The Open University

Innovation
Knowledge
Development

Non-Government Intervention and Prices of Medicines in India: Case Studies of CDMU and LOCOST

IKD Working Paper No. 46

February 2009

Sudip Chaudhuri[1]

Contacts for correspondence:

1 Sudip Chaudhuri, sudip@iimcal.ac.in
Indian Institute of Management Calcutta, Kolkata, India

www.open.ac.uk/ikd/publications/working-papers

Non-Government Intervention and Prices of Medicines in India: Case Studies of CDMU and LOCOST

Sudip Chaudhuri

Abstract

Access to medicines is poor in India, despite a large pharmaceutical industry. Non-governmental action in India has concentrated on campaigning, with relatively little direct NGO activity that aims to influence the supply chain for essential medicines from manufacturer to user. This paper examines two exceptions to that generalization: LOCOST (Low Cost Standard Therapeutics) and Community Development Medicinal Unit (CDMU). The case studies aim to evaluate the strengths and weaknesses of such NGO intervention in essential medicines markets, and the constraints on their effectiveness in the Indian context. The case studies demonstrate both the importance of NGO market intervention in the largely unregulated Indian markets, to improve access to reliable and appropriate medicines, as well as the difficulties such interventions face.

Acknowledgements

This working paper could not have been written without the active help of CDMU and LOCOST officials. They provided me with much of the information used for the case studies and spent hours helping me to understand the operations of their organizations. At LOCOST, I benefited from interactions with T Srikrishna, K S Srinivasmurthy and particularly with S Srinivasan. At CDMU, Sushanta Roy put in tremendous efforts to collect and present the data asked for. I benefited from discussions, particularly with him, Sulagna Dutta, Amitava Guha and D P Poddar and also with S N Chatterjee, A Hazra, A Sen and S K Tripathi. The research for writing this paper has been funded by the Economic and Social Research Council (ESRC), UK, (grant number RES-155-25-0046) under its Non-Governmental Public Action (NGPA) research programme. The idea for writing this paper came from the coordinator of the project, Maureen Mackintosh. I not only tremendously benefited from discussions with her on several occasions. She also provided detailed comments and editorial inputs on an earlier version of the paper. I also benefited from discussions with Meri Koivusalo, another member of the research team, who also shared with me some of the interviews conducted by her. I am grateful to all those mentioned above.

Access to medicines and NGOs in India

Access to essential medicines is very low in India. An estimated 499–649 million people in 1999 (about 50–65 per cent of the population) did not have regular access to essential medicines in the country (WHO, 2004, pp. 62–3). The reason is not lack of production. India has one of the most developed pharmaceutical industries among the developing countries. India is world's fourth largest producer of pharmaceuticals in terms of volume and the 13th largest in terms of value. India is internationally recognized as a low cost producer of quality drugs, exporting drugs to different parts of the world. The turnover of the industry (domestic sales plus exports) has increased phenomenally from Rs 50000 million in 1990 to Rs 500000 million in 2004-05 (Draft National Pharmaceuticals Policy, 2006, Department of Chemicals and Petrochemicals, p. 1). The Indian industry, comprising about 6000 units including some very large ones, produces about 350 pharmaceutical ingredients ranging from simple painkillers to sophisticated antibiotics and complex cardiac products (Chaudhuri, 2005, pp. 15-17, 50). The problem is that appropriate drugs of proper quality do not reach most of the poor people of the country.

Consumers get drugs from:

(i) the retail market, by paying the full price

(ii) the retail market, with their costs is reimbursed partially or fully by health insurer - private or public; and

(iii) institutions such as public health authorities, NGOs and faith-based facilities.

In India, Delhi and Tamil Nadu are examples of how organized buying by public health authorities can make a difference to price and quality. Tamil Nadu reformed its drug procurement and distribution system by setting up the Tamil Nadu Medical Services Corporation (TNMSC) in 1995. The prices of the drugs procured by TNMSC are not only significantly below the retail prices of same products, particularly those of the leading brands in the market (Srinivasan, 1999; Sakthivel, 2005). The prices also show a declining trend, as Lalitha (2008) shows for the period, 2002-03 to 2006-07. But in India, public funding of drugs is grossly inadequate (Sakthivel, 2005). What is worse, in most cases the available funds are not properly spent. Excessive availability of unnecessary

drugs is coupled with poor availability of the required quality of essential drugs at the right time and at the right place (Roy Chaudhury and Gurbani, 2004). The reach of insurance is also very low and has not compensated for public sector failings (CII & Mckinsey, 2002; Rao, 2005).

Most people are forced to rely mainly on the private retail market, bearing the full costs, except in areas and sectors where some NGOs and faith based organizations are active. Domestic retail sales constitute about 79% (Rs 279 billion) of the total domestic pharmaceutical market of Rs 353 billion in India in 2006-07, the remaining 21% being institutional sales (www.cygnusindia.com). Lack of information on the part of consumers in these markets generates perverse incentives for suppliers. They can sell sub-standard drugs, unnecessary or inappropriate drugs. The larger and often the leading suppliers can also use branding to charge higher prices (Mackintosh, 2008). Several studies have documented such market failures in India (see for example, LOCOST/JSS, 2004, Chaudhuri, 2005).

As Mackintosh (2008) shows, although the context and the character have changed in recent years, European-based social enterprises have been able to intervene in medicines markets to make better quality drugs more affordable in Sub-Saharan Africa. In this paper we examine key examples of India's experience.

There is significant non-government activity in the heath sector in India. A lot of NGO efforts and resources are used for campaign and advocacy to influence public policy. The All India Drug Action Network (AIDAN), a network of several NGOs, for example has been very actively involved in issues such as rational use of drugs and appropriate price control. An important achievement has been that several categories of harmful and irrational formulations have been weeded out. NGOs such as the National Working Group on Patents Laws and the Lawyers Collective have successfully campaigned to limit to some extent the scope of product patent protection when India's patent laws were amended to comply with TRIPS. Secondary patents, for example are not patentable in

India “unless they differ significantly in properties with regard to efficacy” (Section 3(d), amended Patents Act, 1970).

NGOs are also involved in running healthcare facilities such as hospitals and clinics where free or subsidized medicines are provided to people. (We will provide examples below). But active non-government intervention to influence the supply chain from manufacturers to users and influence the market has been very uncommon. Two exceptions are: LOCOST (Low Cost Standard Therapeutics) and Community Development Medicinal Unit (CDMU). LOCOST manufactures drugs for other NGOs and CDMU is involved in wholesaling activity: procuring drugs from manufacturers/distributors and distributing these to other NGOs. We focus in this paper on CDMU and LOCOST. Our basic objective is to understand what has been their impact and what have been the constraints for such NGO activities.

Research Methods

Except where otherwise mentioned, information used in these case studies have been obtained from data and documents obtained directly from CDMU and LOCOST. To start with, officials (as mentioned in the acknowledgement) connected with these organizations were interviewed with semi-structured questionnaires. Lists were prepared seeking data on different aspects of the operations of these organizations. Clarifications were sought and different issues were discussed further through several visits to CDMU during 2007 and 2008. LOCOST in Vadodara was visited during August, 2006. This was followed up with email correspondences.

The paper also used the results of structured interviews of 17 member organizations of CDMU in and around Kolkata. These interviews sought information not only on the background and the nature of their activities. An attempt was also made to understand their experiences with CDMU and to document their observations and suggestions. These were cross checked with CDMU officials before using the information in the paper.

CDMU

CDMU was set up in Kolkata in 1984 as a Central Drug Marketing Unit of the West Bengal Voluntary Health Association. It became an autonomous organization in 1986 with a new name but the same acronym. The following are the goals of CDMU as mentioned in its website (www.cdmubengal.org):

- To provide quality essential drugs to member-partners at affordable cost and assist them in maintaining their health programs.
- To provide unbiased drug information to health professionals and consumers.
- To organize seminars, workshops and training programs on 'Rational Drug Use'.
- To publish journals, handouts and booklets on various aspects of health and drugs in the context of rational therapeutics.
- To negotiate with the Government to formulate people-oriented drug policies and weed out irrational and hazardous drugs from the Indian market.
- To conduct community-oriented research on drugs.

Since its inception, running the procurement and distribution network of essential medicines has remained by far its most important activity. The CDMU Documentation Centre was set up in the early 1990's to supplement CDMU's pharmaceutical supply system. It was based on the realization that it is not enough to procure and distribute medicines. It is also important to provide information on rational use of medicines. The Documentation Centre publishes a quarterly 'Rational Drug Bulletin," which propagates the concept of essential drugs and rational use. It has prepared several information-education-communication (IEC) materials. Some of the notable publications are: *Standard Treatment Guidelines* for primary heath care (jointly with another NGO, SAHAY); a book on rational use of medicines in Bengali for common people; a series of booklets in Bengali providing information on about 50 commonly used medicines (in collaboration with WHO, Regional Office for South East Asia). The Documentation Centre regularly organizes meetings / workshops / seminars on rational use of drugs.

In this case study, we will focus on CDMU's drug procurement and distribution activities.

Procurement and sales

A team of experts selects (updates) CDMU's essential medicines list on the basis of the WHO List of Essential Drugs and the National Essential Drugs List of India. Specific care is taken not to include any unproven, hazardous or irrational drugs in the list. This was quite remarkable when it was started in the mid-1980s. The more successful and widely known pooled procurement by TNMSC and Delhi hospitals carry out similar selection exercises. But these started functioning since the mid-1990s. CDMU was perhaps the first organization in India to apply WHO concepts of essential medicines in an organized way to influence proper use of drugs.

Till 2006-07, the medicines selected used to be purchased by CDMU through an open tender system. Quotations were invited from manufacturers (or their distributors) for supply of medicines (and surgical items) as per CDMU's *Catalogue of Drugs & Medical Supplies*. The Catalogue listed the medicines to be procured for different dosage forms, strength and pack sizes. Only those having valid licences from Drug Control Authorities were eligible to quote for supplies of drugs. After the conclusion of the tender process, CDMU used to publish a Price List, which detailed the medicine item (in generic name), the manufacturers selected to supply the medicine, the pack size and the price. Where more than one manufacturer was selected, the names of all those selected were published. CDMU has discontinued the tender system from 2006-07. The same general procurement procedure is followed, but now CDMU negotiates the prices with the manufacturers and the prices announced in the Price List are no longer definitive but indicative.

Organizations willing to procure medicines from CDMU are required to register as its members on payment of a token fee. Profit-seeking organizations are not eligible to be members of CDMU. The drug items listed in the Price List are procured by CDMU from manufacturers/distributors and supplied to member organizations (MOs) on the basis of

the indents received from them. MOs are required to send their indents by generic names only. Where more than one manufacturer is mentioned in the price list, MOs may indicate their preference for a particular manufacturer. If requests are received from MOs to supply drugs outside the list, it is the policy of CDMU to try to accommodate such requests provided the formulations are not irrational. In fact CDMU also provides a list of irrational formulations in the Price List to dissuade the MOs from dealing in these.

As our interviews with MOs show, CDMU's pharmaceutical supply system was a welcome relief to the MOs. In view of the deficiencies of public health facilities in India as mentioned above, many poor people depend on NGO and faith-based heath care facilities. But many of these organizations are too small to float tenders and purchase drugs through competitive bidding. Hence they relied essentially on the market to purchase drugs at high prices. In India retail sales margins are high and cheaper medicines are often not stored in remote parts of the country where many of these NGOs operate. CDMU could not only ensure supplies, but at much lower costs. We considered the 50 largest selling brands as reported by ORG-MARG (2002) and selected for price comparisons 18 brands for which price data were available from CIMS (2003) for different manufacturers selling identical products with same composition and dosage forms. In the case of only one drug (carbamazepine), the CDMU price of the corresponding year was higher. For each of the remaining 17 products, the retail price of the brand leader exceeded the lowest CDMU price by a wide margin. Not considering the extreme cases of nimesulide (1721.5%) and ampicillin/cloxacillin (83.3%), the extent to which the retail prices were higher, varied between 126.8% (for ranitidine) and 653.6% (for diclofenac sodium) (see Table 7.5, Chaudhuri, 2005).

The number of MOs registered increased from only 38 in 1986 to 396 in 1997-98 and procurement by them increased steadily and sharply from Rs 2.23 million in 1986 to Rs 18.4 million in 1997-98. Since then drug sales have fluctuated (Rs 21.88 million in 2000-01; Rs 14.68 million in 2002-03) and have remained stagnant. The drug sales of Rs 19.22 million in 2007-08 were only marginally higher the sales achieved a decade back (Rs 18.4 million in 1997-98) (Table 1).

During 2007-08, out of the more than 600 registered MOs, only 339 procured drugs from CDMU. Larger MOs dominate the procurement – 54 MOs each with a procurement of more than Rs 100000 accounted for about 2/3rd of the procurement in 2007-08. The average procurement of the remaining 285 MOs was only Rs 25,000 in 2007-08. But the small volume underestimates the socio-economic significance. Many of these MOs are located in remote parts in hill areas of North Bengal, Sundarban areas and districts such as Medinipur with poor access to healthcare facilities.

The MOs are basically NGOs and faith-based organizations providing free or subsidized healthcare. Some of them purchase drugs regularly, others occasionally. Some do so only when organizing relief work during natural calamities. Many MOs depend on donations and hence their purchases also fluctuate depending on the funds position. Many of these MOs who got registered and purchased drugs once upon a time are no longer in existence.

Persistent losses and declining sales

Despite the significant socio-economic role which CDMU has been playing, it has not been able to generate a surplus from its operations. In all the years of its independent existence since 1986, it has incurred losses every year, except in 2007-08. The losses have been basically funded though donations from various sources. Losses as a percentage of total income fluctuated have fluctuated around 2%. The loss percentage shot up to 4.58% in 2001-03 but in 2007-08, CDMU has earned a marginal profit of 0.2% of total income (Table 1).

The operations of CDMU are classified between those organized from the Head Office in Kolkata and those from the Branch Office in Siliguri. The latter caters to the MOs located in North Bengal (districts of Darjeeling, Jalpaiguri, Coochbehar, Dinajpur (North and South)). MOs located in other parts of the state deal with the Kolkata office. Kolkata Office is larger in terms of both the number of MOs and the volume of drug sales. During

2007-08, 179 of the total number of MOs of 339 (52%) were under the Kolkata Office and the remaining 160 MOs (48%) under the Siliguri Office. In terms of sales of drugs, Kolkata accounted for 60% of total sales of Rs 19.2 million in 2007-08 and Siliguri the remaining 40%.

The Siliguri branch generates surplus. But such profits have not been adequate to cover the losses incurred by Kolkata operations and hence the overall the profits of CDMU as a whole have been negative, as noted above. Such profits/losses are not merely a manifestation of the relative efficiency with which the operations of the two offices have been run. Kolkata office bears the burden of not only additional costs including costs relating to its Documentation centre. It also suffers from some external constraints as we will see below.

Like the Kolkata operations, Siliguri sales also fluctuate. But the fluctuations are smaller and the sales trend is upward for Siliguri. During 2001-02 and 2007-08, Siliguri sales increased from Rs 5.3 million to Rs 7.7 million. During the corresponding period, Kolkata sales have fluctuated around Rs 10 million. Kolkata sales went down from Rs 10.2 in 2001-01 to Rs 8.6 million in 2003-04. It recovered to Rs 11.6 million in 2007-08 which is only marginally higher compared to its sales in 2000-01.

As a part of staff welfare activities, a number of tea gardens in remote areas in the North Bengal districts of Darjeeling and Jalpaiguri run health care facilities. These tea gardens dominate the procurement in Siliguri – 119 of them accounted for 94.5% of the total drug sales of CDMU's Siliguri branch. The distribution of sales is much more even in Siliguri than in Kolkata. In these remote areas, the options of the tea gardens to procure drugs from other sources are much limited.

The rest of the case study deals with CDMU's drug procurement and distribution activities of the Kolkata office:

In the last few years, the number of MOs buying drugs from the Kolkata office has fluctuated between 119 (2001-02) and 211 (2004-05). In 2007-08, 179 MOs bought drugs from CDMU, Kolkata. A major problem of CDMU has been that it has not been able to retain MOs, particularly some major ones.

In 2002-03, only 18 MOs out of the 179 active MOs each with a share of above 1% and procurement above Rs 100000, accounted for 76.96 % of total sales. The top three accounted for 37.92% and top five 50.23 %. The share of these 18 MOs in 2007-08 declined to 43.40%. Four out of these 18 MOs, stopped procuring drugs from CDMU by 2007-08 (Infant Jesus Church (Jeshu Niketan), St Xaviers, Ursula, St Xaviers, Dumka and Calcutta Rescue). Another 7 MOs reduced the amount of drugs purchased (Howrah South Point, Bharat Sevasram Sangha, Tagore, Antara, Child in Need Institute (CINI), Leprosy Mission Hospital, Snehalata Guha Maternity Hospital). These 11 MOs, who are now buying less or have stopped buying, accounted for 55.19% in 2002-03, but only 16.15% in 2007-08 (see Table 2).

The situation would have been worse if CDMU had not been able to attract few other large organizations. In response to the declining sales trend, an initiative was undertaken in 2003-04 to bring in new organizations. Representatives from CDMU met the people concerned. The Institute for Indian Mother & Child was one such which responded positively. From Rs 81000 in 2003-04, its procurement went up to Rs .97 million in 2007-08 making it Kolkata office's 3rd largest MO. Among the other MOs who did not buy any drug from CDMU in 20001-02 but are now major purchasers are Shramajibi Swastha Udyog, G K Khemka Memorial Hospital, Society for People's Awareness, Child & Social Welfare.

Quality, price and supply failings

The major reasons why CDMU is increasingly finding it difficult to expand its drug sales, in particular why some of the important MOs have stopped buying or buy less than what they did earlier are identified as follows:

- Poor Quality
- Higher price
- Erratic supply

Let us discuss some cases to highlight these factors:

Howrah South Point:

Howrah South Point was founded in 1976 by a French priest to provide medical support to under-priviledged and handicapped children. It is now run by Indian social workers and activities have been expanded to include education and housing of the poor and deprived. It has received financial assistance from a number of foreign and Indian sources including German Doctors' Committee, Mr. & Mrs. Dominique Lapierre, Spastic Society (http://howrahsouthpoint.free.fr). CDMU has been a major supplier of medicines to Howrah South Point. In 2003-04 it purchased medicines worth about Rs 2.4 million from CDMU. Since then their procurement has gone down. In 2006-07 it was about Rs 1.1 million. The next year it has increased to Rs 1.4 million. Their main complaint is with the quality of the drugs supplied by CDMU. Funded by the German Doctors' Committee, they installed a quality testing equipment and found that some of the drugs supplied by CDMU are sub-standard. They informed CDMU about such sub-standard drugs (for example aspirin, ethambutol, co-trimoxazole) but CDMU was unable to take any specific action. They are buying increasing amounts directly from the companies or from the distributors

Antara

Antara was founded in 1980 in a village (Hariharpur) near Kolkata by Mother Teresa and some doctors and social workers. It provides treatment and helps the rehabilitation of poor people suffering from mental disorders including alcoholism and drug addiction. Anatara is financially supported by "Friends" from different parts of the world including

USA, UK, Germany (http://www.antaraonline.org). Antara procured medicines worth Rs 346000 in 2002-03. This dropped to about Rs 130000 in 2006-07. Sales have somewhat recovered in 2007-08 (Rs 241000). Again the main complaint is quality assurance. Earlier they relied on CDMU for the entire supply. Later they stopped buying psychotropic drugs from CDMU – these are procured either from the market or directly from the manufacturers.

Calcutta Rescue

Calcutta Rescue was set up in 1979 by a British doctor, Jack Preger. It provides medical care, basic education and social support to very poor people. It receives financial assistance from groups and individuals from western countries. (http://www.calcuttarescue.org). It procured about Rs 161000 worth of medicines in 2002-03. They have stopped buying because despite repeated complaints, matters relating to quality did not improve. They wanted the supplies to be restricted to national level companies who are believed to have better quality. But CDMU could not ensure that either.

Leprosy Mission Hospital

This is a large leprosy care hospital in Kolkata. They have progressively reduced their procurement from Rs 191000 in 2001-02 to merely Rs 28000 in 2007-08. Their complaint has been not only quality but inability to supply all their requirements – often out of say 15 drugs required by them only 10 would be supplied by CDMU. CDMU was able neither to take steps to ensure quality nor to supply branded medicines as asked by them. The Leprosy Mission now shops around through tenders and did not find CDMU to be cheapest for all the drugs required.

CDMU's inability to ensure quality to the satisfaction of the MOs has cost them very dearly.

CDMU's quality assurance system primarily consists of insisting on a valid licence from Drug Control Administration. In India the quality of drugs manufactured, sold and distributed is regulated by the Drugs & Cosmetics Act, 1940 and Rules, 1945, as amended. Legally, no drug can be imported, manufactured, stocked, sold or distributed unless it meets the quality and other standards laid down. Anyone who manufactures or sells a substandard drug is punishable with imprisonment and fines. Specific permission (a licence) is required from the state drug control administration for each drug to be manufactured and for each factory where the drug is to be manufactured.

Schedule M of the Drugs and Cosmetics Act lays down the Good Manufacturing Practices (GMP) that manufacturers are required to follow to ensure consistent quality standards. Schedule M was amended in December 2001 to upgrade the requirements to WHO GMP standards. These requirements cover all aspects of production including materials, buildings, equipment, training and personal hygiene of workers, disposal of waste, health, clothing and sanitation of workers, equipment standards, manufacturing operations, quality control systems and so on.

The central and the state governments share responsibility under the Act. The central government (through the Central Drugs Standard Control Organisation (CDSCO), headed by the Drugs Controller General) is responsible for such functions as laying down the standards for drugs, regulating the entry of new drugs and imported drugs, monitoring adverse drug reactions. The more routine task of quality control of drugs manufactured and sold is the responsibility of the state drug control organisations. They issue licences to drug manufacturing and sales establishments, and are supposed to monitor the quality of drugs and the conditions of the factories and take up prosecution of offenders.

But these elaborate legal and administrative provisions are, however, not effectively implemented in India. As a result the fact that Drug Control Authorities have permitted a medicine's manufacture and sale is no guarantee of its quality (Chaudhuri, 2005, chapter 7).

Other measures have been adopted from time to time by CDMU, for example, basic physical testing done in-house; analytical testing by external government approved laboratories, review the feedback of the MOs regarding quality. In some cases the manufacturers have been black listed. Such measures have been essentially ad-hoc. If analytical testing were done on a systematic basis, if the feedback received from the MOs were analysed systematically and prompt action taken, things could have been quite different. Interviews of CDMU and MOs suggest that CDMU dealt with the fundamentally important issue of quality in a very lackadaisical manner. This did not instill any confidence among MOs who are particular about the quality standards and CDMU suffered tremendously in terms of lower procurement. Lack of proper quality assurance also prompted some MOs, for example Calcutta Rescue to go for branded products of more reputable companies thereby negating the very purpose of setting up CDMU.

Here a comparison with the Delhi and Tamil Nadu experiences is pertinent. The more successful intervention of these ventures is explained by their ability to economize on prices through competitive bidding without compromising quality. The government of Delhi totally overhauled its procurement of drugs in 1994 (Roy Chaudhury and Gurbani, 2004). One of the most innovative elements of the new system was the introduction of a two-part tender system – a technical bid and a price bid. The former ensures that competition is restricted to firms which are in a position to supply quality drugs. Encouraged by the experiment, the technical professionals associated with the "Delhi Model" formed an NGO, Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) with the objective of extending it to other states with the help of WHO.

Tamil Nadu is one of states which initiated a similar pooled procurement system (Roy Chaudhury and Gurbani, 2004). The quality assurance processes followed by TNMSC are even more extensive. Manufacturers are short-listed for the purpose of price bid only after the tender committee is satisfied with the data provided relating to productive capacity, manufacturing standards, sales turnover and after an inspection of the unit and quality checks of samples of drugs collected from the unit. Even after the suppliers have

been selected through this process, each consignment of supplies is again quality checked on a sample basis. The drugs are not accepted and distributed unless and until the results are positive (Lalitha, 2008).

Though a precursor to the Delhi and Tamil Nadu models, CDMU never gave the quality issue the importance it deserves. The result has been that its turnover and impact have been much less than what it could have been.

Pricing problems

When CDMU introduced the tender system and started procuring and supplying drugs to MOs, it was a significant financial relief for the latter. The effective option for most of them was purchasing drugs from retail outlets and often high priced branded products were purchased. They had practically no connection with or information about manufacturers or distributors, who could supply at lower prices. Given the convenience of getting all essential drugs from CDMU, it was not worth even for the larger MOs to explore other options.

But CDMU's success coupled with some changes in the industry and the market changed the relationships between MOs, manufacturers and distributors.

CDMU all through has followed a very transparent system. The Price List issued and distributed to the MOs contained not only the names of the drugs but also those of manufacturers. Thus the MOs came to know who the manufacturers are. As a result, MOs, particularly the larger ones with significant drug budget could approach the manufacturers and negotiate directly. (This has not been possible in the cases of public health facilities served through pooled procurement in Delhi and Tamil Nadu. The former are mandated to buy through such pooled procurement and not directly from the suppliers). CDMU levies a service charge of 10% on the drugs supplied. Hence directly approaching the manufacturers makes it cheaper for the MOs.

Moreover, CDMU's success in expanding sales quite sharply in the earlier years attracted the notice of some manufacturers. It was not difficult for the manufacturers to get to know about the names of the MOs from the loosely structured administration of CDMU. It became profitable for some manufacturers/distributors also to directly deal with MOs, particularly the larger ones. Among the advantages of directly dealing with MOs are that they can save the administrative hassle of responding to a tender including payment of security deposit. A financially unstable CDMU could not always pay the suppliers on time, which effectively increased their costs. These suppliers could save costs if they directly supplied to the MOs and get the payment promptly. In such cases they could even offer a price even lower than that of the CDMU tender quoted price.

These are not theoretical possibilities. This is precisely what has been happening in a number of cases. Among the manufacturers who have established a direct contact with MOs are Caplet, Stadmed, A N Pharmacia. Among the MOs who buy directly from manufacturers/distributors are Antara, Howrah South Point, Belari Pally Bikash Samity, CINI. Antara as we have noted above have stopped buying psychotropic drugs from CDMU and source them directly from manufacturers (and distributors). Howrah South Point is one of the largest MOs of CDMU – in 2007-08 it was the second largest. But its procurement from CDMU has declined over the years as we have discussed above. CDMU not only introduced manufacturers to MOs. Its dealings with MOs also paved the way for a connection between MOs and distributors, as in the case of Howrah South Point. Among the drugs purchased by the latter are some which CDMU considers as irrational and hence as a matter of policy does not supply. These are supplied by some distributors whom CDMU introduced to Howrah South Point. Overtime, these distributors started supplying other drugs as well and became competitors of CDMU.

Thanks to CDMU, MOs now know the market much better. Whereas previously CDMU shopped in the market on behalf of the MOs, now many MOs do so themselves. In fact some of them, for example Leprosy Mission Hospital and Tagore Society for Rural Development have started a tender process themselves. MOs (for example Sundarban Shramjibi Hospital) have complained from time to time, and enquiries by CDMU have

also confirmed that some drugs indeed are available in the wholesale market at prices lower than those charged by CDMU, as for example for metronidazole, mebendazole, ranitidine, cotrimoxazole, ciprofloxacin. If CDMU were able to guarantee the quality of the drugs, then some these MOs perhaps would have preferred CDMU despite the higher costs. But in its absence it is no wonder that CDMU observes a loss of markets to its competitors.

Of course there are MOs who patronize CDMU, as we have noted above. It includes MOs who are small and /or located in remote parts with no effective options to explore alternatives. Competing manufacturers and distributors are much less active in the remote areas of North Bengal, for example where many of the MOs of the Siliguri branch of CDMU are located. Not surprisingly therefore, Siliguri's sales have been much more steady than Kolkata's.

Among the MOs who continue to patronize are also large MOs such as Southern Health Improvement Samity (SHIS), Institute for Indian Mother & Child, Shramajibi Swastha Udyog, Oxfam India Trust. The latter primarily procures relief materials. Oral rehydration salts (ORS) supplied by CDMU to Oxfam are sourced from a reputable large pharmaceutical company in India. No questions have been raised about its quality. The President of SHIS has been a member of the Executive Committee of CDMU. This may have been a factor behind their decision to procure substantial volume of drugs from CDMU. But the relationship of SHIS with CDMU has not always been rosy. In fact in 2001-02 they did not buy any drugs from CDMU. Unless matters improve at CDMU, these larger MOs may also follow the other MOs mentioned above who are buying less and less from CDMU.

Management weaknesses

The pharmaceutical market after TRIPS has become more competitive and complex than it was earlier. But CDMU over time has become financially and otherwise weaker and have been unable to effectively deal with the new developments. Its inability to generate

surplus and enlarge its financial resources has led to a perennial working capital problem. Many of the MOs, themselves financially unstable, could not always pay CDMU in time. In turn CDMU always could not clear their dues to manufacturers/distributors in time. This made CDMU's purchases costlier, as we have mentioned above. What is worse, there have been occasions when distributors refused to supply to CDMU until the past dues were settled. This contributed to CDMU's delays in supplying drugs to MOs.

A weak management structure has contributed to CDMU's woes. CDMU is run by an Executive Committee. The day to day administrative matters in Kolkata are handled by an Administrative Manager who reports to the Honorary Secretary, who is a member of the Executive Committee. All major decisions are taken by the Executive Secretary who reports to the Executive Committee. In Siliguri similarly the Branch Manager looks after administration under an executive Committee member located in Siliguri. Lack of proper coordination between the Administrative Manager and the Secretary and the inability to take prompt actions have often been a serious problem in the Kolkata office. For several years in the 1990s, the salaried Administrative Manager operated almost independently. He was suspended in 1998 on grounds of malpractices leading to a court case. (He died before the case could be settled). On the other hand, there have also been complaints in the later period that the Administrative manager lacked the required functional autonomy.

One reason why Siliguri has done much better financially and otherwise is that such management problems have been fewer there. Our interviews of CDMU and MOs show that despite complaints of uncooperative and unresponsive behaviour of some staff of CDMU, hardly any systemic corrective action has been taken to improve matters. The difficult environment in which CDMU operates requires a proper management strategy. This has been conspicuous by its absence. However things have started improving. Since a new Secretary assumed charge in November 2007, a number of changes have been introduced including putting in place a proper management structure and autonomy and accountability of the administrative head.

LOCOST

LOCOST was set up in Vadodara in 1983 and started drug supply operations in 1985. It was set up by a small group of health professionals who were members of Medico Friends Circle, an all-India organization of individuals concerned about the health situation in the country particularly in rural areas. It was born out of the realization that often good quality drugs were costly, cheaper drugs were not of proper quality and many essential drugs were not available particularly in remote parts of the country. Initially the drugs supplied were procured from small scale manufacturers. Soon, it started manufacturing drugs on loan licence, i.e., drugs were manufactured under the LOCOST label by another manufacturer under the direct supervision of LOCOST personnel. LOCOST set up its own plant in 1993 to have a better control over supplies and quality. Most of the drugs supplied are now manufactured in its own plant.

Like CDMU, LOCOST stresses rational use of essential drugs. It not only manufactures and supplies such drugs. It has also been involved in campaign and advocacy on issues relating to rational use, safety and pricing. It is an active member of AIDAN. It is also involved in educational activities to promote rational prescribing and use.

LOCOST's small-scale manufacturing unit makes over 60 essential medicines in more than 80 formulations (liquid, capsule, tablet) and supplies at a fraction of the market price and still manage to generate a surplus. LOCOST has made a name for itself. Pharmabiz has reported how LOCOST has improved affordability of medicines (Table 3).

LOCOST caters to organizations similar to CDMU – mainly voluntary organizations involved in health care. Among the well known organizations who regularly buy from LOCOST are:

- Jan Swasthya Sahyog, Bilaspur district of Chhattisgarh
- Society for Education, Action and Research in Community Health (SEARCH), based in the tribal-dominated Gadchiroli district of Maharashtra

- SEWA- Rural (Society for Education, Welfare and Action – Rural) based in Jhagadia, a tribal area of Bharuch district of Gujarat,
- TRU (Trust for Reaching the Un-reached) working in different parts of Vadodora.
- Christian Fellowship Hospital, Oddanchatram, Tamil Nadu
- Ramakrishna Mission TB Sanatorium, Ranchi, Jharkhand.

Unlike CDMU, which is mainly concentrated in the state of West Bengal, LOCOST products are supplied to organizations in different parts of the country. It in fact set up depots in Bangalore and Guwahati to cater to the needs of the organizations in South India and the North East respectively.

The manufacturing procedure at LOCOST is relatively simple. It is not involved in the production of active pharmaceutical ingredients (APIs). The APIs are bought and processed to manufacture different types of formulations conforming to the quality standards prescribed by WHO. It has an in-house quality-control laboratory where medicines are tested before being supplied. This is another major difference with CDMU. LOCOST realized from the very beginning that what is important is not only the price but also the quality. In fact it started it own manufacturing to have a greater control over the quality. The result is that LOCOST has not suffered like CDMU with customers shifting to other sources. Even when some drugs are available at lower prices in the market, some NGOs continue to buy from LOCOST because of the quality assurance. LOCOST too did face some problems relating to quality. There have been cases where goods have been returned to LOCOST by customers. But LOCOST officials pointed out that they have always taken the complaints seriously, improved matters and have been able to earn the trust of most of the customers.

LOCOST drug sales doubled between 2000-01 and 2007-08 to reach Rs 25.47 million 2007-08. But sales were stagnant for few years between 2002-03 and 2004-05 at around Rs 17 million (Table 3). Unlike CDMU, LOCOST is a profitable organization. It incurred a loss in 2004-05 and 2005-06. But in 2007-08 it has earned a handsome profit of Rs 3.4 million (13.3% of its total income) (Table 4).

Minor expansions of its plant between 1993 and 2002 were financed from its own surplus. Between 2002-03 and 2004-05, LOCOST renovated the plant in a major way to conform to the revised Schedule M guidelines. The total amount spent on fixed assets between 2002-03 and 2004-05 was Rs 61.15 lakhs. Its own resources were not adequate for the purpose. Ford Foundation provided grants worth Rs 32.79 lakhs between 2001-02 and 2004-05 and Bread for the World, Rs 27 lakhs in 2004-05 ("Sources and Application of Funds" Accounts of LOCOST). LOCOST stopped manufacturing liquids because it could not afford the costs that would have been necessary to upgrade the plant for the purpose.

But as is clear from above, LOCOST has been able to manage its growth much better than CDMU. LOCOST did not suffer from management problems as CDMU did. LOCOST has functioned with a much better sense of purpose. One of the founders, S. Srinivasan continues to be actively associated with LOCOST as its Managing Trustee. Unlike the situation at CDMU, he in fact draws a salary. It is 2/3rd the highest managerial salary of LOCOST. He has guided the organization with a strategy right from its inception. The two management personnel are also better qualified and have been working with LOCOST for quite some time. The management structure is much more streamlined. Accounts have been computerized. One person looks after entire distribution and another after accounts. There is also greater flexibility of work. The driver, for example also does other types of work when free. The salaries paid to workers are modest but compares favourably with what is paid in similar small scale units.

Despite the significant socio-economic role played by LOCOST, its turnover has remained relatively low. Out of the 468 companies listed by ORG-IMS, 271 companies have retail sales of more than that of LOCOST in 2007-08. Expanding sales has not been easy. LOCOST's competitors began to take note of it as it became bigger. The pharmaceutical market has become very competitive and complex. Implementation of Schedule M has increased operating expenses and has taken away some of its competitiveness. Pharmaceutical companies are actively involved in marketing –

different incentives and inducements are used to influence the doctors, consumers and drug procuring institutions. However LOCOST spends nothing on marketing. This is one of the reasons why its costs and prices are low, but this has also put it in a disadvantaged situation when dealing with organizations which are susceptible to marketing gimmicks and incentives. LOCOST has also lost customers because of its policy of restricting its sales to only rational drugs.

Conclusion

The NGOs studied in this paper are addressing a huge problem in India, that of lack of access by large numbers to safe, rationally prescribed and appropriate medicines. Each of the two organizations studied has intervened effectively to improve access. In the process, the two have influenced the medicines market, demonstrating that non-profit manufacturing and distribution can be effective, and creating low cost procurement options for MOs and organizations serving the most disadvantaged. The case studies show that quality control is central to effective market intervention, followed by effective management and financial stability, including access to financial support from donors. The case studies also show that medicines markets and manufacturers respond to NGO intervention, forcing NGOs constantly to rethink their strategy. In particular, transparent procurement by NGOs can improve market functioning but also open up opportunities for direct supply by manufacturers to large organisations that undermine in turn the role of the NGO wholesalers. In this respect, NGO intervention in Indian domestic medicines markets appears to face similar market constraints to those faced by international NGOs intervening in the India-East Africa supply chain, also studied in this project (Mackintosh 2008).

Table 1 Drugs Supplied by CDMU and profits earned

Year	Total drugs supplied (Rs million)	Profits (Rs 000)	Profits as % of total income
1986	2.23	-75	-2.47
1987	3	-97	-2.66
1988-89	3.23	-49	-1.26
1989-90	4.41	-10	-0.18
1990-91	4.71	-114	-1.97
1991-92	6.1	-26	-0.36
1992-93	8	-46	-0.5
1993-94	9.9	-327	-2.43
1994-95	13.5	-323	-1.79
1995-96	15.41	-725	-3.67
1996-97	16.57	-431	-2.04
1997-98	18.4	-459	-1.99
1998-99	17.99	-102	-0.46
1999-2000	16.86	-351	-1.65
2000-01	21.88	-271	-1.03
2001-02	15.56	-357	-1.83
2002-03	14.68	-842	-4.58
2003-04	15.6	-530	-2.65
2004-05	19.02	-339	-1.39
2005-06	16.17	-109	-0.53
2006-07	17.26	-392	-1.76
2007-08	19.22	45	0.18

Source: Income and Expenditure Account of CDMU (various years).

Note: Figures for 1988-89 are annualized from the figures for the 15 month period, January 1988 to March 1989

Table 2 CDMU's drug sales to major member organizations

Name of member organization	2002-03 Sales in Rs 000	2007-08 Sales in Rs 000	2002-03 Sales as % of total sales	2007-08 Sales as % of total sales
Howrah South Point	1718	1400	16.97	11.32
Infant Jesus Church, Jesu Niketan	1071	0	10.58	0.00
Southern Health Improvement Samity	1050	1494	10.37	12.08
Bharat Sevashram Sangha	736	168	7.27	1.36
Belari Pally Biksh Samity	510	493	5.04	3.99
Tagore Society for Rural Development	450	65	4.44	0.52
Antara	346	241	3.42	1.95
St Xaviers College, Ursula Health Centre	301	0	2.97	0.00
Child in Need Institute	287	30	2.84	0.25
Leprosy Mission Calcutta	191	28	1.89	0.23
Snehalata Guha Maternity Hospital	182	65	1.80	0.53
Calcutta Rescue	161	0	1.59	0.00
Mission of Mercy Hospital	158	115	1.56	0.93
Ramkrishna Mission Pallimangal, Kamarpukur	149	42	1.47	0.34
St Xavier College, C/o St Joseph School, Dumka	144	0	1.42	0.00
Vivekananda Swasthya Seva Sangha	125	190	1.23	1.53
Oxfam India Trust	109	843	1.08	6.81
Sajanipara Medical Centre	103	194	1.02	1.57
Total	10126	12368	76.96	43.40

Source: CDMU

Table 3 Comparison of LOCOST and market prices, selected medicines

Drug	LOCOST price	Market price
Albendazole	Rs. 11.0 per 10 tabs	Rs 9- Rs.12 per tablet
Amlodipine	Rs. 2.50 per 10 tab	Rs. 14 to Rs. 48 per 10 tabs
Atenolol 50 mg	Rs. 2.80 per 14 tab	Rs. 4- Rs. 22 per 10 tab
Enalapril 5 mg	Rs. 3.0 per 10 tabs	Rs. 16- Rs. 23 per 10 tabs
Fluconazole 150 mg	Rs. 35.00 per 10 tabs	Rs. 28-32 per 1 tab

Source: Joe C Mathew, "LOCOST markets essential drugs at a fraction of top branded products", Pharmabiz, May 22, 2006.

Table 4 Drugs Supplied by LOCOST and profits earned

Year	Total drugs supplied (Rs million)	Profits (Rs 000)	Profits as % of total income
2000-01	12.34	291	2.4
2001-02	13.74	238	1.7
2002-03	16.54	719	4.3
2003-04	16.68	1004	6.0
2004-05	17.58	-162	-0.9
2005-06	18.27	-288	-1.6
2006-07	22.38	884	3.9
2007-08	25.47	3431	13.3

Source: Income and Expenditure Account of LOCOST (various years).

References

Chaudhuri, Sudip, 2005, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries*, New Delhi: Oxford University Press.

CII & Mckinsey & Co, 2002, *Healthcare in India: The Road Ahead*, New Delhi: Confederation of Indian Industry and Mckinsey & Co.

CIMS, 2003, *CIMS: Updated Prescribers' Handbook*, Bangalore: Medimedia Health Pvt Ltd, January – Update 1.

Lalitha, N, 2008, "Tamil Nadu Government Intervention and Prices of Medicines, *Economic & Political Weekly*, January 5.

LOCOST/JSS, 2004, *Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India*, LOCOST and Jan Swasthya Sahyog, Vadodara and Bilaspur.

Mackintosh, Maureen, 2008, "Social Enterprise as Market Regulation: non-governmental interventions in essential medicines wholesaling to low income countries", *IKD Working Paper* No. 30, March, Open University Research Centre on Innovation Knowledge and Development, Milton Keynes.

ORG-MARG, 2002, "Retail Store Audit For Pharmaceutical Products in India", Baroda: AC Nielson ORG-MARG Pvt Ltd, June.

Roy Chaudhury, Ranjit and Nirmal Kumar Gurbani, *Enhancing Access to Quality Medicines for the Underserved*, New Delhi, Anamaya Publishers.

Sakthivel, S., 2005, 'Access to Essential Drugs and Medicine', Background paper of the National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India (accessed from www.mohfw.nic.in).

Sujatha Rao, K, 2005, 'Health Insurance in India', Background paper of the National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India (accessed from www.mohfw.nic.in).

Srinivasan, S, 1999, 'How Many Aspirins to the Rupee?: Runaway Drug Prices', *Economic and Political Weekly*, 27 February.

WHO (World Health Organization), 2004, *The World Medicines Situation*, Geneva: World Health Organization.