

The Centre for International Public Health Policy



PHARMACEUTICALS DISTRIBUTION SYSTEMS IN INDIA

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A.1 Introduction

After discussions in our inception workshops, held in Delhi and Kathmandu in December 2006, we decided to begin our research by focusing on issues of pharmaceuticals production and distribution in South Asia, as these were the areas about which we knew least. This paper represents our first attempt to summarise what we have learned about distribution in the initial phase of research. It is based on reviews of current discussions on the web, academic and 'grey literature' writings, as well as our own interviews with retailers, wholesalers, medical representatives, donor representatives, senior doctors and producers.

This working paper provides a broad-brush picture of the different agents in the system and their organisation, the different procurement pathways, and the licensing aspects of the regulatory framework. We show some of the problems with over-neat descriptions, and the challenges that these problems pose for the legal and regulatory framework relating to drug distribution. Certain themes remain under-specified in this report, for example the implications of widespread parallel systems of distribution related to the indigenous systems of medicine (also known as AYUSH, from Ayurvedic, Unani, Siddha and Homoeopathy).

According to a recent definition, the drugs distribution systems of some countries can be described as 'unregulated' if they meet the following criteria:

'From a more technical perspective, an unregulated market for drugs can be considered to exist where: (a) Unlicensed individuals and/or entities trade in drugs that they are not authorized or entitled to deal with or in contravention of the applicable laws, regulations and norms; or (b) Licensed individuals and/or entities trade in drugs that they are not authorized or entitled to deal with or in contravention of the applicable laws, regulations and norms' (International Narcotics Control Board 2007: 1-2).

One purpose of this paper, then, is to ask how far this description is true of the drug distribution system of India, and whether the implications of this situation are fully captured by some standard descriptions of the system and its regulations.

In the simple models popular with industry analysts [see Diagrams 1 and 2], the Indian drug distribution system has a small number of layers (four or five): the pharmaceutical manufacturers; clearing (or carrying) and forwarding agents (CFAs)/depots/super stockists; stockists; wholesalers;

and retailers. The simple models also define only a small number of routes through which drugs flow.

According to Diagram 1, stockists supply wholesalers as well as hospitals and other kinds of medical institution (such as Government and other procurement agencies); according to diagram 2, there is no distinct role of wholesalers, and the super-stockists have also disappeared. We start by examining the layers identified in these diagrams: who are the CFAs, stockists, wholesalers and retailers and what is the extent to which they conform to the formal accounts?

A.2 Roles and Statuses in the Retailing of Drugs

A.2.1 Clearing and forwarding agents/Depots and Distributors

The position of CFAs is one of the weakest in the supply chain: they exist only because of India's particular taxation systems, and new retail chains are attempting to by-pass the CFA and deal directly with producers. The rationale for the CFA depends on the divisions between central and State sales tax systems:

“The distribution set-up in the Indian pharma industry is highly fragmented and has evolved on the basis of the two tier sales tax structure, viz. the central sales tax (CST) and the local sales tax. While the inter-state sale of goods attracts CST, inter-state transfer of goods does not attract any tax. Therefore, in order to avoid CST, all the medium and big pharma cos have a Carrying and Forwarding Agent (CFA)/company depot in each state and transfer goods as inter-state stock transfer. The smaller companies (sales less than USD 20 million or Rs 100 crore) adopted the super-stockist model as the cost of infrastructure for depots or CFAs outweighs the accrued tax advantages” (Ernst & Young 2006: 10).

In principle, each of the larger pharmaceuticals producers has one CFA in each of India's States; in practice, especially in the case of a larger company, there may be several in each of the larger States, but not all States may warrant a CFA (Kanoria 2006). If the 60 or so large companies have an average of 25 CFAs, then there are about 1500 in total: but things seem to be more complicated than this. Iyer provides a brief account of the growth of CFAs in India following liberalisation. Pharmaceuticals companies, Iyer suggests, increasingly replaced company-owned depots and warehouses with CFAs, in order to cut overheads: for example, Glaxo replaced all its

warehouses with CFAs in 1996. By implication, some companies may still have depots under their direct control, rather than using CFAs. There is also some confusion over whether CFAs are essentially part of a production company and operate under contract to a single company, or if they can work for several companies: the Ernst and Young account above suggests the former, whereas Kanoria (2006), suggests that a typical CFA would represent about six companies. From the point of view of the stockists, however, when they receive goods from a CFA they are invoiced in the name of the producer, not in the name of the CFA.

The fee of the CFA may be a fixed percentage margin or may depend on turnover, and again there is uncertainty about how much they receive: is it as reported by Kanoria [chairman & MD of Anglo-French Drugs & Industries Ltd], between 2 and 4 per cent (Kanoria 2006), or as reported by Iyer, from 4 per cent on a high turnover product to 10 per cent on a low turnover one (Iyer 2000)? It is also not clear what has been happening to the CFAs when companies merge or are taken over: as with the stockists (see below) mergers and take-overs produce a theoretical surplus of CFAs, and we do not yet know what happens in these circumstances, whether each is given a region within a State, or retains part of the business of the combined company.

The Indian sales tax system is being slowly but steadily replaced by a value added tax, and if this process is successfully completed, the taxation incentive for this system may disappear. Finally, the new retail chains are negotiating direct contracts with producers, thus saving themselves the fees paid to CFAs. In response, the members of the retail pharmacy organisations are also developing co-operative marketing arrangements (see below). If these succeed, the CFA's days may be numbered.

A.2.2 Stockists/wholesalers

Iyer argues that during the 1970s and 1980s, as attempts were made to expand drug distribution to emerging markets, many small players (it is not clear if this means retailers or production companies) became stockists and wholesalers, in order to compete (with retailers, presumably) and because of the higher profitability of drug marketing in comparison to drug production (Iyer 2000).

Stockists typically market products of 6-8 pharmaceutical companies, only a few distribute products of more than 50 companies (Iyer 2000). Mergers and acquisitions of pharmaceutical

companies have almost doubled the number of stockists per company and created quite tough competition at this distribution level. Stockists of the same company are competing against each other and thus possibly strengthening the bargaining position of retailers. Stockists have their own visiting salesmen who contract and stock retailers on a frequent basis. Once again we have disagreements over the margins paid to wholesalers and stockists: according to Kanoria (2006) stockists get 8-10% of their sale price to the retailer; Iyer (2000), by contrast, reported a margin of 8% on the maximum retail price of price-controlled drugs and 16% on de-controlled drugs.¹ How far these formal agreements work in practice is unclear, however. Some stockists apparently pass up to 6% to retailers, leaving themselves with margins of only 2-2.5% (here, Iyer refers to Kishore Shah, president of the Retail Chemists and Druggists Association, the Mumbai branch of AIOCD.) On the other hand, stockists also sometimes get discounts of 5-10% from manufacturers in the form of free packs, some of which they may pass on as a discount to retailers.

Both Iyer (2000) and Ernst & Young (2006) estimate the number of stockists in India at 60,000. As with the number of retailers (see below), this seems to be a figure supplied by the All-India Organisation of Chemists and Druggists (AIOCD), who claim to be able to control entry into this position. Indeed, there are also different licensing arrangements for wholesalers and for retailers. With the increasingly tough competition, and with many stockists moving to the apparently more lucrative retailing, we might expect a decrease in the number of agents at this level.

A.2.3 Retailers/pharmacies/dispensing practitioners

The remainder of the market is made up of a large number of small-scale suppliers, who often act as prescribers as well as retailers. The number of retailers is subject to some considerable margins of error: the Ernst & Young report indicates that there are about 500,000 retailers or pharmacies in 2005 (Ernst & Young 2005), whereas Iyer mentioned more than 550,000 retailers by 2000 (Iyer 2000). Once again, these figures seem to be the same as the claimed membership of the AIOCD, and since it is not clear whether all retail outlets selling pharmaceuticals are in fact members, these figures should be used with care. Industry sources claim that retailers account for about 70-80 per cent of the pharmaceuticals sales in the country, with the remainder being sold directly through hospital pharmacies (Jayakumar 2007). In rural and small-town India (probably accounting for 25-35 per cent of the market) private medical practitioners (whether formally trained or not) usually keep stocks of most of the medicines they expect to prescribe. Most small

¹ Kolkata sources say that this varies wildly and margins can be much higher.

hospitals and nursing homes also have in-house pharmacies and require patients to buy the drugs on the premises, whether they are in- or out-patients.

Pharmacists' recommendations about drugs and their alternatives seem to be based on profitability and on relationships with representatives of various companies. We were told by some Kolkata sources that the power of the retailers partly comes from their power NOT to sell a particular brand. They can let it gather dust and ship it back to the supplier, pushing the more profitable brands instead.

Retailers are entitled to margins of 16% for controlled formulations and 20% for decontrolled formulations on the Maximum Retail Price: this is set by law and may be printed on the medication (Domain-b 2000a; see also Kanoria 2006). But this formal position seems to mask considerable variations, whether by company, retailer, drug or for particular times when there is an imbalance between demand and supply, or when a stock of drugs is nearing its 'sell-by' date. Regarding the profitability, manufacturers, stockists, distributors and sometimes medical representatives offer price reductions to the retailers to move drugs more quickly or to increase the margin that can be earned by the retailer (Interview, Delhi, 3 November 2006).

The retailers probably comprise a wide variety of very different kinds of operation, ranging from small shops to retail chains. We discuss small shops further below, but in general these are closely linked to other small shops in India's retail sector. In many cases these are family firms, with a single owner or a set of brothers, continuing a longer family tradition. They will normally have a small number of employees, who often turnover quite quickly: these ex-employees can often be found in rural areas or in small towns having set up business as drug retailers themselves, or having established a position as an RMP (Rural or Registered Medical Practitioner, the largest category of practitioners, who are usually not actually registered and have no, or no relevant, formal qualification). Indeed, at the rural or small-town level, the distinctions between retailer and practitioner may be hard to establish.

At the other end of the retail continuum are chains of retail outlets. Retail pharmacy chains are relatively new to India, and have been generating considerable conflict with the existing retailers since about 2000 (Iyer 2000). For example, Subhiksha started as a supermarket-cum-pharmacy chain in 1997, now has around 170 stores with a turnover of over Rs 300 crore, mostly in Tamil Nadu (Babu 2006). Subhiksha demanded (and apparently received) 60 per cent of the stockists' margin, and cut the prices to consumers by covering the cost of the 6 per cent local sales tax. The remaining retailers persuaded stockists to stop supplying Subhiksha, and after a court case, the

stockists were forced to resume supplies, on condition that Subhiksha did not reduce prices. 'Though this dramatic turn of events has united the rest of the trade, the Subhiksha kind of practices are likely to be the future norm. In order to cope with the impending competition, the others are merging to form co-operatives to derive similar benefits from stockists' (Domain-b 2000b). Similarly, The Medicine Shoppe, one of the largest retail drug stores in the US, opened two retail outlets in Mumbai in 1999 and by May 2006 had 103 stores across six states, mainly in urban areas (Acumen Fund 2006).

By 2007 these early initiatives had spread to include Apollo, Lifeken (with 60 stores in Bangalore and Chennai), Medicine Shoppe (which operated), CRS Health, and Health Glow. There are also proposed large-scale projects of Ranbaxy/Fortis Healthcare, Zuellig Pharma, and the Reliance Anil Dhirubhai Ambani Group, who are trying to develop retail pharmaceuticals chains. An example of the kinds of changes that these chains are introducing can be seen in the account of the plans of Ranbaxy (a leading drug manufacturer) and Fortis (who are building up a chain of high-technology hospitals):

"The 'one stop shop' chain will offer prescription and OTC drugs, health supplements, health foods, alternate medicines like ayurveda and homeopathy, home and personal care products, telemedicines and pathology collection centres under one roof. To be operated round the clock, it would extend value added services like free home delivery, prescription reminder service, loyalty programmes and OPD appointments", company CEO Ashish Kirpal Pandit said (Bureau Report 2007).

A manager in one of these chains explained how their system of 450 clinic-based pharmacies (in hospitals and under their direct control) and 50 franchisees works:

"What we do is, we tie up with the manufacturers. When you have 450 pharmacies across the country you have huge negotiation powers with them. That group does not do the purchasing through the distributor necessarily. They will position themselves as the distributor and buy from the manufacturer and get the wholesale margins. They buy it at that price but sell it at the consumer rate. So once your margins go up you can afford to provide better services and added benefits for your patients and customers. So cut out the middle man. You cannot cut out hundred percent but you can certainly cut out up to 70%. You'll still need to buy from other people" (Interview, Manager in Kolkata, 22 February 2007).

Although these innovations are largely an urban phenomenon, and probably mostly restricted to the metropolitan cities (Mumbai, Kolkata, Delhi, Chennai, Bangalore and Hyderabad) Medicine Shoppe India has planned by 2011 to establish 130 health centres in rural areas, with financial assistance from the Acumen Fund, which supports 'social entrepreneurship' (Acumen Fund 2006).

A.2.4. Challenges to this picture

This simple picture is misleading, for two main reasons. Firstly, individuals or companies can occupy more than one position. Secondly, and partly as a result, the allocation of margins to different levels of this structure is more apparent than real. Not only can some actors accrue the margins applicable to more than one level, and others have to share theirs with layers above or below them, but some companies seem to operate ad hoc schemes to reward some players (usually, but not always, the final retailers) with special or time-limited offers. It is also clear that changes underway in the retail sector (with the attempts by large retail chains to negotiate direct contracts with producers, cutting the stockists/wholesalers, and perhaps also the CFAs, out of the supply chain) will lead to an as yet untested situation. Here the power of the retailers associations may make a crucial difference.

B. Public and private sector procurement systems

The two main procurement systems in India comprise state or government procurement and procurement by large private health institutions. Each of these may comprise systems within systems, but not all of them may be very systematic. It is hard to get consistent and reliable estimates of the scale of these different procurement systems. According to a report prepared for the National Commission on Macroeconomics and Health, in 2002 the combined budget for drug procurement by both the Central and State Governments was Rs 20,000 million (Sakthivel 2005: 186). The annual household expenditure on health care was estimated at Rs 428,560 million in 1999-2000, and about 75 per cent of this was thought to be on pharmaceutical products, suggesting that government procurement accounts for about 6 per cent of total pharmaceutical sales in India (Sakthivel 2005: 186). Further information on expenditure by function suggests that the Medical Stores Depots and Drug manufacture account Rs 4,585 million in 2001-02, out of a total expenditure by public sector bodies (central and state) of Rs 25,200 million (National Health

Accounts Cell 2005: 33). Figures for private sector and NGO procurement suggest that they are of much smaller significance. But for some drugs (probably including Rifampicin and Oxytocin), the public sector may be much more important.

B.1 Central and State Government procurement

There is no single central government procurement office although 25 per cent of the total public sector drug volume is procured by the central government for the Central Government Health Services, Defence (Armed Forces Medical Services), Public Sector Units, and State Sector Units that negotiate prices directly with producers / manufacturers.

The Medical Stores Organization (MSO) is responsible for the procurement and supply of quality medicines and medical instruments to Central government hospitals and dispensaries in rural and suburban areas. It has seven depots located in Mumbai, Kolkata, Chennai, Guwahati, Hyderabad, Karnal and New Delhi. It acquires drugs directly from pharmaceutical companies through tenders in order to reduce prices, but only about Rs 1,140 million worth of stores were purchased by it in 1997-98 (Ministry of Health and Family Welfare 1999: Ch. 24).

The MSO also distributes drugs supplied by international organizations such as UNICEF, CIDEA, WHO, USAID. It has particular responsibilities for vaccines received from WHO, UNICEF, USAID and other various International Agencies under various agreements entered with Government of India, and it is responsible for stores required for National eradication programmes such as Anti-Malaria, Anti-Leprosy, Anti-TB, AIDS, NMEP, RCH, CSSM, as well as Family Welfare (including maternal and child health) under National Health and Family Welfare Programmes. In addition to the depots, there are three Chemical testing laboratories attached to the Medical Store Depots at Mumbai, Chennai and Kolkata for testing the quality of the drugs and medicines (Government Medical Stores Depot 2006).

Most public sector drug procurement is carried out by the State governments, and practices vary considerably across the country. In the Army, the Central Command for the armed forces has a medical depot, which works on “rate contracts”. They float tenders for supplying the drugs that they need for armed forces personnel. Pharmaceuticals companies with “GMP” capacity—usually the bigger ones, but not necessarily so, and they could be MNC or local companies—are entered onto an approved register by the armed forces. When new drugs supplies are needed, these

companies receive requests to submit tenders. Because these companies are all considered to manufacture quality products, the decisions about which companies' quotes to accept are supposedly made on the basis of price, and usually the cheapest two or three companies will be asked to provide the drugs. In most other public sector cases, it would seem, there is a mix of centralised procurement like this for a limited range of basic medicines, and localised procurement for more specialised drugs. In practice, such systems are cumbersome, inefficient, and open to corrupt practice. We were given a vivid account of practices in the recent past in military procurement:

There is room for "manipulation" and "influence" (X said with a grin) and this was where he came in: he had the advantage (as he described it) of being the nephew of a General who had been trained in Edinburgh and had specialised in gynaecology, public health and pathology. He had been the Principal of the Pune Armed Forces Medical College. It was this latter that gave X the advantage or the "selling point" (as he put it) because most of the medical staff in the Lucknow Central Command depot had passed through the Pune College and had known his uncle—so they tended to say that they would trust him because he was the nephew of General X. Mr X said that he had been working for a local company called XYZ, which had 3-4 products registered with the armed forces depot, soluble aspirin and cough syrup included. He commented that there is a huge consumption of aspirin in the armed forces, because there is a lot of tension and headaches; and that when the *jawāns* [armies] from the plains go to the hill they often get chest infections and coughs. He said that the armed forces buy "crores upon crores" of soluble aspirins (Interview, Lucknow, 14 March 2007).

The Government of Uttar Pradesh (one of our focus States) is by general consent reckoned to be more corrupt than most. A senior medical administrator who tried to reduce corrupt practices was gunned down in the street in July 2000. In an interview with a senior policeman we were given some insights into the processes at work:

The budget for medicines for the Judges of the High Court in Allahabad is 50% of the budget for the whole district, and Pilibhit [a small, poor and remote district] has the same drugs budget as Lucknow [the State capital]! In both cases procurement is managed so that large purchases are made of glucose drips, tonics etc. These are added indiscriminately to the prescriptions written by Government doctors, who are rewarded by medical representatives of small companies, who dominate the local procurement committees. The Chief Medical Officer of a District also takes a commission on the local

purchase of medicines, which is why there are only low-quality, out-dated drugs in health centres. On an average doctors' prescription there will be perhaps 10 drugs, six of which will be useless and only two will come from the hospital stores. There's a 'drugs mafia' that is so well entrenched that, people say, no-one can become Minister of Health without their approval (Interview, Lucknow, 24 January 2007).

The State governments of Tamil Nadu, Orissa, Andhra Pradesh, Delhi and Rajasthan have started centralised drug procurements systems in an attempt to overcome these kinds of problems, but only those in Tamil Nadu (the Tamil Nadu Medical Services Corporation (TNMSC) and in Delhi are regarded as fully successful. The TNMSC was established in 1994, and started work in 1995. According to its website it uses the WHO list of essential medicines, with 90 per cent of its budget going on the procurement of 268 items on this list via an open tender system. Purchases are made not through agents or distributors but only from manufacturers with a Good Manufacturing Practice (GMP) certificate, a market standing for at least three years and a minimum turnover, to eliminate very small firms that may fail to meet their delivery commitments. It also follows WHO's recommendation in using international non-priority or generic names (INN).

“With the dual objectives of maintaining quality and preventing wastages and pilferages, all tablets and capsules are procured with only strip or blister packing, as against the earlier practice of bulk packing which requires manual handling at the time of distribution. Both inner and outer packages of all items as well as the tablets and capsules are required to bear the logo of TNMSC with a marking to show that the drugs are manufactured only for State Govt. supply and Not for Sale” (Tamil Nadu Medical Services Corporation 2007).

Some indicators of the complexity of the public health system at the state level can be gathered from the different categories of institutions that the TNMSC supplies: Medical Teaching institutions; District Head Quarters Hospitals; Taluk Head-Quarters hospitals, Primary Health Centres, and through them, Sub-Centres; ESI [Employees' Social Insurance] Hospitals and Dispensaries; TNEB [Tamil Nadu Electricity Board] Medical Facilities; Panchayat Union Dispensaries; Police Medical Facilities; Juvenile Homes; Prison and Rehabilitation homes; Co-operative Sugar Factories; Veterinary Institutions; Transport Corporation Dispensaries; Social Welfare Department; and Social Defence Institutions.

The 'Delhi Model' is a joint initiative, also with WHO backing, but including an input from the Delhi Society for Promotion of Rational Use of Drugs (see Chaudhuri 2005: 255 for a summary). Its main purposes, like those of the TNMSC, are to reduce the range of medicines purchased, in line with

WHO recommendations on essential drugs, and to reduce the prices paid without compromising on quality. The programme has five components: development of a drug policy; list of essential drugs (EDL); pooled procurement; quality assurance; and training in rational prescribing (Roy Chaudhury et al. 2005). Its impact on drug procurement in Delhi is limited, however. Although it supplies hospitals and health centres run by the State government, this means that it covers only about one third of the hospital beds in Delhi, excluding (for example) the largest public sector hospitals (AIIMS, Safdarjang, for example), which are run by the Central Government.

B.2 Private purchasing by large users

Large private hospitals negotiate prices with CFAs and distributors to avoid stockist and retailer margins in addition to getting bulk purchase discounts. We have also been told in Kolkata that private hospitals also get their drugs straight from manufacturers. Some private hospitals invite tenders. Small hospitals and dispensing practitioners buy drugs from wholesalers.

The Community Development Medicinal Unit (founded in 1984 in Kolkata as the Central Drug Marketing Unit, CDMU) operates in much the same way as the TNMSC and 'Delhi Model'. It supplies approximately 450 organisations, at prices well below those quoted by manufacturers for general purchase (Chaudhuri 2005: 254). In addition, NGO-run institutions can also buy directly from producers who offer them special terms. One of these is LoCost, set up in 1983 in Baroda to supply not-for-profit institutions.

B.3 Challenges to this picture

One problem in understanding this system is that the system is not static and the apparent divisions between the private sales of drugs through retailers and the more centralised systems are somewhat illusory. Pharmaceuticals move between the different supply chains at several points. Thus, for example, drugs procured under the government and non-government systems leak out into the general retail system, as hospital employees or government doctors use them as part of their private practices. Drugs sold through the general retail system also augment the drugs procurement processes, since the drugs procured in these ways are rarely sufficient to meet

overall demand (nor do they cover the full range of drugs prescribed in the public sector). A clear visual impression of this is provided by the location of private retail pharmacies, as pointed out by activists in West Bengal:

“In a study where we compared availability in private and public sectors, we found it’s atrocious in the public sectors. Most of the medicines we asked for were not available which was available in the private sector. We identified retail shops just outside the government hospitals. We find most of the retail shops are really around the government hospitals and as you move further the density of retail shops per population decreases. The more distant you are from a health facility the lesser the chance of getting a medicine shop. In other countries, before giving a license to a medicine shop they see that is the location and how distant it is from the nearest medicine shop. It’s not regulated here” (Interview, West Bengal Health Association, 10 January 2007).

C. The role of collective organisations in the retail sector

The main association is the All-India Organisation of Chemists and Druggists (AIOCD), with its State branches. This dates from 1921, when the Bengal Chemists & Druggists Association (BCDA), was established, followed by associations in Madras, Bombay and Delhi. In 1944, these established the All India Federation of Chemists & Druggists, but it was faced with competition from the All India Retail Chemists Association, and, from 1972, from the Indian Organization of Chemists & Druggists. In 1975 the three all-India bodies merged into the All India Organization of Chemists & Druggists (AIOCD).

Since 1981 the AIOCD has been negotiating agreements with the drug producers associations (the Indian Drug Manufacturers Association (IDMA), and the Organisation of Pharmaceutical Producers of India (OPPI)). One agreement, which dates back to 1984, specifies the percentage of trade margins for various categories of drugs, and allows the local branches of the AIOCD to block the entry of new companies. For example, in Kolkata:

“Before the company appoints us as stockist we need a ‘No Objection’ letter [from the Bengal Chemists and Druggists Association, BCDA]. They just act as watchdogs. Also they see if there are already enough stockists for a certain company, then they try to stop new stockists for that company from entering the market. Also the manufacturers are afraid of

them [the BCDA], they will not do anything wrong" (Interview, Distributor in Kolkata, 3 March 2007).

Recent press reports suggest that all the distributors in the country are members of AIOCD, and that it is powerful enough to stop producers from supplying goods to retailers who don't agree to their terms (Bhasin 2007). According to the manager of a retail chain in Kolkata, the BCDA is a guild that is even able to force pharmacies to break the law (by adding local sales tax to the maximum retail price):

"They are forcing people to charge tax or else there was threat of physical violence. They were even forcing us, who were not charging tax according to the law. [Otherwise you would have advantage over the others?] Correct, and they will not sell as much. [They were threatening you?] Yes, we had our glasses broken. The window panes and all were broken in Salt Lake as we decided that if we cannot do something according to the law, we will not" (Interview, Kolkata, 22 February 2007).

The AIOCD is in the process of floating corporate retail drug companies in Maharashtra and Delhi, and possibly elsewhere, to help their campaign of confronting the organised retail drug chains (Jayakumar 2007). They are responding to the perception that consolidation in drug distribution, while still at a very formative stage, is likely to lead to corporatisation. "Corporatisation would lead to elimination of at least one layer of distribution. This would enable companies to offer higher margins to retailers. Consumers too will benefit as drug companies would be in a position to pass on the benefits to consumers. Corporatisation of trade would mean fewer players. This would improve administration and enhance customer relationship," says the distribution head of a leading Indian company (Dogra 2006). There seems to be a general perception that, in the metropolitan and second-tier cities, there is a surplus of pharmacy stores, and that new trading practices (often but not only with foreign funding and following foreign models) will pose a major threat to existing stores. Fewer commentators, however, have noted that these changes are likely to have different effects on the large number of stores serving the countryside and poorer urban areas.

In order to counter the influence of the AIOCD the new retail chains are reported to be sponsoring a new body, to be called the Association of Professional Chemists and Distributors of India (APCDI). The idea was initiated by Rajendra Pratap Gupta, head, retail and supply chain, Reliance Health. Other organised retailers have agreed to the idea. However, many insiders have responded to the move with scepticism, saying that taking on the AIOCD is extremely difficult (Jayakumar 2007).

D. Licensing

As we noted at the beginning of this paper, the existence of licensing, and the extent to which it is applied fully, are the main criteria for deciding whether or not a country has an 'unregulated' drugs market. This perspective tends to underplay the other social, political and economic functions fulfilled by licences, and we will discuss these briefly at the end of this section. In discussing licensing, therefore, we shall first describe the formal system and then try to understand the everyday experience of the licensing system. Except where otherwise indicated, we draw here on the work of Gross and Patel for details (Gross & Patel 2002).

In India, the major source for pharmaceutical regulation of all products, whether imported or made in India, is the Drugs and Cosmetics Act 1940 (DCA), under which are the Drugs and Cosmetics Rules (DCR). The DCA regulates the import, manufacture, distribution and sale of drugs in India and the legislation is enforced by the Union Government (Department of Chemicals and Fertilizers, Ministry of Chemicals and Petrochemicals) in New Delhi, with the office of the Drug Controller of India (DCI) having prime responsibility. At the field level, however, enforcement is done by the individual State governments through their Food and Drug Administrations. Matters of product approval and standards, clinical trials, introduction of new drugs, and import licenses for new drugs are handled by the DCI, while approvals for setting up manufacturing facilities, and obtaining licenses to sell and stock drugs are provided by the State Governments (Gross & Patel 2002).

Other relevant legislation includes the Pharmacy Act, 1948; the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954; the Narcotic Drugs and Psychotropic Substances Act, 1985; the Medicinal and Toilet Preparations (Excise Duties) Act, 1956; the Drugs (Prices Control) Order 1995 (under the Essential Commodities Act); the Industries (Development and Regulation) Act, 1951; the Trade and Merchandise Marks Act, 1958; the Indian Patent and Design Act, 1970; and the Factories Act (Central Drugs Standard Control Organization 2007). The Pharmacy Act of 1948 has a particular significance for the retail trade, because it regulates the profession of pharmacy in India, especially with respect to the requirements for registration of pharmacists (Central Drugs Standard Control Organization 2007).

D.1 Licenses to manufacture drugs

“All manufacturing of drugs in India requires a license. Manufacturing is defined by the DCA as including any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. It does not include dispensing or packing at the retail sale level. A license is required for each such location at which drugs are to be manufactured, and also for each drug to be manufactured. The license has to be renewed periodically.” (Gross and Patel, 2002)

The Re-registration Circular Letter by Directorate General of Health Services (Drugs Control Section) from December 2004 specifies that the license is valid for three years from the issuing date, unless it is sooner suspended or cancelled (Drugs Control Section 2004). The Drugs and Cosmetics Rules specify the GMP and requirements of premises, plan and machinery, rules for maintenance of raw materials and records, and requirements for the quality control system:

“The DCA also specifies other conditions for the grant or renewal of a license: competent technical staff including a pharmacy/pharmaceutical chemistry/science/chemical engineer/chemical technologist/equivalent foreign qualification with experience in drug manufacture, requirements of the testing laboratory and qualifications of the head of the testing unit. The applicant must also show (in case of patent or proprietary medicines), that the medicines contain the constituent ingredients in the therapeutic/ prophylactic quantities as determined in relation to the claims or conditions for which the medicines are to be used, that the medicines are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulation, are stable in the conditions of storage recommended, and contain such ingredients and in such quantities for which there is therapeutic justification” (Gross and Patel, 2002).

Manufacturers of certain drugs (involving recombinant DNA technology, use of nucleic acids as the active principles and formulations based on use of specific cells/ tissue – targeted formulations) need an additional license in accordance with the Industrial Policy issued by the Central Government. Other manufacturers “have only to file an Industrial Entrepreneur’s Memorandum (IEM) with details of the proposed items to be manufactured, the capacity, the location, the source of technology, the raw material requirement, the process description and other details’ (Gross and Patel, 2002).

Gross and Patel (2002) also list other registration and licensing requirements regarding drug manufacturing facilities: License for Capital Goods import (for items other than those freely importable under the Import Policy); License for raw materials import (for items other than those freely importable under the Import Policy); Factories Act registration; Labour laws registrations; Pollution Control Board clearance; Electricity supply; Building permission; Water supply; Land lease/purchase; Excise duty registration; Sales tax registration; Explosives license; Licenses to store petroleum products; Registration under the Boilers Act; Registration with the State Director of Industries; Registration under Standards of Weights and Measures Act.

The other formalities are to be complied with at the State or local government level, where the factory is located.

D.2 Licensing of Drug Retailers

Under the DCA, sales offices, pharmacies or any other sales outlet or stocking point for drugs must be licensed to do so by the State Government having jurisdiction over the office/pharmacy. Where drugs are sold/ stocked for sale at more than one place, a separate license is required for each such location. A license once issued is valid till December 31st of the year following the year in which the license has been granted. The requirements and conditions for a license to stock and sell drugs (other than on a wholesale basis) include:

- specified minimum area and equipment
- compounding of drugs on the premises should be done by a Registered Pharmacist
- sales of any drugs on prescription should be under the supervision of a Registered Pharmacist (qualification and experience profile are specified), and a prescription register (for compounded drugs) or cash or credit memo book (for other medicines) maintained
- prescription register or sale memo should contain the specified particulars of the sale (including batch number of manufacture in case of prescription drugs)
- no prescription drug is to be sold without a prescription

There are restricted licenses for outlets that do not need the services of a Registered Pharmacist (called “drugstores”), and those where no compounding takes place (called “chemists and druggists”). Outlets may use titles such as “Pharmacy,” “Pharmacist,” “Pharmaceutical Chemist,”

or “Dispensing Chemist” only if they use the services of a Registered Pharmacist and maintain a pharmacy for compounding.

Wholesale and retail outlets would also need local registration under:

- the Shops and Establishment Act
- the Standard of Weights and Measures Act
- labour legislation
- sales tax legislation

A recent description of the limitations of the small-scale retailing operations that, apart from the exaggerated expectations with respect to ‘modern aspects’, is a fair description of the mismatch between regulations and practices:

“India's pharma trade, particularly, the retail pharmacies, continues to be disorganized and unprofessional. Most of these 6 lakh [600,000] chemist shops are being run by traders with no sufficient storage space, no air conditioning and with no presence of pharmacists at the counter. Although these are statutory requirements, very few among the trade follow them. And with perpetual shortage of inspection staff, drug control department in most states do not take any timely action against such offences. With substantial growth in demand for pharmaceuticals over the years, the number of pharmacies is multiplying leading to severe competition and unethical practices amongst them. One of the main concerns is pertaining to the delivery of drugs to patients, the primary responsibility of a retail pharmacy. For proper delivery of drugs to patients, advice of a qualified pharmacist is considered necessary. For this, the pharmacist should be equipped with the knowledge of community pharmacy, modern aspects of dispensing, patient counselling, biochemistry and clinical pharmacy and drug store management. But most pharmacies in the country do not have a pharmacist at the counter leading to several unreported dispensing errors” (Francis 2006).

The formal regulations concerning pharmacies require a degree in pharmacy, a medical qualification, a science degree and 2-3 years experience in prescribing, or matriculation with science subjects and five years of experience. Since there are only about 200,000 pharmacy graduates, most pharmacies do not have the services of someone trained in pharmacy or pharmacology. A common practice is to open a shop taking the name of a pharmacist, who may be named on several other licences as well, and may rarely if ever attend the pharmacy:

“Many Ayurvedic medicine shops also keep English medicines without holding any license. It is a rule to display the photo of the license holder in the shop. It is not allowed to sell without prescription. It is a rule to keep a record of what they sell and purchase. Shop-owners pay money to pharmacists to obtain license. They [pharmacists] are being paid money on a monthly basis by the shopkeepers: one pharmacist may have several shops opened in his name but none of these shops has a qualified pharmacist on site” (Interview, Lucknow, 12 February 2007).

It is not clear what kinds of enforcement activities take place with respect to these retail and wholesale licences. The range and complexity of the rules offer plenty of opportunities for retailers to fall short of the requirements (Narayanan 2007). The Delhi State association affiliated to AIOCD attempted to circulate the photographs of "original" drug inspectors who are in charge of their respective regions in 2004, after two persons were arrested for posing as drug inspectors and moving around the state, extracting "bribes" and "collecting fines" from the retail chemists (Bureau Report 2004).

Most retailers and wholesalers we have talked to about licenses suggest that the process of getting a license is a chore, and that the regulations have no real intrinsic significance. Here are a distributor and a wholesaler talking about the experience:

D: Our license is 50 years old and we keep renewing it every year. The rules have changed a lot but since we just renew it, it does not apply to us as such. When there is a change in ownership, they do inspection thoroughly again. So when I took over from my father, they came for a more thorough inspection. They see if we have a working fridge or not, and such other things. They require qualified people in the shop before issuing license. In my father's time it was easy, but it was not as easy in my time (Interview, Kolkata, 3 March 2007).

SE: So you what do you need from the government? You need the license?

W: Yes and there are a lot of rules.

SE: What are they?

W: Like I have to have a place, you have to give a drug license, you have to have your sale tax number, you have to have your income tax number. So all these stipulated rules you will have to follow. Until and unless, you have the drug, real number that we call, and the wholesale license number, you cannot deal with medicines. Nobody can come up and bring up a shop and start working for medicines. You have to have a license for that. You have to be qualified enough and there are a lot of paper works.

SE: What kind of qualifications do they look for?

W: The primary qualification is the place. It has to have a stipulated height and other requirements, the place should be clean enough. There are a whole lot of rules. These will have to be met and then the government will give you a license. Once you have the license, then only you can buy and purchase medicines.

SE: Is it difficult to get a license?

W: Nowadays, the government is not willing enough to give. I think India has the highest number of retail shops. Every nook and corner, you will find a retail shop. So now they are curtailing down on the license.

No category of drugs is legally specified as 'OTC'. The DCA specifies certain drugs to be sold only under prescription, and the remaining drugs can be sold without prescription, though only by licensed outlets. The list of prescription drugs covers all antibiotics, a number of painkillers, etc. Prescription drugs cannot be advertised in the general media. The DCA also provides a list of ailments that no drug may purport to prevent or cure. In practice, retailers rarely require a formal prescription from a practitioner before they sell a drug, even if it is on a Schedule of drugs that require such prescriptions. However, this does not mean that self-medication is common: 'pharmaceutical use is determined as much by practices of dispensation and by how practitioners understand what constitutes therapy as by household understanding of the normal and the pathological' (Das & Das 2006: 69). At the prompting of the pharmaceutical industry, the Government of India has set up a committee of officials to draw up a list of OTC items that would be allowed to be advertised in the general media. At present there are a few so-called OTC drugs (15-20 types) such as rubs and balms, pain relievers, antacids, etc. Health drinks are, of course, commonly advertised (Gross & Patel 2002) as are Ayurvedic, Unani, Siddha and Homoeopathic [AYUSH] preparations.

Our own research so far suggests that licences fulfil a number of functions within the drug distribution system, and that within these functions, that of protecting the consumer or ensuring professional practice come rather low down in the priorities. As many commentators have discussed, in a 'licence Raj', as India was described as having developed under Nehru, and which is still partly in place today, those who issue the licences are able to earn 'economic rents' by exploiting the positions they hold. But it is also the case that those who manage to acquire licences expect them to be used to reduce competition from new entrants. In addition, licences are somewhat of a fetishistic commodity: their appearance on the walls of offices or shops is testimony to the moral rectitude of the owners, and a statement about their social position, rather than a sign that particular professional norms are being up-held. All of these apply, of course, throughout the world: but the balance between the different functions seems to be more weighted towards the more restrictive, self-interested functions of licences than is true in many other places.

E. Towards a more accurate reflection of drug distribution in India

Diagram 3 [see the end of this paper] is an attempt to use the material discussed so far in this paper to move towards a more useful representation of the drug distribution system than is provided by either Diagram 1 or 2. One example of additional complexity is the distinction we have made between large and small-scale producers. While the border between them may be uncertain, it is clear that the extremes operate in very different ways. The large companies should again be distinguished according to whether they produce the active pharmaceutical ingredients (API) or are merely in the business of formulations. A further distinction is to show that the CFA is to some extent part of the production company, even though if they represent more than one company that depiction is somewhat misleading.

Large companies distribute their products through either company depots or CFAs, whereas the smaller companies use super-stockists. But the boundary between the two kinds of companies is not as clear-cut as they might seem, because small companies also often act as additional producers for the large companies. Small companies often formulate drugs and package them

with the name of the large company, on what is called a 'loan licence': a license to manufacture a product in the factory premises owned by another party, (Gross and Patel, 2002). These drugs are then sold in exactly the same way as the branded versions that have been produced in factories owned by the large producer. The use of loan-licensing may be to avoid excise duty or sales tax, or to take advantage of the small-scale producer's ability to pay lower wages, and smaller social welfare payments and other perquisites. The practice of loan-licensing also provides one of the channels by which 'counterfeit' medicines reach the market. In such cases, the small company produces more than the quantity contracted for, and then sells the remainder. In this case the term 'counterfeit' refers to the lack of approval from the company whose name appears on the package: the drug quality may or may not be acceptable, because the purpose here is to avoid the drugs appearing in the books of the wholesalers or retailers for taxation purposes.

Individuals also cross the boundaries between some of these categories, making them more fluid and permeable than they appear in this diagram. One example is the distinction between retailer/pharmacist and practitioner: it is common in much of the north Indian countryside (and also in smaller towns) for patients to approach a pharmacist and receive a diagnosis and prescription (often including powerful prescription drugs) without the intervention of any other kind of practitioner. Similarly, in most small towns and villages, the practitioner himself (and occasionally herself) also prescribes and dispenses the medicines they prescribe: indeed, there is rarely a consultation fee, but the practitioner makes his/her income from dispensing prescriptions. Finally, the ethnographic material suggests that it is also necessary to deconstruct the idea that drugs, once having reached a patient, are then consumed by that person. Rather, we have also to understand the life of drugs after this point, in which the portion unconsumed may be passed on, sold or traded with other patients; and prescriptions may have a life of their own, generating further drug purchases either for the original patient or for someone else entirely (see Working Paper 2, and (Das & Das 2006).

The main additional links in Diagram 3 [see end of paper], as compared with Diagrams 1 and 2, are those that reflect the 'leakages' from one procurement system (mostly the Government procurement system) to and from the private retail chains, which we have discussed above. We might also want to clarify the relationships within the chain of distribution from Government procurement agencies to hospitals, clinics and medical or para-medical workers (which are addressed more in Working Paper 1b, with respect to Nepal, and in Working Paper 2, with respect to Oxytocin and, eventually, to Rifampicin). We hope to discuss these issues more fully during the workshop.

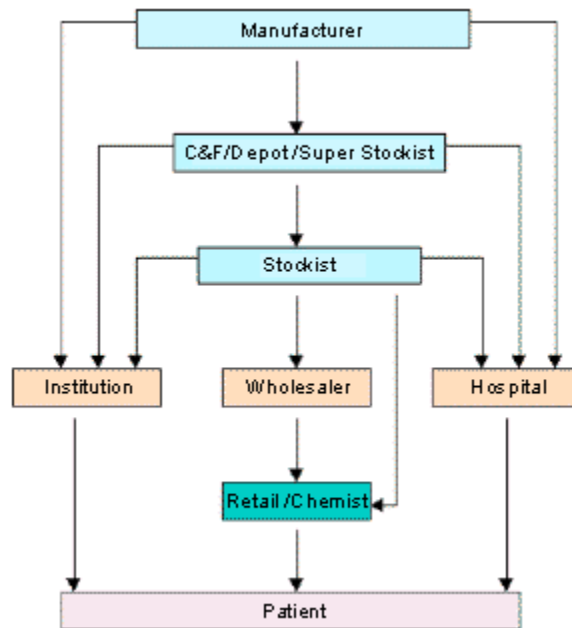
F. Discussion

As we have made clear throughout this paper, it is entirely provisional, and it will have met its aim if it generates discussion and helps to clarify decisions with respect to our plans for the next stage of our research. Among some possible areas for further attention might be:

- Which parts of the licensing arrangements are taken more, and which parts less seriously by licensing bodies?
- How can we best move beyond a simple framing of ‘the problem’ as one of corruption, or of inadequate resources being allocated to regulation?
- What is the significance of the social construction of pharmaceuticals distribution by commercial analysts such as Ernst & Young or KPMG?
- Is it worthwhile to follow-up further the issue of counterfeit medicines?

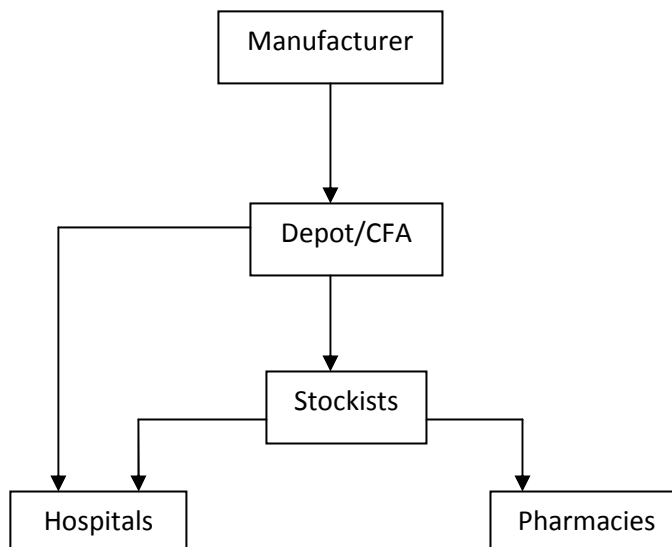
Diagram 1

Channels of drug distribution



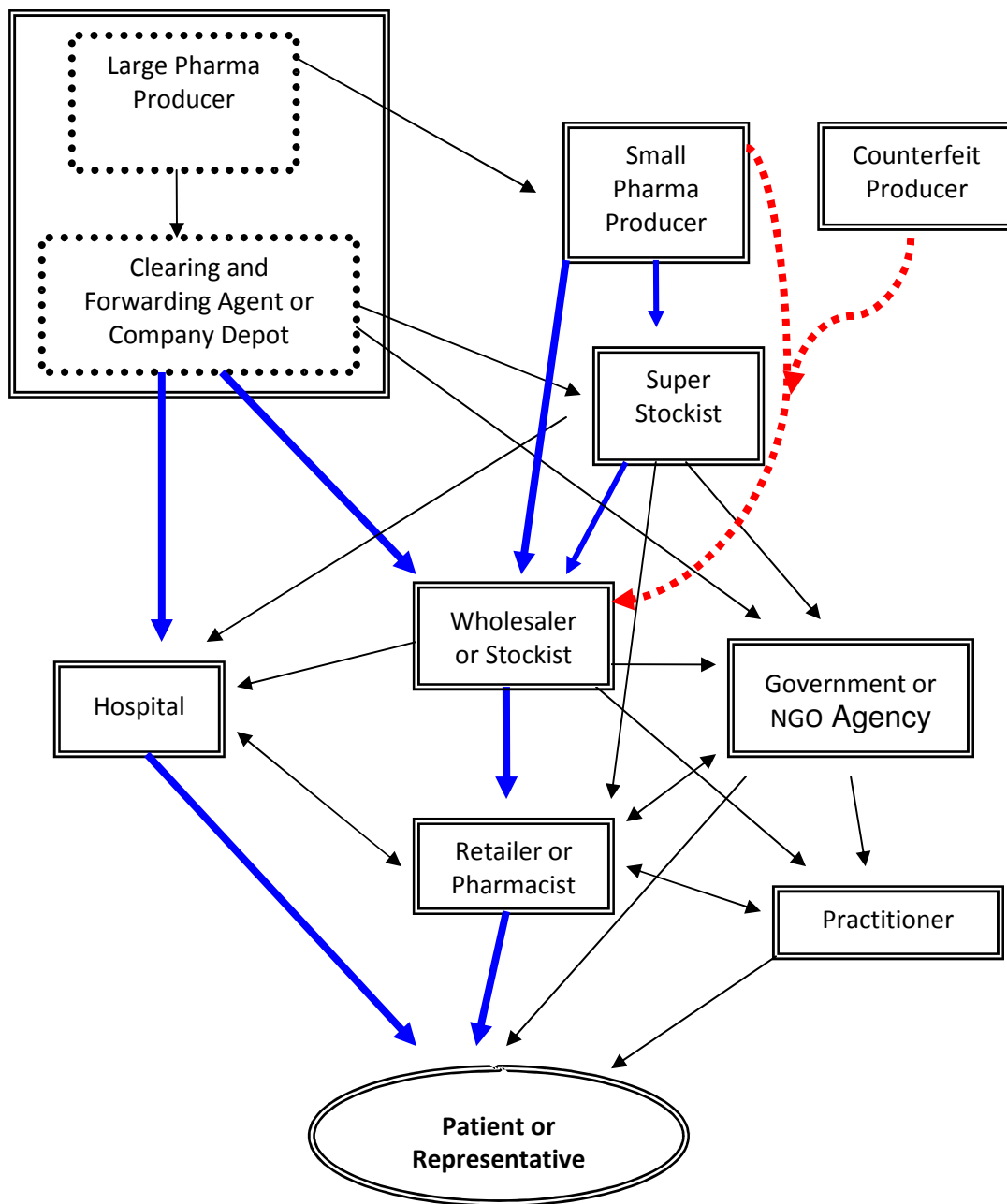
Source: http://www.domain-b.com/industry/pharma/20000107distribution_channels.html

Diagram 2: Current Distribution Setup in India






Source: (Ernst & Young 2006: 11)

Diagram 3: Showing more complex relationships



Patterns of distribution of pharmaceuticals in India

Key

-  Main channels
-  Other channels
-  Channels for counterfeit drugs

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