erosion of political will – will end up creating havoc with people's health needs. The drug industry would tend to look at the bottomline, irrationalities and non-essentials would proliferate, and prices would shoot up.

Some questions do remain however which this book has not answered and just as well. Would there have been a drug policy in 1982 without the concatenation of a president Ershad and a Zafrullah Chowdhury? Or if one were an inevitable history theorist, would the NDP 82 have come to pass nevertheless? Can a rational drug scenario be ushered in, say, in India, within the ambience of a relatively more democratic governance, even if the country were up for grabs? Ershad took the right decisions at crucial times. Was it only due to adroit lobbying on the part of the author and his fellow activists? Or president Ershad instinctively knew – even if he were languishing in a prison cell as he is now – that history will remember him for a couple of good deeds like the NDP 82 and therefore exculpate him at the end of the day? Of course, it also reminds us that nature does not serve up its principal actors in textbook fashion: where the great are good and clean all the way, and the bad are bad 'uns all the way. A dictator can do good, even great things, even if only for political convenience and connivance while a democratically elected leader can wimp along without being able to say boo even to your local 'basti' don.

It does appear nevertheless, in an era of political correctness, of consistency of correct means and noble ends, the author Zafrullah Chowdhury – pioneer surgeon, health activist, freedom fighter, NGO leader and the father of NDP 1982 – has tripped, and egregiously at that, in supping with a dictator even if to light a million candles. His enemies, ordinary self-serving profit maximisers in the garb of doctors and businessmen, seem to revel in his current discomfort. His friends fervently would hope his discomfort and that of his colleagues are but a passing phase. In which there may be only singing about the dark times, but singing regardless.[5]

Notes

1 Branded generics refer to drugs marketed under generic names with a prefix attached to the generic name to indicate the manufacturer. Commodity generics are drugs marketed simply under generic names.

2 Wolfe, Sydney M and Benjamin Gordon, Public Citizen Health Research Group, letter to Harman E Kirby, Deputy Assistant Secretary (Acting), Department of State, Washington, DC, September 15, 1992, PED, 1992, p 82.

3 Wolfe, Sydney M and Benjamin Gordon, letter to Major General Shamshul Huq, Minister of Health and Population Control, Dacca, Public Citizen Health Research Group, Washington, DC, August 9, 1992, PED, 1992, p 80.

4 Gonoshasthaya Kendra (GK) is the organisation started by the author and his colleagues to demonstrate model grass roots alternatives in community health and integrated rural development among other areas.

5 The reference is to the Brechtian quote on the page facing the title page in the book: "In the dark times will there be also singing? Yes, there will be singing about the dark times."

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