



Pharmexcil Digest

Vol.1 Issue 4 October 2009

Chairman

Shri Smitesh Shah

Vice Chairman

Shri N.R. Munjal

Executive Director

Dr. P.V. Appaji

Advertisement Tariff

| | |
|------------------|-----------|
| Back Page | Rs. 7,500 |
| Back Inside | Rs. 5,000 |
| Front Inside | Rs. 5,000 |
| Inside Full Page | Rs. 4,000 |
| Inside Half Page | Rs. 2,000 |

Subscription Tariff

| | |
|-------------|-----------------------|
| Members | : Free |
| Non Members | : Rs. 25/- per issue |
| | : Rs. 125/- per Annum |

Contents

| | |
|--|----|
| 1. CHAIRMAN'S MESSAGE | 1 |
| 2. EXECUTIVE DIRECTOR'S DESK | 2 |
| 3. SPECIAL FEATURE | 4 |
| 3.1 PHARMEXCIL AWARDS | 4 |
| 4. ACHIEVEMENTS OF INDIAN PHARMA..... | 17 |
| 4.1. ANDA APPROVALS RECEIVED BY INDIAN COMPANIES IN SEPTEMBER 2009 | 17 |
| 4.2 NEW DRUG APPLICATION (NDA) OF INDIAN COMPANY IN US FDA | 18 |
| 4.3 RECENT NDA APPROVALS BY U.S. FDA THROUGH 505(B)(2) | 18 |
| 4.4 INDIA'S PHARMACEUTICAL EXPORTS STATISTICS | 19 |
| 5. PHARMEXCIL FEATURE ARTICLE | 21 |
| 5.1. CERTIFICATE OF SUITABILITY OF EUROPEAN PHARMACOPOEIAS (CEPS) – INDIA STATUS | 21 |
| 6. PHARMEXCIL ACTIVITIES | 23 |
| 6.1 PHARMEXCIL ACTIVITIES DURING SEPTEMBER 2009 | 23 |
| 6.2 PHARMEXCIL NEW COMMITTEE OF ADMINISTRATION | 25 |
| 6.3 CIRCULARS ISSUED BY PHARMEXCIL | 26 |
| 6.4 UPCOMING PHARMEXCIL ACTIVITIES | 26 |
| 6.5 PHARMEXCIL STUDY REPORTS | 27 |
| 7. INDIAN PHARMA IN MEDIA..... | 28 |
| 8. UPCOMING PHARMA EVENTS..... | 31 |
| 9. IMPORTANT GOVERNMENT NOTIFICATIONS | 33 |

PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt., of India)
H.O.: 101, Aditya Trade Centre, Ameerpet, Hyderabad – 500038
Tel: 040-23735462/23735466, Fax: 91-40-23735464
E-mail: info@pharmexcil.com

Knowledge Partner



For more information, visit www.datamonitor.com

DISCLAIMER

This monthly update has been prepared as a service to pharmaceutical exporters from India and pharmaceutical importers in other countries, by PHARMEXCIL (Pharmaceuticals Export Promotion Council of India). No part of this report may be reproduced, stored in a retrieval system or transmitted in any form or by any means, without prior permission, in writing from PHARMEXCIL and Datamonitor, India.

PHARMEXCIL does not recommend or endorse any specific companies or commercial products and brand names which may find mention in these Monthly News Digest. Through the information contained within these monthly updates PHARMEXCIL does not express any opinion whatsoever concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

1. Chairman's Message



Dear Member,

It is indeed a great pleasure and an honor for me to present the fourth successful issue of 'pharmexcil Digest', the monthly communication vehicle of Pharmexcil.

At the outset I would like to congratulate our outgoing chairman, Shri Venkat Jasti, for his successful completion of 2 years in office as Chairman of Pharmexcil. His various contributions to the council are much appreciated and we wish that our healthy association with him continues into the future.

The "Indo-Africa Pharma Business Meet" organized by Pharmexcil as part of Brand India Campaign was held in Hyderabad from September 25 – 27, 2009. The event was highly successful with more than 600 participants from India and African countries. I would like to take this opportunity to share with you that Shri K. Rosaiah, Honorable Chief Minister of Andhra Pradesh, Govt. of AP has agreed to allot land in Hyderabad for World Pharma Trade Centre convention centre for Pharmexcil – this was announced by the CM during the inaugural session of the Business Meet. Shri Anand Sharma, Honorable Minister for Commerce & Industry, Government of India also expressed his willingness to fund the construction cost of the centre. This indeed reflects and is in recognition of the instrumental role played by Pharmexcil since its inception in 2004 in facilitating the growth of exports of pharmaceuticals, which accounted for roughly about 4.7% of the total exports from India in 2008-09.

Pharmexcil's 5th Annual General Meeting was held on September 25 2009. During the meeting the succeeding Chairman elected as per the constitution of the council was announced. While I have assumed the Chairman's office, Shri N.R. Munjal, Chairman, Ind-Swift Labs Limited has been elected to the office of Vice-Chairman of Pharmexcil. While eight members were elected, three members are elected for the first time and the remaining five are continuing members. I welcome all the newly elected members to the Committee of Administration and look forward to greater co-operation in facilitating the exports of pharmaceuticals from India.

Yours Sincerely,

Smitesh Shah

2. Executive Director's Desk



Dear Member,

I am delighted to share with you the success of the Reverse Buyers Sellers Meet “Indo-Africa Pharma Business Meet” organized by Pharmexcil in Hyderabad from September 25 – 27, 2009. The event attended by about 600 participants from India and Africa, has met its objective of driving the message that the generic drugs supplied by the Indian pharmaceutical industry to Africa are safe, efficacious and affordable. It has also provided a platform for creating business opportunities for players in Indian and African pharmaceutical industry. About 80 foreign delegates, representing FDA /Drug regulatory bodies from 15 African countries and pharmaceutical importers/buyers from these countries participated in this business meet.

I would like to take this opportunity to thank Shri Anand Sharma, Honorable Minister for Commerce & Industry (GoI) who has graced the inaugural session as Chief Guest; Shri K. Rosaiah, Honorable Chief Minister of Andhra Pradesh, Govt. of AP for delivering the key note address and Prof. Peter A Nyongo, Honorable Minister for Medical Services, Govt. of Kenya; Shri R.S. Gujral, Director General of Foreign Trade, GoI; Shri Debasish Panda, Joint Secretary, Department of Health and Family Welfare, GoI; Dr. Surinder Singh, Drug Controller General of India, GoI and Shri Ashok Kumar, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers for participating in this business meet and supporting Pharmexcil in organizing this event as part of “Brand India Campaign” to counter the growing concern about the quality of Indian generics.

In a press meet after the Business Meet, Dr. Paul B Orhii, Director General, National Agency for Food and Drug Administration and Control (NAFDAC) of Nigeria has informed that about 20 Indian pharmaceutical companies expressed their interest in setting up manufacturing plants in Nigeria and NAFDAC has plans of joining with the National Institute of Pharmaceutical Education and Research, Mohali to train its people.

During the month Pharmexcil has also participated in “Pharmed & Healthcare Vietnam 2009” by organizing an India pavilion for the benefit of small exporters; most of the participants succeeded in generating good business leads.

I am happy to share with you that an article titled “Presence of Indian pharmaceutical industries in US market: An empirical analysis” that was prepared by Pharmexcil in association with Mr. Lanka Srinivas, a seasoned professional from the Indian pharmaceutical industry was published in Journal of Generic Medicines, August 2009. I would like to congratulate all the authors of this article and would further encourage my colleagues at Pharmexcil and the various stake holders in the industry to contribute various articles that highlight the strengths of Indian pharmaceutical industry since that helps in creating good visibility for the Indian pharmaceutical products in the international media.

Last but not the least; I would like to express my sincere gratitude to all my colleagues in all the Pharmexcil offices for making the “Indo-Africa Pharma Business Meet” a grand success by putting in their best efforts.

Yours sincerely,

Dr. P. V. Appaji

3. Special Feature

3.1 Pharmexcil Awards

Out Standing Export Performance by Indian Pharmaceutical companies at Indo-Africa Pharma Business Meet, Hyderabad

Inaugural session: As part of “Brand India Campaign”, Pharmexcil organized prestigious 3-day 'Indo-Africa Pharma Business Meet' from September 25 - 27 2009 at Hotel Marriott, Hyderabad. The welcome address and presentation on Indian pharmaceutical industry was delivered by Shri Venkat Jasti, Chairman of Pharmexcil. Shri Anand Sharma, Hon'ble Minister for Commerce & Industry, GoI has graced the inaugural session as Chief Guest and Shri K. Rosaiah, Hon'ble Chief Minister of Andhra Pradesh, Govt. of AP delivered the key note address. Prof. Peter A Nyongo, Hon'ble Minister for Medical Services, Govt. of Kenya addressed the gathering during the inaugural session. Shri R.S. Gujral, Director General of Foreign Trade, GoI; Shri Debasish Panda, Joint Secretary, Department of Health and Family Welfare, GoI; Dr. Surinder Singh, Drug Controller General of India, GoI also addressed the gathering during the inaugural session. The message by Shri Ashok Kumar, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers was presented in absentia.

Delegates and participants: About 80 delegates comprising importers/buyers, FDA /Drug Regulatory officials and media personnel from 15 African countries namely Algeria, Benin, Botswana, Cameroon, Egypt, Ethiopia, Ghana, Kenya, Libya, Mozambique, Nigeria, Tanzania, Tunisia, South Africa and Zambia participated at the event hallmarked by the presence of captains of Indian pharmaceutical industry and U.S. FDA regulatory officials in India. In total about 600 participants attended the business meet during the 3 days in the Buyers/Sellers meet and technical sessions.

The event was highly successful and received applause from all quarters of the industry. Representatives from nearly the entire pharmaceutical industry in India participated at the event. Participants expressed their satisfaction about the arrangements on the occasion.

Technical sessions: On Day 1, Dr. R. S. Prasad, MD, Suven Nishtaa Pharma Pvt. Ltd and Dr. Gopakumar Nair, Patent Attorney, Advisor (patents) – Pharmexcil presented on “Emerging opportunities in Pharmaceutical Product Services” and “Recent trends in IP related

barriers to legitimate trade of generic medicines” respectively. Technical sessions on the current scenario of exports to Africa from India, Potential of Indian Systems of Medicine along with the limitations of these exports to Africa, Overview of drug regulatory systems in various African countries by respective regulatory authorities, etc were held on Day 2. Some of the speakers on Day 2 were - Mr. Vishnu Sriram, Vice President, Aurobindo Pharma Ltd, Dr. S. Rao, Consultant, Department of AYUSH, GoI, Mr. Ranjit Puranik, CEO, Shree Dhootapapeswar; Dr. G.V.R. Joseph, Asst. Director, Dept. of AYUSH; Mr. Madhu, Vice President, Natural Remedies; Dr. Paul B. Orhii, Director General, NAFDAC, Dr. Esnat Mwape, Director General, PRAZ, Zambia, Dr. Joh Munyu, Chief Executive Officer, Kenya Medical Supplies Agency (KEMSA), Prof K. Ganapathy, President Apollo Telemedicine Networking

Foundation, etc. Mr. Bruce Ross, Country Director, USFDA, during his presentation highlighted the empiric need of USFDA in setting up their office in India with the increasing share of pharmaceutical imports from India to US in the last few years. The list of technical sessions held at the meet is given in the table below. All the presentations can be accessed from the following link on the pharmexcil website

<http://www.pharmexcil.com/v1.aspx/Conferences.aspx>)

Pharmexcil Awards: Pharmexcil has announced awards for outstanding performance in exports and for companies who have secured patents in 2008-09. The awards were presented by Shri Anand Sharma, Hon'ble Minister for Commerce & Industry, GoI. The following table lists all the award-winners in each of the categories.

| 3.1.1 Details of the Inaugural/Technical Sessions Organised during 25th – 27th Sept. 2009 at Indo –Africa Pharma Business Meet at Hyderabad | | | |
|--|---|--|--|
| Date /Session | Presentation | Presentation by | Video/Photos |
| 25 Sep 09 Inaugural Session. | <u>a) Welcome address & Presentation on Indian Pharmaceutical Industry-Pharmacy of the World by</u> | Shri Venkat Jasti, Chairman- PHARMEXCIL | <u>Video</u> |
| | Address | Prof.Peter A Nyongo,Minister for Medical Services, Govt. of Kenya | <u>Video 1</u> <u>Video 2</u> |
| | Key note Address by Special Guest of Honour | Shri K. Rosaiah, Honorable Chief Minister of Andhra Pradesh, Govt. of AP | <u>Video</u> |
| | Inaugural address by Chief Guest | Shri Anand Sharma, Honorable Minister of Commerce & Industry, Government of India | <u>Video 1</u> <u>Video 2</u> <u>Video 3</u> <u>Video 4</u> |
| | Vote of Thanks by | Shri Smitesh Shah, Vice Chairman, Pharmexcil | <u>Video 1</u> <u>Video 2</u> |
| Distribution of Awards by Pharmexcil | | | <u>(Photo Gallery)</u> |
| Business Session | | | <u>(Photo Gallery)</u> |
| Sessions by Drug Regulatory Authorities | | | |
| 25 Sep 09 | <u>1. Drug Regulatory Framework and New Initiatives in India</u> | Shri Debashish Panda,IAS, Joint Secretary, Ministry of Health & Family Welfare | Photos |
| | <u>2. Policy of DCGI on COPP's</u> | Dr. Surinder Singh, DCGI Government of India | <u>Video</u> |
| 25 Sep 09 Technical Session I | <u>1.India - Emerging Leader - Pharmaceutical Product Services</u> | Dr. R S Prasad, MD, Suven Nishtaa Pharma Pvt Ltd | Photos |
| | <u>2. Recent trends in IP related Barriers to legitimate trade of generic medicines</u> | Dr. Gopakumar Nair, Patent Attorney , Advisor (Patents) - Pharmexcil | Photos |
| 26 Sep 09 Technical Session II. | <u>1.Export of Pharmaceuticals to Africa – General Issues</u> | Mr. Vishnu Sriram, Assistant Vice President -Aurobindo Pharma | Photos |
| 26 Sep 09 Technical Session III. | <u>1.AYUSH Sector in India</u> | Dr Sreedhar Rao, Consultant -Dept. of | Photos |

| | | | |
|--|---|--|--------|
| | | AYUSH | |
| | <u>2.AYUSH Export Potential</u> | Mr. Ranjit Puranik CEO, Shree Dhootapapeswar | Photos |
| | <u>3.Regulatory Status for AYUSH in African countries</u> | Dr. GVR Joseph, Asst Director, Dept. of AYUSH | Photos |
| | <u>4.World class Botanical Extracts from India</u> | Mr. Madhu, Vice President, Natural Remedies | Photos |
| | <u>5.International Regulatory Harmonization-A challenge</u> | Dr. Milind Joshi, President, J B Chemicals & Pharma Ltd. | Photos |
| | <u>6.Pharmaceutical Exports to Nigeria- Role of QCS</u> | Mr.R.W.Gudal, Ex.Jt.Commissioner and Drugs Controller | Photos |
| | <u>7.Drug Regulatory Mechanism in Nigeria</u> | a.Dr.Paul B.Orhii,JD,MD, Director General (NAFDAC) b.Ms.H.J.Keri, Director, Establishment Inspection(NAFDAC) | Photos |
| 26 Sep 09 Technical Session IV | <u>1.Assisting health care in Africa-The Apollo Story</u> | Dr.K.Ganapathy,Preside nt Apollo Telemedicine Foundation | Photos |
| | <u>2. USFDA Offices in India</u> | Mr. Bruce Ross, Country Director, USFDA-Delhi, India | Photos |
| | <u>3.Kenya Market Overview</u> | Dr. John Munyu,CEO Kenya Medical Supplies Agency | Photos |
| | <u>4.Functions of the Board -Pharmacy and Poisons Board, Govt. of Kenya</u> | Dr.Pius Wanjala,Member, Pharmacy and Poisons Board | Photos |
| | <u>5.Overview of Botswana</u> | Mr. George Proctor,CEO,Gemi Pharmacure | Photos |
| | <u>6.Drug Registration Procedures in Tanzania</u> | Dr.Nditonda B. Chukilizo, Tanzania Food and Drugs Authority | Photos |
| | <u>6a.Medicines Registration Process in Tanzania(Char)</u> | Dr.Nditonda B Chuklizo, Tanzania Food and Drugs Authority | Photos |
| | <u>7.Zambia Drug Registration & Challenges</u> | Mr.Esnat Mwape, Director General, PRAZ | Photos |
| <i>The presentations are available at Pharmexcil's website under Conferences & presentations</i> | | | |

3.1.2 Inaugural Session

Top Right: Shri Anand Sharma, Hon'ble Minister for Commerce & Industry, alongwith Shri K. Rossaiah, Hon'ble Chief Minister of Andhra Pradesh, Prof. Peter A Nyongo, Hon'ble Minister for Medical Services, Govt. of Kenya inaugurating Indo-Africa Business Meet. Also on the podium are Dr. Surinder Singh, DCGI officials of Pharmexcil Shri Venkat Jasti, Chairman, Shri Smitesh Shah, Vice-Chairman, Dr. P.V. Appaji, Executive Director.



3.1.3 Pharmexcil Award Distribution Ceremony



3.1.4 Buyer Seller Meet in Progress

Business Session in progress. Also in the photographs, Dr. Paul B Orhii, Director General, National Agency for Food and Drug Administration and Control (NAFDAC)



3.1.5 Technical Sessions



3.1.6 Cultural Program



3.1.7 Dinner Party



3.1.8 Overseas Participants





3.1.9 Pharmexcil Outstanding Export Performance Award Recipients

1. Outstanding Contribution to the Pharmaceutical Industry

Ranbaxy Laboratories Limited

2. Category-wise Outstanding

| | |
|---|--------------------------------|
| Overall Export Performance Award in Drugs & Pharmaceuticals | Cipla Ltd |
| | Dr. Reddy's Laboratories Ltd. |
| Outstanding Export Performance Award in Formulations Category | Aurobindo Pharma Ltd. |
| | Lupin Limited |
| API / Intermediates Category | Matrix Laboratories limited |
| | DIVI'S Laboratories Ltd. |
| Biotech Category | Serum Institute of India Ltd. |
| Herbal Category | Laila Nutraceuticals |
| SSI Category | Bliss GVS Pharma Ltd. |
| | Shalina Laboratories Pvt. Ltd. |
| Excepients/Devices/Packaging Material Category | Associated Capsules Ltd. |
| Merchant Exporters Category | Advance Exports |

3. Outstanding Export Performance Award in Fast Emerging companies category

| | |
|--|---|
| Formulations Category | Wockhardt Limited |
| | Aventis |
| | Medreich Limited |
| API / Intermediates Category | Granules India Limited |
| | |
| Aarti Drugs Limited | MSN Laboratories Ltd |
| Biotech Products Category | Unique Biotech Ltd. |
| Herbal Products Category | OmniActive Health Technologies Limited |
| | |
| SSI Category | MEDICAMEN Biotech Limited |
| | Shreechem pharmaceuticals Private limited |
| Excepients/Devices/Packaging Material Category | Suru International Pvt. Ltd. |
| Merchant Exporter Category | Hightech Healthcare |

4. Certificate of Appreciation for outstanding Export Performance

| | |
|---|---------------------------------------|
| Pharmaceutical Formulations | Gland Pharma Limited |
| | Indoco Remedies |
| | Alkem Labs. Ltd. |
| | Promed Exports Pvt. Ltd |
| | Natco Pharma |
| API/Drug Intermediates | Hetero Drugs Limited |
| | Malladi Drugs & Pharmaceutical Ltd. |
| | ANUH Pharma |
| | Bacfo Pharmaceuticas Ltd. |
| Herbal Products | Welex Laboratories Pvt.Ltd. |
| | Unique Pharmaceuticals Labs Ltd. |
| | Charak Pharmaceuticals |
| | Vicco laboratories Ltd |
| SSI Category | Bakul Pharma Pvt. Ltd |
| | Aico Laboratories India Ltd. |
| | Galentic Pharma Private limited |
| | Sudeep Pharma |
| | Murli Krishna Pharma Pvt. Ltd. |
| | Fourrts India Lab. Ltd. |
| | Indus Pharmaceuticals |
| | Biochemical & Synthetic Products |
| Excepients/Devices/Packaging Material Category | Ideal Cures Pvt. Ltd. |
| | Dr. Sabhrawal Medical Pvt. Limited |
| | M.B. Sugars & Pharmaceuticals Limited |
| Merchant Exporter Category | Amol Pharmaceuticals Pvt. Limited |
| | Aquatic Formulations (India Ltd.) |
| | Indus Pharmaceuticals |

Pharmexcil Patent Awards

Gold Recipients

| | |
|---|--|
| Biotech | Biocon Ltd, Bangalore |
| Active Pharmaceutical Ingredients (API) & Formulations | Natco Pharma Ltd., Hyderabad. |
| Active Pharmaceutical Ingredients (API) | IPCA Laboratories Ltd., Mumbai. |
| | Hetero Drugs Ltd., Hyderabad. |
| NCEs / Drug Discovery | Glenmark Pharmaceuticals Ltd., Mumbai. |
| | Suven Life Sciences Ltd., Hyderabad. |
| | Wockhardt Research Centre, Aurangabad. |

Silver Recipients

| Product Category | Company Name |
|--|--|
| Active Pharmaceutical Ingredients (API) | Matrix Laboratories Ltd., Hyderabad. |
| | USV Ltd., Mumbai. |
| Formulations | Indoco Remedies Ltd., Mumbai. |
| Vaccines | Bharath Biotech International Ltd., Hyderabad. |

Certificate of Appreciation

| | |
|----------------------------------|--|
| Herbals | Venkateswara Ayurveda Nilayam Limited, Chitaluru, A.P. |
| Pharmaceutical Excipients | Ideal Cures Pvt. Ltd., Mumbai. |
| Herbals | Green Chem Ltd., Bangalore. |

4. Achievements of Indian Pharma

4.1. ANDA approvals received by Indian companies in September 2009

About 40% of total ANDA approvals granted by USFDA in August 2009 are for India based pharmaceutical companies

| ANDA Approvals by USFDA to Indian Pharmaceutical Companies during the month of September 2009 | | | | | |
|--|------------------------|--|--------------------------------|---|------------------|
| Sl. No | Company | Active Ingredients | Dosage form | Strength | Marketing Status |
| 1 | AUROBINDO PHARM (4) | FLUCONAZOLE | FOR SUSPENSION; ORAL | 50MG/5ML ;200 MG/5ML | Prescription |
| | | RISPERIDONE | SOLUTION; ORAL | 1MG/ML | Prescription |
| | | RIBAVIRIN | TABLET; ORAL | 200MG | Prescription |
| | | RIBAVIRIN | CAPSULE; ORAL | 200MG | Prescription |
| 2 | ORCHID HLTHCARE (3) | PIPERACILLIN SODIUM; TAZOBACTAM SODIUM | INJECTABLE; INJECTION | EQ 2GM BASE/VIAL; EQ 250MG BASE/VIAL ;EQ 3GM BASE/VIAL; EQ 375MG BASE/VIAL ; EQ 4GM BASE/VIAL; EQ 500MG BASE/VIAL | Prescription |
| | | PIPERACILLIN SODIUM; TAZOBACTAM SODIUM | INJECTABLE; INJECTION | EQ 36GM BASE/VIAL; EQ 4.5GM BASE/VIAL | Prescription |
| | | ZALEPLON | CAPSULE; ORAL | 5MG ; 10 MG | Prescription |
| 3 | SUN PHARM INDS LTD (2) | CAFFEINE CITRATE | SOLUTION; INTRAVENOUS | EQ 30MG BASE/3ML (EQ 10MG BASE/ML) | Prescription |
| | | CAFFEINE CITRATE | SOLUTION; ORAL | EQ 30MG BASE/3ML (EQ 10MG BASE/ML) | Prescription |
| 4 | DR REDDYS LABS LTD | NATEGLINIDE | TABLET; ORAL | 60MG;120 MG | Prescription |
| 5 | GLAND PHARMA LTD | ONDANSETRON HYDROCHLORIDE | INJECTABLE; INJECTION | EQ 2MG BASE/ML | Prescription |
| 6 | GLENMARK GENERICS | VERAPAMIL HYDROCHLORIDE | TABLET, EXTENDED RELEASE; ORAL | 240MG | Prescription |
| 7 | HETERO DRUGS LTD | LITHIUM CARBONATE | CAPSULE; ORAL | 150MG ;300MG ;600MG | Prescription |
| 8 | WOCKHARDT | TIMOLOL MALEATE | SOLUTION/DROPS; OPHTHALMIC | EQ 0.25% BASE ;EQ 0.5% BASE | Prescription |
| 9 | ZYDUS PHARMS USA INC | RAMIPRIL | TABLET; ORAL | .25MG;2.5MG ;5MG ;10MG | Prescription |

Source: U.S. FDA website, Pharmexcil Research

4.2 New Drug Application (NDA) of Indian company in US FDA

| Sl. No | Sponsor Applicant | Appl. No | Date of Approval | Form | Dosage | drug name | Active Ingred |
|--------|-------------------|----------|------------------|--------------------------------|-------------------|-----------------------|-----------------------------|
| 1 | Ranbaxy | 6927 | 1949 | Cream; Topical | 10% | Eurax | Crotamiton |
| 2 | | 9112 | 1955 | Lotion; Topical | 10% | Eurax | Crotamiton |
| 3 | | 14685 | 1964 | Solution; Oral | EQ 10mg Base/ 5ml | Aventyl Hydrochloride | Nortriptyline Hydrochloride |
| 4 | | 12104 | 1974 | Spray; Topical | 0.147mg/GM | Kenalog | Triamcinolone Acetonide |
| 5 | | 17556 | 1974 | Cream; Topical | 0.10% | Halog | Halcinonide |
| 6 | | 17823 | 1977 | Solution; Topical | 0.10% | Halog | Halcinonide |
| 7 | | 17824 | 1977 | Ointment; Topical | 0.10% | Halog | Halcinonide |
| 8 | | 17950 | 1978 | Cream; Topical | 0.20% | Westcort | Hydrocortisone Valerate |
| 9 | | 18726 | 1983 | Ointment; Topical | 0.20% | Westcort | Hydrocortisone Valerate |
| 10 | | 18738 | 1985 | Solution; Topical | 1% | Exelderm | Sulconazole Nitrate |
| 11 | | 19155 | 1985 | Lotion; Topical | EQ 12% BASE | LAC-Hydrin | Ammonium Lactate |
| 12 | | 19152 | 1986 | Tablet, Extended Release; Oral | 240mg | Isoptin SR | Verapamil Hydrochloride |
| 13 | | 18737 | 1989 | Cream; Topical | 1% | Exelderm | Sulconazole Nitrate |
| 14 | | 19967 | 1990 | Cream; Topical | 0.05% | Ultravate | Halobetasol Propionate |
| 15 | | 19968 | 1990 | Ointment; Topical | 0.05% | Ultravate | Halobetasol Propionate |
| 16 | | 20508 | 1996 | Cream; Topical | EQ 12% BASE | LAC-Hydrin | Ammonium Lactate |
| 17 | | 21591 | 2003 | Solution; Oral | 500mg/5ml | Riomet | Metformin Hydrochloride |
| 18 | Glenmark Generics | 50299 | 1971 | Suspension; Oral | 100,000 Units/ ml | Nilstat | Nystatin |
| 19 | Dr. Reddy's LA | 18578 | 1982 | Cream; Topical | 1% | SSD | Silver Sulfadiazine |

4.3 Recent NDA Approvals by U.S. FDA through 505(b)(2)

| Sl. No | Approval Date | FDA Appl. | Drug Name | Active Ingredients | Company | Approval Status |
|--------|---------------|----------------|-----------------------------------|-----------------------------------|-----------------------|-----------------|
| 1 | 05/07/2009 | (NDA # 022356) | Limivudine; Zidovudine | Limivudine; Zidovudine | Hetero Drugs Ltd. | Tentative |
| 2 | 07/16/2009 | (NDA # 022342) | Stavudine; Lamivudine; Nevirapine | Stavudine; Lamivudine; Nevirapine | Emcure Pharma | Prescription |
| 3 | 07/23/2009 | (NDA # 022296) | Limivudine; Zidovudine | Limivudine; Zidovudine | Aurobindo Pharma Ltd. | Prescription |

4.4 India's Pharmaceutical exports Statistics

| India's Exports of Drugs, pharmaceuticals & fine chemicals (2003-04 to 2008-09) | | | | | | | |
|---|---------|------------|---------|------------|---------|------------|-------------|
| Commodity Name | 2006-07 | | 2007-08 | | 2008-09 | | CAGR |
| | US\$ | Rs. Crores | US\$ | Rs. Crores | US\$ | Rs. Crores | |
| Drugs, pharmaceuticals & fine chemicals | 5.94 | 26,895.18 | 7.64 | 30,759.64 | 8.61 | 39,537.66 | 21.33/21.98 |
| Growth Rate (%) | 18.93 | 21.61 | 28.69 | 14.37 | 12.64 | 28.54 | |

Source: DGCIS, Pharmexcil Research

| Region-wise Exports of India's Pharmaceutical Products (US\$ million) | | | | | |
|---|----------|----------|-------------------|---------------------------|----------------|
| Region | 2007-08 | 2008-09 | % Share (2008-09) | CAGR (2004-05 to 2008-09) | YoY Growth (%) |
| EU | 1,595.96 | 1,972.77 | 22.91 | 22.08 | 23.61 |
| North America | 1,647.24 | 1,784.34 | 20.72 | 25.73 | 8.32 |
| Africa | 1,061.90 | 1,369.13 | 15.90 | 32.06 | 28.93 |
| Middle East | 655.45 | 725.97 | 8.43 | 21.89 | 10.76 |
| LAC | 575.74 | 663.97 | 7.71 | 20.45 | 15.32 |
| CIS | 531.58 | 593.50 | 6.89 | 18.51 | 11.65 |
| Asean | 524.73 | 512.46 | 5.95 | 13.29 | -2.34 |
| Asia (Excluding Middle East) | 514.90 | 401.93 | 4.67 | 5.32 | -21.94 |
| South Asia | 342.36 | 349.42 | 4.06 | 11.71 | 2.06 |
| Other European Countries | 94.41 | 110.85 | 1.29 | 18.18 | 17.41 |
| Oceania | 73.33 | 98.91 | 1.15 | 24.92 | 34.88 |
| Other America | 17.25 | 19.83 | 0.23 | 16.35 | 14.96 |
| Other | 9.15 | 6.98 | 0.08 | 11.97 | -23.72 |

Source: DGCIS, Pharmexcil Research

| Region-wise Exports of India's Pharmaceutical Products (Rs. Crores) | | | | | |
|---|----------|----------|-------------------|---------------------------|----------------|
| Region | 2007-08 | 2008-09 | % Share (2008-09) | CAGR (2004-05 to 2008-09) | YoY Growth (%) |
| EU | 6,422.17 | 9,059.01 | 22.91 | 22.73 | 41.06 |
| North America | 6,628.50 | 8,193.70 | 20.72 | 26.40 | 23.61 |
| Africa | 4,273.06 | 6,287.08 | 15.90 | 32.77 | 47.13 |
| Middle East | 2,637.60 | 3,333.69 | 8.43 | 22.54 | 26.39 |
| LAC | 2,316.78 | 3,048.98 | 7.71 | 21.09 | 31.60 |
| CIS | 2,139.10 | 2,725.33 | 6.89 | 19.14 | 27.41 |
| Asean | 2,111.52 | 2,353.21 | 5.95 | 13.89 | 11.45 |
| Asia (Excluding Middle East) | 2,071.97 | 1,845.71 | 4.67 | 5.89 | -10.92 |
| South Asia | 1,377.66 | 1,604.53 | 4.06 | 12.31 | 16.47 |
| Other European Countries | 379.92 | 509.03 | 1.29 | 18.82 | 33.98 |
| Oceania | 295.09 | 454.21 | 1.15 | 25.58 | 53.92 |
| Other America | 69.45 | 91.10 | 0.23 | 16.94 | 31.17 |
| Unknown | 36.83 | 32.07 | 0.08 | 12.61 | -12.92 |

Source: DGCIS, Pharmexcil Research

| India's Top 20 Export Destinations for Drugs, pharmaceuticals & fine chemicals | | | | | |
|--|--------------|---------------|------------------|---------------|------------------|
| | | Rs. Crores | US \$ Million | Rs. Crores | US \$ Million |
| Rank (2008-09) (in Rs. Terms) | Importer | 2007-08 | 2007-08 | 2008-09 | 2008-09 |
| 1 | USA | 5,839.35 | 1,451.13 | 7,103.27 | 1,546.88 |
| 2 | Russia | 1,243.81 | 309.10 | 1,519.20 | 330.84 |
| 3 | Germany | 1,448.01 | 359.84 | 1,441.87 | 314.00 |
| 4 | Austria | 111.38 | 27.68 | 1,417.15 | 308.61 |
| 5 | UK | 1,146.52 | 284.92 | 1,233.09 | 268.53 |
| 6 | South Africa | 684.27 | 170.05 | 1,126.75 | 245.37 |
| 7 | Canada | 789.15 | 196.11 | 1,090.43 | 237.46 |
| 8 | Brazil | 771.61 | 191.75 | 1,018.89 | 221.88 |
| 9 | Nigeria | 671.24 | 166.81 | 1,001.74 | 218.15 |
| 10 | Ukraine | 497.14 | 123.54 | 687.22 | 149.66 |
| 11 | Israel | 456.80 | 113.52 | 686.09 | 149.41 |
| 12 | Netherlands | 522.69 | 129.89 | 669.98 | 145.90 |
| 13 | Spain | 501.42 | 124.61 | 620.02 | 135.02 |
| 14 | Turkey | 502.10 | 124.78 | 614.20 | 133.75 |
| 15 | China | 879.42 | 218.54 | 561.53 | 122.28 |
| 16 | Kenya | 366.60 | 91.10 | 543.86 | 118.44 |
| 17 | Viet Nam | 483.56 | 120.17 | 536.62 | 116.86 |
| 18 | Belgium | 273.28 | 67.91 | 520.90 | 113.44 |
| 19 | Italy | 471.28 | 117.12 | 507.85 | 110.59 |
| 20 | Mexico | 442.49 | 109.96 | 501.54 | 109.22 |

Source: DGCIS, Pharmexcil Research

5. Pharmexcil Feature Article

5.1. Certificate of Suitability of European Pharmacopoeias (CEPs) – India Status

Introduction to CEP: CEP stands for Certificate of suitability of European Pharmacopoeia monographs. COS (“Certificate of Suitability”) means the same, though often used is not the official acronym. The European Directorate for Quality Medicines and Healthcare (EDQM) grants CEPs to manufacturers or suppliers of substances for pharmaceutical use when they have demonstrated compliance with the monographs of the European Pharmacopoeia. It guarantees that all the impurities and potential contaminations related to the manufacturing process (including the manufacturing site and raw materials) are satisfactorily controlled using the requirements of these monographs. Moreover, CEP certification procedure is aimed at facilitating and simplifying exchanges between the partners during the product registration to ensure that the quality of substances is guaranteed and that these substances comply with the European Pharmacopoeia.

Scope of coverage of CEP: The EDQM issues “Chemical CEP” includes active ingredients (organic or inorganic, obtained by synthesis, extraction or fermentation), herbal drugs/ herbal preparations; “TSE CEP” products with risk of transmitting spongiform encephalopathies e.g.

mad cow disease which covers products of ruminant origin used in the preparation of active substances, starting materials, intermediates, reagents used in their manufacture (e.g. bovine serum albumin, enzymes, culture media, etc.), also a combination of above two. The biotech products, finished formulations and human tissues derivatives are beyond the scope of EDQM’s certification procedure.

CEP’s are recognized by about 90 countries globally

CEPs are recognised by all signatory states (37 members) of the European Pharmacopoeia Convention and by the European Union. There are also other countries which have also chosen to recognise them. The other countries accepting CEP’s are Algeria, Argentina, Armenia, Aruba, Australia, Bahrain, Belarus, Bolivia, Botswana, Brazil, Bulgaria, Chile, Columbia, Dutch Antilles, Ecuador, Georgia, Ghana, Hong Kong, Indonesia, Israel, Jordan, Kazakhstan, Kenya, Kuwait, Lebanon, Libya, Malawi, Malaysia, Mexico, Moldova, Morocco, New Zealand, Nigeria, Oman, Palestine, Paraguay, Qatar, Romania, Russian Federation, Saudi Arabia, Singapore, South Africa, Taiwan, Tanzania, Tunisia, Ukraine, United Arab Emirate, Venezuela, Yemen, Zambia and Zimbabwe.

Average time taken to obtain a CEP is about 18 months

The target time for initial assessment of a CEP application is 5 months. In most cases, the need for additional data is identified during this initial assessment. Consequently a request for additional information is sent to the applicant, who has to respond within 6 months. The target time for assessment of the response is 4 months, totalling the target processing time to 15 months. At this point in time, the average time to obtain a new CEP for chemical purity is 18 months.

India leads in number of CEP's granted by EDQM globally

To know the position of India in Certificate of Suitability, Pharmexcil carried out a research based on the data available from the European Directorate of Quality Medicine (EDQM). India received the highest number (21.47%) of CEP approvals from EDQM, out of 48 countries globally. India is followed by its closest competitor Italy (11%) and USA (10%). This

demonstrates the dominance in quality compliance of Indian companies and their significant role as a source of bulk drugs in global scenario. The research finds that 136 companies have received approval for CEPs from EDQM accounting for more than 200 different molecules. At the same time analysis of export data reveals that more than 27% of India's Bulk drug exports in the year 2008 were destined to European Union growing at a 5 year CAGR of 18.38%.

India accounted for 31% of the CEP's granted during January – July 2009

The table below shows the percentage share of the leading pharmaceutical manufacturing countries in CEPs granted by EDQM since 2006. In the first seven months of 2009 (Jan-July 2009), India's share in grant of CEP's reached 30.5% from that of 11.6% in 2006; demonstrating India's strengths/ ability and aggressiveness in adhering to global quality standards.

| Country-wise Share in CEP's granted by EDQM, 2006 – July 2009 | | | | | | | |
|---|------------------|----------------------|-------|-------|---------------|-------------------|-----------|
| Sl. No | Top 10 Countries | Percentage share (%) | | | | Total No. of CEPs | Overall % |
| | | 2006 | 2007 | 2008 | Jan-July 2009 | | |
| 1 | India | 11.65 | 14.76 | 24.37 | 30.58 | 539 | 21.47 |
| 2 | Italy | 13.01 | 8.73 | 10.74 | 11.4 | 274 | 10.91 |
| 3 | USA | 12.20 | 13.72 | 9.05 | 7.44 | 254 | 10.12 |
| 4 | Germany | 9.76 | 10.40 | 8.69 | 8.10 | 228 | 9.08 |
| 5 | China | 5.69 | 4.99 | 10.37 | 8.60 | 194 | 7.73 |
| 6 | France | 8.94 | 6.65 | 7.00 | 2.81 | 156 | 6.21 |
| 7 | Spain | 5.69 | 5.61 | 4.46 | 6.45 | 131 | 5.22 |
| 8 | Switzerland | 4.07 | 3.33 | 3.62 | 3.14 | 88 | 3.50 |
| 9 | Japan | 2.44 | 2.70 | 2.05 | 3.47 | 82 | 3.27 |
| 10 | Israel | 3.79 | 3.12 | 2.05 | 1.49 | 57 | 2.27 |

Source: Pharmexcil Research based on EDQM data

6. Pharmexcil Activities

6.1 Pharmexcil Activities during September 2009

1. Secretary, DoP meets pharmaceutical industry associations

Secretary, Department of Pharmaceuticals, Government of India convened a meeting of all national pharmaceutical associations including Pharmexcil on 17th Sep 2009 at New Delhi to review the problem of counterfeit/spurious drugs in domestic and international markets. He has advised all associations that they should be cautious when reports on surveys relating to spurious/counterfeit drugs are released to the media. Keeping in view the Nigerian experience where medicines produced in China under 'Made in India' labels were seized, severely impacting the credibility of Indian generics, it was considered whether any agency like Pharmexcil can be advised to take up the task of monitoring the movement of Indian generics to Nigeria for a brief period. Other alternatives like establishing pharmacy chains, strengthening of interaction between Indian FDA and Nigerian NAFDAC were also discussed.

2. AIDCOC meeting at Chennai

All India Drug Control Officers Confederation (AIDCOC) had organized its annual day at Chennai on 13th Sep 2009. Several state drug controllers and senior regulatory officials from

various states participated in the event. On invitation by AIDCOC, Dr. P.V. Appaji, Executive Director, Pharmexcil participated in the program and made a presentation on "Status of Indian Pharma in International Markets". He thanked all regulatory authorities for their cooperation in promoting pharmaceutical exports from India. The regulatory officials were appreciative of the role played by Pharmexcil and also expressed that they have benefited from the presentation made by the Executive Director, Pharmexcil.

3. HADSA nutraceuticals meeting at Mumbai

FICCI along with Health Foods and Dietary Supplements Association (HADSA) organized the 2nd International Conference on Nutraceuticals, Dietary Supplements and Functional Foods at SciTech Centre, Jogeshwari, Mumbai from September 10 - 11, 2009. The event was supported by Pharmexcil. HADSA is a member of International Alliance of Dietary/Food Supplement Associations (IADSA) which has alliances with more than 38 dietary supplement associations spread over 6 continents. Several international dignitaries from

IADSA also participated at the event. The USA, Europe and other countries were highlighted by various prominent speakers. nutraceuticals markets. Mr. Ranjit Puranik, Panel Chairman of AYUSH & Herbal products of

4. Pharmexcil's 5th AGM

Pharmexcil's 5th AGM was organized on September 25, 2009 (A.N.) at Hotel Marriot, Hyderabad. Shri Smitesh Shah, Chairman and Managing Director of Calyx Chemicals & Pharmaceuticals Ltd. assumed the office of Chairman, Pharmexcil and Shri N.R. Munjal, Chairman, Ind-Swift Labs Limited assumed the office of Vice-Chairman of Pharmexcil. The Chairman congratulated and welcomed members who were newly elected for the first time to

market potential and regulatory requirements in Pharmexcil also actively participated at the event. Executive Director, Pharmexcil was invited as Chairman for a session relating to International

Pharmexcil's Committee of Administration Shri Nipun Jain, Pharmchem, Shri Rajen Shah, Raptim Research Ltd. (in R&D Category) and Shri Ashutosh Gupta, Medicamen Biotech Ltd. (in Status Holders category). The performance and audit reports of Pharmexcil were reviewed and approved at the AGM. The list of members forming the new Committee of Administration, Pharmexcil is as given below:

6.2 Pharmexcil New Committee of Administration

| | | | |
|----|---------------------|---------------|--|
| 1. | Shri Smitesh C.Shah | Chairman | Calyx Chemicals & Pharmaceuticals Ltd. |
| 2. | Shri N.R.Munjaj | Vice Chairman | Ind-Swift Laboratories Ltd |

A. Government Nominees

| | | | |
|----|---|------------------------|--|
| 1. | Shri Rajeev Kher Smt. Mridul Jain (Aalternative for Mr. Rajeev Kher) | Jt. Secretary Director | Dept., of Commerce, Govt., of India |
| 2. | Shri Arun Jha | Jt. Secretary | Dept., of Pharmaceuticals, Govt., of India |
| 3. | Shri Paresh Johri (Alternative for Mr. G S Sandhu) | Dy. Secretary | Dept., of C & PC, Govt., of India |

B. Immediate Past Chairman

| | | | |
|----|-------------------|---------------------------|-----|
| 1. | Shri Venkat Jasti | Suven Life Sciences Ltd., | R&D |
|----|-------------------|---------------------------|-----|

C. Elected Members

| | Name | Organisation | Category |
|-----|------------------------|---------------------------------------|-------------------|
| 1. | Shri Mahesh Doshi | Dy-Mach Pharma | Status Holder |
| 2. | Shri B. N. Singh | Alkem Laboratories Ltd | Status Holder |
| 3. | Shri Ashutosh Gupta | Medicamen Biotech Ltd. | Status Holder |
| 4. | Dr.M. Sivakumaran | Aurobindo Pharma Ltd. | Status Holder |
| 5. | Shri D.B.Mody | J B Chemicals & Pharmaceuticals Ltd., | Non-SSI |
| 6. | Shri K. Subbarao | Glochem Industries Ltd., | Non-SSI |
| 7. | Shri Rajen Shah | Raptim Research Ltd. | R&D |
| 8. | Shri Rajeev Ramu Deora | G Amphray Laboratories | SSI |
| 9. | Dr.V.Satyanarayana | Sipra Labs Ltd | SSI |
| 10. | Shri Jayant Tagore | Synthokem Labs Pvt ltd | SSI |
| 11. | Shri Sunil Goenka | Siddharth International | Merchant Exporter |
| 12. | Dr.Ranjit Puranik | Shree Dhootapapeswar Ltd | Herbals |
| 13. | Shri Nipun Jain | Pharmchem | SSI |
| 14. | Shri Krishna Prasad | Granules India Ltd., | Others |

6.3 Circulars issued by Pharmexcil

| List of circulars issued by Pharmexcil during the period, September 01 2009 – October 05 2009 | |
|--|--|
| Date of issue | Subject of Circular |
| 1 Oct 09 | Arab Health 2010 |
| 15 Sep 09 | Pharmexcil Awards for Outstanding Export Performance - Final Request |
| 14 Sep 09 | Pharmexcil Digest (News Letter- September 2009) |
| 9 Sep 09 | 5th Annual General Body Meeting |
| 8 Sep 09 | Indo-Africa Pharma Business Meet |
| 3 Sep 09 | Awards for companies who secured Patents - Last date extended |

Note: The complete text of the circulars can be accessed in the following location on the Pharmexcil's website.
<http://www.pharmexcil.com/v1.aspx/NewsBulletin.aspx>

6.4 Upcoming Pharmexcil Activities

The following table lists the upcoming events of Pharmexcil in the near future.

| List of upcoming events participated by Pharmexcil | | | |
|--|--|-----------------------|---|
| S. No | Event/ Conference | Date | Description/ comments |
| 1 | CPhI Worldwide, Spain | October 13 – 15, 2009 | Pharmexcil is organising India Pavilion |
| 2 | Delegation to CIS countries including Azerbaijan | November* | Pharmexcil is leading a delegation to Azerbaijan in November. Buyers/sellers meet will be followed by interactive session with local doctors, regulatory authorities, media and Indian residents. The delegation coincides with the International fair in Baku. |
| 3 | CPhI India 2009, Mumbai | December 1-3, 2009 | Pharmexcil will be participating in CPhI India 2009. |
| 4 | Arab Health 2010 | January 25 – 28, 2010 | Pharmexcil will be organizing 'India Pavilion' at 'Arab Health' a mega event at Dubai, UAE. |

All the above information can be accessed from Pharmexcil website on the following link:
<http://www.pharmexcil.com/v1.aspx/NewsBulletin.aspx>
*Date to be finalized

6.5 Pharmexcil study reports

1. Publication of Research Paper by Pharmexcil - Presence of Indian pharmaceutical industries in US market: an empirical analysis

Pharmexcil has published empirical analysis of Indian Pharmaceutical Companies in U.S. Prescription and OTC market. The Article has been published in Recent issue (Sep 09) of Palgrave Macmillan, Journal of Generic Medicine (UK) which is one of the reference journal for Global generic associations like EGA, IGPA & GPhA the abstract of which is given below.

Abstract

An exhaustive study was undertaken for DMFs & ANDA/NDA held by Indian companies' vis-à-vis Rest of World. The data was analyzed on various parameters like dosage forms, therapeutic categories, and patent & exclusivity protection of the molecules. The article consists of strategic presence of Indian companies in reference to the above parameters and also their position as compared to Rest of world.

Link to the abstract of the published paper is mentioned below.

The United States is the largest pharmaceutical market in the world with generic sales accounting for US\$58.5 billion and is India's largest export

destination. India accounts for one out of every four Abbreviated New Drug Application (ANDA) approvals in the years 2007 and 2008, ranks first in total Type II active Drug Master Files (DMFs) with US Food and Drug Administration and it also received 31 per cent of all tentative approvals (as on 11 December 2008). In 2008, the exports of formulations from India to top 28 regulated countries surpassed Active Pharmaceutical Ingredient (API) exports firmly demonstrating the shift in credibility and Quality Compliance. India has rich vendor base with 3.75 DMFs per molecule and has filed more than 450 different APIs. Has India tapped the US market to its fullest potential? Where do the opportunities for further growth for India lie in this market? To answer this question, a comprehensive study of DMFs and ANDAs filings by their therapeutic categories, dosage forms, strengths, companies, countries and other key parameters like patents was undertaken. The study reveals that ANDAs from India are confined to small number of highly competitive molecules, and has to move into the new orbit of working in complex chemistry, Biotech-based medicines, and advanced formulations.

7. Indian Pharma in media

1. India objects efforts of developed nations taking advantage of the flexibilities in TRIPS

At the 47th meeting of the Assemblies of the World Intellectual Property Organization (WIPO) in Geneva, India has strongly objected to the efforts of the developed nations to miss utilize the flexibilities provided in TRIPS by stretching the definition of counterfeit drugs. This action that has been resorted to by some of the developed nations is preventing the flow of affordable genuine generic drugs to the developing nations and is negatively impacting the perception of legitimacy of the global IP framework.

2. Dr. Mashelkar to head the advisory committee recommending steps for improving the Indian Systems of Medicine for international acceptance

Dr. R.A. Mashelkar will be heading the advisory committee constituted by Ministry of Health & Family welfare, GoI to recommend measures to be taken for improving Indian System of Medicine (ISM) for international acceptance. The GoI is drafting a proposal for creation of Council for International Co-operation in Indian Systems of Medicine (CICISM). About six sub-committees were formed to study/ design and implement strategies focused on ISM in the areas of education and training, trans-disciplinary research, clinical services, IPR, public awareness,

etc. The committees will be submitting their recommendations by March 31, 2010.

3. CDSCO to implement WHO Certification Scheme and issue COPP

On September 01 2009, Drug Controller General of India, Dr. Surinder Singh issued a letter stating that Certificate of Pharmaceutical Products (COPP) and Certificate of GMP under WHO Certification will be issued by the National Regulatory Authority i.e DCGI office from October 01 2009. COPP will be issued by regulatory officials of Central Drugs Standard Control Organization (CDSCO) across India after inspection of manufacturing facilities. COPP is mandatory for import of drugs by various countries that require WHO accreditation. Earlier these certificates were issued by state drug regulatory authorities and this decision of transferring approval of plants by central regulatory authority was taken during 40th Drug Consultative Committee (DCC) meeting in June 2009, after several issues raised by WHO over the issuance of these certificates.

4. Various ministries and pharmaceutical associations in India discuss strategies to thwart reports of false representation of Indian made drugs

Department of Pharmaceuticals (DOP) held a joint meeting with senior officials from Ministries like Ministry of Commerce & Industry, Ministry

of Chemicals & Fertilizers and Ministry of Health & Family Welfare and representatives from pharmaceutical industry associations such as Indian Pharmaceutical Association (IPA), Small and Medium Enterprises Pharma industries Confederation (SPIC), Indian Drug Manufacturers Association (IDMA), Federation of Pharma Entrepreneurs (FOPE), Confederation of Indian Pharmaceutical Industry (CIPI) and Pharmexcil. DOP has updated the steps taken by GoI after the incident of supply of fake drugs by Chinese players with “Made in India” labels.

Some of the major outcomes of the meeting are to request, Ministry of Commerce & Industry to form lobbying groups in the African countries to highlight the quality of Indian made generics and also to condemn immediately any false media reports on the quality of Indian made generics by all pharmaceutical industry associations. IPA has requested for clear definitions of counterfeit and spurious drugs in the Drugs and Cosmetics Act and also to remove the IPR related issues like misbranded from section 17 of the Drugs and Cosmetics Act. The other suggestions were to publish a list of GMP certified units in India and to provide the info to all the Indian overseas missions and the foreign missions in India; to insist on direct imports from India rather than from the transit points like Dubai, Singapore, etc.

5. IIFT study report lists trade barriers in 24 countries that account for 50% of exports from India

Dr. Rahul Khullar, Commerce Secretary has launched a study report by Shashank Priya and Reiji k Joseph of the Centre for WTO Studies, IIFT and commissioned by Ministry of Commerce & Industry, GoI. The report highlights the trade restrictions by importing countries that hinder exports of goods and services from India. Dr. Khullar, after the launch of the report said, “This will act as a reminder to us on what can be done to address these barriers and figure out solutions.”

Some of the trade barriers related to pharmaceutical exports highlighted in the report include, labeling and tariff issues, intellectual property rights related norms, technical barriers to trade, sanitary and phyto-sanitary measures, etc. The report clearly highlights host of trade and non-trade restrictions for pharmaceutical exports to Japan such as submission of registration documents in Japanese language, maintaining a five year inventory for medicines, etc. These restrictions are the primary reasons for lower share of exports from India to Japan, which imports about \$10 billion worth of pharmaceuticals.

6. WHO's SEARO makes a resolution to separate enforcement of IPR from availability of safe and efficacious medicines

WHO's South East Asia Regional Office (SEARO) at its 62nd Annual Regional Committee meeting held in Kathmandu from September 7-10, 2009 has passed a resolution and requested member states to refrain from IPR enforcement from the accessibility/ availability of safe, efficacious and quality medicinal products in the developing countries. Further, the member states were asked to refrain from seizure of medicinal product consignments to the developing nations under the guise of IPR enforcement and thus creating barriers to trade and restricting availability of medicines. The meeting also

deliberated on the usage of terms like "counterfeit" and "substandard" medicinal products interchangeably although they carry very different meanings; while "counterfeit" relates to infringement of IPR, "substandard" refers to a failure to meet regulatory standards.

SEARO include 11 member countries namely, Bangladesh, Bhutan, DPR Korea, India, Indonesia, Myanmar, Nepal, Sri Lanka, Thailand, Maldives and Timor-Leste. The forum discusses /reviews issues related to health in the region and prepares an action plan for the future.

8. Upcoming pharma events

Following tables provides the list of major upcoming events in the pharmaceutical and allied sectors in India and globally:

| List of upcoming events in Pharmaceutical and allied sectors | | | |
|--|---|------------------------|--|
| S. No | Event/ Conference | Date | Description/ comments |
| National | | | |
| 1 | Seminar on 'good cleaning validation practices', Mumbai | October 12 2009 | For process engineers, production staff, quality assurance, validation and other technical management personnel |
| 2 | International meet on clinical trials, Mumbai | October 23 – 24, 2009 | The Institute of Quality at the Confederation of Indian Industries (CII) is organizing a two-day international conference on clinical |
| 3 | 5 th Nutraceutical Summit, The Lalit New Delhi | October 28 – 30, 2009 | Focuses on strategies to harness India's strengths in terms of its tremendous bio-diversity, wealth of traditional knowledge and R&D prowess. |
| 4 | Pharmac India 2009, Ahmedabad | November 07 -09 2009 | The objective of the exhibition is to provide a platform to explore new areas and markets for exports/ imports and first hand information on the latest technology. |
| 5 | Conference on Drug Discovery and Clinical Development in India, | November 15 – 18, 2009 | Provides update on global regulatory landscape, Overview of Global Medical Device Regulations, Regulatory Policy roundtable, Drug Discovery, Quality, Pharmacology and Toxicology, Development of Biologics, etc. |
| 6 | Symposium on Medicinal and Nutraceutical Plants, AIIMS, New Delhi | November 25 – 27, 2009 | The main aim of the symposium is to provide a common efficient academic platform to the persons/groups involved in research on various aspects of Medicinal and Nutraceutical Plants. |
| 7 | India Pharma Summit 2009 | November 30, 2009 | The event brings all the stakeholders on one platform to generate a healthy debate as well as to come up with workable solutions to the issues currently facing the pharma sector. |
| 8 | CPhI India 2009, Mumbai | December 1-3, 2009 | The objective of CPhI India 2009 is to discuss the key issues, trends and developments at one location and also to generate new alliances, renew existing partnerships and benefit from the dynamic networking opportunities available to actively drive business forward. |
| 9 | India Chem Gujarat, Gujarat University Exhibition Hall, Ahmedabad | December 12-14, 2009 | The exhibition cum conference will also discuss & deliberate on the R&D, infrastructure & environmental concerns of the industry and will aim at developing winning strategies for building & strengthening the awareness. |
| 10 | Telemedicon 2009, Pune | November 6 – 8, 2009 | The congress updates latest developments in Telehealth segment and also analyses the emerging opportunities and challenges for the Indian Telemedicine industry. |

| International | | | |
|----------------------|--|-------------------------------|---|
| 1 | Mid East Medical International Comprehensive Exhibition 2009 | October 19 – 23, 2009 | An Excellent opportunity to enter the Iraqi market, the largest Arab market, especially with the current strategic plans to rebuild Iraq. |
| 2 | National Ayurveda Convention 2009, Pennsylvania | October 30 – November 01 2009 | The theme of this year's convention is 'Ayurveda for Optimum Health and Wellness -An Integrative Approach'. The three-day event will feature presentations by more than 10 Integrative Medicine doctors and ayurvedic doctors on a variety of health and wellness topics. |
| 3 | Innovation Showcase, Ulm, Germany | November 2 – 3, 2009 | This event provides delegates with the opportunity to meet representatives of these companies and their suppliers and to visit some of the award-winning facilities. |
| 4 | PharmExpo Uzbekistan 2009, Tashkent | November 11 – 13, 2009 | Participation in this event is a good opportunity to meet with representative of Government, manufacturers, trading companies, distributors and customers. |
| 5 | World Forum for Medicine International Trade Fair with Congress, Dusseldorf, Germany | November 18 – 21, 2009 | The leading medical devices manufacturers exhibition in Europe |
| 6 | Arab Health 2010 | January 25 – 28, 2010 | Arab Health is one of the major International exhibitions for surgicals, medical equipment, pharmaceuticals etc., held every year in Dubai and is one of the most sought after event as far as Healthcare Industry is concerned. |
| 7 | International Conference on Drug Discovery and Therapy, Dubai, UAE | February 1 – 4, 2010 | The conference provides a platform for all pharmaceutical scientists, internists and primary care physicians to discuss and learn about all the important international breakthrough developments on drug discovery and on new therapeutics |

9. Important Government Notifications

| Sl. No. | Date | Notification no. | Source | Subject |
|---------|-----------|--------------------------------|---|---|
| 1 | 19-Aug-09 | Narcotic control notification | Ministry of Finance - Dept. of Revenue | Narcotic drugs and psycotropic substance (National Fund for control of drug abuse)Ammdement rule 2009 [in subclause (3) of clause 4. Were the applicant is govt. dept. or any agency of the govt., the maximum grant of the fund would be hundread % of project cost. [seventyfive percent of the project cost will be substituted] |
| 2 | 19-Aug-09 | 122(re - 2008)/2004 - 2009 | Ministry of Commerce and Industry - Dept of Commerce | It is mandatory for all companies and their subsidiaries to obtain permission of central govt. before entering into arrangement or understanding that involves an obligation to facilitate or undertake on-site verification or access to records/ documents by foreign govt. or foreign third parties |
| 3 | 27-Aug-09 | Foreign trade policy 2009 - 14 | Ministry of Commerce and Industry | Highlights of Foreign trade policy - 2009 - 14 |
| 4 | 27-Aug-09 | 2/2009 - 14 | Ministry of Commerce and Industry - DGFT | Export obligation period for penicillin and its salts - ITC HS code 29411010 |
| 5 | 27-Aug-09 | 03/2009 - 14 | Ministry of Commerce and Industry - Dept of Commerce - DGFT | Automatic endorsement of permitted for import under target plug scheme (excipients) |
| 6 | 9-Sep-09 | F.No.X.11014/3/2008-DFQC | Ministry of Health and Family Welfare - Dept of Health | Drugs and Cosmetics 5th amendment Rules. Rule 3A, for sub rule (3). The functions of laboratory in respect of testing of condoms shall be carried out at the Central drug testing laboratory, chennai. |
| 7 | 11-Sep-09 | NPPA order, Sl. No. 312 - 314 | Ministry of Chemicals and Fertilizers - NPPA | Ceiling price - dextropropoxyphene HCl, dextropropoxyphene napsylate, Naproxen, Naproxen sodium, Cephazolin sodium (sterile), |
| 8 | 14-Sep-09 | NPPA order, Number 315 - 347. | Ministry of Chemicals and Fertilizers - NPPA | Ceiling prices inclusive of excise duty and education cases, sales tax / Vat of each of the scheduled formulation specified in the notification. |
| 9 | 15-Sep-09 | drugs and cosmetics | Ministry of Health and Family Welfare - Dept of Health | Oseltamivir and Zanamivir: Regulation on manufacture, sale and distribution. |
| 10 | 18-Sep-09 | drugs and cosmetics | Ministry of Health and Family Welfare - Dept of Health | Prohibition of advertisement, regulation, trade and commerce, production, supply and distribution - Act, 2003 (34 of 2003) |
| 11 | 23-Sep-09 | 107/2009 | Ministry of Finance - Dept. of Revenue | Amendment in the notification number of 67/2006-custom dated 30th June 2006. [Rate of import from countries listed in appendix I & appendix II] |
| 12 | 28-Aug-09 | drugs and cosmetics | Ministry of Health and Family Welfare - Dept of Health | Notification Number GSR. 46(E) dated 22nd Jan, 2009. the word after six month appearing in the sub-clause (2) of clause 2 of the drugs and cosmetics (First amendment)Rules, 2009, may be read as "after one year" |