Tracing Pharmaceuticals in South Asia

Draft working paper

Regulation without Implementation: India in a global pharmaceutical world

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Abstract

A major concern for theorists of the governance of pharmaceuticals is that of ‘regulatory capture,’ when ‘the pharmaceutical industry influences the perspective of the regulatory agency—so it comes to adopt its interests over and above those of patients’ (Abraham, 2002: 1498). Pharmaceuticals can be inappropriate, dangerous, ineffective or of low quality, and the problems for public health may arise in any or all of the processes of production, distribution and consumption of pharmaceutical products. Looked at from the perspective of south Asia, focusing on the individual state may itself be a mistake: pharmaceutical regulation since the colonial and post-colonial eras has always been globalised. India has never made regulation policy in an international vacuum, and local concerns have often been outweighed by global ones. But globalisation poses only some of the problems faced by states: some fields of action (such as the regulation of pharmaceutical prescription and distribution) are clearly ‘national’, yet they have always posed considerable regulatory problems. The purpose of this paper is to survey recent attempts to reform pharmaceutical regulation in India, and to suggest some basic problems of these attempts.

India has an increasingly inadequate public health service, and this generates inherent contradictions. Internally, to implement the strict regimes that exist on paper (in the various Acts, Rules and Regulations) would be massively politically unpopular. While the urban middle classes and large drug producers might support such a move, it would disrupt existing patterns of corrupt practice, would leave a vacuum in services to poor people (especially in rural areas), and would grant unearned quasi-monopoly powers to ‘recognised’ practitioners, distributors and producers. Externally, global institutions or other governments try continually to influence policy in areas over which they have no formal responsibility. In international agencies, the ‘modelling of regulations’ is carried on using expertise that is ‘detached from local contexts’ (Jansen & Roquas, 2005: 142, 143). And foreign governments (such as the US) are already intervening in Indian production standards, with no requirement to take account of the effects of their actions on drug supplies within India.

In this paper we explore how issues of regulatory capture, the limitation of domestic ‘reach’ in implementing pharmaceuticals policy, and the changing global environment, play out in the case of India. What kinds of local contexts are and are not brought into play by the advisory committees constituted by the Government of India to propose changes in the regulation of pharmaceuticals since 1995? In particular, what models of Indian society and economy have underpinned these efforts, and with what kinds of effects?
**Introduction**

How do we build up the capacity of the state to do whatever it wants? Often this is posed as a question of governance reform. But our debate over governance reform has also taken a misleading turn, because it assumes that governance reform is about implementing designs created by committees of technocrats. Rather, the first order of business is to restore credibility to the state itself (Mehta, 2009).

In our research on ‘Tracing Pharmaceuticals in South Asia’ we considered issues of regulation and inappropriate use at all stages, from the sourcing of raw materials (bulk drugs) to the final consumption of the product. In contemporary India, however, pharmaceutical regulation is rarely seen as a ‘cradle-to-grave’ approach. The regulation of some parts of the process attracts far more attention than others, and the links between these parts are poorly co-ordinated. The second is that regulation takes place with two significant disconnects. The first is between the assumptions underpinning regulatory measures on the one hand and the everyday conditions of drug production, distribution and consumption on the other. The second is that the local regulation of production, distribution and consumption is inadequate to deal with the global context within which these processes take place.

Two examples from our research set the framework for these issues of ‘disconnection’ that we consider in this paper. The first comes from our observations of everyday medical practice and how it does not match the assumptions, rules, norms and expectations that underpin much policy discussion of pharmaceuticals regulation in state capitals or in New Delhi. We are faced with a surfeit of possible examples, whether from our own visits to factories involved in formulating, packaging and dispatching pharmaceuticals, from wholesalers’ depots and pharmacists’ shops, or from the conditions in which these drugs are prescribed and then consumed.

**Example 1: Subho Ghosh**

Subho Ghosh set up his clinic near Bolpur, a university town in West Bengal, after working for ten years as an assistant to his father and uncle, neither of whom had formal qualifications works. They had picked up homoeopathy, and learned allopathy from a friend who worked in a hospital. Subho opened his clinic, he says, in order to make treatment available locally so that patients do not have to spend a lot of money travelling to town. In his everyday practice he kept a stock of medicines to prescribe, but if he had no stock of some drug he would write a note and the patient could buy it from one of the three or four pharmacy stores nearby.

Subho described his treatment of TB: he had just attended a course to involve private practitioners in the national TB control programme. He said he never used Rifampicin, because his patients were too poor to buy such medicines: and the other – homoeopathic – drugs he knew about were not strong enough to cure TB. We then asked him about his role in childbirth. He named a homeopathic medicine, *Pulsatilla*, which he would prescribe because ‘it will dilate the passage, make it normal so that the delivery is easy. This is not effective in cases of the first pregnancy.’ Although he did not recognise the term ‘oxytocin’ he did recognise ‘syntocinon’. 2 In delivery cases,

‘the midwives come and inspect first … When the labour pain starts, they call me. When the midwife says the time is right, then I administer syntocinon. [You do not see the position yourself?] No, no.’

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2 Syntocinon is the trade name for a commonly available form of synthetic oxytocin in India, produced by Novartis; Pitocin (produced by Pfizer) is another.
Finally he talked about psychiatric medicines: he denied having patients with depression but he did prescribe one sedative:

‘Alprazolam, to keep the brain cool. Besides there are drugs like Calmose etc. which I do not use. [You do not use them?] No. [And Amitriptyline or Fluoxetine, anything like that?] No. No, I do not use them.’

He orders his medicines from a wholesaler in Burdwan, not directly but with the help of friends who collect them on his behalf. He prefers branded products:

‘Because they are generic medicines, they are not effective. And we do not understand everything about generic medicines. We cannot understand which are generic from their names’ (Interview 22 March 2008).

This example – like others we could cite at different points in the supply chain such as medicine shops – describes a situation of jagār medicine: medicine that is ‘make-do-and-mend’ or ‘Ersatz’ medicine (Pinto, 2004). Even though the ideal and symbolic appeal of ‘real medicine (provided by government and nongovernment health institutions) remains strong, much everyday provision comes from ‘practitioners who are neither “quacks” nor legitimate doctors but who invent roles for themselves as medical authorities’: Pinto also suggests that such practitioners are ‘representatives of development, not aberrations from it’ (Pinto, 2004: 337). In many parts of rural India, and in some parts of urban India as well, the state has failed to provide adequate numbers of properly trained ‘legitimate’ health workers. As a result, ‘equality for all is precluded and what remains is equality for some’. Targeting the ‘inventive quasi-institutional practitioners’ misses the point: these people survive in the spaces left vacant by the state. They are not outside local power relations, nor is their presence just a sign of the temporary, as-yet-inadequate spread of cosmopolitan medicine. Rather, their activities provide evidence of how development, as a global project of myth-making, gains its local character (Pinto, 2004: 355-56, 358).

**Example 2: The US FDA and Ranbaxy**

Our second example comes from the other end of the global-local spectrum: the activities of the US Food and Drug Administration [FDA]. As the FDA expands its global reach, it investigates in minute detail how Indian multinational companies, in this case, Ranbaxy, produce generic drugs. In September 2008 the FDA issued two Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for bulk pharmaceuticals produced by Ranbaxy’s Dewas and Paonta Sahib plants. The FDA had concerns about deviations from US current Good Manufacturing Practice (cGMP) requirements, although ‘FDA has no evidence of harm to any patients who have taken drugs made in these two facilities’ (US Food and Drug Administration, 2008a). In respect of the Dewas unit, the 13-page Warning Letter details many concerns about possible cross-contamination of drug production, and of weaknesses in sterile processing arrangements observed during a 2-week visit by two investigators. The Letter also lists inconsistencies in Ranbaxy’s written reports that claim that the company is complying with quality assurance procedures (US Food and Drug Administration, 2008b). In the case of Paonta Sahib, the 7-page Warning Letter focuses on the results of a 5-day visit: the first reported concern was that the company’s ‘written records of major equipment cleaning and use are inaccurate’ (US Food and Drug Administration, 2008a: 2). The letter specified that ‘our investigative team uncovered fourteen (14) instances … where … records for equipment used in manufacturing operations … included initials or signatures of employees who reportedly verified cleaning of equipment but were not shown as present by security log records’ (US Food and Drug Administration, 2008a: 2). In February 2009 the FDA followed up these Warning Letters with an Application Integrity Policy [AIP] letter to Ranbaxy, which charged that:
These and other findings indicate a pattern and practice of submitting untrue statements of material fact and other wrongful conduct, which raise significant questions regarding the reliability of the data and information contained in applications (pending and approved) that your firm has filed with the Agency (US Food and Drug Administration, 2009).

Our point here is not whether pharmaceuticals produced by these plants were or were not dangerous or sub-standard, or were at enhanced risk of being so. Nor do we deny the possibility that the FDA selected Ranbaxy to benefit its competitors. Rather, the example shows how the FDA can and will play crucial and detailed roles in setting production and record-keeping standards at Indian factories – roles that are likely to become more common since the FDA has established a New Delhi office (in January 2009) and intends to use it to monitor about 100 production plants in India (Shankar, 2009). These activities take place completely outwith the oversight of the Government of India – who might well, by their tolerance of these activities, rather welcome the initiative, even if they are unable for political reasons to admit this. The FDA, of course, is acting only to protect US consumers: although it is sometimes argued that its actions will improve the quality of medicines worldwide, it seems more likely to lead to double standards – high standards for exported medicines and low standards for local, and especially rural, markets. Site visits of the scale and intensity mounted by the FDA far exceed those of the Government of India’s own regulators who are supposed to carry out the same tasks and to protect Indian consumers. In other words, perhaps without the general public being fully aware of what is going on, India is de facto accepting the idea that it should not duplicate approval processes within country but should instead rely on the expertise of stringent external regulatory authorities. On the other hand, we do not know if the products of these hyper-regulated factories are entirely for export, or if they also serve the local market.

These two examples do not make a case for more (or less) stringent implementation of the existing rules and regulations. Instead, they lead to two main conclusions. The first is that at neither of the two extremes (the regulation of everyday local practices, and the regulation of complex globalised technical practices) is the Government of India (or the governments of its constituent states) able play an independent and effective role. The second conclusion is that, whereas there are alternative actors able to step in and take over Indian government roles where failures impact on international trade, the equivalents at the local level (whether civil society activist or advocacy groups, professional associations or political parties) are either non-existent or too weak to have a similar impact.

Such a situation – of apparently strong regulations but weak implementation – is not unique to pharmaceuticals, of course. Myrdal regarded India as a classic ‘soft-state’ (Myrdal, 1968). More recently, Chhibber has argued that state intervention in India was not per se a mistake, rather its state-led development problems must be put down to the poor quality of that intervention (Chhibber, 2003). In the rest of this paper we provide some examples of how this situation has arisen, and of attempts by the Government of India to prevent or ameliorate the inadequacies of pharmaceuticals regulation in the country. In what follows, when we use the term 'pharmaceuticals’ regulation’ we mean the regulation of any aspect of the production, distribution, prescription or consumption of a pharmaceutical product or the raw materials that are used in its production.

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3 Indeed, the UK and Australian joint review of the same facilities in October 2008 approved them for a further 3 and 2 years respectively: see (Grogan, 2009).
4 The two extremes are, of course, related. Were the GOI able to regulate their local market it would be considered more trustworthy in international contexts.
Regulation in India: The Global and the Local

Since colonial times, the regulation of pharmaceuticals in India has been a problem for the Indian state. Under British rule, the state was faced with alternative medical traditions (which served the majority of the Indian population), making it difficult to legislate a single common standard pharmacopeia, or to establish a single set of rules for licensing medical practitioners qualified to prescribe the substances included in the list. The General Medical Council in London recognised Indian medical degrees in 1882. From 1907 to 1930, the Government of India tried to maintain this recognition, under increasing pressure to create an Indian Medical Council, which finally emerged in 1936 (Jeffery, 1979). But even then registered practitioners gained little benefit from becoming licensed by the Council, since their competitors could also practice and prescribe drugs (both cosmopolitan and according to local formularies) with little difficulty. The regulation of pharmaceuticals’ production was piecemeal until the Drugs and Cosmetics Act of 1940, and the (by now, much-amended) Drugs and Cosmetics Rules of 1945. An Indian Pharmacopeia was published in 1955, building on work that started in 1944. Until then, the British Pharmacopeia (with some additions) operated within the country (Singh, 1994).

In Independent India, the regulation of pharmaceuticals was divided between the Department of Chemicals and Fertilisers (for matters related to production quality and pricing) and the Ministry of Health (for the registration of pharmacists entitled to stock and sell medicines, and of practitioners entitled to prescribe them or to inject them).

One mechanism to overcome these divisions has been to draft Pharmaceuticals Policies, for example the Drug Policies of 1978, 1986, 2002 and 2006. These have been contentious: for example, the 2002 Policy was challenged in the Karnataka High Court through public interest litigation. The Court agreed with the petitioners that, if implemented as framed, the new policy would ‘bring the control of prices entirely at the whims and fancies of manufacturers’ and that it would defeat ‘the very purpose of equitable distribution and availability of essential drugs at a fair price’ (The Hindu Business Line, 2002).

We return to this issue below, since price control has been a recurrent issue.

A second means of integrating cross-Ministry concerns is through ad hoc commissions. Since 1948 a plethora of commissions, committees and task forces have reported on pharmaceuticals issues. Here we deal only with those established since 1995, when the Government of India began to grapple with the impact of the new form of globalisation in pharmaceuticals ushered in by the Doha round of international trade negotiations and the creation of the World Trade Organisation, TRIPS and the extension of patent protection to pharmaceutical products in India. The issues considered by several of these reports go to the heart of the regulation problems that we have been considering in our research.

Four main topics have dominated the committees that have reported since 1995:

1. Drug price controls
2. Controlling spurious or counterfeit medicines
3. Improving the chances of inventing and patenting new chemical entities
4. Establishing a centralised National Drug Authority

Four other concerns have been noticeable by the lack of attention they have attracted (All-India Drugs Action Network, 2006: 1):

5. Ethical promotion
6. Labelling and consumer information 
7. Elimination of irrational drugs and combinations 
8. Pharmacovigilance

We shall discuss these in turn, before considering the wider implications of these patterns for the quality of pharmaceuticals regulation in India.

1. Drug Price Control
A major concern of regulation has been of prices, and (not surprisingly), the main tussles have been between industry representatives (wanting to limit or remove price controls) and those claiming to speak for the consumers (calling for their extension and tightening). In 1970, almost all bulk drugs and their formulations were under price control, but the number was reduced to 347 bulk drugs in 1979, 142 in 1987 and then to 74 in 1995. A Drugs Price Control Review Committee (DPCRC) was set up in 1999: its recommendations led to the 2002 Pharmaceutical Policy, which proposed that, in order to reorient the domestic drugs and pharmaceuticals industry in the face of the challenges and opportunities from the liberalised economy, India’s accession to TRIPS and the impending advent of the product patent regime,

the span of price control over drugs and pharmaceuticals would be reduced substantially. However, keeping in view the interest of the weaker sections of the society, it is proposed that the Government will retain the power to intervene comprehensively in cases where prices behave abnormally (Department of Chemicals and Petrochemicals, 2002: section 11).

In over-ruling the Karnataka judgement that suspended the application of this policy, the Supreme Court nonetheless demanded that the Department of Chemicals ‘consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control and to review the drugs which are essential and life saving in nature’ (Department of Chemicals and Petrochemicals, 2005: 2). In July, 2003, therefore, the Government prepared a ‘National List of Essential Medicines’ (NLEM) consisting of 354 drugs, of which only 50 were under price control (Department of Chemicals and Petrochemicals, 2005: 3). The relevant Lok Sabha Standing Committee in 2005 strongly recommended bringing more NLEM Drugs under price control (citing the examples of Canada, Japan, and the UK) (Standing Committee on Chemicals & Fertilizers (2005-06), 2005: 49-50).

There are, thus, on-going pressures to maintain or even strengthen price controls: and considerable dispute about whether the existing controls are successful. As elsewhere, of course, brand leaders are able to reduce price competition by enhancing the ‘reputation’ of their branded goods, and by offering inducements to prescribers to use their products even though they are pharmacologically indistinct from those of their cheaper competitors. In many market segments, the brand leaders show both the highest prices and the largest sales, suggesting that these strategies are successful. Such companies usually avoid the drugs that are under price control. Some people argue that the prices of most drugs in India are below international comparator prices, in part because of the long history of freedom from product patent controls and thus the dominance of generic products in the market, and in part because of strong price competition by many small producers. Certainly in 1995 prices in India were well below what they were in, for example, Pakistan, UK or USA (see, for example, Keayla, 1996; Lanjouw, 1997). On the other hand, some critics (including the Federation of Medical Representative Associations of India [FMRAI]) point to the myriad ways in which the drug price control orders can be evaded (All-India Drugs Action Network, 2006; L. Taylor, 2007). Certainly, the division of responsibilities between the body responsible for approving drugs for marketing (the Drug Controller General of India, attached to the health ministry) and that responsible for price regulation (National
Pharmaceutical Pricing Authority, or NPPA, under the ministry of chemicals and fertilisers) does not help. The NPPA faces great difficulty in recovering its claims for fines from drug companies who breached the system of drug price equalisation account, and claims of violations of drug price control orders amounting to over Rs 13,000 million are being challenged in the courts.

How has the acceptance of WTO rules under TRIPS affected pricing of medicines in India? Around the time in 1995 when India signed up to TRIPS, many commentators predicted that this would lead to massive price increases in India (see Lanjouw, 1997 for a critical response). Since then, commentators have been more cautious (see, for example, Grace, 2004). The Ministry of Chemicals and Petrochemicals believes there are no upward price pressures in the Pharmaceuticals market (Department of Chemicals and Petrochemicals, 2008: 17). This situation can be read in several different ways. On the one hand, it could be argued that price controls have been successful; an alternative conclusion would be that the prices of drugs (and their availability for the poor) are set by a highly competitive market, and the drug price control orders play very little part in keeping prices low. We still await a definitive study of how adherence to TRIPS and the advent of product patent protection have affected either the availability or pricing of drugs (whether on or off patent) in India.

2. Controlling Spurious and Counterfeit Medicines

The picture presented by mass media is one in which India is a major source of spurious and counterfeit medicines, both globally and within India itself. A programme made by the BBC is often cited, and an article in The Lancet (Chatterjee, 2001) but India is also listed by the Pharmaceuticals Security Institute [PSI] as one of the top five sources of counterfeit drugs (N. Taylor, 2008b). Accusations that the extent of counterfeiting in India is substantial, dangerous to the public and leading to large losses for legitimate producers are regularly put forward by representatives of Indian companies (see for example, Mashelkar, 2003: 75-76). In 2002, a submission from the Confederation of Indian Industry (CII) to the 2003 Mashelkar Committee claimed that the WHO had estimated that

‘35% of fake drugs produced in the world come from India, which has a Rs. 4,000 Crore spurious drug market. About 20% of medicines in the country are fake or sub-standard. Of these, 60% do not contain any active ingredient, 19% contain wrong ingredients and 16% have harmful and inappropriate ingredients’ (Mashelkar, 2003: 76).

But in neither case was any evidence produced. The CII failed to provide the Mashelkar committee with evidence to support its claims, and the WHO denied ever having produced a study with the results attributed to it (Mashelkar, 2003: 76-7). In 2007 the OECD cited 2005

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5 In India, a drug is defined as spurious “a. if it is manufactured under a name which belongs to another drug; or b. if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or c. if the label or container bears the name of an individual or company purporting to be the manufacture of the drug, which individual or company is fictitious or does not exist; or d. if it has been substituted wholly or in part by another drug or substance; or e. if it purports to be the product of a manufacturer of whom it is not truly a product.” (Drugs and Cosmetics Act, Amendment Act of 1982, Section 17-B)

6 The nearest source we have found for these figures is a WHO IMPACT report that repeats an estimate that ‘many developing countries of Africa, parts of Asia, and parts of Latin America have areas where more that 30% of the medicines on sale can be counterfeit. Other developing markets, however, have less than 10%; overall, a reasonable estimate is between 10% and 30%.’ The same source states specifically for India that ‘Indian pharmaceutical companies have suggested that in India’s major cities, one in five strips of medicines sold is a fake. They claim a loss in revenue of between 4% and 5% annually. The industry also estimates that spurious drugs have grown from 10% to 20% of the total market’ (World Health Organisation, 2006).
European Commission statistics that 75 per cent of the cases of counterfeit medicines seized on the EU borders originated from India (Barnes, 2007). By 2007, however, only 35 per cent of medicines seized by the EU and treated as counterfeit came from India, while medicines originating in Switzerland comprised 39 per cent of the total – not highlighted by the OECD (European Commission, 2008).

If we accept the existing data, according to the PSI the extent of counterfeiting varies dramatically by drug: ‘Over 60 per cent of drugs seized were for treatment of erectile dysfunction and although a breakdown into individual medicines is not available it seems likely Viagra (sildenafil citrate) accounts for a sizeable chunk of this’ (N. Taylor, 2008b). But there is no good evidence for how far this applies in India. Dr M Venkateswarlu, former drugs controller general of India, estimated that: ‘At present, about 5 per cent of the drugs available in India are counterfeit while 0.3 per cent are spurious’ (Taylor, 2008a). His figures seem to derive from a report for WHO published in 2007 and based on an attempted random collection of 10,743 samples, of which 23 percent were deemed prima facie suspect, but only 8 of these samples (0.3 percent of the original drugs collected) failed an assay test (Sheth, Reddy, Regal, Kaushal, Sen, & Narayana, 2007).

Given the lack of reliable evidence in this area, it is not surprising that unsubstantiated claims and rumour drive out harder sources of information. The CII agenda seems to be to separate the respectable, safe, large producers from the myriad of small and medium enterprises, and thus to establish trust in the big Indian companies and enhance their export potential. But perhaps, as Delhi’s then deputy drug controller said in 2001, ‘Fake drugs are not Delhi’s problem and a lot of the times it is just old brand rivalry. The big fish cannot bear to find smaller chaps coming out with similar medicines so they say ‘spurious, duplicate, &c.’ (Chatterjee, 2001)

3. Improving the environment for inventing and patenting new chemical entities

With the transformation of the international trade regimes, the Government of India is increasingly active in assisting Indian companies with export, new drug discovery and clinical research (Department of Chemicals and Petrochemicals, 2008: 16-7). Figures showing the low level of R&D expenditure in the Indian industry, compared to its overall size, are quoted to show that such measures are necessary. The Government has introduced tax relief on research and development expenditures, loans on easy terms for drug discovery, and schemes to encourage collaborations between companies and public sector institutions.

In the run-up to the 2009 national elections, the Department of Chemicals and Petrochemicals announced eye-catching proposals to raise up to $2 billion annually through tax-free bonds to promote drug discovery and innovation-based pharmaceuticals industry in the country until 2020, with the hopes of gaining about 10-20 percent share of the world’s R&D business (Anon., 2009c). Following a contorted logic, a spokesman claimed that these measures would also reduce prices in the domestic market:

"Our idea is to fill in the missing links in drug discovery, starting from identifying the disease to inventing drugs and securing patent rights. This offers the population a chance

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7 This study used flawed methods of collecting samples, and therefore cannot be relied on, but the contrast with the industry estimates is too large to be ignored.
8 Interview, small-scale industry representative, 23 March 2008: ‘probably it’s a concerted effort by those people including the people in the government to somehow or the other side-line the small scale.’
9 The Government is also addressing the complications generated by the rise of technologies such as biogenetics (See Anon., 2005 for discussion of the 2003 Mashelkar Task Force report).
to have new cutting edge drugs at more reasonable prices than today." a senior official of
the department of pharmaceuticals said (Anon., 2009b).

Critics of these plans suggest that inadequate attention has been paid to the conditions in which
drug discovery and testing is currently regulated. Specialists in medical ethics have accused some
drug companies carrying out clinical trials in India of ‘compromising science and ethics in the
pursuit of profit’ and that inadequacies in the oversight mechanisms allow clinical trials to recruit
the ‘desperate’ and ‘most vulnerable’ members of Indian society (N. Taylor, 2009).

Ensuring that these latter concerns are addressed is a task well beyond the competence of the
regulatory agencies at present. Although they have been given some training by US and EU staff,
the numbers of inspectors available to monitor even the 200 or so trials registered with the
Clinical Trials Register of India [CTRI] by March 2009, let alone the 850 or so registered with the
US FDA as taking place in India, seems totally inadequate. The interests of the ‘industry’ and the
lure of growth, foreign exchange earnings and increased employment seem to run well ahead of
the ability to ensure that public health is not compromised.

4. Establishing a centralized National Drug Authority

Under the Constitution of India, the regulation of ‘Drugs’ is a concurrent subject, so the
responsibility is divided between the Central Government and the State and Union Territories
Governments. Unlike the movements to decentralise aspects of governance in India, since at
least the 1970s the central Governments has tried to reduce states’ autonomy and centralise
control in this field. The Hathi Committee of 1975 first proposed a national pharmaceuticals
agency, to provide uniform standards and a single authority to register drugs, because:

[Q]uality control of products manufactured anywhere in India was not solely the
responsibility of the State in which the manufacturing unit is located, since the product is
sold all over the country. If a unit in one State was allowed to manufacture and market a
product of substandard quality, this would nullify the measures taken by other states. It was
essential that the Central Government should assume responsibility for ensuring statutory
enforcement and control over the manufacture of drugs all over the country and also
supervise their wholesale distribution among the various States (Hathi, 1975: para. 33).

Although the 1978 national drug policy made no mention of this, the 1986 Drug Policy proposed
a National Drug and Pharmaceutical Authority (NDPA). The 1994 Drug Policy suggested a
National Drug Authority to monitor drug quality according to standard procedures. The 1999
Mashelkar Committee proposed establishing a Monitoring Authority to oversee Good
Manufacturing, Good Laboratory and Good Clinical Practice – but this, too, was not
implemented. The 2003 Mashelkar Committee proposed to strengthen the existing Central Drugs
Standard Control Organization (CDSCO) and the State Drug Controllers and create a Central
Drug Authority – a line also followed in the 2002 Drug Policy. Apparently, 15 State
Governments supported this idea (Ramachandran, 2003). Nonetheless, in 2005 the Pronab Sen
Committee returned to a centralising proposal, to ‘integrate the offices of the Drugs Controller
General of India, the Central Drugs Standard Control Organisation (CDSCO) and the National
Pharmaceutical Pricing Authority (NPPA), along with all the powers and functions of these
bodies’ (Sen, 2005: 55-56).

Despite these repeated proposals, by 2009 the Government of India had made little progress
towards creating a National Drug Authority. Opposition was strongest in Maharashtra, where the
state Drug Controllers’ Association opposed any dilution of their own rights. A test case for
centralised versus local autonomy has been the struggle to ban 294 fixed dose combination drugs declared irrational by the then-DCG(I) Dr Venkateshwarlu's directive of October, 2007. Drug companies whose licences are still valid can continue to manufacture these fixed dose combinations, whereas the State Licensing Authorities [SLAs] were refusing, in early 2009, to renew the licenses that had expired (Anon., 2009a).

In general, however, it seems likely that the proposals for an NDA emerge from frustration at the inability to solve two problems. The first is varying procedures and standards imposed by SLAs, a situation which has seen some producers apply for licenses from compliant SLAs if their own State is unwilling to grant a license quickly or on reasonable terms. Individual States have the right to refuse to licence production, but once a drug is approved in one State it can be sold throughout the country. Thus commodification precedes regulation: with nifty footwork, companies can avoid regulation almost completely. By acquiring a licence to import medicines but avoiding the processes required to market them, some firms can supply Indian consumers completely out of the purview of the drug control regime.

The second is the severe shortage of resources for testing drugs and licensing producers on the basis of the quality of facilities. Thus, despite repeated proposals from committees for the creation of new posts and investment in laboratory equipment, the current infrastructure is completely inadequate to cope with the numbers of drugs, producers, pharmacies and prescribers. According to Dr Venkateshwarlu (DCG(I) 2006-08) ‘there is now a six to nine month backlog at each of the plants which results in less then [sic] 1 per cent of drugs being tested’ (N. Taylor, 2008a).

What is left out?

Among the issues that are not given the same degree of attention are the following.

5. Ethical promotion and the restriction of incentives to prescribers and pharmacists.

Major issues arise with the possibility that drugs are prescribed or dispensed more for the financial interests of the prescribers and dispensers than the needs of the patient. One example is the substitution of drugs by the pharmacist:

This is again a peculiarity of the Indian market, if you prescribe in generics you would expect the retailer to give that medicine which is the lowest price. Here if you write the generic name the retailer interprets it like he has the license to give any medicines. So he gives that one that will fetch him the maximum commission (Interview Dr Hazra, CDMU, 29 December 2006).

In Nepal, attempts to control substitution and a linked system of ‘bonuses’ as incentives to pharmacists to do this, generated a heated debate and was stalled by the opposition of almost all sections of the pharmaceutical supply chain (Harper, Rawal, & Subedi, 2009). Evidence for the existence of undue pressures on prescribers in India is also abundant: medical representatives were willing to talk in some detail about the range of incentives they had available in return for substantial orders. They are under great pressure to extend the incentives given on the launch of a new drug, or to provide incentives to pharmacists if doctors are being given one. We asked one medical representative whether doctors ask him for tickets to go abroad:

Medical Rep: Actually, now there is a slight change in the market. We ask doctors. If we think someone is right to go abroad. Then we ask doctors. Some are interested but some
are not. If they want to go … we do.
Researcher: one of our friends is working in Kolkata, when she was taking interview she was told, one doctor was gifted with a car by the company. Is there any case of …?
Medical Rep: Yes, but only in metro cities.
Researcher: Not here in Bijnor?
Medical Rep: In Bijnor, if I am promising a car to the doctor then the doctor has to commit to me. Then I will tell the doctor that … every month … suppose the cost of the car is 2 lakh rupees, then he has to give us the business of 50-60,000 or 70,000 per month in one or two years. He will have to write a lot of medicines. If the doctor is ready to commit then we don’t have any problem. We have a doctor, a very good doctor from Meerut, No.1 Gastroenterologist in UP. He was gifted with a car.

(Interview transcript, 27 October 2007, Bijnor)

Although there is a longstanding critique of these activities (Gulhati, 2004), then, there is little embarrassment amongst medical representatives in talking about them (see also Roy, Madhiwalla, & Pai, 2007). The slogan ‘convince, confuse, corrupt’ seems to capture the sequence of efforts they make to sell their products – despite a somewhat grudging admiration for doctors who refuse to be seduced into prescribing on this basis, or who check whether their patients have been given the drug they actually prescribed, rather than a substitute. It is hard to find any information about the effectiveness of the voluntary codes run by the larger pharmaceutical associations. In early 2009 Government officials hinted at the creation of legal restraints on unethical promotion, but this seems to have been pre-election posturing rather than a serious proposal (Alexander, 2009).

6. Local-language labelling and information sheets.

We know that many prescribers and most patients in India are not literate in the English that is used in drug information packs. Add to this that – as in many other countries – drug information varies from brand to brand, leading to the possibility of misleading patients and prescribers about appropriate use, co-occurring effects and drug interactions. A WHO study called for ‘further training and continued education aimed at drug regulatory officials’ to ‘provide the necessary knowledge and enable national authorities to meet the need for drug information that is independent of commercial interests’ (Reggi, Balocco-Mattavelli, Bonati, Breton, Figueras, Jambert et al., 2003) but no substantive moves have been made in this direction in India.

A particular issue in India is the labelling of Ayurvedic medicines: after complaints that some ingredients turn out to be heavy metals or even steroids, Ayurvedic medicines for export now need to be labelled with their ingredients; no equivalent regulations apply for drugs sold within India (Chandy & Mathew, 2006: 59). Many pills are sold in small numbers, cut off from the full strip and without any information on co-occurring-effects or advice about co-consumption with other medicines. In the absence of effective information, the Indian Medical Association’s call to be allowed rights to prescribe “off-label”, activists noted ‘the western example of offlabel use being cited by the IMA cannot be applied to India because Indian patients often have poor levels of literacy and education’ (Sharma, 2004: 1372). Obtaining informed consent is so hard, some argue, that off-label uses would be equivalent to treating patients like guinea-pigs. Despite these concerns, few efforts have been made to change the situation.
7. Eliminating harmful, ineffective and irrational combinations of drugs.

Activists have been involved in trying to reduce the number of drugs for sale in the Indian market, and particularly combinations of drugs, since the early 1980s. The Government of India introduced a ban, using the generic name of the drugs involved, but manufacturers avoided the ban by saying that their drug name was not on the list. In pharmacology the number of drugs that should be used for therapeutic reasons is around 7000 but the Indian market contains almost 70000 drugs. This ‘massive gap between science and non-science’ leaves a huge number of drugs to be banned (Interview, Dr Hazra, 29 December 2006). Although irrational combinations was an issue taken up with some zeal by Dr Venkateshwara, his successor has taken what some see as a ‘softer’ stand, for example allowing 150 fixed dose combinations to stay on the market as long as they are checked for harmful effects (Anon., 2008).

An additional issue in India is the possibility of registering a drug as Ayurvedic, and thereby avoiding both licensing and price controls. Most of the evidence about the significance of these processes, however, is little better than anecdotal:

Then, Rhône-Poulenc, the French MNC, was marketing a drug which they sell as allopathic drug in the rest of the world. Its trash! But here in India, it is licensed as an Ayurvedic drug. Once a drug is licensed as an Ayurvedic drug, it does not come under the purview of price control. You can charge anything! Then there is no testing also. So a modern drug, marketed elsewhere as allopathic, only in India it is marketed as Ayurvedic drug. There is no herb there! Just by pleasing the drug control authorities, you can get the license (Interview, PK Sarkar, BODHI, 24 Jan 2007).

While Drug activist groups (such as AIDAN, the All-India Drugs Action Network, and the FMRAI, Federation of Medical Representative Associations of India) are actively engaged in campaigning against these practices, progress is very slow. The magnitude of the task is reflected in the fact that the single best-selling formulation in India – Corex, an expectorant, sold by Pfizer – is regarded by many as one of the key examples of ineffective combinations.

8. Pharmacovigilance

Pharmacovigilance, also known as post-marketing surveillance or Phase IV trials involves issues of safety and ongoing technical support of a drug after it receives permission to be sold. Clinical trials rarely involve enough patients to be sure that less common side effects and Adverse Drug Reactions [ADRs] are picked up by the time a drug enters the market. In addition, in everyday use, a drug is used in combination with many others, and drug interactions may only be picked up some time after the drug has been introduced. Pharmacovigilance is gaining importance in developed countries and can lead to drugs being recalled. But record-keeping by Indian doctors is completely inadequate to contribute substantially to these processes (Anon., 2007). With WHO support, a National Pharmacovigilance Programme was launched in India in 2005 (Patvardhan, 2005) but its effectiveness remains unknown. This might not be a problem, were the populations covered in developed countries similar (in body mass, for example), disease patterns alike, and the kinds of multi-drug prescribing akin to those in south Asia. None of these is likely to be true, however, so it is likely that there are safety issues that are not being picked up.

Effective pharmacovigilance systems would take not only a greater investment in testing laboratories to eliminate the possibilities of spurious drugs being implicated in adverse reactions, but also some system of tracing patients and being able to record which drugs they had taken. Such a system might be possible within the urban middle class market (where body mass and
disease patterns may not be very dissimilar from those of developed countries. But in urban slums and the rural areas, especially where the public health system has collapsed, the chances of any ADRs being picked up are slight. Once again, no serious attention has been given to these issues within any of the documents we have been able to access.

Modelling of Regulations: The Role of Local Context

What do these eight examples of regulatory concerns and absences demonstrate? We will address this through two main questions:

(a) How far do they suggest that the pharmaceutical industry – whether MNC or Indian origin – dominates how the ministries responsible for regulation so that they regard the interests of the industry as coterminous with that of India as a whole?

(b) What kinds of models of society lie behind the proposals – and the gaps in proposals – that emerge from these examples?

\(\textit{(a) Regulatory Capture}\)

Regulatory capture matters if it leads to higher prices, lower levels of availability or lower safety standards. Abraham concludes that, in the case of the European and US drug regulatory systems,

The present drug regulatory systems are insufficiently robust … because they prevent proper public accountability, are highly vulnerable to industrial capture, and permit the industry’s scientific experts to have extensive conflicts of interest while providing their expert advice (Abraham, 2002: 1501).

Abraham goes on to call for a regulatory system that is transparent in its procedures, makes available all the data on which it takes its decisions, capable of independent testing by providing state-funded state-of-the-art testing facilities, and able to prevent all conflicts of interest between regulators and their other activities, whether at the time or after retirement.

One complication to applying this perspective in India is that the industry is divided into different sectors, and is represented separately: the OPPI (Organisation of Pharmaceuticals Producers of India) represents the large multinational research-based companies, mostly foreign-owned; IPA (Indian Pharmaceutical Alliance) with leading domestic pharmaceutical companies; CIPi (Confederation of Indian Pharmaceutical Industry) and SPIC (Small Pharma Industries Confederation), both of which claim to represent small-scale producers; and BDMA (Bulk Drug Manufacturers Association) representing companies making the active pharmaceutical ingredients. We have already noted some bases of division amongst them (for example with respect to spurious drugs, and to subsidisation of drug discovery in India).

Nonetheless, the general perspective (suggesting that, frequently, regulators will find a single interest group in favour of particular decisions) holds at least some of the time. As a result, few of these issues – of public accountability through rights of access to regulatory information, independent tests and technical expertise, clear and independent funding, and control over conflicts of interest – are dealt with properly in the Indian system. The regulatory bodies are under relatively little pressure to build public health concerns – especially those that affect the mass of the Indian poor – into their deliberations. Only on price control – and then only partially so – can the Indian system be said to operate really independently of the pharmaceuticals industry. On irrational drugs – those acknowledged on all sides to have no efficacy or to be harmful – the
Regulators have failed to achieve more than a small part of their stated goals despite efforts over several years. On prices, Indian regulators are continually challenged – by legislators as well as by civil society institutions – to implement the rules and to extend them to a greater proportion of the essential drugs list; in no other sphere are there organised interests to push regulators to act other than in the interests of the industry.

To what extent are regulators themselves ‘captured’, either by straightforward corruption or by the lure of lucrative positions after leaving government service? The former is frequently alleged: many of our interviewees accused the lower-level officials of awarding licences (whether for production or sale) after receiving a bribe to do so. If (as seems likely) such bribes are only partially retained by these officials but are passed up the system (e.g. through higher officials taking a share, or by posts being ‘sold’ to the highest bidders) then this suggests that changes in the practice are likely to be hard to eliminate.\(^\text{10}\) Whether a ‘revolving door’ applies in India is not yet established: we could not discover, for example, whether or not recent holders of senior positions in the major drugs control agencies (National Pharmaceutical Pricing Authority (NPPA), CDSCO (Central Drugs Standardization and Control Organization), Indian Council of Medical Research or NIPER) have moved into the industry after retirement, but anecdotal evidence suggests that some at least have developed consultancy careers in this way. And the most prominent member of pharmaceuticals committees from 1995 to 2007 – Dr R A Mashelkar, also a member of the Scientific Advisory Council to the Prime Minister and of the Scientific Advisory Committee to the Cabinet – has moved into board-level positions with at least eight private companies, three of which (Indigene, GencMedix and Piramal Life Sciences) have strong pharmaceuticals interests, and another (Reliance Industries) includes basic chemicals as well as retail interests. To be clear, we are not suggesting there is any impropriety whatsoever in his actions, but can imagine that examples of this kind might well encourage other senior regulatory officials to treat the pharmaceuticals industry with additional care and attention.

(b) Models of Society

In the commissions that have been established since 1995, the interests are always represented are those of civil servants from some (but not always all) of the relevant Ministries of the Government of India: Health, Chemicals and Pharmaceuticals, Home Affairs, Finance and Planning, for example. State Governments – responsible for the ground troops (such as drugs inspectors, or District Health Officers) tasked with implementing regulations, are usually conspicuous by their absence, as are representatives of rural medical practitioners, pharmacists and drug wholesalers and consumers. Some committees do draw on a wider range, such as the Commission on Macroeconomics and Health, whose membership came from a larger set of constituencies, including (for example) the Voluntary Health Association of India, the Society for Education, Action and Research in Community Health, a journalist, economists and doctors from the private sector, as well as various Ministers and ex-Ministers. The 1999 Mashelkar Committee, however, leaned heavily on industry representatives, especially large Indian multinationals, such as Ranbaxy’s and Dr Reddy’s.

The voices of others could also be provided by those invited to give evidence to the committees, or who came invited. For example, the deliberations of the 2003 Mashelkar Report had presentations by scientists; by representatives of the Indian Medical Association (IMA), the Delhi Pharmaceutical Trust, Ahmedabad-based Consumer Education and Research Centre (CERC) and the Confederation of Indian Industry (CII).

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\(^{10}\) For more on how corruption practices are sustained in Indian bureaucracy, see (Wade, 1985).
The preponderance of membership, submissions and evidence, then comes from industry representatives and scientists. The regulation of drugs and medicines, it seems, is rarely perceived to be a matter of governance, of public health, or of politics. Significantly, in our view, what is missing from these commissions are two things. The first is a frank acknowledgement of how little effect the current regulations have: how far they are flouted in practice, however well they have been crafted. There seems to be a wilful blindness towards the everyday circumstances in which most drugs in India are produced, distributed and consumed – and the conditions within which substantial numbers of people get such limited access that these concerns seem illusory. The second, and linked to this, is the absence of a clear strategy to change that situation. The end state – a ‘modern’ society where rational considerations hold sway, preferably through the activities of small numbers of producers and marketing firms, with an honest and efficient, technically qualified regulatory agency to keep an eye on them – is imagined, with no defined steps that might lead to that situation, except for more laws or regulations added onto the existing ones. In other words, policy debate proceeds to ignore institutionalised corrupt practices and vested interests and relies on ‘a conceptualisation of policy that is technical and depoliticised’ (Harriss-White, 1996: 85).

The image of society, industry and politics is dual: an existing modern sector that is assumed to be distinct from a non-modern one, and it is assumed that the modern sector will – within a finite period – swallow the non-modern sector up. The liberalisation of the Indian economy since 1991 might be thought to hasten such a process. But it is clear that deregulation of pharmaceuticals is not a defensible option in India, at least not in the ways that are being tried out in other industries. No alternative strategy has been set out. Furthermore, the modern sector is in fact interlinked with the non-modern one. Small-scale manufacturers, for example, make many of the drugs sold by the large companies under loan licences, and the expansion of sales outlets is heavily linked to the unlicensed practitioners and quasi-legal pharmacies, for example. In this sector of the economy, the mirage of ‘India Shining’ seems to have completely eclipsed that part of the ‘Republic of Hunger’ that, in part, makes the former possible.

Conclusion

The regulation of pharmaceuticals in India is only a particular example of how it is modernising: the government rationalise, try to apply scientific knowledge to controlling this area of social life, and in this way extend their reach, in order to reduce the risks to which their citizens are subject. In the specific field of pharmaceuticals, such interventions are justified both by the relative ignorance of patients about their medical needs and by the potential for unfree competition posed by very large companies in oligopolistic markets. Not unreasonably, when India ‘models its pharmaceutical regulations’ it, draws on a range of international examples – including Canada, the UK, and the USA – because these countries face many similar challenges. But despite the rising strength of Indian manufacturing capacity, India’s system of pharmaceutical regulation remains partial and ineffective. One reason for this is that the expertise mobilised in attempts to reform the current system is curiously ‘detached from local contexts’ (Jansen & Roquas, 2005: 142, 143). The national commissions, committees, task forces and expert groups, whether set up by the Health Ministry, the Department of Chemicals and Pharmaceuticals, or the Planning Commission, focus on only a sub-set of the significant issues and rarely draw on knowledge of everyday practices of the distribution, prescribing and consumption of pharmaceuticals. What is needed is an engagement with those everyday practices – an engagement that commissions, task forces and expert groups seem unlikely ever to achieve.
References


Montpellier, France: Decision News Media SAS.


