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BIBLIOGRAPHY

List of Seminars


4. Seminar on US GAAP, IFRS and Indian GAAP: A Comparison, conducted by The Associated Chambers of Commerce and Industry of India (ASSOCHAM), Knowledge partner- PriceWaterHouse Coopers, conducted on 30\textsuperscript{th} September 2007 at Corporate House, Gautam Nagar, Gulmohar Enclave, New Delhi.

List of Articles


Articles in Newspapers


List of Journals and Magazines


2. Drug Point, 2005-2007

3. Pharma Focus Asia, 2006-2008

4. Journal of Finance

5. Indian Management

6. Journal of Management Studies

7. Indian Journal of Commerce

8. Business India

9. Business Today


List of websites


2. www.medindia.net/buy_n_sell/Phanri_industry/ph__rdindia.asp


7. www.pfizer.com

8. www.npil.com

9. www.wockhardtin.com

10. www.gsk.com

11. www.crisil.com

12. www.dbresearch.com


List of Reports


4. The Competition Act, 2002; No. 12 of 2003: As Amended by The Competition (Amendment) Act, 2007. Issued by the Competition Commission Of India


12. Annual Reports of Pfizer, 2000-2008


15. Annual Reports of Wockhardt, 2000-2008

16. “Accounting Standard -14, Accounting for Amalgamations”, Issued by Institute of Chartered Accountants of India


19. Administrative Staff College of India (ASCI), 2000, Issue Paper No. 3.


25. The Patents Act, 1970

26. The Patents (Amendment) Act, 1999

27. The Patents (Amendment) Act, 2002

28. The Patents (Amendment) Act, 2005

29. The Patents (Amendment) Rules, 2005

30. The Patents (Amendment) Rules, 2006


List of Books


LIST OF PRESENTATIONS AND PUBLICATIONS

Presentations

1. Paper presented in ‘Eighth International Conference’ on “Measuring Value for Shareholders in a Merger” conducted by Delhi School of Professional Studies and Research, New Delhi, 3-5 January 2007.

2. Paper presented in the ‘Ninth International Conference’ conducted by Delhi School of Professional Studies and Research, New Delhi, 3-5 January 2008 on the topic “International Mergers and Acquisitions in the Pharmaceutical Industry (A case study of Pfizer and Warner Lambert)”.

3. Paper presented in the ‘Eighth International Conference’ conducted by Research and Development Association, Jaipur, 5-7 January 2008 on the topic “Analysing Profitability and Solvency of a firm in a Merger (A case study of Pfizer and Warner Lambert)”.


Publications


QUESTIONNAIRE NO.1 – For Employed Doctors, Private Medical Practitioners, Company Employees, Chemists and Pharmaceutical Distributors

1. What in your opinion is the most valuable contribution of the pharmaceutical industry to the economy
   a. Provision of healthcare
   b. Foreign exchange earnings
   c. Attracting Foreign Direct Investment in the country
   d. Any other that you would like to specify
      (You can tick more than one option)

2. What in your opinion is the biggest challenge/problem of pharmaceutical industry
   a. Spurious medicines
   b. Safe R&D trials
   c. Environmental pollution
   d. Price control of medicines
   e. R&D of new medicines
   f. Any other that you would like to specify
      (You can tick more than one option)

3. What suggestions would you like to give for the growth of Indian pharmaceutical industry?

4. Do you think mergers and acquisitions help to increase revenue and market shares of firms?
   a. If yes, how
   b. If no, why
5. Do you think mergers and acquisitions done to acquire the profitable products of the rival firm should be allowed?
   a. If yes, why
   b. If no, why

6. Do you think mergers and acquisitions help to increase the Research and Development output of firms?
   a. If yes, how
   b. If no, why

7. Do you think mergers and acquisitions done to enter foreign markets are proving successful for Indian companies?
   a. If yes, how
   b. If no, why

8. Do you think mergers and acquisitions help to help to decrease the costs of the combined firm?
   a. If yes, how
   b. If no, why

9. Do you think that there has been an increase in the prices of medicines since 2005?
   a. If yes, by what percentage

10. Do you think that there has been a decrease in the availability of medicines since 2005?

11. Do you think that the Patents (Amendment) Act, 2005 has harmed the Indian pharmaceutical companies?

12. Do you think that the Patents (Amendment) Act, 2005 has triggered more mergers and acquisitions in the pharmaceutical industry?

13. Any of your view and suggestions that you would like to express on the current topic.
QUESTIONNAIRE NO.2 – For Patients and General Public

1. What in your opinion is the most valuable contribution of the pharmaceutical industry to the economy
   a. Provision of healthcare
   b. Foreign exchange earnings
   c. Attracting Foreign Direct Investment in the country
   d. Any other that you would like to specify
      (You can tick more than one option)

2. What in your opinion is the biggest challenge/problem of pharmaceutical industry
   a. Spurious medicines (these are duplicate medicines that are manufactured illegally)
   b. Safe R&D trials (pharmaceutical companies conduct trials on human beings to test the effectiveness on medicines. Many times the patient does not know that the medicine prescribed to him by the doctor is a trial medicine)
   c. Environmental pollution (Drug companies throw factory waste in open rivers)
   d. Price control of medicines (Companies want to fix the prices of medicines themselves and the government feels that prices of medicines should be controlled by it.)
   e. R&D of new medicines
f. Any other that you would like to specify
   (You can tick more than one option)

3. What suggestions would you like to give for the growth of Indian pharmaceutical industry?

4. Do you think mergers and acquisitions help to increase revenue and market shares of firms? (Pharmaceutical companies are merging with each other or acquiring other firms so that they can increase their sales and become big in size)
   a. If yes, why
   b. If no, why

5. Do you think mergers and acquisitions done to acquire the profitable products of the rival firm should be allowed? (Pharmaceutical companies are trying to acquire those firms that have medicines which sell a lot)
   a. If yes, why
   b. If no, why

6. Do you think mergers and acquisitions help to increase the Research and Development output of firms? (Research and Development is a process through which new medicines are discovered)
   a. If yes, how
   b. If no, why

7. Do you think mergers and acquisitions done to enter foreign markets are proving successful for Indian companies? (Indian pharmaceutical companies are acquiring companies that are already established in foreign countries so that they can establish themselves there in less time)
   a. If yes, how
   b. If no, why

8. Do you think mergers and acquisitions help to help to decrease the costs of the combined firm? (When two firms merge or one firm acquires another firm,
do you think that the cost of running the combined firm is less than the cost of running the two firms independently)

a. If yes, how
b. If no, why

9. Do you think that there has been an increase in the prices of medicines since 2005?
   a. If yes, by what percentage

10. Do you think that there has been a decrease in the availability of medicines since 2005?

11. Do you think that the Patents (Amendment) Act, 2005 has harmed the Indian pharmaceutical companies? (Indian companies could earlier manufacture the medicines invented by other companies. This Act allows that any medicine invented after 1995 can be copied by any company in India only after it has completed 20 years in the market)

12. Do you think that the Patents (Amendment) Act, 2005 has triggered more mergers and acquisitions in the pharmaceutical industry? (Have you noticed any sudden increase in mergers and acquisitions by pharmaceutical companies in India after 2005)

13. Any of your view and suggestions that you would like to express on the current topic
DEFINITION OF PHARMACEUTICAL TERMS

1. Abbreviated new drug application (ANDA)
An abbreviated new drug application is described as an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics and intended use, among other things to a previously approved application.

2. Active Pharmaceutical Ingredients (APIs)
The substance in a drug that is pharmaceutically active.

3. Anaesthetics
Anaesthetics are medicines that block or temporarily take away the condition of having sensation (including the feeling of pain). This allows patients to undergo surgery and other procedures without the distress and pain they would otherwise experience.

4. Biotechnology firms
Firms that use micro organisms like bacteria, yeast etc. or biological substances like enzymes to cure diseases in human beings and animals.

5. Bulk drugs
These are active ingredients with medicinal properties and are the basic raw materials for making formulations.

6. Cardiovascular diseases
Diseases that involve the problem of heart or blood vessels.

7. Drug
A drug is any chemical agent that affects the function of living things. Drugs are articles (other than food) intended for the use in the cure or prevention of disease in man or other animals.
8. **Diabetology**
The branch of science that deals with the study and cure of diabetes.

9. **Epilepsy**
It is a disease related to brain.

10. **Evergreening**
The practice of the patent holding firms to extend the life of their patents beyond 20 years.

11. **Formulations**
The act of developing or preparing a drug, or the final product itself is called formulation. These are specific dosage forms of a bulk drug or of a combination of different bulk drugs and the final form in which the drugs are sold i.e. syrups, injections, tablets and capsules.

12. **Generic Drug**
A generic drug is a medicinal product that has the same active ingredient, but not necessarily the same inactive ingredients as a brand-name drug. A generic drug may only be marketed after the original drug’s patent has expired.

13. **Good Clinical Practices (GCP)**
International ethical and scientific quality standards for designing, conducting, monitoring, recording, auditing, analyzing and reporting clinical studies are known as Good Clinical Practices. They ensure that the data reported is credible and accurate.

14. **Injectable**
A drug or medicine that can be injected

15. **Lifestyle diseases**
Diseases that are caused due to a change in the lifestyle like, blood pressure, diabetes, obesity, depression etc.

16. **Medical Practitioner**
A medical practitioner is a medical doctor who is registered with the relevant body, and as such is licenced to practice medicine. The medical practitioner is the person who is ultimately responsible for the care of the patient.

17. **Neurological diseases**
Diseases that involve the problem of nerves
18. New Chemical Entity
A new chemical entity (NCE) is a compound not previously described in the medical literature.

19. OTC drugs (Over The Counter drugs)
These are the drugs that are available for purchase without a physician’s prescription

20. Patented drug
A medicine that is under the protection that it cannot be copied or produced by any company other than the company that invented it.

21. Pharmaceutical Industry
The pharmaceutical industry is related to the manufacture and sale of pharmaceuticals. It involves the discovery, development, and manufacture of drugs and medications by public and private organisations.

22. Research and Discovery, Drug Development
There are mainly three stages that a drug has to pass through before it can be sold in the market:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Process</th>
<th>No. Of Molecules</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Discovery</td>
<td>Screened to find if they are biologically active</td>
<td>5000-10,000 approximately</td>
</tr>
<tr>
<td>Pre-Clinical Testing</td>
<td>Selected Molecules are tested on animals</td>
<td>250 approximately</td>
</tr>
<tr>
<td>Clinical Testing</td>
<td>Test on human beings to find efficacy and toxicity of the drug</td>
<td>5 approximately</td>
</tr>
</tbody>
</table>

And finally, out of 5,000-10,000 molecules only 1 gets approved. The combined process of Pre-clinical testing and clinical testing is known as drug development. Of this clinical testing is the most lengthy and difficult process. These trials are aimed at establishing the safety and efficacy of the drugs. Typically after the pre-clinical testing on animals there are four phases that each drug has to go through:

Phase-I: Study on humans (usually healthy volunteers) to establish basic safety of drugs (sample size 20-80)
Phase-II- Study for side effects, risks and efficacy of drugs (sample size 100-300)
Phase-III- aimed at establishing safety and determining the ideal dosage of the drug on a wider patient population (sample size 1,000-5,000).
Phase-IV- Post marketing trials.

23. Solid dosages
These are solid medicines that are taken through mouth

24. Therapeutics
It is the branch of medicinal study that deals specifically with the treatment of disease and the art and science of healing

25. United States Food and Drug Administration (USFDA) and United Kingdom Medicines and Healthcare products Regulatory Agency (UKMHRA)
These are scientific, regulatory, and public health agencies. They are responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products and medical devices. They are also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

26. Urology diseases
Diseases that involve urinary problems

27. Wholesalers/ Pharmaceutical Distributors
Wholesalers/Pharmaceutical Distributors are the people who frequently physically assemble, sort and grade goods in large lots, break bulk, repack and redistribute in smaller lots.
A-5

CONVERSION RATES OF CURRENCY

The financial figures of Pfizer and GSK have been converted into Indian currency. Pfizer has headquarters in USA, hence the Annual Reports are made in terms of millions of US dollars. These figures have been converted into millions of Rupees. The exchange rate has been taken as on 31st December for each year. This is the date as on which the Balance Sheet is prepared by Pfizer for each financial year. Similarly, GSK has headquarters in UK. The Annual Reports of this company are made in terms of millions of sterling. These figures have been converted into millions of Rupees. The exchange rate has been taken as on 31st December for each year. This is the date as on which the Balance Sheet is prepared by GSK for each financial year.

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<th>Year</th>
<th>Pfizer (USA)</th>
<th>GSK (UK)</th>
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<tr>
<td>2000</td>
<td>46.7</td>
<td>69.7</td>
</tr>
<tr>
<td>2001</td>
<td>48.3</td>
<td>70.2</td>
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<td>2002</td>
<td>48</td>
<td>77.1</td>
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<td>2003</td>
<td>45.6</td>
<td>81.1</td>
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<td>2004</td>
<td>43.7</td>
<td>84.3</td>
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<td>2005</td>
<td>45.2</td>
<td>77.8</td>
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<td>2006</td>
<td>44</td>
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<td>2007</td>
<td>39.4</td>
<td>78.8</td>
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<td>2008</td>
<td>49.7</td>
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(Source: www.oanda.com)
# LIST OF PATENTED NCEs

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<th>INDIAN AUTHORISED AGENT</th>
<th>NAME OF MANUFACTURER</th>
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<td>1.</td>
<td>DECEMBER 2007</td>
<td>M/S. ABBOTT INDIA, MUMBAI</td>
<td>M/S. ABBOTT, GERMANY</td>
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<td></td>
<td>LOPINAVIR/ROTINAVIR (ALUVIA) TAB</td>
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<td>2.</td>
<td>JANUARY 2008</td>
<td>M/S. BAYER HEALTH, THANE</td>
<td>M/S. BAYER, GERMANY</td>
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<td></td>
<td>SORAFINIB 200MG TABLET</td>
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<tr>
<td>3.</td>
<td>ABRAXANE (NANOPARTICLE PACLITAXEL)</td>
<td>M/S. BIOCON LIMITED, BANGALORE</td>
<td>M/S. ABRAXIS BIOSCIENCE, USA</td>
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<td>4.</td>
<td>FEBRUARY 2008</td>
<td>M/S. NOVARTIS HEALTHCARE, MUMBAI</td>
<td>M/S. NOVARTIS PHARMA, SWITZERLAND</td>
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<td></td>
<td>DEFERASIROX (ASUNRA) DISP. TAB. 100MG &amp; 400MG</td>
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<td>GALVUS (VILDAGLITIN) TAB.</td>
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<td>6.</td>
<td>FEBRUARY 2008</td>
<td>M/S. MSD PHARMA, BHIWANDI</td>
<td>M/S. MERCK &amp; SHARP, ITALY</td>
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<td></td>
<td>SITAGLIPTIN PHOSPHATE</td>
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<td>7.</td>
<td>MARCH 2008</td>
<td>M/S. SANOFI SYNTHELABO MUMBAI</td>
<td>M/S. SANOFI WIMTHROP, FRANCE</td>
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<td>July 2008</td>
<td>PEMETREXED DISODIUM POWDER FOR SOLUTION</td>
<td>M/S. ELI LILY &amp; CO. HARAYANA</td>
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<td>9</td>
<td>August 2008</td>
<td>1. FIXED DOSE COMBINATION OF SITAGLIPTIN PHOSPHATE AND METFORMIN HCl TABLETS (50mg/500mg &amp; 1000mg)</td>
<td>M/S. M.S.D. PHARMACEUTICALS PVT. LTD., MAHARASHTRA-421302</td>
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(Source: Indian Patent Office, New Delhi)
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<td>9464</td>
<td>15791</td>
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<td>13722</td>
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<td>25203</td>
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<td>11068</td>
<td>11090</td>
<td>11388</td>
<td>13849</td>
<td>20885</td>
<td>23312</td>
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<td>1346</td>
<td>1437</td>
<td>2368</td>
<td>3918</td>
<td>1641</td>
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<td>374</td>
<td>225</td>
<td>237.5</td>
<td>522.5</td>
<td>287.5</td>
<td>281.5</td>
<td>235</td>
<td>338.5</td>
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<tr>
<td>Dividend paid (per share)</td>
<td>4.4</td>
<td>5.5</td>
<td>8.5</td>
<td>10</td>
<td>3</td>
<td>3</td>
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<td>4.2</td>
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<td>R&amp;D Expenditure</td>
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<td>92</td>
<td>130</td>
<td>169</td>
<td>289</td>
<td>845</td>
<td>1134</td>
<td>1865</td>
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<td>Sales revenue from foreign market</td>
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<td>1077</td>
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(Source: Annual Reports of PHL)
GlaxoSmithKline
(Figures in millions of Sterling except per share data)

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<td>Equity Shareholders</td>
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<td>11.92</td>
<td>12.8</td>
<td>12.22</td>
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<td>Dividend paid (per share)</td>
<td>0.38</td>
<td>0.39</td>
<td>0.44</td>
<td>0.41</td>
<td>0.42</td>
<td>0.44</td>
<td>0.48</td>
<td>0.53</td>
<td>0.57</td>
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<td>R&amp;D Expenditure</td>
<td>2019</td>
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<td>2900</td>
<td>2929</td>
<td>2899</td>
<td>3136</td>
<td>3457</td>
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(Source: Annual Reports of GlaxoSmithKline)
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(Source: Annual Reports of Wockhardt)
### Pfizer

(Figures in millions of Dollars except per share data)

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(Source: Annual Reports of Pfizer)