Chapter 7

MAPPING THE QUALIFICATION OF DRUGS IN THE CONTESTED TERRAIN OF DRUG REGULATION IN INDIA

This chapter attempts to map the qualification of drugs in the contested terrain of drug regulation in India. The previous chapter, through the case study of a controversial drug Nimesulide, demonstrated how the terrain of drug regulation is a contested terrain, consisting of heterogeneous actors or a hybrid group involved in the shaping of knowledge claims related to attributes of drugs.

The present chapter examines the ways in which the discourse of the firms, in relation to the qualification of drugs, is received and shaped by the members of this hybrid group such as health activists, regulatory bodies, academicians, physicians etc in the context of different regulatory issues. Accordingly, the chapter examines the contestations among these actors on a range of issues such as the generation of patents, R&D activities, licensing of medicines, the conduct of clinical trials, compliance with manufacturing protocols, marketing practices, monitoring of adverse drug reactions and policy issues and their implications for the different ways in which drugs are qualified by these actors. In addition, the chapter also attempts to understand the negotiations among these actors with respect to such qualification. In this sense, the qualification of drugs is sought to be understood within a relatively larger and denser canvas.

However, even in this contested terrain, there may areas of convergence (Abraham 2008:870) between actors, which are dictated by common interests. Accordingly, the chapter

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174 In doing so, the chapter does not attempt to examine all aspects of these issues. Rather the effort has been to selectively focus on those aspects, which are relevant to the research problem.
attempts to highlight not only contested spaces and practices in the sphere of drug regulation but also areas in which a few of these actors may converge for mutual interest.

The arena of patents and R&D related activities

The principal contestations in this sphere stem from government regulations on patents, the R&D strategies of firms, the provisions regarding Exclusive Marketing Rights (EMR) and the provisions on data exclusivity. The Indian government’s rationale for initiating the new patent regime in the country in 2005 has been on the grounds that it would stimulate research and development activities and innovation by encouraging firms to invest more in these activities. However, health activists have contested the patenting related strategies of ‘evergreening’ (Chaudhuri 2007) resorted to by firms, particularly multinational companies, in order to extend exclusive marketing rights on their products. In the pharmaceutical industry, such ‘evergreening’ may relate to a product (a specific molecule), a process (e.g. the process to manufacture this molecule), a medical indication (e.g. the effect of this molecule on the human body) or a combination of products (e.g. a fixed dose combination of two molecules). The result is that a single medicine can be protected by a large number of patents, each relating to a different invention. Moreover, if years later, the concerned firm discovers that the molecule works against another disease or affliction than the one it was originally patented for, another patent can be filed by it for the new use of this old molecule. (Pascal et al 2004).

The government perspective has been that Section 3(d) of the Indian Patent Act, 2005 adequately ensures prevention of the filing of frivolous patents and “ever-greening” and thus ensures curbs on wasteful R&D in terms of me-too molecules.\textsuperscript{175}

\textsuperscript{175} The section deals with the definition of patentability and specifies that patents will not be granted automatically for different forms of the same molecules, such as salts, esters, polymorphs etc and that decisions
However, questions have been raised on the adequacy and effectiveness of these amendments to the Patent Act on the grounds that what constitutes a significant difference in efficacy has not been clearly defined in the clause.

Now of course, under Section 3(d) of the Indian Patent Act, it mentions that small changes in molecular structure do not qualify for patenting of the new molecule, unless the new molecule significantly differs in efficacy. There is ambiguity about what this significant difference in efficacy actually means. Laws cannot cover all ambiguity, so these clauses have to be interpreted. This is usually left to the interpretation of the technical bodies. But some people are of the view that you should not have left that window open. This is just one example. There are other similar clauses. You can also understand patents in terms of whether patenting is actually promoting real or desirable innovation, how desirable or essential or rational these patented drugs really are. The ways in which these legal clauses will be interpreted is ultimately a political decision.176

This skepticism is shared by other health activists, who contend that the introduction of the term “efficacy” into patent law is a deviation since “efficacy” has traditionally been a requirement, which has been used in the context of regulation. They also argue that with reference to the interpretation of these clauses, the efficacy arguments could be interpreted as “novelty of effect”, which would soon pave the way for further interpretation as “novelty of use”. However, the definition of a “new chemical entity” in terms of “novelty of use” has been excluded in the latter part of Section 3 (d) of the Act. These concerns about the definition of “new chemical entities” have been voiced as it is widely believed among

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176 Respondent 42. The respondent, who is a medical practitioner and reputed activist, has worked and published extensively on patents and drug pricing issues and is a member of the Jan Swasthya Abhiyan, New Delhi. (Interview carried out on 22/02/08)
activists that this would be a determining factor in the scope of protection of new drugs and
the availability of generic alternatives.¹⁷⁷

A recent report commissioned by the Department For International Development
(DFID), in the context of access to medicines, has partially endorsed the government’s
claims and argued that the government’s post-2005 policies with regarding to the
implementation of the TRIPS agreement have focused on maintaining the availability of
drugs for local consumption and exports at low prices and cushioning the impact of the
patent regime on the domestic industry. The report has also sought to highlight how such
initiatives have been met with approval by domestic manufacturers, in terms of according
legitimacy to their generics production activities. However, the report argues for greater
legal clarity on aspects related to the implementation of the patent regime, on what is
patentable in India, on the conditions or grounds in which patents granted within India could
be over-ridden by Indian firms and the procedures to be followed for pre-grant and post-
grant oppositions. (Sampath, Gehl 2008:11).

In the period prior to the amendment of the Act, the U.S. based firm Pfizer emerged
as the biggest pharmaceutical patent applicant in India as the Kolkata-based Patents Office
opened the mailbox of patent-pleas for pharmaceutical and agrochemical inventions for
1995-2005. These mailbox applications are meant to recognize inventions as India switches
to a new product patent regime. Among Indian firms, Dr Reddy’s Laboratories, with 205
mailbox submissions, was the most aggressive patent seeker. Ranbaxy Laboratories proved
to be a less aggressive user of the mailbox with just 38 filings. Delhi-based company
Panacea Biotech put 75 applications, followed by bigger firms like Dabur India with 56, Sun

¹⁷⁷ Report of the WHO-SEARO-Centad workshop on ‘Definition of New Chemical Entities: Implications for
flexibilities in Patent and Drug Regulatory Laws held on August 4-5, 2008 in New Delhi.
Pharma with 46, Cipla with 45. However, India’s second position in the chart after US, as opposed to other countries, does not truly reflect its true patenting prowess as opposed to other countries and is reckoned to be much less in fact. Proximity has been cited as one of the reasons for disproportionately high number of Indian pleas. A vast majority of these filings are reckoned to be either frivolous or preventive pleas.\footnote{See IDMA Bulletin XXXVI (12) March 30 2005. ‘Patent Mailbox Opens, Pfizer is top applicant’, Source: Financial Express, March 21, 2005} It is believed that the new amendments to the Patent Act in 2005 would act as a deterrent to such pleas in the future.

These facts are significant as they indicate at the paucity of future innovative potential as embodied by therapeutically better products in the Indian pharmaceutical market. They seem to corroborate the perceptions of activists that patent filings are more about monopoly and retaining market share than innovation.

Organizations such as Medicines Sans Frontiers have also been making concerted efforts to outline and disseminate the disabilities arising in terms of access to essential medicines for developing countries through patents. The organization contends that though patents are by no means the only barrier in terms of access to essential medicines, they are a significant determinant in the sense that they grant the patent holder a monopoly on a drug for a number of years. It argues that the patent holder’s freedom to set prices has resulted in drugs being unaffordable to the majority of people in developing countries and that for neglected diseases such as sleeping disease or Chagas disease or leishmaniasis, which affect only poor people, a patent holder would never be able to make a profit by charging high prices, so little R&D is conducted on these diseases. The patent holder’s monopoly ensures that a higher price than necessary is paid for patented inventions. The steep prices charged for AIDS cocktail drugs are cited as an example. The organization’s stance is that each
country must be able to design and operate its patent system in its own best national interests, using the flexibilities in the TRIPS agreement since people in developing countries are not getting their part of the patent bargain. (Boulet et al 2004). These initiatives are motivated by the trepidation that the amendments to the Patent Act in India will not curb R&D efforts deemed as frivolous and wasteful.

With reference to the quality discourse, it is perceived that the efforts to bring about harmonization of standards, specifically with regard to IPR laws and regulatory protocols has led to a needless mixing of IPR issues with issues related to drug quality. These efforts are seen as oriented towards the idea of creating “exclusive rights” and “facilitating a monopolistic or oligopolistic trade regime”. The issue of access to medicines for the poor is a recurrent trope in these contestations.

As far as R&D issues are concerned, the contestations centre on the claims made by domestic firms about their drug discovery capabilities and the nature of their R&D activities. The claims made by firms about their growing R&D capabilities in drug discovery are dismissed on the grounds that most of the leads generated by firms through reverse pharmacology had failed in the stage of clinical trials. These failures are also articulated in terms of the absence of a research ambience and insufficient expertise in the areas of methodological tools, toxicology and molecular biology.

Frankly, it’s too early to comment. Not a single drug has come out into the market as yet. As of now, what we have are leads. There are these 12-14

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179 The report brought out by MSF as part of their Campaign for Access to Essential Drugs, attempts to disseminate and demystify several other issues related to patents elaborately. However, only aspects germane to our concerns have been mentioned here.

180 Presentation made by Mr Santhosh M.R. entitled “New Threats to Access to Medicines” at the “Universal and Rational Therapy Dissemination Workshop of Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption” held in New Delhi on April 8-9, 2009.
leads, which are in the Phase I or Phase II clinical trials stage. What we have seen is, during Phase I, Ranbaxy has fallen, with their lead for prostate cancer; Reddy’s have fallen in Phase II with their diabetes drug. Glenmark claims that they have a couple of leads in the Phase II stage. You need a large amount of funds to do basic research, which we simply don’t have. There are several reasons why we haven’t been able to succeed. We have no knowledge or haven’t been able to develop expertise in using tools of drug development or animal models; we’re weak in toxicology and molecular biology. Abroad there is so much of research going on as far as methodology for new drugs is concerned. Same in the case of toxicology. Abroad, you have firms with years of carrying out these basic research traditions, they have the ambience, a tradition of collaboration. Where do you find all this here? Well, what we’ve done is, we’ve used reverse pharmacology and come up with 12-14 leads.181

The leads generated by Indian firms are also dismissed on the grounds that less than five percent of these molecules would reach the stage of commercialization. These articulations also attempt to link the R&D activities carried out by the firms in terms of their potential incentive for monopoly pricing. The argument is that firms in India target diseases which have a market abroad rather than focusing on the needs of the Indian population.

Pharma R&D is driven by IPRs. This is because monopoly pricing is possible. So they target diseases which have a market abroad rather than in India. HIV-AIDS is a rare example, where research efforts are in conjunction with the Indian situation. When you have a monopoly pricing system, firms are only going to innovate for obesity or baldness. (laughs). Indian firms are not even able to do that properly. You have this 10-90 gap, where 90% of the research is done for 10% of the population. You have to ask the question, whether this new product is an actually new entity or just a combination. As far as R&D efforts are concerned, Phase I and II is entirely a matter of speculation. Out of the 15 or so leads, less then 5 per cent may have the actual potential to get into the market. These leads are generally original but some of them might be me-too molecules, which have been originally patented by firms abroad and Indian firms tinker with these

181 Respondent 35, a prominent academician and activist, is the ex-President and patron of Delhi Society for Promotion of Rational Use of Drugs. The respondent has also served as a member in the National Pharmacovigilance Committee. (Interview carried out over telephone on 26/02/08).
molecules, then make variations in the chemical structure and apply for patent.\textsuperscript{182}

In terms of issues related to data exclusivity, health activists and domestic firms have raised objections on grounds of the losses accrued to generic manufacturers through delay in securing approval for production, imports, exports or distribution of such products or in terms of a wrongly approved drug due to non-disclosure of information and on grounds of public health interests. The argument here is that data exclusivity would lead to increased costs in terms of the obligatory health care to be provided by the state.\textsuperscript{183} Multinational firms in India and their representative body, the Organization of Pharmaceutical Producers in India (OPPI), however, seem to be pressing the government for data exclusivity. Regulators, on their part, seemed to be cognizant of and receptive to the anxieties expressed by multinational companies. As a regulator remarked:

\begin{quote}
With regard to data exclusivity, mechanisms to dispel the anxieties of firms, particularly multinationals, have not been framed.\textsuperscript{184}
\end{quote}

Further, the respondent admitted that majority of the new drug applications received for registration from firms were for old drugs with new indications, new combinations, new routes of administration etc.

\textit{We have received around 150 new drug applications. Majority of these are basically subsequent new drug applications (SNDA) with claims for old drugs, in terms of new route of administration, dosage, new fixed dose combinations etc. Only about 18-20 applications are for new leads. For new drug application, we sometimes take outside expertise. Say for oncology, we may use a subject expert. There are no particular criteria.}

\textsuperscript{182} See fn. 176 for profile of the respondent
\textsuperscript{183} Presentation by Mr Narendra Zaveri entitled “Data Exclusivity-I: What is the claim for?” at the workshop on ‘Definition of New Chemical Entities: Implications for flexibilities in Patent and Drug Regulatory Laws’ held in New Delhi from August 4-5, 2008.
\textsuperscript{184} Respondent 27 is a drugs controller with the CDSCO, in charge of new drug applications. (Interview carried out on 16/01/2008)
These experts may be from public or private sector. They may be pharmacologists, toxicologists, biochemists etc.

If drug quality is understood as subsuming therapeutic efficacy, these observations also point to the gap between real needs and manufactured needs in terms of the absence of any added therapeutic advantage of these new combinations or products, inspite of firms’ claims of generating innovative products. The motivation to come up with these leads is simply articulated in terms of firms’ need to generate greater revenues and eliminate competition.

A few health activists have recently attempted to join hands with the WHO in the context of the General Strategy and Plan of Action (GSPOA) initiative on public health, innovation and intellectual property rights. The GSPOA initiative has attempted to find solutions to amend the neglect of public health-related R&D by advocating the encouragement of alternative models like the Open Source Drug Discovery and other kinds of incentives for firms engaging in research in neglected therapeutic areas. A senior scientist and policy analyst passionately outlined the need for such initiatives.

The R&D component of CSIR is changing. You find R&D related linkages being organized in terms of a certain portfolio. Firms are actually capturing these public institutes. If you look at process R&D in CSIR, the thrust on this has actually reduced. Majority of the R&D is on the Type I diseases. Here also we are only at the basic research stage, or say pre-clinical development. We haven’t been able to take our leads through to clinical trials. There is not much R&D for the Type II or Type III diseases. The situation is not very different from that in the earlier patent regime. The private sector is doing business as usual. Now, the share of R&D in the private sector has gone up. Multinational companies are spending about 2% on neglected diseases. But they are the biggest beneficiaries from the government.  

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185 Respondent 44 is a senior scientist at a CSIR laboratory in New Delhi, which attempts to analyze issues related to science and development and generate appropriate policy related solutions. The respondent, an
The sphere of Clinical Trials

With reference to clinical trials, the perceptions among the hybrid groups are again varied, though there is obviously agreement on the fact that these trials ought to be conducted in ways that are safe and transparent. The discourse here is constituted by several kinds of articulations. One such articulation valorizes India’s emergence as a hub for clinical trials. The observations here are in terms of how India is emerging as an advantageous site for clinical trials on grounds of its diverse genetic pool and disease variation, the presence of numerous government funded and private medical and pharmaceutical institutions with state of the art facilities, the cost efficiencies, amounting to nearly 60%, in comparison to developed countries, advantages in terms of the quick recruitment of large number of patients, skilled human resources and opportunities for young Indian professionals in terms of demand for capabilities in different areas. In this context, the amendments in the Drugs and Cosmetics Act in relation to clinical trials and the increased stringency of the Schedule Y provisions are welcomed since they confer greater credibility to these trials and speed up international approval. The focus of such articulation is also on the emerging opportunities of the market and how the country has “miles-to-go” before it can capitalize on the advantages that these trials could offer.

The advantages outlined in this context for India are in terms of the opportunities for trial participants to avail of cutting edge biomedical innovation, reimbursements received by hospitals for participation in trials, which could benefit all patients served by the hospital, opportunities for researchers to participate in international standards research, exposure of

engineer by qualification, has published extensively on issues related to the pharmaceutical industry in India. (Interview carried out on 27/03/08)
Indian health care system to international clinical research, the maturing of the regulatory environment etc. However, at the same time, there is also a cautioning against risky practices in the scramble to capitalize on the advantages of the new economic order. In a nutshell, such articulation legitimizes the conduct of clinical trials on a large scale in India with the caveat of elaborate safeguards to ensure ethical practices. (Maity and Raghavendra 2007:1-10).

Other articulations in this context emphasize on the need to balance economic opportunity with public health concerns. Though these articulations express concern over the potential distortion of public health related research efforts, the emphasis on expensive therapeutic drugs rather cheap drugs and vaccines and the inadequacy of the regulatory system to monitor such trials, they also point to the potential benefits of these trials in terms of attracting foreign investment, development in areas such as clinical epidemiology and applied research. (Dandona 2006:55-56).

The views expressed by a respondent also echo this pragmatic outlook. The respondent, in addition, also outlined other desirable conditions such as the setting up of accreditation centres for investigators and the detailed perusal of informed consent records and other important dossiers by Institutional Ethics Committees and the stance is that these desirable conditions render the burgeoning number of trials in India both useful and profitable.

If these clinical trials are done in accordance with Schedule Y norms, they are useful because they add millions of dollars and bring in money and create expertise. Ethics committees are not always competent to judge the worth of the clinical trial material. You need to do surprise checks, take into account things like informed consent and side effects. You need to give Institutional Ethics Committee members important dossiers in advance. They should be paid a nominal fee. These are practices which are followed in countries like the United States. Then, there are these problems about
ownership of data. You cannot get the clinical trial material published. That’s desirable on grounds of ethics, equity and transparency. You need to have proper accreditation centres for investigators. If you are looking at informed consent, there should be evidence on how many people refused to give consent and on what grounds. There are good and bad trial centres. If we object to trials in toto, we are going to be the losers. What you need to do is to set rigid controls, to have non-medical members in ethics committees to set the house in order. During the last 15 years we have prepared the ground in clinical trials and now we have to prime ourselves to take advantage of it. But our regulatory authorities do need to pull their socks up by way of more staff and expertise.  

Yet another kind of articulation is more strident and sharply critical, claiming that clinical trials in India constitute a rehashing of colonialist practices (Nundy and Gulati 2005:1633-36). The observations in this context are to the effect that the recent move on the part of the government to do away with the “phase lag” constitutes a strategy to enable firms to profit in the relatively liberalized regulatory regime. The argument here is that the scramble by multinational firms to carry out clinical trials in India stem from the difficulties that these firms experience in carrying out trials in their own countries due to the safety and compensation requirements and the dwindling number of patients volunteering for trials. The articulations here are in terms of the unethical conduct of such trials, the inadequacies in the regulatory machinery and the vulnerability of the Indian population. The argument is also advanced that these trials are conducted in diseases which do not really benefit the Indian population, are based on drugs with minimal therapeutic advantage and do not

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186 See fn 181 for profile of the respondent
187 In January 2005, an amendment to Schedule Y of the Drugs and Cosmetics Rules did away with the phase lag in international clinical trials conducted by foreign sponsors. This practically translates into absence of restrictions on concurrent clinical trials in India and means that Phase 2 and Phase 3 trials of drugs discovered abroad may now be conducted in India in the same phase and at the same time as they are conducted in other parts of the world. Phase I trials, carried out on a small group of healthy volunteers, collects data pertaining to the safety and adverse reactions of the drug. Phase II, conducted on a larger group, looks at efficacy and safety of the drug. Phase III trials try to validate the results obtained from the earlier phases on a larger group of people and Phase IV trials are carried out after a drug obtains marketing approval. Here trials may be done in order to ascertain new uses of the drug or to monitor drug interactions.
constitute a guarantee that they would be available to the local populace after the trial period.

A recent exploratory study on clinical trials, conducted by the Centre for Studies in Ethics and Rights, Mumbai (Srinivasan 2009:1-44) emphasizes on these above-mentioned deficiencies and takes a highly cynical view of government priorities and policies on the ethical conduct of such trials. The study attempted to look at ethical concerns related to clinical trials conducted in India, the results of which were used in the approval of new drugs in the European Union. It examined biomedical research practices in terms of a) clinical trials in humans, used for drug development and approval; b) trials conducted for marketing purposes; c) research conducted in the ‘garb’ of clinical practice and d) ‘unscientific’ and ‘unethical’ research practices for collecting information towards drug development (ibid: i). The investigation especially focused on one trial of lapatinib, a drug for breast cancer, carried out by Glaxo-Smithkline; one trial of resperidone, a psychiatric drug, carried out by Johnson and Johnson and two trials of quetiapine, another psychiatric drug, carried out by Astra Zeneca. The investigation concluded that these trials violated Indian Council of Medical Research’s ethical guidelines for biomedical research and the guidelines enshrined in the WMA Declaration of Helsinki and benefited from a weak regulatory apparatus that is over-reliant on local institutional ethics committees and is permissive towards unethically conducted trials. The report also concluded that government policies seemed to take a neutral stance towards the mushrooming of CROs and the conflict of interests involved in their generation of infrastructure in small towns in the country, their identification of trial sites in small private hospitals, their rush to generate databases of potential trial participants and provide substantial incentives for medical professionals
recruiting patients in these trials. The study was also critical of government policies in the context of their prioritizing the production of good quality data according to Good Clinical Practices (GCP) and treating the ethical considerations involved in these trials as being of secondary importance. (ibid:iii,5).

In terms of the emphasis of the present study on the qualification of drugs by these groups in the context of clinical trials, the details presented in the above-mentioned investigation are especially significant. To cite an example, in the context of examining the approval history of lapatinib, the CSER investigation highlights the disagreements between the European Medicines Agency (EMEA) and Glaxo Smithkline on the clinical benefits of lapatinib and how the firm convinced the regulatory body that the use of the drug in combination with other drugs ensured minimal severe or life-threatening toxicity and that its benefits were greater than the risks. The trials in India were apparently conducted in the context of the ‘conditional approval’ given by the EMEA, which necessitated further evidence on the drug’s safety and efficacy profile. In this regard, the investigation also dwells on how firms’ strategies to increase the indications for use of these drugs have led to a corresponding expansion in their market. Multinational firms thus have a vested interest in ensuring early and favorable results with respect to these drugs, which is strategically executed through clinical trials in countries like India, which have a lax regulatory regime. (ibid:20).

The example of lapatinib, provided in the study, is interesting because it demonstrates how the drug was qualified in different ways by the regulatory body and the firm and the subsequent negotiations among them with respect to the safety and efficacy of the drug. The ‘conditional approval’ given by the EMEA is one example of how the trial
results conducted in countries like India are crucial in terms of how these drugs get qualified and approved by regulators in the West.

But in continuation of the discussion on the contestations among the hybrid groups in this sphere, the remarks made by a respondent highlighted the conditions which facilitated the manipulation of data by contract research organizations at trial sites such as improper procedures in relation to informed consent, recruitment of poor and vulnerable population, inadequate expertise of ethics committee members and ineffective review procedures by local regulatory authorities:

Schedule Y may be conceptually good. But the techniques for obtaining informed consent from participants are not very transparent. These patients are poor and illiterate. They may be explained these things in a brief, hasty and abrupt manner. Often, the side effects are not properly conveyed to them. Since these documents are not in public domain we don’t know what is happening. DCGI may review these trials with the documents but anyway they don’t audit in person. In a country like India, that is also very important. In these Institutional Ethics Committees (IEC), majority of them do not have any conflict of interests. I have also been a member in a few of these committees. But all the members in these committees may not be well trained to review the documents. So there you have scope for corruption, because they may cook the data. To give a very simple example. They may have favourable data for two patients; they may cook data for 4 people.

The respondent added:

Ethics committee members usually don’t have the time to go through all the documents thoroughly. These discrepancies may not be visible to them. Then, corruption is also possible if some firm goes to a private practitioner with some old drug and wants clinical trials to demonstrate some new results or benefits through dosage or route of administration, there also the material may not be genuine. The DCGI just audits the documents. So they won’t have an idea of the practices in that particular clinic.188

These views were corroborated by another respondent who called into question the expertise of the regulators and stressed on their dependence on the Institutional Ethics

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188 Respondent 36 is the Executive Vice-President of Delhi Society for the Promotion of Rational Use of Drugs and a professor of pharmacology at a medical college in Delhi (Interview carried out on 27/02/08)
Committees to uncover and correct malpractices. The respondent also dwelt on the shortcomings of the Institutional Ethics Committees in terms of improper recruitment procedures, absence of systematic SOPs for the conduct of the proceedings of these committees and violations of protocols related to the functioning of these committees.

Schedule Y and GCP is fine but if you look at Institutional Ethics Committees, they have many shortcomings. Sometimes, the members are not recruited according to the protocols, the investigators want to have their own people, the SOPs for the conduct of the IECs are either not there or they are not systematic, they meet very infrequently, they have the tendency to review the trials by correspondence rather than by actually attending the convened meetings and sometimes they don’t go through documents systematically. If the concerned firms or CROs find that the trial is not approved at a particular site, they go and find another favourable site. DCGI virtually has no expertise to assess ethical issues in these trials, they are dependent upon the IEC chaps to point out what’s wrong, which virtually never happens.

However, the articulations of another respondent, engaged with the training of firm personnel with regard to clinical trials, outlined the procedures mandated by the revised Schedule Y guidelines such as reporting of adverse events to IECs within a week, written informed consent of trial subjects and mechanisms to ensure accuracy and validity of trial data. The respondent elaborated on the ‘legitimate’ reasons for data-related inadequacies during trials such as the quitting of personnel mid-way through the trials, trial subjects not following dosage related instructions or delays in randomization of trial subjects.

Now with the new Schedule Y guidelines, we need to have written informed consent with only eligible subjects. You have to report all adverse events to ethics committees within seven days, provide required reports to committee members, there are mechanisms to ensure that trial data are accurate, complete and verifiable from source data, that all illegible data, errors and omissions are collected. In our training academy we sensitize firms to abide by all these guidelines. Now after the trial, as per Indian regulations, the trial data has to be archived for 15 years. It’s not as if all this is done arbitrarily. Ethics committees take a lot of time to sanction approval. Inspectors may

189 Respondent 41, a very senior and reputed activist is the editor of Monthly Institute of Medical Specialities (MIMS) India(Interview carried out on 19/02/08)
also come down for regulatory visit. Inspectors review documents, facilities, records and any other resources considered by them to be related to the clinical trial. There are some problems here; these may be genuine, for instance resource changes happen, during trials, sometimes resident doctors may quit the organization, laboratory data for some subjects may go missing, randomization may not be on schedule, trial subjects may take one dose of prohibited medicine, may not take medicine in correct dosage or may take concomitant medicine longer the time frame permitted by the protocol. These are the examples where there is poor adherence to protocols.  

The discourse of clinical trials is thus constituted by several kinds of articulations ranging from the need to maintain a balance between market potential and public health to emphasizing exclusively on ethical issues and issues concerning public health. The arguments against the inadequacy of infrastructure and expertise, both research-wise and clinically, pointed out by critics of drug trials, mostly health activists, are justified by a few academicians on the grounds that isolationism would be unviable in the current climate. Curiously enough, another argument advanced is that just as manufacturing standards witnessed an improvement in India, after firms began adopting stringent standards for export purpose, the same trend would be visible in the domain of clinical trials in order to attract foreign investment. (Mamdani and Mamdani 2005:132-33). However, one could argue that this argument is invalid in the context of clinical trials.

The remarks made by a young regulator seem to corroborate health activists’ accusations about the neutral stance of the regulatory authorities on clinical trials conducted by contract research organizations and multinational companies in India and their refusal to

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190 Respondent 20 is General Manager of the Academy for Clinical Excellence, which trains firms on how to carry out clinical trials (Interview carried out on 29/04/08)

191 In Chapter 5 reference has already been made to how large firms have adopted stringent manufacturing standards. However, such production facilities have been set up with an eye on international regulatory approval for the export of generics rather than in terms of catering to the domestic market. For the domestic market, large firms generally choose to get their products manufactured by small and medium scale firms through contract manufacturing.
grant any substantial credibility to concerns about ethical violations. Risk benefit assessments of clinical trials are articulated by the regulator in this context in very instrumental terms of the country’s obligation to be a part of trials and share the risks involved in the testing of drugs that its subjects could potentially benefit from in the future.

Whatever trials are sanctioned they are conducted in multi-specialty hospitals. The doctors there are academic-minded. It is not easy to corrupt them. The kind of reports which come in the media, they are reducing trust in the doctors and it affects our regulatory image. Now if you see, for the last 50 years or even more, American and European subjects were tested for so many drugs. We enjoyed all those benefits because our firms could make those drugs by copying in the earlier patent regime. Now it’s time that we not only enjoy benefits but we share in the risks also. So don’t visualize this by highlighting one or two cases. Anyway, if you compare demographically, in our country, the percentage of subjects participating in clinical trials is negligible. Yearly, there are large numbers of trials which are approved. We regulate the sponsors, we get all the documents from them. There it is mainly self-regulation. They (the sponsors) have to follow the ICMR guidelines and also the modalities for GCP inspection. We take help from outside experts also. After our recent amendments, we have become more stringent. We have to verify whether the impact of the drug is synergistic, there is safety, efficacy etc.192

Another regulatory official’s remarks reinforce regulators’ faith in IECs capacity to monitor trials adequately and regulators’ perceptions that ethical violations constitute an exception rather than the norm. The motivation of Contact Research Organizations to regulate themselves and conduct these trials according to protocols is articulated in terms of their desire to remain in the market for the long haul and thereby ensure that their credibility is not harmed through unethical practices. The utterances are also to the effect that the recent amendments to Schedule Y and regulators’ stringent monitoring of documents related to the trials are a sufficient guarantee of compliance with protocols.

192 Respondent 25 is a junior and newly appointed regulator in the CDSCO, in charge of Schedule Y related compliance (Interview conducted on 18/01/08)
If you ask me my opinion, there should be some data exclusivity but it also should be used for the masses. There should be provision to have some ready-to-compare data if similar data comes. The priorities of our new Schedule Y provisions are to take care of trial subjects, to ensure that there is unbiased reporting of trial results by the contract research organization or firm and to take due action in case of adverse reporting. We try to ensure that their documentation is perfect. Our new Schedule Y standards for clinical trials are comparable to ICH-Good Clinical Practices (GCP) standards. If you are thinking that there should be auditing of CROs by making personal inspections, nowhere in the world, this has been done. I personally feel there is more accountability due to new Schedule Y provisions. Now with our new ethics committee composition format, things are better. All these things have been well defined in the guidelines. Also things like proper consent of human subjects. The documents should be translated in the local language for them. See self-regulation is being done by CROs in India. They are doing that because they want to play a long innings in India. Moreover, we are also regulating them. Some NGOs and activists are making this unnecessary noise. Okay, two or three clandestine activities, you tell me in which part of the world it is not there? That does not mean the entire system is faulty.\textsuperscript{193}

These articulations also point to regulators exhibiting a ‘culture of trust’ rather than an ‘adversarial culture’ in connection with the implementation of the Schedule Y protocols by sponsors and their dependence on the IEC committees to point out ethical lapses.

But to again return to the quality question, there is a perception among health activists that the drugs, for which Phase II and the multicentric Phase III trials are sought to be carried out in India, are only incrementally better than the older drugs. (Nundy and Gulati 2006). Thus the anticipated therapeutic benefits are articulated as being minimal and as not justifying the risks involved in these trials, however minimal these are construed as being by the institutions involved in the process. There is also the trepidation that commercial pressures may lead to more emphasis on clinical trials for expensive therapeutic drugs than

\textsuperscript{193} The respondent is a senior regulator at the CDSCO. (Interview conducted on 18/01/08)
on preventive vaccines and cheap drugs. In a nutshell, firms’ qualification of drugs tested in clinical trials is broadly based on their commercial worth and their potential to give expected results in animals and human subjects. The qualification of these drugs as useful or desirable, by activists, is in terms of norms related to whether the risks to the largely vulnerable, poor and treatment naïve Indian subjects are adequately balanced and justified by benefits in the form of increased therapeutic worth and their affordability for the masses. Notions about ethical practices and safety also get configured into these assessments. In contrast, the norms assessments by regulators are either not oriented towards or are neutral to the question of the therapeutic worth or efficacy of these drugs. Such qualification merely hinges on whether the results or claims made by firms with regard to these drugs are in accord in terms of compliance with protocols and related documents.

**Licensing issues and regulatory expertise**

In the context of licenses issued by state-level regulators to firms to manufacture drugs, the contestations again hinge on these regulators’ expertise and efficiency to ensure compliance with protocols and the relationship between firms and regulators. The perception among health activists and even industry representatives like the Indian Drug Manufacturers’ Association, which largely represents small and medium scale firms and a few large firms, is that the state regulatory authorities are either corrupt or they do not possess the requisite training or expertise to monitor protocols adequately, there is severe shortage of staff and that regulators’ testing of finished products is done in government laboratories, which lack adequate equipment. The levels of adherence to and monitoring of these standards are perceived to be different for different states. States like Gujarat,
Maharashtra and in the South are perceived to have better levels of enforcement than other states in the country. (Srivastava 2008). Notions about quality are articulated in this context in a fairly narrow sense in terms of enforcement of protocols by regulators or adherence to these protocols by firms.

The observations made by a respondent link the weak enforcement measures in the states to the corruption prevalent in the central administration. The respondent’s perceptions also contrast the ‘institutionalized’ corruption among regulatory officials or pharmaceutical firms’ lobbies in the West to the ‘dispersed and individual level’ corruption in India:

If you look at regulation, particularly at the state level, it’s in shambles. See any new product has to get drug registration and market approval. There is no scientific scrutiny here, only direct corruption. Are we to believe that approval for 1016 fixed dose combinations, supposedly given by state drug authorities, was given without the drug controller having given the registration? All this has come out because of a public interest litigation we filed in 2006. The drug controller sat on it for six months and then gave an order, which was basically a love letter to firms. This, when it is fully within his control to ban what he knows to be irrational drugs. Now they are waking up to the crisis. But it’s not as if you don’t have corruption abroad. In US or Europe you might have institutionalized corruption. So to the individual it would seem as if there is less corruption. There you have a lot of Congressmen lobbying for the pharmaceutical sector, lobbying for OTCs etc. Here it is more dispersed and at the individual level.196

Issues related to Fixed dose combinations

The issues related to fixed dose combinations197 have also generated a huge amount of debate among firms, health activists and regulators. It might be worthwhile to dwell on some recent happenings in the industry in order to understand the ways in which such drugs are qualified by different groups.

196 See fn. 176 for profile of the respondent
197 Fixed dose combinations involve the combining of two or more drugs in order to get a new product. The rationale for these combinations is that these drugs will act synergistically or that each of these drugs will enable the other to be more effective so that the combination will be therapeutically superior than each of these drugs individually.
In 2007, the Drugs Controller General of India (DCGI) ordered the withdrawal of 1015 combinations. This led to speculation among firms in terms of the criteria used to define the irrationality of these combinations. Later, the central drug authority whittled down the number of withdrawn combinations to 274 drugs. It decided to take action only against those combinations, licensed by state drug authorities, which did not possess prior marketing approval from the Central Drugs Standards Control Organization (CDSCO). The drugs controller general ordered that fresh permissions for the marketing of these combinations be submitted. The order was subsequently challenged in the Madras High court by organizations representing small scale firms such as Conferation of Indian Pharmaceutical Industries (CIPI). Subsequently, a stay was obtained from the court and presently the issue is under out of court settlement on the agreed terms that fixed dose combinations, which are not rational, shall be surrendered by the industry. An article198, in this regard, mentions how no comprehensive database of such fixed dose combinations was available with the regulators due to lack of coordination between the drug control departments of various states. The article also alludes to the ambiguities in the guidelines and criteria for decisions and enforcements on such banned combinations. It cites the example of a controversial drug, *tinidazole*, and cursorily mentions about how the Drugs Technical Advisory Board had approved the combination as rational even though it was initially rejected by the Maharashtra Food and Drug Administration (FDA).

The remarks made by the deputy drug controller of the Central Drugs Standards Control Organization in this connection indicate the government’s wariness to take a stand on the ‘rationality’ or therapeutic benefit of such combinations and to transform the issue as

198 Article entitled “Several irrational combinations may bypass DCGI’s list of 1015 drugs”. Pharma Biz. June 30, 2007
being related to non-compliance with procedural protocols for approval and the laxity of state regulatory authorities:

We are not using any words like irrational or harmful for these drugs. We are only saying that they were licensed by state authorities and that they need to be re-submitted to us for approval. Our Drugs Consultative Committee decided to take this action only on those drugs, which were not registered with the DCGI under form 46 for import or manufacture of new drug for clinical trials or marketing. It’s a question of how you would define this term in terms of the appropriate action that has to be taken.199

The inordinately large presence of these combinations in the industry is also sought to be explained in terms of firms’ strategies to circumvent price controls.200 The respondent’s utterances here also point to the absence of scientific scrutiny of these combinations and insufficient evidence and inadequate monitoring of adverse drugs reactions by regulators. This is in regard to firms’ claims that these combinations have not resulted in adverse reactions or deaths and therefore need to be qualified as safe.

If irrationality was really the criteria, set by the drug controller, then many more combinations should have come under the net. When there were 1015 such combinations which were selected, why did these come down to 294 or so drugs later on? Whatever it is, they don’t do any scientific scrutiny. You have to do a certain amount of testing, before approving these combinations. Most of the fixed dose combinations in the market are unnecessary. An FDC is useful, when one active ingredient actually helps in the effect of the other active ingredient, or both of them in combination have a better therapeutic effect. Most of the combinations in the market are not at all like that. The real reason why the firms do this is, if you change the combination, you introduce a new combination; you get out of price control. You combine something like paracetamol and aspirin and you say this is a new drug and you introduce it in the market. When firms say, there have been no deaths, no reports of adverse drug reactions, the question is, how do you know or assess that FDCs haven’t caused any harm when there is no proper monitoring of ADRs? In small towns and villages, some one takes a drug and dies of an adverse reaction, who knows? In ADR monitoring, your

199 The respondent was the deputy drug controller during the time of the interviews. He is presently a joint drug controller in the CDSCO. (Interview conducted on 16/01/08).

200 For eg, if a product, say paracetamol, which is under price control, is combined with another active ingredient, then the resultant combination, if approved, can be marketed as a new product, at a price fixed by the firm, thereby evading price control.
method should be rigorous, sample size matters, how did you do it, all this counts\textsuperscript{201}

Another respondent also cautions against the adoption of a much generalized criteria in relation to fixed dose combinations, by mentioning their usefulness in the case of diseases like tuberculosis and AIDS. Even while conceding the uselessness of most fixed dose combinations, the attitude of regulatory authorities in issuing related ban orders is perceived as ‘arbitrary’ and ‘unscientific’. The respondent invokes the trope of rationality in seeking to articulate about drug quality. Drug quality is also conceived in terms of several technical parameters like safety and efficacy, having the active ingredient in the requisite quantity that is claimed in the drug, in addition to affordability. The qualification by the respondent here is delineated in terms of both technical and normative dimensions.\textsuperscript{202}

Our organization advocates the manufacture and marketing of rational drugs. There is this trend in the market of selling irrational combinations, which is dictated purely by commercial interests. There are paracetamol tablets containing phynylphrine in the market. What is their therapeutic effect? It’s negligible. Firms say it has good bio-availability. But it can also cause hypertension. When you are talking about quality, there are two things involved here. It should not be spurious. It should be therapeutically rational. Sometimes, there are combinations like tremedol with paracetamol. Again this has either minimal or no therapeutic advantage. I would say around 70\% of the doctors do not have proper judgement about these things. When we are talking about good quality, we should take into consideration things like safety, efficacy and costs. The drug should have all these things and it should be affordable. But you cannot generalize in the context of FDCs. There are FDCs which are required for diseases like TB and anti-retroviral. Again, one valid reason they could introduce it here is there is genetic variation, may be the drug is not showing adverse reaction in this population. Instead of coming down on FDCs very illogically, you need to have a scientific basis to monitor them.\textsuperscript{203}

\textsuperscript{201} Respondent 43 is an activist, who was involved extensively with Voluntary Health Association of India, New Delhi. The respondent has authored a book on banned and bannable drugs and is a doctor by qualification. (Interview conducted over phone on 11/12/07)
\textsuperscript{202} These dimensions will be elaborated upon in the concluding part of the chapter
\textsuperscript{203} See fn. 188 for profile of the respondent
These concerns articulated above, related to combinations, largely by health activists, are by no means new and have been expressed by health activists since the eighties. A later and revised edition of a volume brought out by Voluntary Health Association of India (Shiva and Rane 2004), as early as in the eighties, qualifies 23 out of the top selling 80 products in the country as irrational and hazardous. It criticizes the regulatory authorities for not implementing recommendations of the Hathi Committee Report of 1975, which had advocated a gradual shift to generic names from brand names for the marketing of drugs. The volume describes how the implementation of this recommendation was blocked by multinational companies like Hoechst and Pfizer by obtaining a stay order from the Delhi high court. These articulations are in terms of the premium that large firms place on their brand value since it helps them to retain their market share in a therapeutic area.

The Central Drugs Standards Control Organization also comes in for censure, with the authors providing an exhaustive list of the strategies adopted by the regulatory body to placate firms. These include absurdities like the banning of drugs under generic names, when their marketing is actually carried out with brand names, thus contributing to the ignorance and confusion of doctors and pharmacists. The other strategies mentioned in the work, ostensibly adopted by regulatory bodies, to protect the interests of pharmaceutical firms include: the wording of ban orders in ambiguous terms, thereby creating the space for legal loopholes and challenging of the ban; non-enforcement of the ban order through failure to withdraw stocks of the banned drugs; willingness to accept applications for the production and marketing of drugs, which have been banned abroad; giving extended prior notice to drug companies before the ban notification in order to facilitate their marketing strategies; the instituting of ban orders without appropriate legal authority in the form of amendments
to the existing drugs; not contesting stay orders on bans made by firms and the absence of transparency in terms of ban orders not being circulated even among government bodies.

These allegations detail the widespread perception among health activists in the country about the various levels of collusion between the drug regulators and firms. The issues outlined above are in terms of the trope of ‘regulatory capture’.

Again, with respect to fixed dose combinations, we find that while firms qualify these combinations as both innovative and therapeutically superior, health activists largely qualify them as irrational, hazardous and motivated more by commercial considerations than innovative effort. The qualification of these combinations by regulators is relatively ambiguous and as much constituted by considerations about the rationality of these combinations and their impact on consumer health as it is by considerations to safeguard manufacturers’ interests. Such ambiguity is reflected in the idiosyncratic and arbitrary ways in which regulatory policies qualify such drugs as irrational or safe provided there is procedural compliance or even reflected in the different assessments of these combinations by central and state regulatory bodies.

Issues related to ‘spurious’, ‘counterfeit’ and ‘substandard’ drugs

The issues related to ‘spurious’, ‘counterfeit’ and ‘substandard’ drugs are an interesting example of the ‘politics of qualification’ by different groups. In 2003, a high-level committee set up by Dr R.A. Mashelkar attempted to understand the extent of prevalence of spurious drugs in the country and recommend effective measures to remedy

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204 Except in a few exceptional cases, like the combinations for anti-retrovirals or TB
205 The different assessments about the combination tinidazole by the Maharashtra FDA and the Drugs Technical Advisory Board is a case in point
the situation.\textsuperscript{206} This was done in the wake of accusations, ostensibly by a WHO study, that 30\% of the drugs in the country were spurious. However, WHO subsequently denied having ever conducted such a study. The Mashelkar Committee report accordingly dwelt on how these figures were exaggerated and that the presence of spurious drugs in the Indian market was miniscule. The Committee subsequently recommended the strengthening of the Drugs and Cosmetics Act by enforcing penal measures in order to deter the production of such drugs in the country. The Committee also proffered the view that the responsibility for management of the spurious drugs issue lay not only with the drug regulatory agencies at the Centre and in the states, in addition to the police, but also with all the other stakeholders, including physicians, pharmacists etc.\textsuperscript{207}

Concerns about spurious drugs have also been articulated by representatives of industry bodies in India in the context of their posing a threat to the credibility of ‘good’ drugs manufactured by ‘genuine’ small and medium scale firms. These articulations emphasize on the technological ‘expertise’ of the firms producing spurious drugs, which ostensibly lead to confusion even among physicians and health professionals in addition to consumers, in terms of the inability to distinguish between ‘genuine’ drugs and ‘fake’ drugs. The observations also stress on the importance of a pro-active role by chemists to weed out such drugs and the measures taken by large firms to prevent fake versions of their products.

Why we call them spurious is because they are sold as blank capsules, or there may be less of the medicine or some spurious powder instead of the active ingredient which is supposed to be there. These are small firms, who want to make a quick buck. They are exploiting the lack of consumer

Usually the drugs of large firms are copied. These large companies may sometimes themselves report it to DCGI office or the police. There are lots of examples. You know, drugs like Decamycin produced by Ranbaxy, or Ranbiotech or Rabipure of Aventis and these are life saving drugs, these drugs have been blatantly copied. Usually the best selling medicines are copied and even trained nurses and doctors, sometimes they can’t distinguish between the fake and real drugs. Some of them are so skillful, they manufacture these drugs with advanced technology and even health professionals and pharma people are baffled. Sometimes because there is rise in prices of essential drugs, these become greater incentives for these spurious drug producers. Now the large firms are planning to use high-end holograms, Holoflex I think makes these holograms, to verify the authenticity. I think some of them must be using these already. See chemists are handling drugs on a day-to-day basis. They will be more aware of which are original and which are spurious. They should cooperate with regulatory authorities and the police. We have good small and medium scale manufacturers, producing good drugs also. But all these things, they are tarnishing the reputation of Indian drugs and our manufacturers in other countries.208

In this context, it might be worthwhile to refer extensively to the document on issues related to counterfeit drugs, prepared by a civil society organization, Third World Network, based in New Delhi.209 The document mentions how the issue of counterfeit drugs was first raised at the Conference of Experts on the Rational Use of Drugs in 1985 in Nairobi in the context of generating a database to understand the extent of the problem. Subsequently the resolution passed by World Health Assembly in 1988, directing the World Health Organization (WHO) to initiate the concerned programmes, is important in the present context in the sense that it required the WHO to initiate programmes not only “on counterfeiting but also to address the problems of falsely labelled, spurious and substandard

208 Respondent 58 is the Executive Director of the Indian Drug Manufacturers’ Association in New Delhi. (Interview conducted over telephone on 28/02/08)

209 See ‘Unpacking the issue of Counterfeit drugs’ prepared by Third World Network, New Delhi. Draft version. (5/1/2008). The researcher is extremely thankful to Mr K. M. Gopakumar, Third World Network, New Delhi for providing access to the document. The researcher does not claim to provide a complete exposition of this document or the issue of counterfeit drugs in full. Only those aspects of the document that have a bearing on the issue of qualification of drugs have been invoked.
drugs.” The document highlights the distinctiveness of each of these terms, in the sense of their addressing issues which are different from each other.\footnote{Ibid:1-2}

Thus ‘false labelling’ is defined in terms of “providing wrong information about the product on the label with regard to the content, place of manufacture, date of expiry etc.” The document also defines “false labelling” in terms of situations where the manufacturer provides wrong information about the chemical composition, dosage, precautions to be taken while consuming the drug, side effects related information etc. In this context, the document quotes the Drugs and Cosmetics Act of 1940:17, which outlines these and other additional conditions in the context of ‘misbranded drugs’. These additional conditions include concealment of damage to the drug through colouring, coating or powdering or polishing and if the drug is made to appear of greater therapeutic value than it is in actual terms. A spurious drug in this context, is understood as a drug, which may not contain the active ingredient specified in the label or may not contain the active ingredient in the specified quantity. The additional conditions outlined by the Drugs and Cosmetics Act: Section 17B in this regard, include the manufacturing of the drug under a name belonging to another drug or if the drug purports to be the product of a manufacturer of whom it is not truly a product.\footnote{Ibid:4}

The document also mentions about how the word “counterfeit” is generally deployed in the context of trademark violations and the literal copying of registered trademarks. The important point highlighted by the document is the element of “intent” in cases pertaining to false labelling and spurious drugs, which is not necessarily present in cases related to counterfeit drugs. It also demarcate the issues related to false labelling, substandard and

\footnote{Ibid:1-2}

\footnote{Ibid:4}
spurious drugs as falling under the purview of regulatory issues and the issues related to counterfeit drugs as falling under the purview of Intellectual Property violations. The document goes on to add how according to the IFPMA-WHO definition, a “drug becomes counterfeit irrespective of its quality when it is deliberately and fraudulently mislabeled with respect to identity or source of the drug or both...The IFPMA-WHO definition merges the problems of falsely labelled and spurious and other quality issues with trademark violation in one definition of counterfeit drugs. In this context, the document also outlines how the inadequacy of the active ingredient may be due to deficiencies in the manufacturing process rather than deliberate intention of the manufacturer.”

The document also points to the influence exerted by the International Federation of Pharmaceuticals Manufacturers’ Associations (IFPMA) in constructing the definition of counterfeit in ways that serve the interests of its members and the shift in the focus of WHO, post-2000 to counterfeit drugs and the neglect of other public health related issues. In this context, the document highlights how the subsequent IMPACT definition of counterfeit drugs in 2007 also retains this tilt towards Intellectual Property issues rather than public health concerns. It mentions about how due to the dominance of brands in the pharmaceutical market, generic competitors try to manufacture their drugs with packaging or tablet taste or appearance or label names, which are similar to the brand leader. The new

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212 Ibid:5
213 Ibid:6
IMPACT definition would treat even safe and efficacious medicines, produced in this manner, as an example of counterfeit drugs. In this connection the document also talks about the entry barriers placed by this emphasis on intellectual property issues on the generic industry, leading to aggressive promotion efforts by generic manufacturers and the consequent high prices of drugs. The central argument forwarded by the document, and one that is germane to the present discussion on the qualification of drugs, is how the issue of counterfeit drugs is shaped by the agenda to put in place a stringent mechanism to prevent Intellectual Property infringements and that ‘legitimate’ health concerns like issues involving spurious and substandard drugs are used as a ‘front’ to forward this agenda.215

There is thus an obvious transnational agenda attempting to shape the ways in which counterfeit or substandard or even spurious drugs are qualified in the Indian context. The preceding paragraphs have amply demonstrated how the qualification of such drugs by international bodies involves the interplay and conflating of regulatory and intellectual property related issues. The qualification of such drugs by Indian firms, health activists and regulators, however, rejects the WHO-IFPMA and IMPACT definition and seeks to separate the issues related to spurious and substandard drugs from the issues related to counterfeit drugs.216 Such qualification advances the argument that issues related to spurious and substandard drugs are related to issues of regulatory transgressions and not that of intellectual property related transgressions. This is because the generic drugs produced by domestic firms for export, even if manufactured as per the protocols mandated by international regulatory bodies, would be defined as counterfeit in terms of the IMPACT definition. Secondly, if the IMPACT definition were ever applied to drugs in the Indian

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215 Ibid: 20-44
216 Researcher’s notes from various meetings attended on ‘access to medicines’ related issues held at Centad and MSF between June 2008 to April 2009.
context, the costs incurred by domestic firms to ensure a distinctive and separate character for these drugs in terms of appearance, taste, packaging, labelling and even the content of the drug in regard to the active pharmaceutical ingredient and market them as distinctive brands would push up the prices of these drugs. Thus the articulations about the quality of such drugs, in the Indian context, especially by health activists and regulators, serves to emphasize as much on public health related concerns in terms of maintaining low costs of generic drugs in the Indian market and separating drugs manufactured in compliance with regulatory protocols from drugs produced by circumvention of these protocols as safeguarding the interests of domestic firms.

Issues related to manufacturing and Schedule M related compliance

In terms of issues related to Schedule M related compliance by firms,\textsuperscript{217} the contestations have centred on the reluctance of small scale firms to comply with the protocols. These firms have also suggested that Schedule M has only been enforced bureaucratically, the actual mechanisms to enforce it in the form of regulatory expertise is absent.\textsuperscript{218}

It has been pointed out that the amendments to the Schedule had been made largely in the context of the deficiencies in the manufacture of Large Volume Parenterals (LVP), related to the presence of fungal growth and particulate matter. The contention of small firms is that these problems are peculiar only to LVPs and do not apply to capsules, tablets and syrups and therefore similar stringency is not valid in the latter case. Such articulations emphasize on the need to consider the costs and resources available to firms while framing

\textsuperscript{217} The details of such compliance have already been outlined extensively in Chapter 5 of the thesis
\textsuperscript{218} Researcher’s notes from interviews
quality related protocols. Several difficulties faced by small firms have been outlined in the context of implementation these revised protocols. These pertain to ostensibly ‘unreasonable’ space stipulations like the requirement of thirty square metres each for the tablet punching and tablet coating sections, ‘ambiguous’ and ‘whimsical’ interpretations of these protocols by regulatory officials, lack of credit facilities for purchasing equipment and instrumentation related to the upgradation and the increase in the cost of overheads due to the expenditure necessary for the upgradation, which coupled with the small batches of drugs produced by the small scale units is perceived as being an unprofitable venture for these units.219

The remarks made by another respondent also articulate similar concerns about the difficulties related to operationalization at the firm level due to ambiguities in the framing of the Schedule M protocols and reflect skepticism about the added therapeutic worth of drugs produced through these protocols.

There are a lot of problems. Schedule M does not specify what type of flooring should be there for the facilities, whether it should be of stone, marble or steel, that’s not clear. Since some of these guidelines are unclear, we cannot calculate the costs of upgradation accurately, we have to operate on the basis of guesswork. What kind of capacity building the government is going to do, that’s also not clear. I don’t think Schedule M actually leads to any improvement in the efficacy of the drug. It only avoids cross-contamination.220

The articulations of another respondent indicate the largely normative and interest-driven nature of the varied assessments made by the hybrid groups about the effectiveness of

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219 Presentation made by Mr. Jagdeep Singh entitled ‘Impact of GMP/Schedule M on Small Scale Pharma In India’ at the “Universal and Rational Therapy Dissemination Workshop of Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption” held in New Delhi on April 8-9, 2009. The author is the Secretary General of the SME Pharma Industries Confederation (SPIC).

220 The respondent, who is the president of the SME Pharma Industries Confederation (SPIC), is actively involved with issues related to the safeguarding of the interests of small firms and domestic manufacturers in the Indian pharmaceutical industry. He is also the owner of a small firm in Haryana.
the Schedule M protocols in augmenting the quality of therapeutic products, in the absence of adequate factual information. These articulations are also critical of government policies on the Schedule M protocols in terms of inadequate monitoring practices, the insistence on similar levels of stringency for different kinds of drugs and the permissiveness of the regulators in allowing small firms to manufacture all kinds of therapeutic products inspite of compliance related problems. The logic of stringency is perceived to be valid only in the case of certain specialized therapeutic products, which require high levels of safety, in terms of manufacturing standards, to be therapeutically efficacious. The argument in relation to the discourse of manufacturing-related stringency, increasingly advocated by international regulatory bodies like the U.S.-FDA and the ICH\textsuperscript{221} and one which, Indian regulatory authorities feel obliged to replicate in the Indian context, albeit through the insistence on Schedule M protocols, is framed in a conspiratorial mode, in terms of a politico-economic conspiracy by larger players and regulatory bodies to push small firms out of the market. In addition, the notion of quality is articulated here through the trope of ‘appropriateness’, in terms of firm-related compliance to ‘appropriately’ specified parameters and the drug’s ‘appropriateness’ for therapeutic use.

Whether Schedule M really leads to better quality, frankly, there isn’t data to show either way. How stringent manufacturing practices have to be, that also depends upon the nature of the drug. All the drugs may not require the same level of stringency. As far as Schedule M is concerned, you have a peculiar situation, because the laws are strict but the system is too lax to impose them. The regulators don’t mind small firms manufacturing all kinds of drugs provided they comply. But they should be allowing them to produce drugs only in certain areas since they are not able to comply.

\textsuperscript{221} International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
Then, if the drug is, let’s say, 100% pure, how much of the drug will get absorbed? Again, only where the band between safety and efficacy is narrow, there 99.5% of purity is essential. It is absurd to insist on some predetermined level for all drugs. ICH and US-FDA standards are however very insistent on certain levels of purity. What will happen is that firms without capital will be pushed out. So quality may be pushed by certain interests. Only Schedule M, without accountability on the part of regulatory bodies, will merely push small firms out. What does quality mean here? See, in technical terms the bioavailability related parameters should be within the specified range of purity. Then the layperson should be confident that he or she is getting an appropriate drug for the ailment.222

The increasing pressure mounted on Indian regulators to harmonize local Good Manufacturing Practices (GMP) related protocols in accordance with those of international bodies is reflected in the observations of this respondent, a regulatory official. These observations are also framed within the history of these protocols in the Indian context.

In the current scenario, we can’t remain isolated. There should be harmonization of protocols with international bodies. When we look at international inspections carried out by US-FDA and WHO, our systems should also be similarly improved. WHO formulated GMP documents in 1975. This was prepared for ease of inspections of drugs of member countries and to facilitate inter-country commerce. There are 191 members in this body. All this, in India, has started in the eighties. There was this public interest litigation in the Himachal high court. Basically it was about the contamination present in large volume parenterals. This was brought to the notice of the National Human Rights Commission. Subsequently, a committee of experts was formed by our regulatory body which has advocated drastic change in GMP. See in 2001, a committee was formed where a draft document was presented to all the stakeholders. Their comments were taken note of. Subsequently we extended the period and made it compulsory from June 30, 2005.223

The respondent is quick to emphasize that GMP protocols do not entail much automation, inspite of some infrastructure and instrumentation related changes, but rather an

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222 See fn. 176 for profile of respondent
223 Respondent 24 is a deputy drug controller at the Central Drugs Standards Control Organization (CDSCO) in New Delhi and in charge of GMP related issues. (Interview carried out on 23/01/08).
increased emphasis on documentation, a stance actively forwarded by the recent Najma Heptullah Committee report on the problems related to Schedule M compliance, which has claimed that 80% of the new Schedule M changes pertain to documentation and only 20% pertain to infrastructure and instrumentation. These claims, however, have been actively disputed by the small firms and even a few health activists. GMP protocols and particularly the Schedule M related changes are qualified by the respondent, not so much in terms of the technical principles undergirding them, but rather as a philosophy entailing a certain mind-set and as emphasizing on the process rather than the final product. The political economy angle of eliminating small players, articulated by a few activists and also small firms, as part of their resistance to these changes, is sought to be diluted on the grounds that these changes are mandatory in the interests of promoting cross-country trade.

GMP does not mean automation. Okay there are some infrastructure and instrumentation changes. It involves a lot of documentation. But GMP is more about a way of thinking. Of course, there is resistance by small scale firms. We gave them a cut-off period. Now that period is over and it has become mandatory. It’s not that we or anybody else are trying to put them out of business. GMP as a system involves emphasis on process. We want to make Indian GMP also equally stringent like international protocols. There is this emphasis because there should be these international norms for cross country trade.

The drive by large firms to acquire international regulatory approvals from bodies like US-FDA or UK-MCA is assessed in terms of their aspirations to enter the international export market for generic products or survive the growing competition in the domestic market. On the other hand, domestic medium or small scale firms’ efforts to acquire Schedule M certification is felt to be the outcome of regulatory compulsions.

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225 This has been documented in detail in Chapter 5 and also in the preceding portions of this chapter.
If you look at GMP requirements, they are required to a greater degree in formulation units than in bulk drugs. This is only because the chance of cross-contamination or mislabeling is more in formulations. See, if you are looking at level of compliance with respect to Schedule M or even any other international certification, you can see three types of behaviour on the part of firms. Some firms change due to market forces. Large firms like Ranbaxy or Cipla or even Reddy’s, they change because they have this vision. They want to go abroad and sell their drugs there. The second type will change because they want to keep afloat in the competition, so they take the extra initiative to change themselves. The third category of firms is very reluctant to change, but they are forced by the regulatory authorities, so they change. That’s the difference.

The articulations about the inadequacies or gaps in the effective implementation of Schedule M protocols by regulators are also framed in terms of the small firms’ emphasis on quick profits rather than the enhancing of their manufacturing capabilities and the absence of adequate technical expertise in these firms to comprehend and implement the intricacies of these protocols. Additionally, these remarks also stress on recent government-led initiatives to address firms’ complaints about inadequate technical and financial support from the Indian regulatory bodies.

What we have observed is that the technical staff of small scale firms is not competent. They are not paid well. And also they are unable to understand the intricacies of GMP. For these firms, their prime target is to increase the profit margin. They feel they are spending money for no reason. They try to reason with us, look no one has died taking our drugs. They are very hard to convince. So what we have to do is to convince them to spend on training workers. Now we have new governmental initiatives on World Bank and WHO funding for upgradation and training programmes. See, difference between these and other bigger firms is that in relatively bigger firms, the employees there may have a selective understanding of the intricacies of a particular task. They are taking initiative and trying to train their workers in-house.

In addition, the criticism by firms and health activists about these implementation related gaps relating to Schedule M is sought to be deflected by dwelling on the administrative tensions prevailing between central and state regulatory authorities, the
resulting ‘fragmented’ control and ‘local’ interpretations of these protocols and the ‘protectionist’ attitude of state regulatory authorities in not providing accurate estimates about the extent of compliance to prevent closure of small pharmaceutical firms in their state.

See we are trying for the central drug authority (CDA). Things are moving now. We are looking at public response, the parliamentary committee associations are going to OPPI and IDMA. OPPI has supported it. State drug controllers are opposing it, they think their power will be drastically curtailed. Even Mashelkar Committee had mentioned about this. There should be uniformity; there should not be fragmented control or local understanding of regulatory protocols. Some small scale firms in different states have complied but quite a few have to comply. If you ask me what the status is, I can only tell you that as far as the law is concerned, they are not surviving. They might be surviving through illegal means, that’s a different thing altogether. Now we have a situation where a few states, in order to protect their industries, they say that they are improving or complying.

The distinctiveness of the Schedule M protocols from WHO-GMP protocols or the protocols formulated by other international bodies is also articulated in terms of the importance of tailoring these to suit the requirements of the Indian context. In this regard, the respondent also provides an elaborate account of the merits of these international protocols in terms of their emphasis on elaborate codification of processes, procedures and methods related to inspection of manufacturing facilities.

Importantly, the philosophical differences undergirding different international regulatory requirements by WHO-GMP and U.S.-FDA and their distinctive approaches to the desirability of automation is also mentioned in this context. The assertions here are to the effect that WHO-GMP like Schedule M lays greater emphasis on documentation and validation of procedures and the stringency levels demanded by these systems do not require automation. On the other hand, the U.S.-FDA system is perceived as highly critical of manual or semi-automatic processes in terms of their inability to completely eliminate
contamination through manual handling of materials and as actively promoting automation in the form of sophisticated machinery and instrumentation, necessitated by the progressive stringency of their manufacturing and testing protocols. Interestingly, the political economy angle invoked by small firms in relation to the edging out of small firms from the Indian market is reflected in the regulatory official’s discourse about the stringency advocated by the U.S.-FDA certification. A similar discourse is deployed by large pharmaceuticals firms in India, which attempt to export their generic products to the United States, in terms of the argument that these requirements act as entry barriers.226

There are these GMP differences between countries. We need to prepare the documents as per our needs. See, US-FDA GMP practices have been codified very elaborately. They have this very thick document. Our GMP is not codified as well as US-FDA. In certain aspects like how do you carry out an inspection? Other differences are in the depth of inspection. We have modified our documents now in lines of these international protocols to ensure the best possible inspection. But there are certain other things. In the WHO-GMP manual, an entire chapter has been devoted to validation. Our GMP on the other hand does not mention validation explicitly. There is more emphasis on automation in US-FDA. They are somehow more dispensed towards machines. These same operations can be equally done by hand, but the values and output may differ. For eg, in the case of a particular impurity, Schedule M may say or WHO-GMP may say, these impurity levels need to be brought down to say 5 micrograms. In US-FDA, they may say, you have to bring this down to 1 microgram. So how do you do it? You need costly machinery for this. For US-FDA, anything touched by hand is contaminated. When firms say, oh US-FDA just want more documentation, they don’t want automation, that’s not right, especially for formulation units. Then things like, analysis according to US-FDA protocols for tablets, all these different tests, that’s done without breaking the tablets. Again in US-FDA, for eg, packing of strips into cartons, they want that to be automated. But then again in WHO-GMP, there is no mention of automation, there they want to know whether you have complied with the parameters, with proof. But certain things, even if you have automation, must be done by humans. Like line clearance, even after the machine has performed its tasks, whether the area has been sterilized before starting the next batch, whether labels have been discarded etc, this has to be done manually.

226 Researchers’ notes from interviews with twenty two personnel from large firms
In terms of the approach of European and U.S. regulators with respect to the auditing of manufacturing facilities in India, the perception was that the inspections carried out by U.S. regulators was largely documentation driven while the European regulators emphasized on the corroboration of the documents with the manufacturing process. The observation here was to the effect that GMP inspections in India were modeled after the European style of auditing. However, these observations seem to contradict the respondent’s earlier remarks about the technology driven nature of US-FDA protocols and the observations made by several personnel employed in large firms during the interviews about the nature of US-FDA inspections.

If you consider the different styles of these international regulatory bodies and how they carry out the inspections, the US inspectors don’t pay much attention to the manufacturing facility. They may do a cursory tour of the facility. But what they actually do is sit in a room with all your documentation and examine it thoroughly. For European inspectors, their style is different. They will check your manufacturing process thoroughly; they carry out a detailed visit to the plant. What they observe there, that should dovetail with your documents. According to me, we have inherited the European system. We try to correlate documents with activity in Indian GMP.

The qualification of these revised Schedule M protocols by the hybrid groups, again seem to be largely normative and interest-driven, and indeed this is as true of the present context as it is with reference to the other sites of contestation invoked earlier. Regulators’ assessments here seem to be shaped more by the anxieties related to join the move towards harmonization by international bodies rather than the consideration of local realities. The qualification of these protocols by health activists seem to devolve around questions concerning the appropriateness of these protocols in relation to the nature of the therapeutic product. The articulations of small firms seem to be couched in conspiratorial mode and
these protocols are viewed as barriers to their survival in the industry. These articulations emphasize on the qualification of these protocols in terms of local concerns and argue for a reassessment of their viability in terms of costs.

The sphere of marketing and prescription related practices

The contestations in this sphere largely center on the prescribing habits of medical practitioners, the marketing practices of firms, the influence of medical advertisements in moulding the consumption of over the counter drugs, the tendency among consumers to engage in self medication and the role of pharmacists in recommending brands to consumers.

As far as medical practitioners are concerned, the evidence by and large about their prescription habits in the Indian context is largely anecdotal in nature. Formal mechanisms to assess the extent of adverse drug reactions and the prescription patterns of physicians are lacking in the Indian context. Though the National Pharmacovigilance Committee was instituted in 2005, it has yet to come up with a report on adverse reactions.

In the context of promotional practices of medical representatives, organizations like the Federation of Marketing Representatives of India (FMRAI), have been advocating rational prescription and promotion practices. The organization recently carried out a study based on data collected from an ORG-IMS survey. The study analyzed 603 top selling drugs during 2006. The ‘rationality’ of these drugs was assessed on grounds of whether they had been included in the British National Formulary or WHO Drug Formulary or whether

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227 Presentation made by Mr. Amitava Guha entitled ‘Irrational Medicine Promotion Practices’ at the “Universal and Rational Therapy Dissemination Workshop of Tracing Pharmaceuticals in South Asia: Regulation, Distribution and Consumption” held in New Delhi on April 8-9, 2009.
any evidences had been presented to the medical profession during the promotion of these drugs. The study concluded that at least 163 of these drugs were irrational in nature. The trope of ‘rationality’ is thus deployed by health activists in their qualifications about the ‘appropriateness’ of these drugs.

In this regard, the remarks of a respondent, a senior marketing executive, are pertinent in terms of outlining the promotional strategies deployed by firms to ensure prescription of their drugs by medical practitioners. These strategies involve a thorough research into prescription habits of the concerned physicians through ‘friendly’ conversations with chemists and the use of subtle techniques of persuasion through a combination of gift-giving, invitations to medical conferences hosted by his firm and ‘scientific’ representation of the drug-related literature to overcome the caution and hesitancy displayed by the practitioner. The frank and strident articulations of the respondent seek to justify his ‘strategies’ on grounds of the ‘cut-throat’ competition in the sector and the institutionalized nature of ‘corrupt’ practices in the system.

We provide the latest information on the drugs that we sell. We provide different studies to the doctors and we don’t have the policy of giving out any free samples. Why accuse only us? Sometimes doctors know that a patient will be cured with 5 tablets, still they will write 10 tablets in their prescription pad. We have several techniques to approach doctors. We first go to the chemist shops in the area and find out what kind of medicines the doctors are prescribing. Then we approach the doctors. If the doctor is of the easily corruptible variety, we don’t bother to talk too much about any medical literature. We give him gifts like refrigerator, equipment etc. Sometimes, the doctor is a more studious variety. Then we have to discuss our literature, give him medical books etc. Ultimately, it all depends upon the potential for business. Our firm does not have the muscle to send them to international conferences and all. All these big and reputed firms are equally corrupt. They give huge amounts of money to doctors as bribes and sponsor their trips to international conferences. When there are so many competitors in the market, how else do you make sure that your products will be sold? Our firm also hosts conferences where our people explain to them about our new drugs and show them studies. We also try to convince them in an academic way. It’s not
only about money. Doctors are also cautious since it’s about the safety of their patients and it also affects their reputation. But frankly, I don’t think too much about your drug quality and all. At the end of the day, I have to meet my targets and report to my boss.  

The articulations of another respondent, a reputed activist and medical practitioner, attempted to root these ‘irrational’ prescription and marketing patterns prevailing in the sector to the ‘over-medicalized’ constructions of health and the ‘biomedical orientation’ towards prescriptions, the paucity of unbiased sources of information about drugs for physicians, the targeting of ‘opinion’ makers in the medical profession to legitimize certain kinds of prescription habits and the willingness of doctors to be lured by the gifts and other incentives provided by the firm or its representatives.

In terms of medical education and training, the allopathic tradition is skewed in terms of over-medicalization of health. That is, for every condition, a medicine is available. As far as marketing is concerned, there are no unbiased sources of information for doctors. Doctors are relying on firms for information, this doesn’t happen only in India. This is because they have no other avenues for information. Companies follow a lot of strategies. As far as individual practitioners go, you have these friendly marketing representatives visiting you, urging you to prescribe a lot of useless pills. Then they provide incentives to chemists. They also target opinion makers. The medical profession is extremely hierarchical. So you have a few opinion makers determining prescription practices. International junkets are organized by firms and ultimately certain drugs are branded as effective or useful. All this combines with the general biomedical orientation towards prescription. There is this famous saying among practitioners that “a good doctor is not the last to give up an old drug and the first to take up a new drug”. There is this French journal called ‘Prescrire’ which came out with an article on prescription habits related to new drugs by doctors. The article talks about

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228 The respondent is a senior marketing executive at a firm based in Mumbai. The firm has an R&D centre in Mumbai with 200 scientists and has a turnover of around Rs 550 crore. The respondent is a B.Pharm graduate, with seven years experience in the pharmaceutical industry. He has been employed in the present firm since four years. Prior to that, he was employed in the same capacity in a small scale firm. (Interview carried out on 05/12/07)
how only about 2.9% of these drugs could be regarded as major therapeutic advances, a further 20% did not have any major therapeutic benefits and 70% of the new drugs prescribed were useless or irrational. The situation is far worse in India. You lose the attitude of skepticism because you are willing to be manipulated.229

In addition, the respondent also elaborated on the peculiarities of the Indian pharmaceutical market, in terms of the absence of norms related to promotional literature on new drugs, the nexus between doctors and laboratories for tests, the marketing of the same drug at different prices in different locations, variations in prices of similar drugs among firms in relation to brand value and market strength and the pressures on practitioners to prescribe inappropriately due to consumer related ignorance.

Table 7.1 provides an indication of the vagaries of drug pricing in the Indian market. The table provides a cursory list of the huge differences in the highest and lowest priced brand with the same active ingredient in the Indian market and the price differences between brands do not really seem to follow any discernible logic.

<table>
<thead>
<tr>
<th>Medicine/ (Active ingredient)</th>
<th>Brand</th>
<th>Company</th>
<th>(Price in Rs.)</th>
<th>Difference (in percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ofloxacin 200mg</td>
<td>ZO Tarivid</td>
<td>FDC Aventis</td>
<td>3.20 31.00</td>
<td>969 %</td>
</tr>
<tr>
<td>Levofloxacin 500mg</td>
<td>Levoflox Tavanic</td>
<td>Cipla Aventis</td>
<td>6.82 95.00</td>
<td>1392%</td>
</tr>
<tr>
<td>Azithromycin 250mg</td>
<td>Zathrin Vicon</td>
<td>FDC Pfizer</td>
<td>8.50 13.14</td>
<td>60%</td>
</tr>
<tr>
<td>Zidovudin 100mg</td>
<td>Zidovir Retrovir</td>
<td>Cipla GSK</td>
<td>7.70 53.52</td>
<td>695%</td>
</tr>
<tr>
<td>Amlodipin 5mg</td>
<td>Amlodac Amlocard</td>
<td>Zydus Pfizer</td>
<td>1.51 6.00</td>
<td>397%</td>
</tr>
<tr>
<td>Glimipiride</td>
<td>Glimister</td>
<td>Mankind</td>
<td>0.80</td>
<td>696%</td>
</tr>
</tbody>
</table>

229 See fn. 176 for profile of the respondent
These questionable practices are articulated in terms of the disconnect and tension between modern medical science and the commercialization in relation to its practice.

As far as promotional literature on new drugs or combinations goes, there are no statutory regulations on this. Then again, doctors and laboratories have a cozy little nexus going on for tests. All this in effect means, there is a clear contradiction between private medical practice and the so called practice of healing. So how do you really make judgements about the quality of a drug in this situation? If you look at regulation of drug prices, the system is in tatters. You have the same drug being sold at different prices, all that it depends on is the kind of profitability margin that is available in different markets. It would be priced differently in metros and small towns, or you have different companies pricing the same drug differently depending upon their brand value and market strength. See, firms will naturally preach the ideology that the market is the best arbitrator of everything and that if you distort the market, quality will suffer. They will tell this with reference to whatever R&D they do, the combination drugs they sell in the name of innovation, GMP, marketing, everything. But what you are seeing in the pharmaceutical sector is the complete opposite. The consumer also goes along with this biomedical notion of health. Patients expect prescriptions. Not just the ordinary variety, but those for which you have to shop in five different places. The idea is, what is expensive is superior. There are these myths which abound. Say, like injections are more effective or say, drips are necessary, when you can achieve the same result with a sugar and salt solution. These irrationalities put pressure on the prescriber. They could actually be honest concessions made by doctor to this. (laughs). To explain how tonics are unnecessary takes ten minutes of a doctor’s time. It’s relatively easier for him to prescribe it. In India, we find that the penetration of new medicines is faster than anywhere in the world.”
The discourse of the respondent is significant in terms of articulating how the notion of quality is deployed as a front by firms to justify the entire spectrum of their activities related to R&D, testing, manufacturing and marketing and to liberalize the regulatory regime in ways that promote their interests.

The present chapter sought to explore how the actors in the hybrid group and located in the contested terrain of drug regulation qualify drugs in various ways in different spheres or arenas of contestation related to R&D activities, patents, clinical trials, compliance with manufacturing protocols, irrational combinations, counterfeit and spurious drugs and the sphere of prescription and marketing.

While the qualification of drugs by firms is largely in terms of ‘innovative effort’, ‘scientific progress’ and ‘commercial viability and profit’ in these different sites of contestation, notions about ‘therapeutic worth’, ‘access to medicines for the poor’, ‘rationality’ and ‘appropriateness’ inform health activists’ qualification of these drugs. Regulators, however, qualify drugs in ways that are more negotiated and therefore relatively ambiguous since they are constituted equally by the larger politico-economic context of harmonization, concerns over public health needs and the need to safeguard the interests of the firms.