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1. Achievements of Indian Pharma

1.1 ANDA approvals received by Indian companies in October 2009

ANDA Approvals by U.S. FDA to Indian Pharmaceutical Companies during the month of October 2009					
Sl. No	**Company**	**Active Ingredients**	**Dosage form**	**Strength**	**Marketing Status**
1	Wockhardt Ltd	Risperidone	Solution; Oral	1MG/ML	Prescription
2	Zydus Pharmaceuticals USA	Topiramate	Capsule; Oral	15MG/ 25MG	Prescription
Source: U.S. FDA website, Pharmexcil Research					

About 14% of total ANDA approvals granted by U.S. FDA in October 2009 are for India based pharmaceutical companies

1.2 Maharashtra Leads in Pharmaceutical Exports

In order to identify state-wise exports from India, Pharmexcil has conducted an elaborate survey of its over 2,800 member exporters from Pharmaceutical industry of India to gather company-wise exports over the years 2005-06 to 2007-08. While it is mandatory for all the members to submit the export figures each quarter, many of the members have not been submitting and Pharmexcil with its active initiative followed up with the members to receive the information. The data reveals that Maharashtra leads in over all exports including Merchant exports (38.98%) followed by Andhra Pradesh (20.5%).

Table 1: State-wise Shares in Exports of Bulk Drugs, Pharmaceuticals, Herbals (2007-08)

Rank	State	% Share (2007-08)	Cumulative % share
1	Maharashtra	38.98	38.98
2	Andhra Pradesh	20.50	59.48
3	Haryana	9.58	69.06
4	Gujarat	7.92	76.98
5	Karnataka	6.66	83.64
6	Tamil Nadu	5.48	89.11
7	Delhi	4.29	93.41
8	Chandigarh	3.14	96.54
9	Madhya Pradesh	1.05	97.59
10	Kerala	1.04	98.63
Source: Pharmexcil Research			

1.3 India ranks 15th globally in exports of pharmaceuticals & bulk drugs

As per the latest statistics available from United Nations 'Comtrade' the Global trade in Bulk Drugs and Pharmaceuticals in the year 2008 stood at US$ 404.2bn growing by 10.37 over the previous year. During that year, exports of Pharmaceuticals stood at US$374.69bn. growing by 10.38%. Germany is the top exporting country with exports valued at US$67.44bn. followed by Belgium and Switzerland in that order (refer table 1). Bulk drugs have a meager share of 7.3% in the total trade at US$29.5bn. Germany was the largest exporter of formulations with exports valued at US$62.47bn. followed by Belgium (US$48.69bn.) and Switzerland (US$40.09bn.). In quantity terms also Germany was the largest exporting country followed by China and India. China was the largest bulk drugs exporting country with exports at US$5.25bn. followed by Germany (US$4.97bn.) and USA (US$4.11bn.). USA was the top importing country followed by Germany and Belgium in that order (refer table 2). Zambia, Mauritania and Azerbaijan are the fastest growing import markets (refer table 3)

India is the 15th largest exporter of Bulk Drugs & Formulations valued at US$5.82bn. with a share of 1.44% during 2008. The country is 9th largest exporter of APIs/Bulk Drugs valued at US$819.1mn. and the country ranked 8th in terms of export volumes. The country also imported bulk drugs valued at US$968.27mn. during that year.

On the formulations front, the country exported US$5.00bn. worth of formulations in 2008 growing by 30.56% over the previous year when the country's formulations exports were valued at US$3.82bn. It ranked 14th in value terms and 3rd in volume terms.

It must be noted that the exports figures provided by Director General of Commercial & Statistics for pharma sector include fine chemicals, herbals & medical devices besides bulk drugs and formulations.

Table 1: Top Exporting Countries of Bulk Drugs & Pharmaceuticals (figs. in US$mn.)*				
Rank	**Country (Exports)**	**2007**	**2008**	**% share**
1	Germany	55,520.78	67,438.88	16.68
2	Belgium	47,377.79	50,665.56	12.53
3	Switzerland	36,232.92	44,145.34	10.92
4	USA	33,379.84	38,076.67	9.42
5	France	28,291.37	33,189.47	8.21
6	United Kingdom	28,975.58	31,342.25	7.75
7	Ireland	18,749.69	22,546.15	5.58
8	Netherlands	15,361.05	17,231.52	4.26
9	Italy	15,646.15	16,595.01	4.11
10	Sweden	8,719.60	9,167.87	2.27
11	China	6,093.35	8,117.00	2.01
12	Denmark	7,237.12	8,076.41	2.00
13	Austria	6,303.99	7,382.23	1.83
14	Canada	6,188.93	6,191.10	1.53
15	**India**	**4,475.95**	**5,822.45**	1.44
Source: UN trade database 'Comtrade', Pharmexcil				
**** HS Codes from Chapter 29 for Bulk Drugs & Chapter 30 for formulations As per ITC***				

Table 2: Top Importing Countries of Bulk Drugs & Pharmaceuticals (figs. in US$mn.)				
Rank	**Country**	**2007**	**2008**	**% share**
1	USA	53,954.01	59,868.18	15.38
2	Germany	40,934.01	46,669.00	11.99
3	Belgium	41,602.36	44,332.86	11.39
4	France	22,068.56	24,820.57	6.37
5	United Kingdom	20,418.65	20,658.26	5.31
6	Italy	18,176.71	19,974.99	5.13
7	Switzerland	16,693.44	17,777.67	4.57
8	Netherlands	16,353.47	12,981.00	3.33
9	Japan	9,145.98	10,998.52	2.82
10	Canada	10,315.06	10,770.32	2.77
Source: UN trade database 'Comtrade', Pharmexcil				

Table 3: Top 20 Importing Countries as per Imports Growth rates		
Rank	**Country**	**CAGR**
1	Russian Federation	33.09
2	China	30.42
3	Brazil	23.39
4	Poland	22.62
5	Greece	17.76
6	Mexico	15.91
7	Germany	15.48
8	USA	14.06
9	Sweden	13.90
10	Austria	13.81
11	Turkey	12.60
12	France	11.68
13	Japan	11.51
14	Canada	11.38
15	Italy	11.36
16	Switzerland	11.09
17	Australia	10.17
18	Belgium	8.43
19	Netherlands	7.02
20	United Kingdom	6.91
Source: UN trade database 'Comtrade', Pharmexcil		

1.4 Focus Region - India's Pharmaceutical exports to CIS & Baltic Countries

Exports of Drugs, pharmaceuticals & fine chemicals from India to CIS & Baltic countries (US$ million)					
Category	**2008-09 (Apr-Dec)**	**2007-08**	**2006-07**	**2005-06**	**2004-05**
Bulk Drugs	19	20	21	16	15
Formulations	430	511	462	384	286
Herbals	0	0	0	0	0
Total exports of Drugs, pharmaceuticals & fine chemicals	449	531.5	482	401	301
Source: Export Import Data Bank, DGFT; Pharmexcil and Datamonitor compilation					

1.5 List of top 5 bulk drugs and formulations exported from India to CIS & Baltic countries (US$ million)

Commodity/ product	2008-09 (Apr - Dec)	2007-08	2006-07	2005-06	2004-05	2003-04
Bulk Drugs						
Ampicilline & its salts	3.08	2.51	0.95	1.19	1.44	1.57
Glucose liquid	0.2	0.69	0.57	0.51	0.23	0.09
Potassium iodide	0.35	0.5	0.04	0.04		0.11
Ranitidine	0.1	0.5	0.04	0.03	0.35	0.08
Ethambutol, Ethambutol Hcl	0.28	0.36	1.35	0.48	0.14	0.08
Formulations						
Ketorolac, Nimesulide, Nabumetone	40.4	34.24	24.73	12.35	6.25	0.93
Omeprazole and Lansoprazole	15.78	19.74	30.6	17.34	18.18	0.78
Ciprofloxacine in capsule, tablets, etc.	10.4	13.03	9.24	5.82	4.85	1.3
Vaccines for Hepatitis	0.6	12.1	7.18	7.74	3.07	0.13
Metronidazole formulations single and combinations	6.03	11.14	13.39	9.69	6.3	4.94

Source: *Export Import Data Bank, DGFT; Pharmexcil and Datamonitor compilation*

2. TRIPS Plus Provisions in Bilateral Trade Agreements

Today free trade agreements (FTAs), in particular with US and EU, form a serious threat to the scope and effectiveness of the Doha Declaration. After having been forced to compromise in multilateral negotiations, US & EU have geared up their efforts to tighten IP standards through bilateral and regional trade agreements. These agreements have, until fairly recently, attracted little attention. They are highly technical and negotiated in secret, without draft texts being available for public scrutiny [Rangel et al. 2007]. Another issue is that the trade ministers, but not the health ministers, are at the negotiating table. Often health authorities find out only after the fact that a trade agreement has consequences for health and pharmaceutical policies [Ellen F.M. 't Hoen 2009].

There have been regular attempts to limit the flexibilities of TRIPS granted by the Doha declaration. Various issues like:

i. grounds on which compulsory license could be granted;
ii. diseases covered by Doha declaration,
iii. parallel imports and
iv. export provisions under compulsory license

are under continuous debate since the negotiations on TRIPS and public health started at the WTO in 1999.

Growing use of intellectual property protection being pushed in various free trade agreements by US & European Union (EU) are limiting access to lower-cost generic drugs in various countries.

The following TRIPS-plus features being negotiated in various FTAs can delay the introduction of generic drugs:

1. **Data exclusivity**: It guarantees additional market protection for originator companies by preventing health authorities from accepting applications for generic medicines during the period of exclusivity regardless of the patent status of the product. In Europe such exclusivity is granted up to a period of 11 years (8+2+1) where as the same is 5 years in USA.
2. **Patent linkage**: Prohibits granting of marketing approval by drug regulatory authorities during the patent term without the consent of the patent holder. These provisions effectively create a new function for health authorities in the enforcement of patents on medicines.
3. **Patent Term Extension**: Extension of the patent term for pharmaceutical products beyond the 20 years which is not covered under current TRIPS Agreement is being resorted to under new provisions such as Supplementary Protection Certificate. In US

the extension up to 5 years is granted under this provision.

4. Extension of the scope of patent protection and data exclusivity to allow known substances to be patented for each 'new indication (use)'.
5. Restrictions on the grounds for compulsory licensing.
6. Prohibitions of parallel importation.
7. Introducing enforcement measures which potentially obstruct the import, transit or export of legitimate generic medicine.

Some or all of these provisions appear in concluded agreements such as the Central American Free Trade Agreement (CAFTA), the US-Singapore Free Trade Agreement, the US-Chile Free Trade Agreement, the US-Morocco Free Trade Agreement, US-Peru Trade Promotion Agreement and other agreements that have already been signed [Ellen F.M. 't Hoen 2009]. The TRIPS-plus provisions reappear or are likely to reappear in trade agreements being negotiated with Thailand, Panama, the Andean countries (Bolivia, Colombia, Ecuador) and the countries of the Southern African Customs Union (SACU) and have also appeared in accession agreements with new WTO Members, for example, China and Cambodia (WTO 2008).

Recent EU-South Korea free trade agreement includes data exclusivity and patent extensions up to 5 years. The free trade agreement currently being negotiated by India and the European Union also includes the similar provisions including the patent linkage.

An EU agreement with India would be particularly harmful, because India plays a key role as the 'pharmacy of the developing world', exporting 67 per cent by volume of the medicines its generic companies manufacture to developing countries, and providing over 80 percent of the world's generic anti-retroviral medicines. If India signed an FTA with the EU containing the harmful demands indicated above, access to medicines in poor countries would be in jeopardy. Not least affected would be EU Member States and the EU, which purchase key medicines for HIV and AIDS destined for developing countries through bilateral and multilateral financing instruments [*Health Action International and Oxfam International briefing paper 20 October 2009*].

The proliferation of TRIPS-plus rules through FTAs poses a very serious threat to the effective use of the patent law safeguards. It also launches the process of globalizing new IP norms and standards, which would not be possible in multilateral negotiations.

Several provisions included in the Central America Free Trade Agreement (CAFTA) like

data protection and patent extensions tighten the IP protection beyond existing TRIPS agreement. A recent study from Guatemala "A Trade Agreement's Impact On Access to Generic Drugs" finds that some drugs that are no longer protected in the US are under IP protection in Guatemala, thus delaying access to affordable generic dugs while generic substitutes are already available in the US as a result of TRIPS Plus provisions in Regional Trade Agreement with US.

Box 1: Public Health Impact of Free Trade Agreements

FTA	Source	Public health impact
EU–Colombia FTA*	IFARMA prospective study commissioned by HAI Europe.	By 2030, patent term extensions could result in an increase of nearly $280m in expenditures for medicines. Data exclusivity rules could result in an increase of more than $340m of expenditures on medicines. Patent extensions and data exclusivity might jointly result in an increase in expenditure of more than $620m. Increased expenditures of this magnitude would be equivalent to the expenditure on medicines of more than five million Colombians belonging to the poorest quintile in the country.
US–Jordan FTA	Oxfam International	Data exclusivity for medicines resulted in significant delays to introducing generic competition for 79 per cent of medicines examined in the study. This led to between two- and ten-fold price increases for key medicines to treat cardiovascular disease and cancer. The availability of generic equivalents would have reduced expenditures on medicines by at least an estimated $6.3–$22.05m during the study period from mid-2002 to 2006.
US– Guatemala FTA (CAFTA)	Centre for Policy Analysis on Trade and Health	An FTA signed between the USA and Guatemala, Honduras, Nicaragua, El Salvador, Costa Rica, and Dominican Republic has led to significant delays in generic competition in Guatemala for medicines needed to treat major causes of morbidity and mortality, including diabetes, heart disease, pneumonia, and HIV and AIDS. This led to increases in medicine prices ranging from 2 to 58 times the cost of the generic equivalent. Delays in generic competition resulted in the introduction of generic competitors in the USA prior to their introduction in the Guatemalan market.

Health Action International and Oxfam International briefing paper 20 October 2009

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3. India Major Pharmaceutical Supplier to United Nations

There are 33 different procuring agencies in United Nations (UN) procurement system forming common forum of UN Global market Place (UNGM). These UN agencies collectively procured commodity & services valued at US$13.6 billion in 2008 which is a growth of 34.4% over 2007. The split of total procurement in terms of goods and services is almost equally divided, with marginally higher share of services (50.4%) in 2008. The top three agencies, accounting for 46% of total procurement value, with World Food Programme (WFP) being the largest procuring body at US$3.03 bn, followed by United Nations Procurement Division UN-PD (US$1.83 bn) and UNICEF (1.54bn). The top 5 countries supplying to the UN agencies are USA (7.7%), India (4.6%), Switzerland (4.2%), France (3.7%) and Italy (3.4%). India has featured in top 10 suppliers since 2000 and in 2008 the country was the second largest supplier to the UN system.

The value of supplies from India to UN agencies increased from US$169 million in 2002 to US$620 million in 2008 registering a compounded annual growth rate (CAGR) of 24% during the period 2002-2008. Supply of goods accounted for 90.7% of the total supplies from India in 2008. India ranks first with a share of 20% in value for the goods procured by UN agencies. Major goods procured from India include vaccines & biologics, pharmaceuticals, medical equipment, cold chain equipment, diagnostic test kits, etc., and these are majorly procured by United Nations Children's Fund (UNICEF).

UNICEF has been working in India since 1949 and is the largest UN organization in the country. The major products procured by UNICEF IN 2008 were Vaccines & Biologics (US$633mn), Pharmaceuticals (US$135mn) and Medical equipments (US$92mn). India is the largest supplier of to UNICEF mainly biologicals & vaccines and Pharmaceuticals accounting for US$295mn. in 2008. About 32% of vaccines/biologicals and 49% of pharmaceuticals procured by UNICEF is sourced from India. The other major suppliers include Switzerland (US$209mn.) and Belgium (US$179mn). Panacea Biotech Ltd is the largest supplier of vaccines/biologicals supplying US$115 million worth to UNICEF followed by Serum Institute of India and Shantha Biotech. On the other hand Ranbaxy and Cipla are the major suppliers of pharmaceutical products to UNICEF.

Other UN agencies procuring Pharmaceutical and related goods from India is United Nations

Population Fund (UNFPA), procuring cheifly contraceptives (refer table 1).

Pharmexcil study reveals that global procurement for pharmaceuticals & related products through UNGM stood at US$1.3bn. in 2008. India has significant presence with UNICEF & UNFPA. However, with the remaining four agencies India does not have any traceable presence.

To become a potential supplier for the United Nations, vendors have to register on United Nations Global Marketplace website (www.ungm.org) which is a 14 step registration process. This registration is mandatory, though free of cost.

Table 1: Procurement of Pharmaceuticals & Related Products by UN Agencies (2008)

Sl. No.	UN Agency	Pharmaceutical & related goods procured	Value (US$ mn.)	Rank among top 10 items (by value)	No. of purchase orders & contracts raised	% Procurement from India
1	PAHO, Pan American Health Organization	Vaccines	271.63	1	658	
		Pharmaceuticals and Animal Vaccines	17.03	2	286	
2	UNFPA, United Nations Population Fund	Contraceptives	87.58	1	702	17.35
		Pharmaceuticals	5.17	10	162	
3	UNICEF, United Nations Children's Fund	Vaccines/Biologicals	633.37	1	N/A	31.28
		Pharmaceuticals	135.16	2	N/A	48.44
4	UNRWA, United Nations Relief and Works Agency	Drugs & Chemicals	7.99	8	202	
5	UNOPS, United Nations Office for Project Services	Medical, Lab. & Hospital equip.	101.28	4	N/A	
		Pharmaceuticals	36.34	5	N/A	
6	IAEA, International Atomic Energy Agency	Medical and surgical equipment and orthopedic appliances	3.44	8	90	

Source: UNGM database, Pharmexcil Research

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4. European Commission finds Innovator Companies Strategically Delaying Entry of Generics

In January 2008 the European Commission launched a sector inquiry into EU pharmaceuticals markets under the EC competition rules (Articles 81 and 82 of the EC Treaty) to establish if information relating to innovative and generic medicines suggesting competition may be restricted or distorted. This inquiry was initiated in January 2008 by Neelie Kroes, European Commissioner for Competition, in an attempt to identify inefficiencies in the pharmaceutical market that create obstacles to rapid access for consumers to affordable generic medicines and to new innovative products. The inquiry was focused on to the time period 2000 – 2007 and involved investigation of a sample of 219 medicines. The main findings were set out in the preliminary Report with title 'Competition between Originator Companies and Generic Companies.'

The report finds that originator companies have designed and implemented strategies (a "tool-box" of instruments) aimed at ensuring continued revenue streams for their medicines. Although there may be other reasons for delays to generic entry, the successful implementation of these strategies had the effect of delaying or blocking such entry. The strategies observed resulted in filing for up to 1,300 patents EU wide in relation to a single medicine (so-called "patent clusters"), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines.

The number of pharmaceutical-related patent applications before the European Patent Office (EPO) nearly doubled between 2000 and 2007. Contrary to what might be assumed, blockbuster medicines' patent portfolios showed a steady rise in patent applications throughout the life cycle of a product. Occasionally, steeper increases were identified towards the end of the protection period conferred by the first patent. The extent to which these instruments are used directly correlated with commercial importance of the medicines. The sector inquiry shows that more life cycle instruments are used for best-selling medicines.

All of the above strategies significantly increased legal uncertainty to the detriment of generic entry and adds to public health budgets. It was found that due to entry of generics, average prices dropped by nearly 20% after the first year following loss of exclusivity and up to 25% in the next two years. The decrease in the average price

index was as high as 80-90% for some medicines in some Member States. Generic entry lead to the biggest generic price decreases in countries such as Sweden, Finland, Denmark, Austria, Germany, Belgium, Luxemburg and the Czech Republic. In each of these countries average prices for the products losing exclusivity appear to drop by more than 50% within the first two years. The sector inquiry confirms that generic entry in many instances occurred later than it could be expected.

Between 2000 and 2007, originator and generic companies engaged, out of court, in at least 1,300 patent-related disputes concerning the launch of generic products. The vast majority of disputes was initiated by the originator companies, which most often invoked their primary patents, e.g. in warning letters. The number of patent litigation cases between originator and generic companies increased by a factor of four between 2000 and 2007. In total, close to 700 cases of patent litigation between originator companies and generic companies were reported in relation to the medicines investigated. Out of these, 149 cases were reported as litigation in which a final judgment was reached by the court.

The duration of patent litigation varied considerably between Member States with an average duration of 2.8 years. The majority of court cases were initiated by originator companies. However, generic companies won the majority of cases in which a final judgment was given (62%). Unlike during the dispute phase, originator companies primarily invoked secondary patents during litigation. The total cost of patent litigation in the EU relating to the 68 medicines on which litigation was reported for the period 2000 – 2007, is estimated to exceed €420 million.

The (426 page) report is detailed and informative: it provides an impressive set of data, facts and figures. The complete Preliminary Report could be assessed at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

On 8 July 2009 the European Commission adopted the Final Report on its competition inquiry into the pharmaceutical sector. It provides information relating to the inquiry, including reports, press releases, frequently asked questions (FAQ), presentations and speeches and other relevant documents. The details of which can be accessed at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

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5. Indian pharmaceutical market: Trends and Outlook

Introduction

In the wake of the recent global financial melt down and slow down in R&D productivity that the global pharmaceutical majors have witnessed, the global pharmaceutical industry is expected to grow at a CAGR 3 – 5%. However, India is expected to grow at an attractive CAGR of 12 – 15%, the reasons for this double digit growth will be discussed in the outlook section.

The Indian pharmaceutical market is highly fragmented which is evident from the fact that the top player holds a market share of less than 6%. However, the top 10 players hold a market share of ~ 36% (Fig 1: Top 10 players in Indian Pharmaceutical Market). There are around 260 large-scale players representing the organized sector of the industry, which contributes to more than 60% of the market in value terms.

Currently anti-infectives contribute approximately 18% to the Indian pharmaceutical market and this segment is growing at a CAGR of 12%. The growth of this segment is mainly driven by use of high-end antibiotics in hospitals, rising incidence of nosocomial infections and high penetration of products which are in their mature to declining phase of the product life cycle. The second and third largest therapy areas (Gastrointestinal and Cardiovascular) along with anti-infectives account for approximately 1/3rd of the Indian Pharmaceutical market.

Company	Rank
Cipla	1
Ranbaxy	2
GSK	3
Nicholas Piramal	4
Zydus Cadila	5
Sun Pharma	6
Alkem	7
Lupin	8
Mankind	9
Aristo	10

Although most large Indian pharmaceutical companies have large portfolio of products, the way they have managed to remain competitive is by developing expertise in specific therapy areas – as is evident from Fig 2, many leading Indian and foreign multinationals in India have developed a specific therapy area focus in order to retain their competitive edge in a largely

generic and undifferentiated market. Presently it is the acute therapies that drive the pharmaceutical market in India, constituting more than 60% of the value sales. However, this trend is changing and moving towards chronic therapy because of rapid urbanization and changing life styles leading to chronic disease like obesity, diabetes and cardiovascular ailments.

The leading players like Sun, Lupin, Cipla, etc., are likely to drive this trend and are already shifting focus towards chronic therapy products.

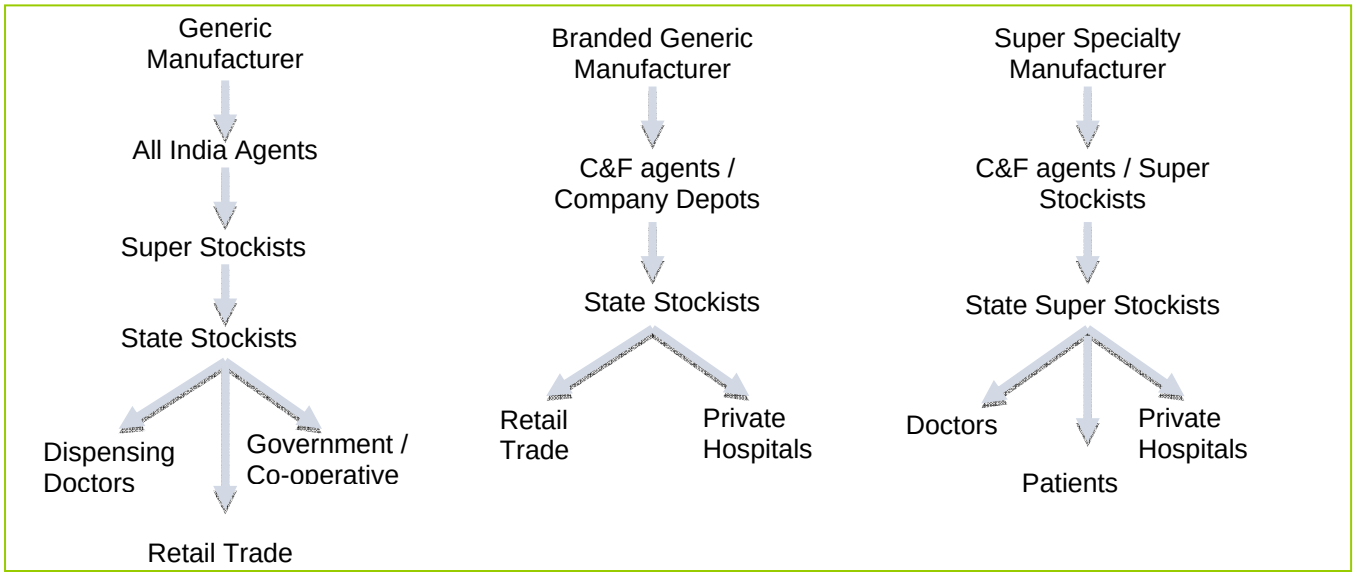
Fig 2: Therapy area focus of major pharmaceutical companies of Indian Pharmaceutical Market

Company	Therapy Area Focus
Ranbaxy	Anti-Infective
Cipla	Respiratory, HIV
Abbott	Anti-diabetes
Sun	CNS
GSK	Derma, Pain, Hormones, Vitamins, Anti-parasitic
Zydus Cadila	Cardiac, GI, Gynec
Lupin	Anti-TB
Himalaya	Hepatoprotective
Allergan	Opthalmology
Novartis	Vaccines

The pharmaceutical market in India is a largely retail market, since nearly two-thirds of the total value sales come from retail pharmacies. Over a period of time various players in the Indian pharmaceutical market have developed well focused and distinctly different distribution channels for generics, branded generics, as well as super specialty products making distribution cost-effective. (Fig 3: Distribution Channels)

More recently however, the traditional neighborhood pharmacies are beginning to give way to bigger retailing chains like Apollo, Health and Glow, Medicine Shoppe, etc. (Fig 4). These chains are well organized and backed or owned

Fig 3: Distribution Channels



by large corporate houses.

Hospital Segment – a sunrise sector

Approximately 18% of the total sales of pharmaceuticals in India take place through hospitals and this segment is becoming increasingly important as many foreign multinationals are entering the hospital market; also this segment is witnessing growing privatization. Major investments have been made by Tatas, Apollo, Escorts, Max and Wockhardt in setting up state-of –the-art private hospitals, as it is estimated that India will need another 750,000 beds and an investment of INR 1,500 billion (USD 37 billion) on new healthcare infrastructure in the next 10 years

Future Outlook

The future outlook of the Indian pharmaceutical market is extremely positive with an expected CAGR of 12 – 15% in the next five years. The factors fueling this growth will be population dynamics, high disease prevalence, increasing healthcare access, along with increasing capacity to spend. These growth drivers have been discussed in greater detail below.

Growth Drivers

India is expected to have a large population base of 1.5 billion people by 2050 - with an increase in life expectancy at birth (age in years) to 69 years from the current 65 years by 2020, geriatric population is set to double over the next 15 years. Further, India contributes to 18% of worldwide mortality and 20% of worldwide morbidity. It is estimated that India has a patient population of 40 millions type 2 diabetics growing at a CAGR of 4%. Every year approximately 85,0000 new cancer patients are added to already existing patient pool of 2 million - India has the highest cases of oral and throat cancer in the world such that every third

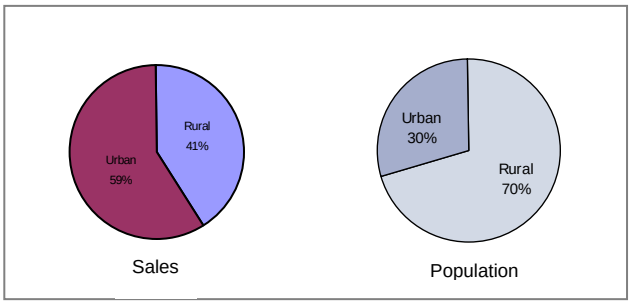
Fig 4: Organized retailing is on the rise

APOLLO GROUP	Largest chain in India, plans of 1500 outlets by 2009 and also planning to open stores at Indian Oil gas stations
HEALTH AND GLOW	Run by RPG Group, has a very strong market presence in South India, the chain also promotes herbal and cosmetic brands
Reliance Industries Limited	Initial investment USD 2.5 Bn, will go up to USD 6.2 Bn. Opening on 3 fronts - urban infrastructure, SEZ, life science and healthcare Partner with farmers, small shopkeepers and traders for organized retailing
The Medicine Shoppe	Part of international pharma chain Cardinal Health Inc. 700 outlets by 2010 Tied up with Bajaj Allianz for free insurance cover of kids
LifeKen Good health + a lot more	Planning a countrywide network in 3 years with 800 outlets Free home delivery, sample collection, medial check up, doctors for emergencies and other facilities for customers

oral cancer patient in the world is from India (Cancer Society of India). According to World Health Organization (WHO), 60 percent of the world's cardiac patients will be Indian by 2010. These factors point towards increase in chronic drug consumption in the future.

Although currently access to healthcare is 30% the government is committed to take it to 80% in the next 15-20 years – this is likely to introduce over 100 million untreated rural patients into the existing patient pool which will expand the existing market. Currently the Indian pharmaceutical market caters primarily to an urban populace with ~60% of the sale coming from urban areas; even though ~ 2/3rd of the population resides in rural areas. (See Fig 5: Low penetration in rural areas). This presents a huge growth potential waiting to be tapped by Indian pharmaceutical market.

Fig 5: Low penetration in rural areas



As literacy levels increase from 65% at present to 95% by 2020 greater numbers of people are likely to find employment. This will lead larger numbers of people to fall into the middle-class bracket – more than 450 million people. This coupled with increasing health awareness and higher levels of disposable incomes as well as opening up of reimbursement avenues is likely to fuel the future growth of the Indian pharmaceutical market.

Conclusion

Looking at the positive impact of increasing patient pool and increasing purchasing power along with health consciousness (due to rising literacy rate) we expect that the strong growth momentum of the pharmaceutical industry in India will continue into the near future. This positive outlook on the Indian pharmaceutical market is further supported by government's agenda of increasing healthcare access to 80% of the population by 2015 and the increased layout in terms of healthcare budget.

Contributed by:
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6. India Emerging as Global API Leader

Introduction

The current economic situation has given the global pharmaceutical industry has propelled many pharma majors to initiate several cost-cutting measures in order to retain their profitability. Active Pharmaceutical Ingredients or APIs form a significant proportion of the manufacturing costs for pharmaceutical companies and creative sourcing strategies have helped many pharma majors reduce their overall manufacturing costs by managing their API sourcing more efficiently.

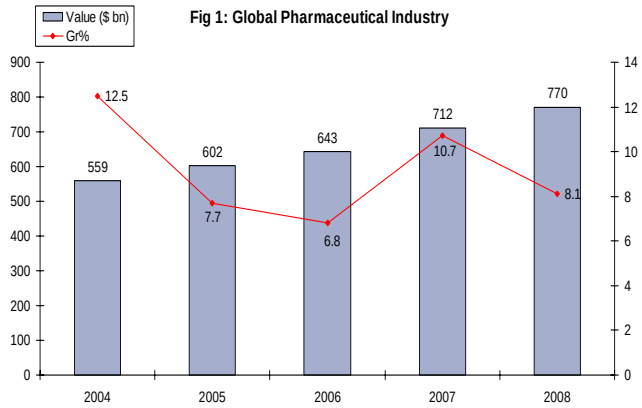
Although West European countries have always held the lion's share of the global API market, more recently, it is the Asian markets of China and India that have been able to provide quality APIs at much lower prices and are hence set to take over the global API scene. India in particular is fairly well poised to achieve the number one slot in times to come.

Global Pharmaceutical Market and its demand for APIs

The global pharmaceutical market, which is currently valued at nearly US$770 billion, has grown at a CAGR of 9.15% since 2004 (Fig 1: Global Pharmaceutical Industry)

APIs have either been manufactured in-house by vertically integrated companies or have been

Fig 1: Global Pharmaceutical Industry



sourced from external suppliers – although most pharmaceutical companies tended to complete the last one or two stages of API synthesis in-house before using it in their formulations. Over time, as product innovation increased in the pharmaceutical industry and as product portfolios expanded, many large pharmaceutical companies began to outsource key APIs that required complex production facilities and highly qualified manpower to produce; thus increasing the size of the global API market.

More recently as more and more drugs go off-patent and the major pharmaceutical markets come under increasing pressure to contain healthcare costs, the generic drugs market is all set to grow rapidly. Between 2008 and 2011 about US$80 billion and between 2011 and 2015 more than US$75 billion worth of branded drugs sales will see generic erosion. The growth of the generic market is likely to get reflected on the API market because although many of the generic companies are vertically integrated and

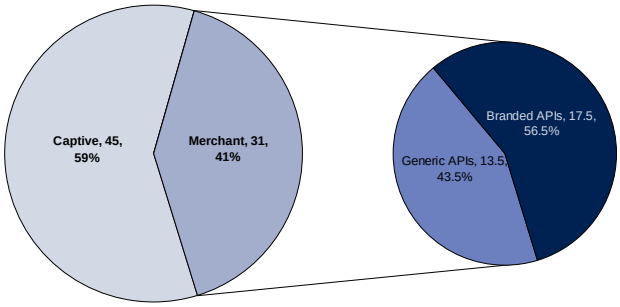
therefore produce APIs for captive consumption, there will be many pharmaceutical companies that will add a 'generic arm' to their business and those will need to source APIs externally.

Global API Market

Generic versus branded drugs' APIs:

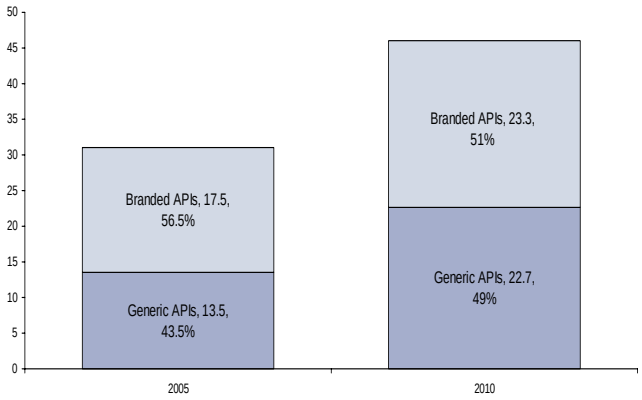
According to the Chemical Pharmaceutical Generic Association (CPA) in 2005 the global API market for human use stood at US$76 billion – of these about 59% were produced by pharmaceutical companies for captive consumption and the remaining 41% were meant for sale to other pharmaceutical companies; also termed as 'merchant market'. This merchant API market includes 43.5% of generic APIs and 56.5% of innovator branded drugs APIs. Fig 2: Global API Market 2005)

Fig 2: Global API Market 2005



Due to expanding generic market worldwide, the balance between generic and branded APIs has shifted since 2005 and thus the future outlook for the merchant API market by 2010 indicates that while the market for generic APIs is likely to grow at an annual average rate of 10-11% from 2005-2010, branded APIs will likely register a growth of just 5-6%; thus shifting the generic APIs to branded APIs ratio from 44:56 to 49:51 and taking the overall merchant API market from US$31 billion in 2005 to US$46 billion in 2010. (Fig 3: Generic and Branded APIs – 2005 to 2010).

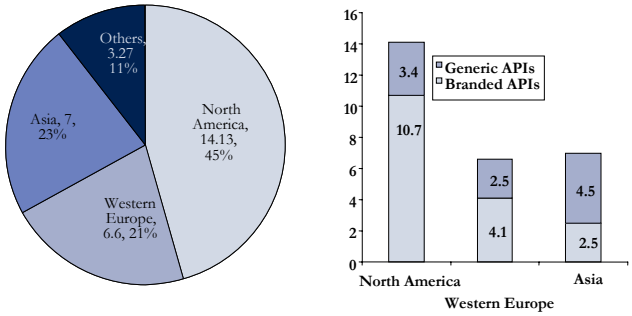
Fig 3: Generic & Branded APIs: 2005-2010



Global API demand and production:

In terms of consumption, North America is the largest market for merchant APIs, followed by Asia and Western Europe. (Fig 4: Global API demand 2005: split by generic and branded APIs) In terms of production, in 2005 Italy was the leading API producer in the world having produced US$3.2 billion worth of APIs of which US$ 2.4 billion were generic APIs. Among the Western European API suppliers, Italy was followed by Spain which produced US$1.02 billion worth of APIs, of which US$820 million were generic APIs. India and China are major

Fig 4: Global API demand 2005: split by generic and branded APIs



contenders in the global API market and are all set to increase their share in the coming years.

Asian countries emerging as global API market leaders

The CPA estimates that the Asia-Pacific region is likely to show the fastest growth in API production however they will cater increasingly to the generic API market than to the branded drugs' API market. The Chinese API market is likely to increase from US$2.3 billion in 2005 to nearly US$6 billion in 2010 (AAGR: 19.3%); of this US$5.1 billion will be generic APIs. The Indian API market is also set to grow faster than the Chinese API market: from US$2.0 billion in 2005 to US$4.83 billion in 2010 (AAGR: 19.3%); and of this generic APIs will be US$1.6 billion.

While in 2005 India and China supplied about 55%-60% and 15%-16% of all generic APIs to Western Europe and the US respectively, by 2010 these two countries are expected to hold 66% and 24% of the generic API markets in Western Europe and the US respectively.

Indian API Market: current and future trends

The Indian merchant API market was worth US$2.0 billion in 2005: about 6.5% share of global merchant API market. This market share is likely to increase to 10.5% by 2010, taking the Indian merchant API market to US$4.83 billion, with an average annual growth of 19.3%; making India one of the fastest growing API markets in the world.

Due to the low cost of labor and basic chemicals as well as the innovative processes employed by Indian manufacturers, most of the APIs from India are very competitively priced compared to other countries. Government incentives further aid in keeping prices low without affecting the profit margins of these manufacturers.

India is currently the third largest API producer in the world with Italy and China taking the top two positions. However, the promising growth figures indicate that India is all poised take up the number one slot soon. This is largely because Indian manufacturers had already envisaged that their sale to foreign countries, especially well regulated markets would drive their growth, Chinese manufacturers are largely catering to their domestic needs. Also Indian API producers have good capability for producing high-tech generic APIs whereas Chinese manufacturers are not well-equipped in that area. Furthermore the Indian API manufacturers are much better organized than their Chinese counterparts and are usually better prepared with the necessary documentation related to drug master files

(DMF), GMP compliance, etc., that clients may need to have. This is evident in the fact that India holds the distinction of having the largest number of DMF submissions; is home to the largest number of U.S. FDA approved plants in the world; and has the highest number of ANDAs approved by the U.S. FDA (other than the US).

One of the major areas where the Indian API manufacturers score over the Chinese is the ability of Indian companies to market their products and companies to clients outside India. Even though both India and China do not have very great track records related to IPR, India is viewed as being better and therefore inspires more confidence in clients from US and Western Europe.

Future Trends in API Markets

With the failure of small molecule drug research and with the increasing success of biotechnology-based therapies, the global pharmaceutical industry is fortifying its pipeline with biotech products. This has opened up a whole new opportunity for bulk biopharmaceutical chemicals. Currently most biotech companies are small set-ups and hence rely on outsourcing for key biopharmaceutical ingredients and in some instances also outsourcing of the entire bio manufacturing process.

However, although API manufacturers could look at the biotech companies as the new customers, currently very few biopharmaceutical drugs have reached commercialisation and among those that are already available the basic ingredients are often produced in-house in order to maintain the high standardisation requirements of biopharmaceutical batches.

Another trend that is already impacting the API manufacturers is the stringent regulatory requirements that have been placed in the form of the Supplementary Protection Certification (SPC) regulations in the EU countries which prohibit any manufacture of generic drugs in advance of its patent expiry. Hence most API manufacturers would now need to move their plants out of the EU countries to ensure that they can manufacture generic drugs prior to patent expiry for the purpose of registration in other countries. This trend will increase the attractiveness of India and China as alternative destinations for manufacturing sites.

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7. Pharmexcil Activities

7.1 Pharmexcil Activities during September 2009

1. Interactive meeting with ADC in Hyderabad on COPP

At the request of senior officials of Assistant Drug Controller's (ADC) office, Hyderabad, Pharmexcil has organized an interactive meeting with pharmaceutical industry on October 9, 2009 at Hotel Aditya Park Inn, Hyderabad. The Drug Controller General of India (DCGI) has published a notification that Certificate of Pharmaceutical Products (CoPP) would be issued by Zonal Offices of Central Drugs Standard Control Organization (CDSCO) with effect October 01 2009 instead of existing system of issue of CoPP by State Drug Control Administration. The interactive meeting was aimed at bringing awareness of the regulation and to facilitate smooth transition. Shri A Chandra Sekhara Rao, ADCI, CDSCO, Hyderabad delivered a presentation on implementation of WHO Certification Scheme (CoPP), elaborating general requirements for submission of application for issue of CoPP, procedure for acceptance, fee structure, etc. The meeting was attended by nearly 60 members of Pharmexcil. The presentation can be viewed by Pharmexcil members at:

http://pharmexcil.com/data/uploads/COPP_by_Shri_A_Chandra_Sekhara_Rao,ADCI,CDSCO.pdf

2. CPhI Worlwide, Spain (India Pavilion)

Pharmexcil organized 'India Pavilion' at CPhI 2009 held at Madrid, Spain from October 13 – 15 2009 for the 4th consecutive year. Pharmexcil had booked 504 square meter space at the exposition. About 43 Indian companies participated through the council and received good number of trade enquires. During the Exhibition, meetings with China Chamber of Commerce and China Council for Promotion of International Trade (CCPIT) were arranged by the organizers. Consular General of Indian Embassy in Madrid visited our pavilion on

October 14 2009. Member of Parliament of Spain and Chairman of Aristo Pharma Ltd, visited our pavilion and was impressed by the arrangements made at India Pavilion.

"CPHI, Worldwide" (Convention on Pharmaceutical Ingredients) is the most patronized exposition of Pharmaceuticals, particularly for Active Pharma Ingredients organized globally. This event brings together more than 1,700 global companies engaged in manufacturing and trading of bulk drugs, drug intermediates, excipients, etc. Leading manufacturers from countries like Germany, UK, France, USA, China, Japan, Mexico, Canada, Brazil, India, etc., participate in the exhibition. Over 25,000 visitors from about 130 countries visit the event regularly.


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3. Workshop on Revised Credit Linked Capital Subsidy Scheme (CLCSS) for Schedule M Compliance

At the request of the Department of Pharmaceuticals, Govt. of India (GoI), Pharmexcil organized an Awareness Building Workshop on Revised Credit Linked Capital Subsidy Scheme (CLCSS) for Schedule M Compliance on October 28, 2009 at Hotel Aditya Park Inn, Hyderabad. GoI has recently revised CLCSS scheme for the Small Scale units to upgrade their units to comply with Schedule M requirements, by extending financial assistance up to Rs.1 crore as loan with 15% subsidy. With a view to increase the awareness and utilization of the scheme Shri A.K. Vishan Das, DDG, Department of Pharmaceuticals made a presentation on the scheme and procedures for granting loans & subsidies. Officials of Ministry of Small and Medium Enterprises (MSME), National Productivity Council, SIDBI, State Bank of India, State Drug Controller Office,,

etc., also made presentations on the scheme (presentations can be accessed at http://www.pharmexcil.com/v1/aspx/Conferences.aspx). The workshop was attended by nearly 100 members of the council.

4. Pharmexcil representation to DGFT on policy inputs provided by members

Pharmexcil compiled various suggestions made by its members following announcement of Foreign Trade Policy 2009-14 and submitted a representation to Director General of Foreign Trade (DGFT) on 20th Oct. 2009. On para 4.16 of FTP 2009-14, pertaining to Advance Authorization Scheme, imposing 15% value addition criteria on imported inputs, Pharmexcil requested DGFT to reverse the provision to earlier policy of 'positive value addition' as it would severely impact exports of exports with high import content and low value added dosage forms. The other major points included are, reinstatement of normal repatriation period to

earlier 360 days, inclusion of Russia and Iraq to the list of countries eligible for MLFPS, Increase of import validity period to 36 months, restoration of provision of 6 months from the date of realization for claiming DEPB, clubbing of advance licenses, simplification of procedure for duty free procurement by principal exporter, etc. The representation and suggestion made to DGFT can be accessed from Pharmexcil website at http://pharmexcil.com/data/uploads/pxl_suggestions_FTP2009-14.pdf. Shri Nipun Jain, Member, Committee of Administration of our council is following up the issues with the office of DGFT.

5. Review Meeting on Implementation of Task Force Report held by Department of Commerce

Senior Officials of Department of Commerce, Ministry of Commerce & Industry, Government of India held a review meeting on Implementation of recommendations of Task Force Report at New Delhi. The department is actively considering creation of National Pharma commission for the development of Indian Pharmaceutical industry. The meeting was attended by council's Committee of Administration (COA) members Shri Nipun Jain and Shri Ashtosh Gupta along with the Executive Director. Shri Lanka Srinivas, Advisor, Pharmexcil was also present at the meeting.

6. Visit of Secretary to Pharmacity, Vizag: Secretary, Dept. of Pharmaceuticals visited Pharma City, Vizag during 22-23rd of October. Secretary was impressed by the developments in Pharma City and advised Council to establish an office at Pharma City and assured fund support by the department. The developers/APIIC also promised to provide office accommodation. The council is taking up necessary action as per the advice of Secretary.

7.2 Circulars issued by Pharmexcil

List of circulars issued by Pharmexcil in the month of October 2009	
Date of issue	**Subject of Circular**
23 Oct 09	Financial assistance for Schedule M' compliance
23 Oct 09	Participate in APTEKA – Moscow 2009
12 Oct 09	Pharmexcil Digest (News Letter – October'09)
8 Oct 09	Seminar on Vendor Registration Process with UN Agencies – Reg
7 Oct 09	Interactive meeting with ADC, Hyderabad
7 Oct 09	CPhI Worldwide, Madrid, Spain 2009
1 Oct 09	Arab Health 2010
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	

7.3 Upcoming Pharmexcil Activities

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

List of upcoming events participated by Pharmexcil			
S. No	**Event/ Conference**	**Date**	**Description/ comments**
1.	CPhI India 2009, Mumbai	December 1-3, 2009	Pharmexcil will be participating in CPhI India 2009
2.	APTEKA 2009, Moscow	December 7 – 10, 2009	Pharmexcil will be organizing 'India Pavilion'. The council has booked a space of around 100 sq.m. and is planning to allot space in 6/9/12 sq.meters sizes to the members.
3.	Delegation to CIS countries including Azerbaijan	January, 2010	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.
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			

8. Indian pharma in media

1. Issuance of CoPP centralized based on WHO recommendation, says DCGI

Dr. Surinder Singh, the Drug Controller General of India (DCGI), clarified that the centralization of issuance of Certificate of Pharmaceutical Product (CoPP) from October 1, 2009, conformed to the WHO's recommendation that the "issue of such important documents should be controlled at central level rather than at state level". He opined that such a move was especially necessary since pharmaceutical exports were steadily on the rise and added that this move would have a definitive positive impact on the world trading community and instilling confidence in them about India's regulatory framework. Dr. Singh also clarified that his order had no bearing on the Drugs & Cosmetics Act since exports is not cited in the Act.

It may be recalled that following the DCGI's order, there has been all-round displeasure and opposition from various sections including the pharma industry and the state licensing authorities. Health secretaries of some states are questioning the Union Health Ministry if the DCGI had the power to issue such an order. The pharma department is following up the matter with the secretary of the health department.

2. Tamil Nadu Drugs Control Officers Association (TNDCOA) obtains stay on ban on states clearing export of medicines

The Chennai High Court stayed the ban sought by the office of the Drug Controller General of India (DCGI) to stop clearances of exports by state-level drug authorities. The DCGI had issued a notice on September 1, 2009, stopping clearances by states, effective October 1, 2009, because of increasing complaints from many countries about the quality of medicines exported from India. The DCGI also contends that certificates issued by states do not conform to WHO rules and regulations. The Tamil Nadu Drugs Control Officers Association petitioned against this directive, claiming that it had no legal basis because the Drugs and Cosmetics Act does not mention exports. Small and medium domestic pharmaceutical companies were also against the ban since they felt that if export approvals were at the central level, it would only delay clearances.

Drug exports account for nearly half (INR 35,000 crore) of the total (INR 85,000 crore) pharmaceutical industry. WHO recommends that the 'WHO GMP Certificate' to be issued by only a national regulatory authority. Countries that do not have their own system in place (like the US and Western Europe) insist upon this certificate

when importing drugs. Large pharma companies may not be affected much by this court directive since their exports are mostly to the more regulated markets like the US. The High Court stay is applicable across the country.

3. DCGI to issue guidelines attached to Drugs and Cosmetics Act to prevent harassment of drug units

Steps are being taken by the office of the DCGI to issue guidelines attached to the recently amended Drugs and Cosmetics Act so that genuine drug manufacturers are not put to trouble by drug inspectors. The amended Act endows more power to drug inspectors but, like the 1993 DCC guidelines, does not make it legally binding on the authorities. This has become a major cause for worry in the pharma industry since there is ample opportunity for misinterpretation and misuse in several provisions of the new Act. Genuine drug manufacturers, whose labels might be used by makers of spurious drugs, may get prosecuted despite being innocent. The Parliament passed the amended Bill in October 2008 and the President approved it in December 2008. On August 10, 2009, the Union Health Ministry notified the Drugs Act Amendment Bill. Under this Bill, production and sale of spurious drugs is a non-bailable offence. The imprisonment term has also been increased to 10 years along with a fine of Rs. 10 lakh.

4. India approaches global NGOs in fight against African anti-counterfeiting laws

Mr. Rajeev Kher, Joint Secretary in the Union Commerce Ministry, said that senior commerce ministry officials have approached international civil society organizations like Oxfam, Quaker Foundation, Third World Network,, etc., to discuss anti-counterfeit legislations being planned by African countries like Uganda, Tanzania and Zambia under which generic medicines are considered counterfeits. The Indian officials recently met some of these NGOs in Geneva and have requested the NGOs to try and convince the African governments that the issue of intellectual property should not be mixed with the issue of counterfeit drugs and that the anti-counterfeit laws being considered by some of the African nations would effectively deny the availability of essential and cheap generic medicines to third world countries.

The African region promises to be a potential gold mine for multinational pharma majors and it is believed that these companies are prevailing upon the African nations to come up with such anti-counterfeiting laws – thereby discouraging generic operators – before investing heavily in these countries. The 'Brand India Campaign' was launched by the Indian government to aggressively try to stop enactment of such laws by the African countries.

5. Counterfeit medicines issue – Now EU worries Indian pharma industry

Indian pharma companies have to deal with fresh developments in Europe which might adversely effect their operations. The European Commission is targeting counterfeit medicines in its new directive, while the Council of Europe has prepared a draft on counterfeiting of medical products. According to Article 6 of this draft, 'Each party shall take the necessary legislative and other measures to establish as offences under its domestic law when committed intentionally, the supplying or the offering to supply including brokering, the trafficking, including keeping in stock, import and export of counterfeit medical products, active substances, excipients, parts, materials and accessories'. It defines a counterfeit medical product as 'a product with a false representation of its identity and/or source'. This attempt by EU nations is similar to the IMPACT attempt in the WHO recently. SME Pharma Industries Confederation vice-chairman, Mr. Lalit Jain, said that they have referred the matter to the Indian government, urging it to ensure that the interests of the domestic industry are taken care of and that developing countries are not deprived of quality medicines at affordable prices. The Council of Europe's draft text will be finalized by the European Committee on Crime Problems (CDPC) at the Committee's plenary meeting.

6. More African nations plans anti-counterfeit laws

Tanzania, Uganda and Zambia are planning to introduce anti-counterfeit legislation on the lines of what Kenya enacted last year. The issue here is that the scope of the Kenyan law goes beyond the Trade-Related Aspects of Intellectual Property Rights (TRIPS) definition of counterfeit, by not restricting itself only to trademark infringement but also includes all IP infringements like patents, copyrights, industrial designs and even plant variety protection. Such legislation effectively blurs the line differentiating generics from counterfeit drugs, leading to legitimate generic drugs being branded as counterfeit. India has been cautioning African countries not to dance to the tunes of multinationals to block the supply of generics. Public interest groups like Medecins Sans Frontieres have also expressed concern that if such IP enforcement measures are used against legitimate, cheaper generics, they might hinder the common man's access to affordable medicines.

7. India urges Argentina for changes in pharma trade policy

Argentina's pharmaceutical import policy figured in the seminar 'Argentina-India: Trade, Investment and Business Opportunities', organized by the FICCI, ASSOCHAM and the CII in cooperation with the Embassy of

Argentina. The Indian Minister of State for Defence, Dr. M.M. Pallam Raju, urged the Argentine president, Cristina Fernandez de Kirchner, to effect a policy change and allow Indian companies to export to Argentina. Currently, according to Argentina's pharma import policy, India does not figure amongst the group of 27 countries that the country allows imports from. Though Argentina does import pharmaceutical raw materials, it does not import finished formulations, this despite the fact that India boasts of good manufacturing facilities, R&D capabilities and the most number of FDA-approved plants outside the US.

According to Argentinean industry sources, the nation's pharmaceutical spend was US$ 3.73 b in 2008 and this figure is estimated to go up to US$ 4.23 b by 2013 growing at a CAGR of 17.8 per cent. India's total exports to Argentina during 2003-04 to 2007-08 grew from US$ 87.33 m to US$ 289.68 m. About 40% of India's total exports are chemical products. Dr. Raju added that with Argentina being a member of the Mercosur Trade Bloc, the India Mercosur Preferential Trade Agreement would aid in further growth of bilateral trade ties between the two countries.

8. Developing nations cause setback to patent harmonization agenda

A renewed mandate for the Intergovernmental Committee (IGC) on Genetic Resources, Traditional Knowledge and Folklore has been reached by the member states of the World Intellectual Property Organization (WIPO). Under this mandate, the IGC would begin text-based negotiations for an international legal instrument which would protect these resources. This has come as a setback to the efforts of the developed nations, led by the US, EU and Japan, who are pushing for global patent harmonization through the WIPO. The developed nations are of the opinion that a political declaration or a recommendation on the issue would suffice instead of a legally-binding instrument. The developed nations came under fire for giving new definitions to counterfeiting and thereby undermining the flexibility offered under TRIPS. Developing nations argued that the credibility of the proposed global IP framework would be lost if, under new definitions of counterfeiting, affordable generic drugs were not made available to the poor. However, it is not yet clear if the agreement will be considered as an international treaty.

9. Action against exporters violating labeling rules

Exporters/manufacturers/merchant exporters have to mention their name and address, with their status as 'Manufacturer', 'Manufactured by' and 'The Manufacturer', on the labels of their

export products. This directive was issued by the DCGI, Dr. Surinder Singh, to state drug controllers and port/zonal officers, asking them to ensure compliance from exporters. The DCGI issued it in the wake of instances where some exporters were exporting drug formulations (manufactured under neutral code of the actual manufacturer), mentioning their name as 'Manufacturer', 'Manufactured by' and 'The Manufacturer'. He said that such labeling would come under the definition of Spurious Drugs in the Drugs & Cosmetics Act. Under Rule 94 of the Drugs & Cosmetics Act, state licensing authorities may grant a manufacturer exemption to mention only neutral code (and not include his name and address) to meet the exporting country's requirement.

9. 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.	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.
2.	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.
3.	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.
4.	India Pharma Summit 2009, Hotel Grand Hyatt, Mumbai	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.
5.	2nd International Symposium on Medicinal and Nutraceutical Plants, New Delhi	Nov 25 2009	All India Institute of Medical Sciences, New Delhi (India) is organizing event from 25-27 November, 2009, in collaboration with International Society for Horticulture Sciences (ISHS), Belgium. 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.
6.	India Pharma Summit, Mumbai	Nov 30 2009	The Department of Pharmaceuticals is holding the first ever Indian Pharma Summit 2009 on 30th of November 2009 at Nehru Centre in Mumbai. The Summit in partnership with FICCI and UBM India Pvt. Ltd.
7.	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, generate new alliances, renew existing partnerships and benefit from the dynamic networking opportunities available to actively drive business forward.
8.	Indo-US Symposium on Ayurvedic, Siddha & Unani, New Delhi (ASU) – 2nd –4th December'09	Dec 2 2009	(CRISM) Centre for Research on Indian System of Medicine is organizing the event at International Guest House, Pusa, New Delhi which will focus on Current Procedure for ASU / Natural plant products.
9.	Oshadhi 11-13 Dec 2009-Herbal Expo & National Seminar on Medicinal Products & Herbal Products, Hyderabad	Dec 11-13th 2009	A.P. Medicinal & Aromatic Plants Board is organizing the event to showcase Foods, Dietary Supplements, Medicines, Cosmetics and other Herbal Products at People's Plaza, Hyderabad.
10.	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.

International			
1	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.**
2	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.**
3	World Forum for Medicine International Trade Fair with Congress, Dusseldorf, Germany	November 18 – 21, 2009	**The leading medical devices manufacturers exhibition in Europe**
4	InfomEx USA, San Francisco, USA	February 16-19, 2009	**The event is one of the leading fine & specialty chemicals trade show in North America connecting a large number of industry professionals, decision-makers and leading suppliers from the specialty chemical and pharmaceutical industry.**
5	LogiPharma Asia, The Hilton, Singapore	November 30 – December 02 2009	**The conference is focused on pharmaceutical supply chain and logistics**
6	8th Annual World Drug Manufacturing Summit 2009, Berlin, Germany	December 02 – 04, 2009	**The focus of the conference is on operational excellence in manufacturing with an emphasis on lowering the cost of manufacturing and effective supply chain**
7	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.**
8	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**

10. Important Government Notifications

Sl. No.	Date	Notification no.	Source	Subject
1	October 15 2009	G.S.R.764(E) No.K.11020 /3/2000-DCC (AYUSH)	Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy	Date of expiry, shelf life and date of expiry with effect from the date of manufacture of Ayurveda, Siddha and Unani medicines to be conspicuously displayed on the label of container or package. This notification is effective from April 01 2010.
2	October 21 2009	F.No.115/1/ 2008-CX-3	Ministry of Finance - Dept. of Revenue	The excise leviable under the section 3 of the Central Excise Act, on packaging material, plastic bags and laminated rolls manufactured with brand name or a trade name of another person who is not eligible for grant of exemption are liable to excise duty.
3	October 27 2009	NO.13 (RE-2009) 2009-14	Ministry of Commerce and Industry Directorate General of Foreign Trade (EPCG-I Section)	Joint Director General of Foreign Trade has requested all Regional Authorities/ All Custom Authorities/ All Concerned to re-fix the annual average export obligation for EPCG Authorizations for the year 2008-09 for the product groups showing a decline of more than 5% in exports during 2008-09 as compared to 2007-08
4	October 27 2009	F.No.01/94/ 180/FTP/09 - 10/AA/AM10/PC-4	Ministry of Commerce and Industry Department of Commerce	The Director General of Foreign Trade makes an amendment in the Handbook of Procedures (Vo.1), 2009-14
5	October 28 2009	F.No.468/16 /2009-Cus.V	Ministry of Finance - Dept. of Revenue	Revision of foreign exchange rates for conversion of imported and exported goods by Central Board of Excise and Customs

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