Pharmaceuticals, Physicians and Public Policy
Unravelling the Relationships

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Abstract: *The relationship among pharma industry, physicians and public policy in not only complex, but often irrational unethical and 'unscientific'. This article introduces a collection of papers deriving from a research project 'Tracing Pharmaceuticals in South Asia' . The research focused on tracing three drugs --- oxytocin, rifampicin and fluoxetine--- from production to prescription.. These drugs belong to three different therapeutic domains – maternal health, tuberculosis and mental health -- and their usage regimens are vastly different. Their relevance in public health policy too is different. This variety has allowed the research team to uncover the complex web of production, distribution and, regulation from different perspectives.*

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When we take the 'routine' headache pill or a prescription medicine, little do we realise that there is a complex web of processes related to pharmaceutical production, distribution and marketing; diagnostic and therapeutic procedures and standards; global trends; as well as policy formulation, implementation and oversight related to government departments as diverse as health, chemicals, industry, labour, law, finance and others, that influence our decisions. It is well known that for the 'patient' the consumption of a medicine, unless it is a result of self medication, is not a matter of 'choice', but is determined both by the science of 'medicine' and by 'market forces' that define the relationship between the doctor and the medical representative (MR).

The series of papers in this issue demonstrate the relationship among pharma industry, physicians and public policy is not only complex, but often irrational, unethical, and 'unscientific'. In times when accountability and transparency are becoming increasingly common ideas, it is important to unravel these relationships and introduce these complexities in scientific and public discourse. This is important because the Indian drug companies are often seen as the 'David' of the global pharmaceutical industry, 'saviours' for millions who can now access affordable anti-retrovirals, and leading the

economic charge from an industrial 'underdog' country in the era of globalised trade. At the same time the cost of healthcare, mostly that of medicines, continues to be a leading cause of impoverishment and indebtedness in the South Asian region.

Although the Indian market is growing fast, it currently accounts for no more than 2 per cent of world pharmaceutical sales by value (somewhat more by volume), with an estimated market of US$10.4 billion in 2007 at consumer prices, or around US$9 per capita. The Nepali market is far smaller, with one estimate placing its pharmaceuticals value at around NRs 6 billion (about US$85 million, or about US$3 per capita). India is attracting increasing attention from multinational drug companies as a market for their products, although the vast majority of pharmaceuticals available in India are already off patent and generics are likely to dominate the market for the foreseeable future [Piribo 2007].

Yet despite its size and sophistication, all South Asia's drugs distribution systems can be described as 'unregulated'. 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 collection, then, is to showcase recent research that tries to go behind some of these general descriptions, and to look at the implications for public health. We hope in this way to contribute to improving the available descriptions of how drugs are produced, distributed, marketed and consumed in South Asia. This collection of papers has been the result of the research and dissemination process associated with a collaborative research project 'Tracing Pharmaceuticals in South Asia', that was conducted across India and Nepal. The research focused on tracing three drugs - oxytocin, rifampicin and fluoxetine from production to prescription. These drugs belong to three different therapeutic domains – maternal health, tuberculosis and mental health -- and their usage regimens are vastly different. Their relevance in public health policy too is different. This variety has allowed the research team to uncover the complex web of production, distribution, regulation from different perspectives. Additional papers were invited from colleagues working on similar issues. In this Introduction we set out some of the context for these discussions, and provide an overview of each of the contributions.

Pharmaceuticals Distribution Patterns

We first describe the formal structure and processes involved in drug distribution in India, some of the problems with over-neat descriptions, and some of the challenges that these problems pose for the legal and regulatory framework relating to drug distribution.

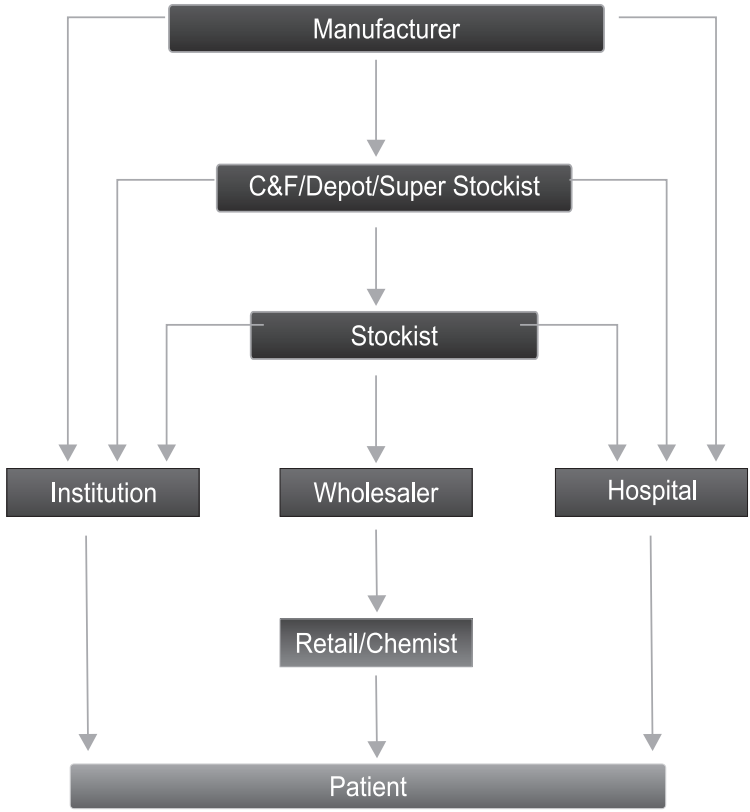
We begin by setting out the broad-brush picture of the different agents in the system and the different procurement pathways. We then deal in more detail with the processes and significance of what seems to be emerging from our work so far. Certain themes remain under-specified in this collection, for example the implications of widespread parallel systems of distribution related to the so-called indigenous systems of medicine (also known as AYUSH, from Ayurvedic, Unani, Siddha and Homoeopathy).

In the simple models popular with industry analysts (see Diagram 1), 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. A similar picture (minus the CFAs) is sometimes presented in discussions of the situation in Nepal.

However, on closer analysis, this neat picture begins to break down. To begin with, the numbers within each of these categories turn out to be highly unreliable. Here we focus on India. At the top of the diagram – the number of production companies – estimates vary. An estimate of over 20,000 – though widely quoted – has been challenged: perhaps no more than 5,000 are active producers. There seem to be no viable estimates of the numbers of CFAs or super-stockists – and numbers seem likely to change quite quickly, since the roles reflect tax and licensing conditions rather than real economic need. Both Iyer (2000) and Ernst & Young (2006) estimate the number of stockists in India at 60,000. This seems to be a figure supplied by the All-India Organisation of Chemists and Druggists (AIOCD).

The number of small-scale suppliers, who often act as prescribers as well as 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] and Francis (2006) estimated 600,000 by 2006. 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 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. Finally, the number of people who fill roles as prescribers – who earn at least a living through this means – are well in excess

Diagram 1: Channels of Drug Distribution



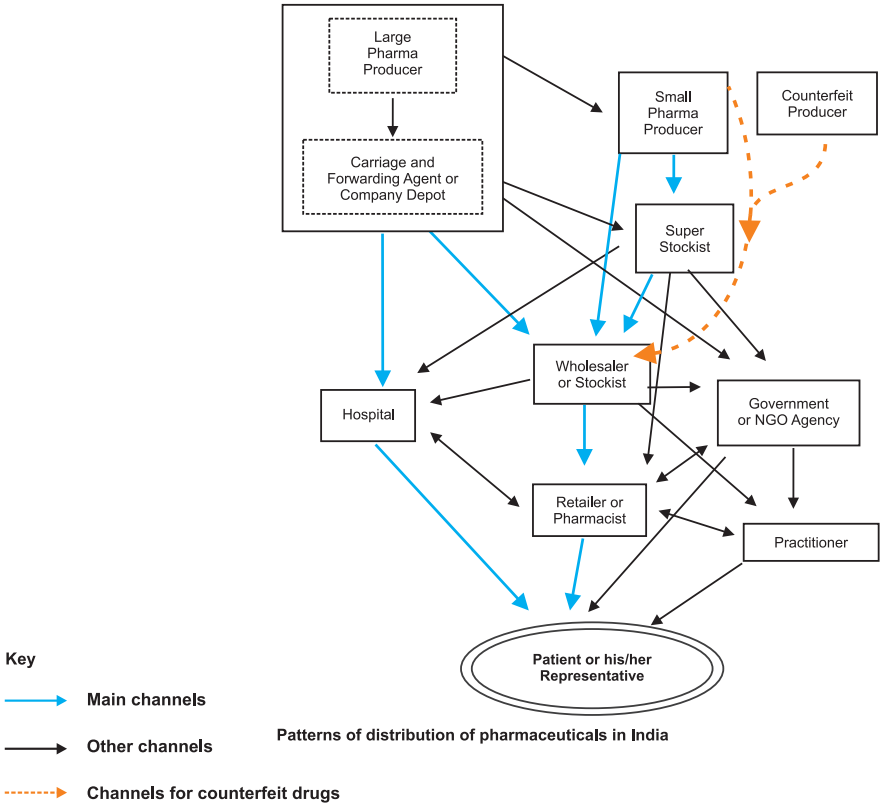
Source: http://www.domain-b.com/industry/pharma/20000107distribution_channels.html

of the official figures of AIOCD

Diagram 2 is an attempt to move towards a more useful representation of the drug distribution system than is provided by Diagram 1. 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 clear-cut: 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]. Alternatively, they may produce on contracts that grant the originator company more control over quality and output issues. But in both cases drugs are then sold in exactly the same way as the versions that have been produced in factories owned by the large producer. The use of loan-licensing or sub-contracting 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

Diagram 2: Showing more complex relationships



Patterns of distribution of pharmaceuticals in India

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.

In this Issue

The papers in this issue develop different issues through more detailed consideration of their causes and consequences. Thus in second paper, Roger Jeffery and Santhosh M.R. discuss the range of regulatory issues considered by the major commissions charged with reforming the pharmaceuticals regulatory system in India since 1995, and show how detached they are from the everyday contexts of drug production and distribution that we have laid out above.

Patricia Jeffery, Gitanjali Priti Bhatia and Sakshi Khurana show in detail how the international guidelines for the use of oxytocin are systematically ignored by most prescribers of the drug – and how little urban policy-makers are aware of this. Oxytocin is an essential drug in emergency obstetric care, and essential obstetric care a matter of highest policy priority considering that the MDG 5 related to maternal mortality is one on which there has been the least progress, and one which is least likely to be met.

Ian Harper compares and contrasts the treatment regimens for the TB control programmes in India and Nepal (and the way rifampicin is used differently in the two countries). Each regimen has its supporters and critics: but one of the conclusions of this paper is the extent to which – once again – the control programme staff have little understanding or interest in how the programme is perceived in the outside world, and how those perceptions shape the ways in which public sector and private sector interact to produce actual patterns of use.

Mental health has emerged as an important public health issue over the last decade and there are serious concerns about the availability of treatment for conditions like depression. Stefan Ecks and Soumita Basu explore the use of the anti-depressant fluoxetine, in and around Kolkata, India, and discover interesting patterns of distribution and use which is almost entirely outside the knowledge or oversight of psychiatrists or others with psychiatric training. These findings have implications for WHO strategies for closing the Mental Health Treatment Gap.

Moving away from drugs to vaccines, Madhavi Yennapu explores the relationship between public and private sector in the context of vaccine production and its implications for the universal immunisation programmes in India. The paper explores the shortage of vaccines which are part of the Universal Immunisation Programme and the easy availability of new vaccines to understand the relationship between industry, physicians and policy making.

Amitava Guha describes key features of the promotion of medicines in India, focusing on the tactics used to confuse, or corrupt practitioners if medical representatives are unable to convince them of the value of their particular brand of medicine. While efforts to regulate such promotion have been missing in India, there have been some examples from the US which shows that such regulation is possible and can be made to work.

Finally, Suchitra Ramkumar looks at the dynamics of drug promotion in Chennai India. Her paper, based on a survey of doctors, medical representatives, laboratories and explores how far are prescribers aware of the pressures from producers and retailers,.

Read together these papers offer an interesting perspective to observe and describe the interactions between patient, prescriber and the pharma industry . These observations also indicate the rules of engagement between the different parties. These rules or standards, by accepted norms of governance, should be determined by public interests, scientific validity, technical efficacy, economic efficiency and principles of equity. The papers indicate that such expectations are not being met both at the level of the interaction between individual elements of the web as well as overall. This consensus of conclusions has great implications for the rational practice of medicine and the overall health and well being of poor people.

Notes:
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