Architecture of Drug Regulation in India
What are the Barriers to Regulatory Reform?

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Abstract : *The regulation of pharmaceuticals in India is generally seen to be in need of reform, and has been the subject of many official commissions since 1995. Most commentators agree that the state should intervene to prevent untrammelled market forces leading to citizens' suffering, because adequate information about the costs and benefits of different pharmaceuticals is inaccessible to most users. But in India, a wide range of stakeholders must be considered before changes can be made to the regulatory framework. In addition, many international agencies influence these processes. Efforts to enhance India's capability to regulate medicines sold within the country come into conflict with other processes that tend to locate responsibility and power elsewhere, whether in the hands of global institutions or with other governments. In this paper the authors we discuss the extent to which the barriers to regulatory reform can be understood as 'industry capture' by reviewing the constitution, focus and effects of the main pharmaceuticals task forces, commissions and committees established in India since 1995.*

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I
Introduction

Pratap Banu Mehta, social scientist, argued recently that governance reform is not so much about "implementing designs created by committees of technocrats. Rather, the first order of business is to restore credibility to the state itself" [Mehta, 2009]. But, in the sphere of pharmaceuticals, this task is not straightforward. Even in (or perhaps, especially in) developed industrial countries "the pharmaceutical industry influences the perspective of the regulatory agency-so it comes to adopt their interests over and above those of patients", i.e. that "the agency could be said to be captured". Regulatory capture matters because "the risk-benefit assessment of drugs has a high degree of technical uncertainty, which is inherent in toxicology, clinical trials, and epidemiology" and it therefore matters whether regulators "give the manufacturer the benefit of scientific doubt about safety and efficacy of their product" [Abraham, 2002: 1498]. Abraham

concludes that, in the case of the European and north American drug regulatory systems, there is insufficient public accountability (inadequate rights of access to regulatory information), a lack of independent tests and technical expertise, insufficiently clear and independent funding (some regulatory agencies are funded at least in part by user fees), and poor control over potential conflicts of interest for regulators.

But the debates that Abraham summarises are concerned largely with only one part of the field of pharmaceuticals regulation – relating to the approval of new drugs, and monitoring their effects. If one takes a 'product-life' approach to pharmaceuticals regulation, however, one needs to look at what happens to such approved drugs once they are formulated, distributed, marketed, prescribed and consumed. In Europe and north America, there tends to be an assumption – which may or may not be justified – that issues of prescriber and retailer regulation, ethical marketing and so on have been largely resolved. On the other hand, there is considerable concern about issues such as post-approval tracking and pharmacovigilance, to pick up adverse drug reactions (ADRs). But in the Indian system, these contextual issues have not been resolved; and ADRs are unlikely to be discovered nor acted upon. In India, and elsewhere, there are serious doubts over whether regulatory bodies are able to build public health concerns – especially those that affect the poor – into their deliberations.

In this paper we address these issues by using our research on 'Tracing Pharmaceuticals in South Asia' to consider issues of regulation and how far this constrains inappropriate use at all stages, from the sourcing of raw materials (bulk drugs) to the final consumption of the product. We consider the recent history of attempts to reform the Indian regulatory system, and suggest that they illuminate two key features of the situation. The first is that in contemporary India, issues of pharmaceutical regulation are rarely discussed in 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; and second, that the local regulation of production, distribution and consumption is inadequate to deal with the global context within which these processes take place.

II
Regulation of Pharmaceuticals in Contemporary India

Pharmaceuticals regulation in India – with apparently strong regulations but weak implementation – is not a unique situation [Myrdal, 1968]. [1] Chibber 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 [Chibber, 2003]. In the rest of

this paper we assess how this situation has arisen with respect to pharmaceuticals and of attempts by the Government of India to prevent or ameliorate the inadequacies of its regulation in the country. In what follows, the term 'pharmaceuticals' regulation' means 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.

Our research confirms the large gap between the regulations that exist on paper and the everyday practice of pharmaceutical use. At the level of the final consumer, there is considerable self-prescription of drugs: with or without a written prescription, ill people or their representatives can purchase virtually any medicines they can afford, without necessarily taking the advice of any kind of practitioner [Das and Das, 2007]. This is so despite classifications of medicines into categories that require the prescription of a qualified medical practitioner before they can be sold. Further, individuals can make a living through prescribing and selling medicines, despite regulations that restrict these activities to the holders of specified qualifications (medical degrees or pharmacy training): a situation of *jugār* medicine: medicine that is 'make-do-and-mend.' 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, 2004: 377].

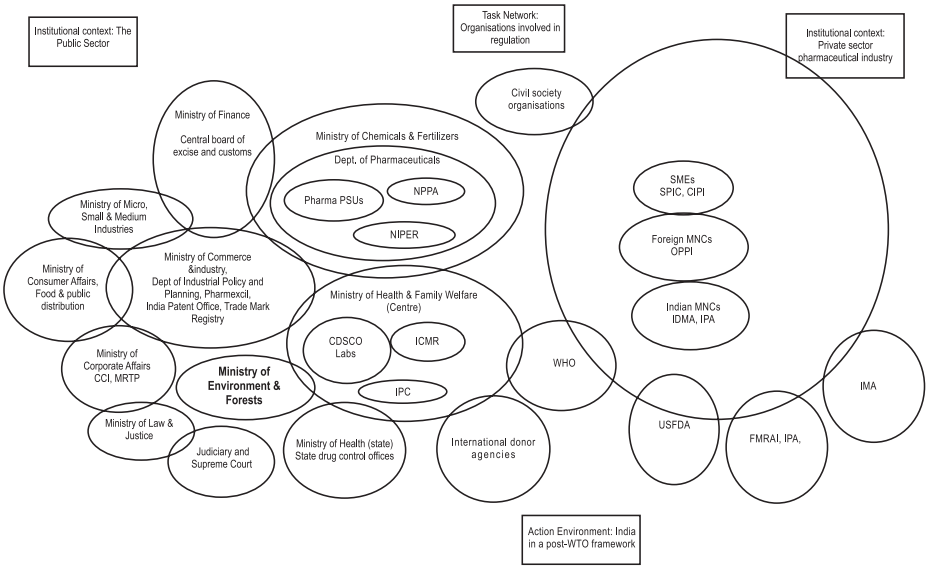
Similar issues can be seen in terms of the licences needed to stock and distribute medicines, or to manufacture them. Although an Indian version of current WHO-Good Manufacturing Practice has been incorporated into the Drugs and Cosmetics Act (DCA) through the amendment of Schedule M, there is considerable doubt whether the rules are applied coherently or universally throughout the industry. Medicines cannot (in general) be introduced into the Indian market without approval by the Drugs Controller General of India (DGCI) whereas State Licensing Authorities (SLAs) issue manufacturing licences: but there inefficiencies and varying standards allow producers to get their new combinations of medicines approved for sale by the less strict SLAs (for a discussion of these relationships, see http://www.assocham.org/events/recent/event_278/_dr._surinder_singh.pdf). And, as we shall discuss later, the processes of removing dangerous or inefficacious medicines is very hard to implement. Few formal regulations affect marketing practices: although some of the producers' associations have promulgated their own guidelines [see, e.g., OPPI, 2007] there is little evidence that such guidelines are followed, nor what action has been taken to discipline any infringements.

In independent India, pharmaceuticals regulation was divided between the Ministry of Chemicals and Fertilisers, now through a separate Department of Pharmaceuticals (for matters related to production *quality* and pricing) and the Ministry of Health (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 through pharmaceuticals policies, for example the Drug Policies of 1978, 1986, 2002 and 2006. These have been contentious, however. The 2002 Policy was challenged in the Karnataka High Court through public interest litigation that claimed that, if implemented as framed, the new policy would 'bring the control of prices entirely at the whims and fancies of manufacturers' and would defeat 'the very purpose of equitable distribution and availability of essential drugs at a fair price' [*The Hindu Business Line,* 2002]. The Karnataka court ruled in their favour, but was over-ruled in the Supreme Court. Nonetheless essential and life saving drugs were ruled to remain under price control [Department of Chemicals and Petrochemicals, 2005: 2].

The global context affects pharmaceuticals regulation in contemporary India not just through the activities of WHO and other UN bodies, but also through the effects of policies adopted by globalised procurement agencies (such as The Global Fund to Fight AIDS, Tuberculosis and Malaria) and foreign regulators (see Diagram). The US Food and Drug Administration [FDA], for example, now investigates whether producers who wish to export either bulk drugs or formulations to the USA follow current Good Manufacturing Practice (cGMP) guidelines (US Food and Drug Administration,

Diagram: OOganisations in Pharmaceutical Regulation in Context (following Matsebula, Goudge and Gilson,2005)



2008a; US Food and Drug Administration, 2008b). It now plays crucial and detailed roles in setting production and record-keeping standards at Indian factories – roles that are likely to become more common since it established a New Delhi office (in January 2009) and will use it to monitor about 100 production plants in India (Shankar, 2009). Site visits of the scale and intensity mounted by the FDA probably 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 developing countries should not duplicate approval processes within country but should instead rely on the expertise of stringent foreign or global regulatory authorities.

Commissions as a Means of Reform

One means of integrating cross-ministry and inter-state concerns is through ad hoc commissions, committees and task forces. Here we describe only those established since 1995, when the Government of India began to grapple with the new form of globalisation 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 and their characteristics shed light on the problems of moving towards a more effective regulatory regime.

In many of these committees, Dr R A Mashelkar played a central role. Those most relevant to pharmaceuticals are the Committee on Research and Development in Drugs and Pharmaceuticals (1999); the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs (2003); the Task Force on Recombinant Pharma (2005); and the Technical Expert Group on Patent Law Issues (2006).

Mashelkar had a distinguished career as a polymer scientist and manager of science. He was the Director General of Council of Scientific and Industrial Research (CSIR) from 1995-2006, a member of the Scientific Advisory Council to the Prime Minister and also of the Scientific Advisory Committee to the Cabinet. He came to public notice for his vigorous attack on American firms attempting to patent turmeric and basmati rice. He has a wide view of the role of science in Indian society, for example, seeing the need for child-centred education, woman-centred families, human-centred development, a knowledge-centred society and innovation-centred India [Mashelkar, 2000]. In the commissions he has chaired the interests that are always represented are civil servants from some (but not always all) of the Ministries of the Government of India that have an interest in the field: Health, Chemicals and Pharmaceuticals,

Home Affairs, Finance and Planning, for example (see Table). State governments – responsible for people 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, such as the Commission on Macroeconomics and Health, do draw on a wider 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, leant heavily on industry representatives, especially large Indian multinationals, such as Ranbaxy's and Dr Reddy's. When new policy proposals are under consideration, the opinions of representatives of producer interests can be canvassed in other ways as well. Ram Vilas Paswan, as Minister for Chemicals and Fertilisers, called in 50 top executives from large Indian companies for consultation on his proposals for a new regulatory framework for clinical trials and the encouragement of innovation in research and development [Anon., 2009b].

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

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

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)

Membership of Key Government Committees Reporting on Aspects of Pharmaceuticals Regulation in India, 1995-2006						
(1)	(2)	(3)	(4)	(5)	(6)	(7)
R. A. Mashelkar (CSIR) (GoI)	✓		✓			✓
Health & Family Welfare (GoI)		✓		✓	✓	
Chemicals & Pharma (GoI)		✓	✓		✓	
Planning Commission (GoI)				✓	✓	
DCG(I) (GoI)		✓	✓		✓	
DGHS (GoI)			✓	✓		
NPPA (GoI)		✓			✓	
State Sec. Health/Drugs			✓			
CII (Industry)			✓			
FICCI (Industry)		✓	✓			
OPPI (Drug Cos.)		✓	✓			
IDMA (Drug Cos.)		✓	✓			
IPAll (Drug Cos.)			✓			
AISSDMA (Drug Cos-Small)			✓			
IPAss			✓			
CCC (Consumers)			✓			
AIDAN (Public health experts)		✓				
Police (Enforcement)			✓			
World Bank (Donors/Technical)				✓		
WHO (Donors/Technical)				✓		

Sources for Table:

- Column 2: Mashelkar, R. A. (1999). Transforming India into a Knowledge Power: Report of the Pharmaceutical Research and Development Committee. New Delhi: Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilisers, Government of India.
- Column 3: Department of Chemicals and Petrochemicals. (1999). Memorandum. New Delhi: Ministry of Chemicals and Fertilisers.
- Column 4: Mashelkar, R. A. (2003). Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs. New Delhi: Ministry of Health and Family Welfare, Government of India.
- Column 5: National Commission on Macroeconomics and Health (2005). Report. New Delhi: Ministry of Health and Family Welfare.
- Column 6: Sen, P. (2005). Report of the Task Force to Explore Options other than Price Control for Achieving the Objective of Making Available Life-saving Drugs at Reasonable Prices. New Delhi: Department of Chemicals & Petrochemicals, Government of India.
- Column 7: Mashelkar, R. A., Mehta, G., Datta, A., Menon, N. R. M., & Sharma, M. (2006). Report of the Technical Expert Group on Patent Law Issues. New Delhi: Indian Patent Office.

Legends:

AIDAN:	All-India Drug Action Network	IDMA:	Indian Drug Manufacturers Ass
AISSDMA:	All India Small Scale Drug Manufacturers Association	IPAll:	Indian Pharmaceutical Alliance
AIOCD:	All India Organisation of Chemists & Druggists	IPAss:	Indian Pharmaceutical Association
CCI:	Consumer Coordination Council	NPPA:	National Pharmaceuticals Pricing Authority
CII:	Confederation of Indian Industry	OPPI:	Organisation of Pharmaceutical Producers of India
CSIR	Council for Scientific and Industrial Research	FICCI:	Federation of Indian Chambers of Commerce & Industry
DCG(I)	Drugs Controller-General (India)	DGHS:	Director-General Health Services
DGHS:	Director-General Health Services	Note: other members have occasionally been included.	

and those championing consumer interests (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 should be reduced substantially [Department of Chemicals and Petrochemicals, 2002: section 11]. But in responding to the Supreme Court's demands (see above) the Department of Chemicals had to '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 then under price control [Department of Chemicals and Petrochemicals, 2005: 3]. The relevant Lok Sabha Standing Committee in 2005 also 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 from civil society and political representatives 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 some (but not all) market segments, the brand leaders show both the highest prices and the largest sales, suggesting that these strategies are successful. [2] Such companies usually avoid the drugs that are under price control. The prices of most drugs in India are below international comparator prices [see, for example, Keayla, 1996; Lanjouw, 1997]. But 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.

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]. Nonetheless, the Ministry started a scheme in 2008 to provide all 350 essential drugs through *Jan Aushadhi* stores at a claimed level of around 75 per cent of the price of branded medicines available in the market: it is as yet too soon to see the impact of this scheme. Apart from this, following the recommendation of Pronab Sen Committee, the Government of India also constituted a 'Committee on Price Negotiations for Patented Drugs and Medical Devices' to explore the possibilities of introducing price negotiations before the grant of marketing approval of patented drugs.

The prices situation can be read in several different ways. On the one hand, price controls may have been successful; alternatively, 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. In 2006, NIPER conducted a study on the *Impact of TRIPS on pharmaceutical prices, with specific focus on generics in India* which concluded that "fears pertaining to TRIPS related increase in drug prices in India are unfounded. Analysis of data on prices of selected drugs, following the TRIPS agreement shows that prices of drugs in India have been by and large stable ... No sudden changes in prices have occurred even after implementation of TRIPS (Post 1995) and are unlikely to occur even after introduction of the product patents" [NIPER, 2006].

Recently, NPPA has launched a grievance redressal cell (Complaint Submission and Redressal System, or CSRS) with a senior officer to hear grievances from the general

public on the issues of overcharging, shortages and sale of scheduled formulations without prior price approval of NPPA (http://nppaindia.nic.in/redressal.htm). However, as in the case of many other grievance-redressal mechanisms, the CSRS remains unknown to the general public.

Controlling Spurious and Counterfeit Medicines [3]

The picture presented by mass media is one in which India is a major source of spurious and counterfeited medicines, both globally and within India itself. A BBC programme is often cited, as is an article in *The Lancet* [Chatterjee, 2001]. India is also listed by the Pharmaceuticals Security Institute [PSI][4] as one of the top five sources of counterfeit drugs [Taylor N., 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 multinational and large Indian companies. 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 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 fact, Indian pharmaceutical companies' unsubstantiated claims seem to be the sole source cited by the WHO [World Health Organisation, 2006]. In 2007, the OECD cited the 2005 European Commission data 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 – but this statistic has not been widely cited [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 … it seems likely Viagra (sildenafil citrate) accounts for a sizeable chunk of this' [Taylor N., 2008b]. But there is no evidence for how far this applies in India. A 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 N., 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 per cent were deemed *prima facie* suspect, but only 8 of these samples (0.3 per cent of the

original drugs collected) failed an assay test [Sheth et al, 2007].[5]

Given the lack of reliable evidence in this area, 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, etc." [Chatterjee, 2001].

Improving 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.[6]

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, in order to gain up to 20 percent of the world's R&D business [Anon., 2009c]. 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 [Taylor N., 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 Registry - 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.

Establishing a Centralised 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, to ensure uniform standards across the country [Hathi, 1975: para. 33].

Although the 1978 National Drug Policy made no mention of this, the 1986 and 1994 Drug Policies proposed National Drug Authorities 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 Organisation (CDSCO) and the State Drug Controllers and create a Central Drug Authority (CDA) – 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]. A Bill was introduced in Parliament to establish a CDA, and Mashelkar's views on this were regarded as so significant by the Parliamentary panel charged with investigating the Bill that it delayed its report until he had been consulted [Shankar, 2008]. The draft Bill was heavily criticised by the committee [Alexander, 2008b] and the need for redrafting led to its being abandoned before the Lok Sabha elections of 2009 [Alexander, 2008a].

Despite these repeated proposals, by 2009 the Government of India had made little progress towards creating a National Drug Authority, perhaps partly because, health being constitutionally on the concurrent list, centralisation of drug control may pose additional legal hurdles. Opposition was strongest in Maharashtra, where the state Drug Controllers' Association opposed any dilution of the rights of state Drug Controllers. 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) 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.

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 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" [Taylor N., 2008a].

What is Left Out?

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

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: as Hazra, CDMU, told us in an interview "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" (December 29, 2006).

Evidence for the existence of undue pressures on prescribers in India is abundant. The Gujarat-based Torrent Pharmaceuticals openly announced in their website incentives for prescribing their medicines. The company then took hundreds of doctors on chartered flight to various tourist destinations such as Bali and Fuket. Though a formal complaint with evidences was made to IDMA on this, no punitive action has been taken so far [Nagarajan, 2008]. Medical representatives were willing to talk to us 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. A medical representative described the process in small-town north India, "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 Rs.2 lakh, then he has to give us the business of Rs. 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' (Interview transcript, October, 27 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 et al, 2007]. Some doctors refuse to be seduced into prescribing on this basis, or 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].

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 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 and 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 off-label 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.

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 have 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 70,000 drugs, and 151 dubious combinations of drugs that are not approved in developed countries [MIMS, March 2009]. Although irrational combinations was an issue taken up with some zeal by Dr Venkateshwarlu, his successor has taken what some see as a 'softer' stand, for example allowing these dubious 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. 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.

Pharmacovigilance

Pharmacovigilance, which includes 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, there are unknown numbers of 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. Furthermore, given the drug consumption patterns we have described for India, there can be no guarantee that drugs approved for limited populations (e.g. sub-sets of sufferers from a particular condition for whom possible risks are outweighed by benefits) will not be consumed by many others for whom

the balance of risks, costs and benefits are very different. Once again, no serious attention has been given to these issues within any of the documents we have been able to access.

Significantly, in our view, two things are missing from these Commissions. 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.

III
Conclusion

The regulation of pharmaceuticals in India is a particular example of how the industry is modernising: the government rationalises, tries to apply scientific knowledge to controlling this area of social life, and in this way extends its reach, in order to reduce the risks to which its 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 and 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 subset of the significant issues and rarely draw on knowledge of everyday practices of the distribution, prescribing and consumption of pharmaceuticals.

It could be argued that there is merely a problem of timing: that it is only a matter of time before the realities of a modernising India catch up with the framework of regulation that has been established. But this seems unlikely. Pinto, for example, suggests that *jugār* 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. Yet 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].

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Notes:

[1] More research is needed into which regulations are implemented, however.

[2] In some cases, branded generic products are more expensive than those produced by innovator brands.

[3] 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 b ears 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)

[4] The Pharmaceuticals Security Institute [PSI] is closely linked to the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). The IFPMA Director-General serves as the PSI President.

[5] 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. A new study on similar lines was started in late 2008, involving the collection of 24,000 samples.

[6] 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).