APPENDIX I

INTERVIEW SCHEDULE

(For Scientists engaged in Discovery Research in Large Firms)

Background and History of R&D Centre

1. Year of Establishment and History
2. Total Strength of Scientists in R&D Centre
3. Break-up of Scientist Strength in terms of different disciplines
4. Details of R&D Centres of the firm in India and abroad
5. Differences in R&D work undertaken in these centres

Background of Respondent

6. Name of respondent
7. Age
8. Educational Qualifications
9. Details of R&D related work experience
10. Details of R&D related experience in the present firm

Organization of R&D activities in the Centre

11. What are the therapeutic areas the firm is engaged in? What are the considerations involved in the selection of these areas?
12. Who makes the decisions on the research projects undertaken by the firm? How are these decisions made?
13. What is the typical composition and size of a project team in terms of scientists from different disciplines?
14. What is the research background of the team leader? Why?
15. What are the patterns of communication within and among teams? Whom do they report to?
16. Explain the trajectory of drug discovery in the pre-clinical stage?
17. Why do you need different disciplines like chemistry, molecular biology, pharmacology, etc in drug discovery?
18. In your opinion, what kind of expertise does your firm have in these areas? How does this compare with such expertise in other firms?
19. How would you (biologist/chemist/pharmacologist/toxicologist) define a good drug?
20. What are the concepts or benchmarks through which the mechanism of action of a disease is studied and assessed? How do these differ for different disciplines?
21. How do scientists in a team arrive at a common understanding of the disease and the candidate molecule?
22. What kind of differences emerge among team members in this process? How are these differences resolved?
23. How do you arrive at decisions on which targets should be pursued and which leads should be synthesized?
24. Are there other differences between team members in terms of aspects like credit-sharing and academic vs. industrial background? How are these differences resolved?
25. What is the significance of in-vitro and in-vivo tests in pre-clinical research in minimizing side effects or optimizing other parameters of the candidate molecule?
26. Describe the methods you follow during these stages? What are the typical problems you encounter during these stages?
27. At what point of time do you decide to proceed to the next stage?
28. Do you have an animal house for testing? What kind of and how many animals do you have there? What kind of tests do you conduct in this regard?
29. How is bioinformatics used in the pre-clinical stage? Are there any differences in the bioinformatics related activities in India and abroad?
30. What kind of expertise does your firm have in areas like genomics and proteomics? How are these disciplines relevant for the pre-clinical R&D carried out in your firm and in other firms in India?
31. Has your firm taken out patents on any lead molecules? How many patents does your firm have in this regard?
32. In whose names are these patents taken out?
33. What kind of confidentiality related protocols are mandated for scientists in your firm?
34. Do you and other scientists participate in national and international conferences and seminars?
35. Provide details of your publications, if any.
36. Has your firm licensed out any of your molecules for development?
37. Are you doing any clinical trials for these molecules? Which organizations have you tied up with in this regard? Specify details about such tie-ups.
INTERVIEW SCHEDULE

(For Personnel involved in production related activities in Large Firms)

Background and History of Firm and Production unit

1. Year of Establishment and History
2. Total Strength of personnel
3. Break-up of Personnel Strength in terms of educational qualifications
4. Details of unit (Bulk Drug/Formulation)
5. No of technical staff and non-technical staff/workers in the unit with details of educational qualification
6. Product profile of your firm with therapeutic break-up
7. Details of markets for these products

Background of Respondent

8. Name of respondent
9. Age
10. Educational Qualifications
11. Details of Production related work experience
12. Details of work experience in the present firm

Organization of production related activities (production of bulk drugs as well as formulations)

13. Describe the manufacturing process/activities you carry out in your unit (bulk/formulation). What are the steps involved here?
14. How many supervisors and workers are employed for each stage/activity in this process? What are the tasks they perform in these stages/activities?
15. What are the educational background/qualification of these supervisors and workers?
16. What kinds of machines have been purchased in your unit in the last five years? Why?
17. What kind of regulatory certification do you have in your unit? Does your unit have US-FDA/UK-MCA/WHO-GMP/Other international certification?
18. How did your unit acquire the certification? What kind of protocols and procedures did you follow in this regard?
19. What kind of auditing/inspection is done by these regulators for the certification?
20. Did you have to automate your manufacturing facility for this certification? What kind of machinery was purchased in this regard?
21. Was this machinery purchased from domestic or international sources? What kind of expenditure did your firm incur in this regard?
22. Does your production system involve use of software guided technology? If yes, then specify details.
23. What kind of quality control related instrumentation do you have in your unit?
24. Have any new instruments/machines been purchased in this division in the last five years?
25. How many personnel are employed in the QC division? What is their educational qualification?
26. Do you get any product manufactured from other firms through contract manufacturing?
27. If yes then specify details about these firms and the products
28. Do you provide technical support/know-how to these firms? If yes, then specify details.
29. Let us suppose a particular drug is produced in different units using local GMP protocols, Schedule M protocols, WHO-GMP protocols or US-FDA protocols respectively. What would be the difference in terms of:
   a) Handling of raw materials
   b) Machines used in manufacturing
   c) Strength of work force and their skill requirements
   d) Protocols/procedures to produce the drug
   e) Quality control related instrumentation/testing facilities
   f) Documentation and standard operating procedures (SOPs)
   g) Parameters of the drug related to bioequivalence/potency/efficacy/safety/purity/minimization of error/contamination
30. What is your opinion about the new Schedule M requirements for firms in India? How do these contribute to the quality of the drug?
31. How would you define drug quality?
INTERVIEW SCHEDULE

(For personnel involved in production related activities in small scale units - bulk drugs/formulations)

Background and History of Firm and Production unit

1. Year of Establishment of firm and History
2. Total Strength of employees
3. Employee profile in terms of educational qualifications
4. Type of unit (Bulk Drug/Formulation)
5. No of workers in the unit with details of educational qualification
6. Product profile of your organization with therapeutic break-up
7. Details about the market for these products

Background of Respondent

8. Name of respondent
9. Age
10. Educational Qualifications
11. Details of Production related work experience
12. Details of work experience in the present firm

Organization of production related activities (production of bulk drugs as well as formulations)

13. Describe the manufacturing process/activities you carry out in your unit (bulk/formulation). What are the steps involved here?
14. How many supervisors and workers are employed for each stage/activity in this process? What are the tasks they perform in these stages/activities?
15. What are the educational background/qualification of these supervisors and workers?
16. What kinds of machines have been purchased in your unit in the last five years? Why?
17. What kind of regulatory certification do you have in your unit? Does your unit have Schedule M certification?
18. How did your unit acquire the certification? What kind of protocols and procedures did you follow in this regard?
19. What kind of auditing/inspection was/is done by regulators for the certification and on a regular basis?
20. Did you experience any problems while switching to Schedule M? If yes, then give details.
21. Did you have to automate your manufacturing facility for this certification? What kind of machinery was purchased?
22. Was this machinery purchased from domestic or international sources? What kind of expenditure did your firm incur in this regard?
23. How useful is software-guided technology in improving the manufacturing process?
24. What kind of quality control related instrumentation do you have in your unit?
25. Have any new instruments/machines been purchased in this division in the last five years?
26. How many personnel are employed in the QC division? What is their qualification?
27. Do you get any product manufactured from other firms through contract manufacturing?
28. If yes, then specify with details about these firms and products.
29. Do you provide any technical assistance/know-how to these manufacturers? If yes, then specify with details.
30. Do you engage in contract manufacturing for other firms? If yes, then provide details.
31. Let us suppose a particular drug is produced in different units using local GMP protocols, Schedule M protocols, WHO-GMP protocols or US-FDA protocols respectively. What would be the difference in terms of:
   h) Handling of raw materials
   i) Machines used in manufacturing
   j) Strength of work force and their skill requirements
   k) Protocols/procedures to produce the drug
   l) Quality control related instrumentation/testing facilities
   m) Documentation and standard operating procedures (SOPs)
   n) Parameters of the drug related to bioequivalence/potency/efficacy/safety/purity/minimization of error/contamination
32. What is your opinion about the new Schedule M requirements for firms in India? How do these contribute to the quality of the drug?
33. What is the extent of compliance by firms on these protocols?
34. How adequate is the local regulatory expertise to monitor such compliance?
35. How would you define drug quality?
INTERVIEW SCHEDULE

(For representatives of industry bodies, regulators, health activists, physicians, pharmacists and scientists/academicians)

Section 1: Patent and R&D related issues

2. Are there different opinions on this issue? Specify with details.
3. Do you concur with the definition of ‘new chemical entities’ in the Act? Please provide details.
4. What is your assessment about Indian pharmaceutical firms involved in discovery research in relation to: output in the form of lead molecules and patents, expertise in different disciplines, degree of success in out-licensing efforts, strategies pursued by different firms and relevance of therapeutic areas pursued by firms for Indian population?

Section 2: Clinical Trials

5. Why do you think multinational firms are entering into collaborations with CROs/firms/hospitals in India for clinical trials?
6. How useful are such trials in the Indian context? How will such collaborative efforts benefit the concerned organizations or Indian patients?
7. Are these trials conducted suitably in terms of: a) patient consent, b) criteria for selection of trial subjects, c) appropriate trial design, d) composition of and review by institutional ethics committees? Specify with details.
8. How do you assess the suitability of drug testing against placebos for diseases for which proven drugs already exist? How essential is such testing in the Indian context? Specify with details.
9. Are Schedule Y protocols and Indian regulatory efforts adequate to protect the interests of patients in these trials? Provide details.

Section 3: Issues related to Manufacturing /Schedule M

10. Let us suppose a particular drug is produced in different units using local GMP protocols, Schedule M protocols, WHO-GMP protocols or US-FDA protocols respectively. What would be the difference in terms of:
   a) Handling of raw materials
   b) Machines used in manufacturing
   c) Strength of work force and their skill requirements
   d) Protocols/procedures to produce the drug
e) Quality control related instrumentation/testing facilities
f) Documentation and standard operating procedures (SOPs)
g) Parameters of the drug related to bioequivalence/potency/efficacy/safety/purity/minimization of error/contamination

11. What is your opinion about the new Schedule M requirements for firms in India? How do these contribute to the quality of the drug?
12. What is the extent of compliance by firms on these protocols?
13. How adequate is the local regulatory expertise to monitor such compliance?
14. How would you define drug quality in this context?

Section 4: Issues related to spurious and counterfeit drugs, fixed-dose combinations and marketing of drugs

15. In your opinion, what is the extent of spurious or substandard drugs in the Indian pharmaceutical market? How are these drugs different from drugs declared as “counterfeit”? Please specify with details.
16. To what extent are the fixed dose combinations in the market therapeutically useful or adequate?
17. How do you assess prescription related practices of doctors and marketing strategies of firms in the Indian context?

Section 5: The Nimesulide Controversy

Background of the Drug

18. What were the claims made about Nimesulide by its originators in the United States in comparison to existing drugs in the same category?
19. Were there any studies supporting or refuting these claims. If yes, then provide details.
20. Was Nimesulide permitted to be marketed in its country of origin? Specify details.
21. In which European countries was Nimesulide granted permission for being marketed? Why?

Launch of the Drug in India

22. When was Nimesulide introduced in the Indian market?
23. What was the reason for its introduction?
24. Do you think Nimesulide is an essential drug in the Indian context?
25. Why do you think the drug was approved by the Indian regulatory authorities and what was the criteria for approval?
26. Do you think these criteria were valid? If yes, then on what grounds? If no, then why not?
27. Do you think adequate evidence was given to the Indian regulatory authorities in terms of published studies, clinical trial related evidence and the drug’s regulatory status in other countries?

Details related to litigation in Delhi high court

28. Do you think the fixed dose combinations of Nimesulide are therapeutically rational? If yes, then why? If no, then why not?
29. Do you think the Indian Medical Association survey on the drug was adequate? Specify with details.
30. Do you think the Drug Technical Advisory Board’s assessment of the drug was adequate? Specify with details.
31. What were the arguments made by the petitioner and the firms in this regard? Do you think these arguments are valid? Specify with details.
32. Do you concur with the Delhi high court judgment on the drug? Specify with details.