Chapter 2

METHODOLOGY

The present chapter elaborates on the methodology deployed in the study. As mentioned in the previous chapter, the study, in a broad sense, attempts to understand the discourse of drug quality in the Indian pharmaceutical industry. This discourse is shaped by actors such as personnel involved with research and development activities, production, clinicians, management committees etc within the sphere of the firm. Outside the sphere of the firm, actors such as health activists, regulatory bodies, physicians, pharmacists, academicians etc are instrumental in shaping this discourse. The study takes as its point of departure, Michel Callon’s formulations about the modern economy as an ‘economy of qualities’, where products are constantly qualified and re-qualified.\(^7\) Other actors.

The notion of ‘drug quality’ and ‘qualification’

In the context of drugs, ‘qualification’ may be understood as involving the attribution of some ‘qualities’, some characteristics to drugs, for instance in terms of efficacy, safety, potency, minimization of error, purity etc. It also includes the socio-technical processes that the drug undergoes to acquire these attributes. This being the case, and as pointed out elaborately during the review discussion, the process of qualification cannot be separated out from notions about quality in our understanding of the discourse of drug quality. The process of qualification of drugs is a continuous and ongoing process. Moreover, these above-mentioned attributes of the drugs may not be observed but are revealed through tests or adherence to particular protocols. Drugs, within this frame of

\(^{7}\) Callon’s arguments have already been elaborated upon in the previous chapter.
analysis, are ‘qualified’ with attributes, which stabilize over a period of time but which are equally subject to change.

Qualification and the role of ‘hybrid forums’ or ‘interest groups’

This qualification also occurs in the context of ‘hybrid forums’ (Callon 2002) or a forum involving a ‘heterogeneous’ group of actors like firms, regulatory bodies, activists, academicians, physicians, pharmacists, IPR specialists etc. This ‘hybrid forum’ may also be understood as ‘interest groups’. Interest groups, in the context of the ‘qualification’ of drugs within the sphere of regulation, may be understood as a group of individuals working on behalf of or supporting a particular cause such as legislations concerning intellectual property rights or institutional ethics committees for clinical trials etc or supporting a special segment such as the small scale sector etc or even advocating issues such as ‘access to medicines’ for the poor or ‘rational’ drugs etc. However, in the context of the present problem, the notion of ‘hybrid forums’ or ‘interest groups’ who attempt to ‘qualify’ drugs in different ways or even negotiate among themselves to arrive at a consensus is equally valid in the context of the firm as it is outside the realm of the firm and in the larger sphere of drug regulation. Within the firms, such groups include R&D personnel, production personnel, management committees, all of whom are involved in the qualification of a particular drug in certain ways. Again, within the pharmaceutical industrial laboratory, such ‘hybrid forums’ exist given the interdisciplinary nature of expertise within a typical firm engaged in discovery research related activities. The individuals constituting the ‘hybrid forum’ here are biologists, chemists, pharmacologists, toxicologists etc.

Thus, as Callon puts it, “talking of quality means raising the question of the controversial processes of qualification, the processes through which qualities are
attributed, stabilized, objectified and arranged.” Such ‘qualification’ may also involve a ‘contested’ terrain. This means that these diverse actors may ‘qualify’ drugs in particular ways depending upon their interests, their evaluation of particular facts related to the drugs etc. and usually, which particular set of actors are involved in such ‘qualification’ depends upon the context or issue in question.

Examining ‘fragments’ of the ‘biography’ of drugs

Using Geest’s biographical approach to understand such ‘qualification’ or understanding the discourse of drug quality in terms of looking at ‘the drug as a social and cultural product with a lifecycle’ of its own’ is a methodologically useful tool in terms of a frame of analysis since one is able to gain an in-depth insight into at least some of the ways and processes through which the attributes of drugs may change or get stabilized in each of the different stages in its lifecycle. The idea of a ‘biography’ is useful, in the present context, in terms of indicating the temporal dynamics involved in the process of ‘qualification’ of drugs and to capture this dynamic adequately. This, however, does not imply linearity of the qualification process in typical ‘bench to bedside’ fashion but recognizes the dialectical nature of such processes. For instance a molecule which does not show the requisite levels of efficacy or exhibits side effects during the stage of testing on animals (in-vivo tests) is referred back to the pre-clinical team. Or to cite another example, if there are problems with respect to the scaling up of the molecule during the commercial production of the bulk drug, these deviations are reported back to the process R&D team. These are instances where the molecule, which was qualified in particular ways, may get requalified.

However, the present study does not claim to examine the qualification of drugs in all the stages of this ‘biography’. Rather, it examines ‘fragments’ of this ‘biography’ by

71 See pages 1-2 and pages 51-52 of the introductory chapter for elaborations in this regard
confining its inquiry to the stages of pre-clinical stage of research and development and the manufacturing of finished formulations with respect to production within the ambit of the firm. Outside the ambit of the firm, it attempts to capture such qualification by examining the contestations among the individuals located in the hybrid group in relation to a controversial drug and within the relatively larger sphere of drug regulation. The idea of a ‘biography’ of drugs is then merely a heuristic device to get a detailed insight into the processes driving such qualification. Also, in the context of the present study, these shifts in the unit of analysis\(^\text{72}\), in terms of examining the qualification of drugs both within the sphere of the firm and in the larger terrain of drug regulation, are essential in order to acquire a fuller and nuanced account of how the discourse of drug quality obtains in the pharmaceutical industry.

**Exploring the complex interplay between the cognitive, normative and politico-economic dimensions**

Methodologically speaking, in the above-mentioned context, the study also attempted to take recourse to the interpretative tradition within sociology. The issues involved in the qualification of drugs may be located within this theoretical tradition, involving the feeding off a critical social science. This essentially also involved understanding qualification in terms of meanings attached to the drugs by different actors and examining their negotiations in terms of the power exercised by the actors of the hybrid group to shape the qualification of drugs in certain ways. The constructionist tradition was also felt to be significant here in terms of the understanding of the qualification of drugs as a ‘negotiated order’. Power in this sense is construed not as monolithic but as dispersed (Busfield 2006: 301-306) and the key sociological question here is how the balance of

\(^{72}\) Which have been analyzed and outlined as separate chapters in the thesis
power operates between these groups and influences the interplay of the cognitive, normative and politico-economic dimensions in particular ways that shape the qualification of drugs. This is the active sociological dimension that the study attempted to retrieve in its examination of the discourse of drug quality with reference to the actors in the hybrid group both within and outside the ambit of the firm.

Understanding ‘drug quality’ through ethnographic accounts of firms and contestations between ‘hybrid groups’

Again, as indicated in the review discussion and more so in the context of the Indian pharmaceutical industry, sociological engagements with pharmaceuticals are marked by a clear absence of ethnographic accounts of the everyday activities and practices of firms and efforts to capture the perspective of the manufacturers. Studies of the pharmaceutical industry in India by sociologists are virtually absent. The few studies that have been carried out (Naraindas 2006, Sujatha 2009, Banerjee 2002, Abraham, L. 2009) relate to the sphere of traditional medicine such as Ayurveda and Siddha medicine. Banerjee’s study is somewhat of an exception in this regard as she charts the transition of Dabur from a traditional Ayurvedic firm to a company, which has gradually modeled itself along the lines of firms in the bio-pharmaceutical industry.

Often, studies on the Indian pharmaceutical industry, especially those deploying public health related perspectives, are characterized by a judgmental frame of analysis, with firms being portrayed as excessively manipulative, commercially inclined and neglectful of public health related concerns. On the other hand, management-related literature on the Indian pharmaceutical industry is generally replete with articles of pharmaceutical firms’

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73 A few studies, deploying perspectives from STS, have attempted to remedy this deficit. These studies have been situated in the West and have been the exception rather than the norm.
supposed expertise in R&D or contribution to health needs of consumers. The idea here is not to dispute such claims. Both these types of claims may be true or valid in particular contexts. However, either demonization or valorization of pharmaceutical companies’ activities can result in biased and one-sided accounts. Nevertheless, there is a need to acknowledge the moral logic (Geest 2006: 312) of pharmaceutical firms’ commercial practices. Their views and motivations need to be taken into account for a more nuanced and holistic account of the culture of pharmaceuticals. As in the Western context, so also in India, the marked absence of this emic perspective in the observations about drug manufacturers has been due to the difficulties experienced by sociologists and anthropologists in establishing contact and rapport with the personnel employed in the industry. Indeed, some of these very problems were experienced by the researcher in the course of the study.

Research Design

As such, the research design of the study is a combination of the Exploratory Design and a Cross-Sectional Comparative Design. In Cross-Sectional Comparative Design, two kinds of situation at a given time are compared. Comparative method is deployed in social science to provide explanations. Here, with respect to firms, this design is used to explain why different types of firms qualify drugs in different ways at a particular point of time or why a particular firm may qualify a drug in different ways for different economic regimes, for example the domestic and the export market or why different actors in the hybrid groups or interest groups qualify drugs in different ways.
Issues related to operationalization of the study

The typical pharmaceutical firm in India, and even the sector as a whole, is a space, which is a closed-off space, and whose inhabitants are extremely guarded about the information they impart to researchers interested in studying their activities. Firms in India do not really encourage visitors to their plants or provide them with details of their R&D, manufacturing, quality control or even financial activities, beyond the few details mentioned in their annual reports or posted on their websites. Accordingly, when the researcher attempted to contact the respondents through post or phone calls or even through e-mail, there were no responses. Calling up scientists and personnel employed in the R&D, production or quality control division in a firm entails passing through a battery of secretaries, who more often than not, deny you access. In some cases, firm personnel are ostensibly too busy to give you that requisite appointment. Even when interviews were eventually set up with these officials, usually employed in a managerial capacity, whether in the R&D or Production divisions of these firms, these were mostly carried out, on condition of anonymity, not in their office, but in a conference room, located on the premises of the R&D centre or production unit. Though the majority of these personnel permitted the researcher to tape the interview proceedings, permission to interview the other employees of the firm or conduct a tour of the R&D division or manufacturing unit was not granted. The researcher could manage a tour of the manufacturing unit and R&D division only in the case of three firms.

The same kind of stone-walling techniques were experienced during contacts with regulators. Though two of the eight regulatory officials who were interviewed eventually opened up to the researcher, in general, the access to these regulatory personnel was gained
only after repeated and exhaustive written requests to the DCGI’s office. Again, officials
generally refused to come on to the phone and had to be contacted via secretaries. Even after
gaining access, the author was able to have in-depth interviews only with two regulators out
of those interviewed. The remaining officials repeatedly inquired of the researcher whether
she was a press reporter, requested anonymity and gave cursory and brief replies to the
questions posed by the researcher. The researcher was also not granted permission to tape
these interviews. The researcher underwent similar experiences with other respondents
which included representatives of industry bodies and pharmacists, consultants and one
physician, among others. The academicians who were interviewed were relatively more
forthcoming in their responses as were majority of the health activists, though some of the
activists were critical of the fact that researchers on the pharmaceutical industry generally
tended to ‘use’ them for obtaining data on controversial or topical issues and lacked
‘commitment’ in terms of highlighting issues related to public health. In general, majority
of the respondents, including the health activists, projected themselves as highly pre-
occupied with their work, with participation in various meetings, conferences and seminars
and advocacy related work and access to them too was obtained with great effort and
difficulty. Three such interviews, though detailed and elaborate, were conducted over phone,
one in March 2007 and two in February 2008.

Another problem experienced by the researcher was in terms of explaining the nature
of the research project to majority of the respondents who were primarily scientists,
engineers or had a background in medicine or pharmacology. The responses of these
individuals were varied in terms of either perceiving a disconnect between the researcher’s
disciplinary background and the ostensibly ‘technical’ and ‘scientific’ sphere of drug
regulation or expressing the apprehension that the sociological framework involved the articulation of these ‘technical’ issues in a ‘conspiratorial’ framework or perceiving the research problem as being one related to understanding ‘organizational dynamics.’ Of course this could also be partly due to the researcher’s own limitations in terms of articulating the nature of the project and grappling with the complexities entailed by inquiry into such a project. Interestingly and predictably enough, in the few interviews with firm personnel, carried out during the researcher’s tenure as a Fellow in a science policy institute of the CSIR, the respondents showed greater willingness to explain the complexities involved in their R&D related efforts and perceive the research project as a ‘legitimate’ and ‘useful’ exercise.

One also observed that, in general, information about various activities related to the sector, especially specifics pertaining to R&D activities or manufacturing related upgradations or strategic decisions by firms and regulators in the new regime was closely guarded by majority of the respondents, especially firm employees, representatives of industry bodies and regulators, partly because such knowledge is perceived to have immense strategic and commercial value.

All these seemingly mundane details related to operationalization are important especially when one contrasts them with the nature of such studies carried out in the West. Such studies, particularly those inquiring into regulatory bodies’ assessments of drugs or R&D related activities of firms are usually carried out in ethnographic mode, with the researchers spending several weeks or months at the concerned firm or the local regulatory office as a participant observer, attending meetings conducted by firm personnel or regulatory officials and even being permitted to peruse documents related to the concerned
drug or R&D activity of the firm. (Gaudilliere 2005, Quirke 2005, Abraham 2002b, Daemmrich and Krucken 2000, Dalgalarrondo and Urfalino 2002). Likewise in the United States, the FDA is known to be even more transparent than European regulatory authorities and documentation and minutes of meetings are put up in the organization’s website. In India, far from permitting access to their meetings and deliberations, officials display extreme reluctance to discuss such issues with researchers as they perceive that this would adversely impact their reputation. Moreover, they do not grant permission to go through any documentation. As such, the application of research techniques used in the West in order to carry out similar studies in India becomes an even more daunting task.

Selection of the Sample and Tools and Techniques of data collection

The Indian pharmaceutical industry is an extremely fragmented and heterogeneous sector, with nearly three hundred large units and over five thousand small and medium scale units.74 In such a sector, studies carried out by economists or those deploying public health perspectives or even studies conducted from a management related orientation typically use survey-based techniques. The selection of firms or respondents is carried out through use of statistical techniques and consequently a certain number of large, medium and small scale firms or respondents in these firms, depending upon the scope of the study, constitute the final sample in these studies.

However, the nature of the present study demanded deeper levels of insight than those afforded through conventional survey related techniques. Accordingly, conventional sampling techniques could not be deployed in the study. Grounded theory allows for the

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74 A few studies (Srivastava 2008), Gehl Sampath (2008) and Chaudhuri (2006) have placed the number of small and medium scale units as being close to ten thousand. However, during the interviews, several respondents observed that the number of small and medium scale firms had declined sharply in the post-patent regime and had shrunk to a little more than five thousand firms.
collection and analysis of data in a qualitative non-statistical and non-mathematical mode. The data thus collected may be supplemented with quantitative data and methods if necessary. Moreover, the techniques proposed in grounded theory are suited to research problems, which seek to understand the subject through an emic perspective. (Mukherji 2000:43). The insights afforded by grounded theory were accordingly deployed to identify potential actors (individuals and groups), who could provide relevant information to the researcher. Subsequently, in-depth interviews were conducted with a total of sixty four respondents for the study.

These interviews were sought to be triangulated with relevant secondary material and also notes and observations made by the researcher in the course of attending and participating in several meetings, conferences and workshops organized by civil society bodies like Medicins Sans Frontiers, New Delhi and Centad, New Delhi, WHO, New Delhi, industry bodies like FICCI, New Delhi and government bodies like the National Health Systems Resource Centre, New Delhi on several issues related to patents, Schedule M, financing of health systems, public funded R&D, issues related to access to medicines etc during the period between January 2008 to April 2009. Detailed notes of the proceedings of these meetings, workshops and conferences were taken down. In this context, the researcher also had the opportunity to have short conversations with the participants, who included individuals representing industry bodies, health activists, regulators in one or two instances and academicians. The researcher was also invited as a resource person and participant in three of these meetings and workshops.
Despite the departure from conventional ethnographic techniques, necessitated by the difficulties in collecting data through such techniques in the Indian context\textsuperscript{75}, the ‘ethnographic’ component of the study was sought to be embodied through these interviews and the notes and short conversations with several individuals located in the hybrid group of drug regulation during participation in these meetings, conferences and workshops.

Primary data was collected from the respondents through the administering of semi-structured interview schedules. In this regard, the study also attempted to use the case study method in order to obtain deeper level of insights into the processes driving qualification within the firm and in the regulatory sphere. Case study may be regarded as a framework for collecting data in a focused manner. Interviews constitute one of the principal methods for collection of data in this context. Such data could be in relation to a specific problem, an institution or even an event.\textsuperscript{(Nakkeeran 2006:113).} Accordingly, with regard to the present study, two case studies were carried out at the firm level order to understand the qualification of drugs by personnel during the stages of pre-clinical R&D and manufacturing of finished formulations. A third case study, through the study of a controversial drug, attempted to demonstrate the mediation of the drug with other agents or actors outside the realm of the firm. This involved the orchestration of a variety of strategies and the deploying of several tools and methods.

The first case study on the qualification of drugs during the pre-clinical stage of research and development was carried out primarily through the narratives of three key informants in the firm since permission for interviews with other employees in the firm was not granted. In addition, only a cursory visit of the R&D unit was permitted by the officials.

\textsuperscript{75} These difficulties have already been elaborately outlined in the previous section
Nevertheless, extremely detailed interviews were carried out with each of these three key respondents. About four rounds of taped interviews were carried out with Respondent 1, the ex-R&D Head of the firm. Two of these interviews were carried out during his tenure as Vice-President, R&D (Discovery Research) in the organization and two interviews were done after his exit from the organization. Two rounds of taped interviews were carried out with Respondent 2, the Vice President (Toxicology) of the firm and one detailed taped interview was done with Respondent 3, the present Executive Vice-President, (Discovery Research).

It is worth noting that these respondents offered very rich insights since they had been witness to several strategic decisions taken by the firm and they had also spent a considerable number of years on the bench since the inception of drug discovery in the Indian industry. One of the respondents, a highly reputed medicinal chemist, had been with the firm during the period 1998-2006. Prior to his joining the firm, he had been serving as a Director at a CSIR lab and post his exit from from the firm in late 2006, now headed a prominent institute, located at a Central university in Hyderabad, which engaged in cutting edge basic research in the pharmaceutical sciences. Respondent 2, a toxicologist, had been with the firm since the early nineties, when the firm first initiated efforts in drug discovery, and had been a vital part of the firm’s early successes and failures. Respondent 3 had about 15 years of experience in multinational firms, both in India and mostly abroad, and enjoyed considerable repute in the fields of clinical development and bioinformatics. These interviews were mostly carried out in the period from January 2006 to May 2008. These narratives were triangulated with the insights derived from firm-related documents such as investor reports, annual reports, in-house journals and other documents, corporate databases,
articles in the media related to the firm and interviews carried out with nineteen respondents from nine other large-scale firms, eight of which were engaged in discovery research, in the industry. These three respondents who highlighted several important processes relating to discovery research and testing in their firm, repeatedly emphasized that their observations had been made in their individual capacity as scientists and did not represent the views of the company.

For the second case study, which involved examining the processes driving qualification of drugs during the manufacture of formulations, detailed taped interviews were carried out with all the supervisorial and managerial level personnel of the organization individually, in addition to a focus group discussion with them. Focus group discussion, which involves explicit use of group interaction to collect data and insights, is used to focus on a topic by exploring in greater depth the problem to be investigated and its possible causes. In this connection, the objective was to examine the discourse of drug quality in the context of the firm’s switch from one set of manufacturing protocols to an ostensibly more sophisticated set of protocols. In addition, discussions were also carried out with some of the workers in the trust during the detailed tour of its manufacturing unit. These interviews and discussions were carried out in April 2008. In this context, access to the respondents proved relatively easier than in the earlier case study.

The third case study, which dealt with the controversial drug *Nimesulide* and the litigation around it, attempted to examine the processes shaping the qualification of the drug by different actors in the regulatory sphere. Here, the lawyers who had filed the public interest litigation in relation to the adverse effects of the drug in the Delhi high court were

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*Ibid*:112
contacted and interviewed and documents related to the case were collected from them. In addition, interviews were also conducted with health activists and regulators.\footnote{Though the firms involved in the controversy were contacted, they refused to grant interviews to the researcher.}

Additionally, the qualification of drugs by ‘hybrid groups’ and the contestations and negotiations among them in the larger terrain of drug regulation was examined through interviews with academicians, health activists, industry bodies, physicians, regulators and firm personnel.

The narratives of the respondents in these different case studies and descriptions based on the researcher’s observation was supplemented with relevant secondary sources including recent newspaper items, articles in periodicals and journals, literature pertaining to drug regulatory protocols, policy documents and reports from the website of the regulatory bodies and civil society organizations, articles from web-based journals and periodicals, material on the firms and their representative bodies posted on their website and other relevant government reports.

**Respondents’ profile**

A total of sixty four respondents were interviewed for the study. Of these, some twenty respondents were interviewed in the period between October 2005 and April 2006. The remaining forty four respondents were interviewed in the period between December 2007 and June 2008. Of the total of sixty four respondents, a total of thirty respondents were employed in the pharmaceutical sector. Of these thirty respondents, eight respondents belonged to the small scale sector. Two of them were owners of small firms located in Haryana. They were also Vice President and Secretary General of the SME Pharma Industries Confederation (SPIC) respectively. One was the CEO/Trustee of an organization
in Baroda, Gujarat. Five of these above-mentioned respondents were employed in this organization in the capacity of general manager, production manager, quality control manager, quality control officer and accounts manager respectively. The other twenty two respondents, who belonged to large firms, both domestic and multinational, were employed largely as R&D (Discovery research, New Product Development or Process Research) or Production personnel in managerial capacity or in the Corporate Communications division in these firms. One of them was also employed in the capacity of Sales Manager.

With respect to the regulators, six of these respondents were employed in the Central Drugs Standards Control Organization (CDSCO) located in New Delhi. Two of them were employed in the state Food and Drugs Administration (FDA) in Hyderabad. The seven activists with whom interviews were carried out belonged to organizations such as Voluntary Health Association of India (VHAI), Delhi Society for Promotion of Rational Use of Drugs (Delhi), MIMS India, Medico Friends Circle and Jan Swasthya Abhigyan. These activists were actively involved with a wide variety of issues related to the Indian pharmaceutical industry such as use of rational drugs, banning of irrational combinations, ethical marketing practices, access to low-cost medicines for the poor, R&D on neglected diseases, ethical conduct of clinical trials and issues related to IPR and data protection.

Of the academicians interviewed, three were employed as scientists at a CSIR policy institute in Delhi and had produced academic work related to R&D and public private partnerships in the industry. Two of them had also worked on public health related issues. One academician, located in Ahmedabad, had carried out extensive research on the industry, particularly on the small scale sector. Another respondent was the director of a pharmaceutical research and training institute in Ahmedabad, which in addition to
collaborating with firms on R&D projects, had also provided training to small scale firms on compliance with Schedule M protocols. Yet another respondent was the director of a clinical research academy in Mumbai, which provided training to firms to conduct clinical research. Two respondents, located in a Central university in South India, had worked on collaborative projects with pharmaceutical firms. One respondent was a reputed physician and Professor of Pharmacology at a well-known multi-specialty government hospital and institute in New Delhi, in addition to being a member of the National Pharmacovigilance Committee.

With respect to the respondents belonging to industry bodies, two respondents were representatives of the Indian Drug Manufacturers’ Association (IDMA), located in Delhi and Baroda respectively. Another respondent was the Secretary General of the Indian Pharmaceutical Association (IPA), an organization representing pharmacists, in Mumbai. With regard to the three consultants interviewed for the study, two of them were employed in a leading consultancy firm, which generated reports on the pharmaceutical industry, in Hyderabad. A third was employed in a consultancy in Delhi, which provided training to employees in pharmaceutical firms on HR related issues. Two other respondents were lawyers belonging to the organization, Social Jurist, which had filed public interest litigation in a Delhi high court with respect to the controversial drug, Nimesulide. Yet another respondent was a well-known physician and a representative of the Indian Medical Association (IMA) in New Delhi. Still another respondent was a journalist, who was a special correspondent for a newspaper and the British Medical Journal. All these respondents were contacted by the researcher for their potential to provide relevant information in the context of the research problem. Though the selection of the respondents
was deliberate and in accordance with the leeway by grounded theory to select potential respondents, still, the heterogeneous nature of the set of respondents interviewed for the study is a pointer to the diversity of the hybrid group involved in the qualification of drugs both within the sphere of the firm and in the larger sphere of regulation.

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Respondents’ Background</th>
<th>Number of individuals interviewed</th>
<th>Location</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Small scale pharmaceutical firms (Three firms)</td>
<td>Eight</td>
<td>Haryana &amp; Baroda</td>
<td>Two of them were owners of firms located in Haryana. They were also Vice President and Secretary General of the SME Pharma Industries Confederation (SPIC) respectively. The third respondent was the CEO/Trustee of an organization in Baroda, Gujarat. Five respondents were employed in this organization in the capacity of general manager, production manager, quality control manager, quality control officer and accounts manager respectively.</td>
</tr>
<tr>
<td>2.</td>
<td>Large scale pharmaceutical firms (Ten firms)</td>
<td>Twenty two</td>
<td>Hyderabad, Baroda, Ahmadabad, Mumbai and Delhi</td>
<td>These respondents were employed largely as R&amp;D (Discovery research, New Product Development or Process Research) or Production personnel in a managerial capacity or in Corporate Communications in these firms. One of them was employed in the capacity of Sales Manager.</td>
</tr>
<tr>
<td>3.</td>
<td>Drug Regulatory bodies</td>
<td>Eight</td>
<td>Delhi and Hyderabad</td>
<td>Six of these respondents were employed in Central Drugs Standards Control Organization (CDSCO) located in New Delhi. The two other respondents were employed in the state Food and Drugs Administration (FDA) in Hyderabad</td>
</tr>
<tr>
<td>4.</td>
<td>Health Activists</td>
<td>Seven</td>
<td>Delhi and Pune</td>
<td>These activists belonged to organizations such as Voluntary Health Association of India (VHAI), Delhi Society for Promotion of Rational Use of Drugs (Deli), MIMS India, Medico Friends Circle and Jan Swasthya Abhiyapan. They were actively involved with a wide variety of issues related to the Indian pharmaceutical industry such as use of rational drugs, banning of irrational combinations, ethical marketing practices, access to low-cost medicines for the poor, R&amp;D on neglected diseases, ethical conduct of clinical trials and issues related to IPR and data protection. One of these respondents had also served as a member of the National Pharmacovigilance Committee.</td>
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<tr>
<td>5.</td>
<td>Academicians</td>
<td>Nine</td>
<td>Baroda, Mumbai and Delhi</td>
<td>Three of these were employed as scientists at a CSIR policy institute in Delhi and have produced academic work related to R&amp;D and public private partnerships in the pharmaceutical industry. Two of them had also worked on public health related issues. One respondent, located in a research institute in Ahmedabad, had worked extensively on the industry, particularly on the small scale sector. One respondent was the director of a pharmaceutical research and training institute in Ahmedabad, which in addition to collaborating with firms on R&amp;D projects, had also provided training to small scale firms on Schedule M related compliance. Another respondent was the director of a clinical research academy in Mumbai, which provided training to firms to conduct clinical research. Two respondents, located in a Central university in South India, had worked on collaborative projects with pharmaceutical firms. One respondent was a reputed physician and Professor of Pharmacology at a well-known multi-specialty government hospital and institute in New Delhi. He is also a member of the National Pharmacovigilance Committee.</td>
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<td>6.</td>
<td>Pharmaceutical Industry bodies</td>
<td>Two</td>
<td>Delhi and Baroda</td>
<td>Both these respondents were representatives of the Indian Drug Manufacturers’ Association (IDMA), located in Delhi and Ahmedabad respectively</td>
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<td>7.</td>
<td>Pharmacists’ body</td>
<td>One</td>
<td>Mumbai</td>
<td>The respondent was the Secretary General of the Indian Pharmaceutical Association (IPA), an organization representing pharmacists, in Mumbai</td>
</tr>
<tr>
<td>8.</td>
<td>Consultants</td>
<td>Three</td>
<td>Hyderabad and Delhi</td>
<td>Two of them were employed in a leading consultancy firm, which generates reports on the pharmaceutical industry, in Hyderabad. One of them was employed in a consultancy in Delhi, which provided training to employees in pharmaceutical firms on HR related issues.</td>
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<td>9.</td>
<td>Lawyers</td>
<td>Two</td>
<td>Delhi</td>
<td>These respondents were lawyers who also represented the organization, Social Jurist, which had filed the public interest litigation in a Delhi high court with respect to the controversial drug, Nimesulide.</td>
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<td>10.</td>
<td>Physician</td>
<td>One</td>
<td>Delhi</td>
<td>The respondent was a well-known physician and a representative of the Indian Medical Association (IMA) in New Delhi</td>
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<tr>
<td>11.</td>
<td>Journalist</td>
<td>One</td>
<td>Delhi</td>
<td>The respondent was a special correspondent for ‘The Pioneer’ and also served as a special correspondent for the British Medical Journal. He had authored numerous articles on health related issues and drug-based controversies for the journal in the last ten years</td>
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