

## Dominance of European Union in World Pharmaceutical Trade

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### Abstract

Millions of needy & suffering patients in Developing and Least Developed countries depend on imported medicine. European Union is poised as the driving engine of pharmaceuticals across the world. The dominance of the region is likely to have commanding influence on accessibility and affordability of medicine to the millions of suffering patients impacting not only their welfare but also health burden. The article attempts to analyze the region's influence on the world trade in pharmaceuticals, emerging challenges to the region's dominance. Export & import statistics available from United Nations commodity trade statistics database 'Comtrade' for formulations & bulk drugs were analysed and econometric analysis (Balassa Index) was used for establishing comparative advantage of different countries. Several of European Union nations have very high comparative advantage in Pharmaceutical industry and the sector, as a major export earner, is very important for many countries of the region. These major countries have a few players dominating the industry. It was noted that several European Countries such as Italy, Netherlands, etc are facing growing negative trade balances both in formulations and bulk drugs, while countries like Italy, Germany, France are facing negative trade balance in Bulk drugs. The previously dominant countries are facing growing challenge from countries of India and China.

**Key word-** Pharmaceuticals, Trade, European Union, Certificate of Suitability, Balassa Index

### INTRODUCTION

As per the UN estimate nearly two billion people living in developing countries are deprived of essential medicine<sup>1</sup>. Poor people in Least developed countries and developing countries lack medical insurance or public health coverage<sup>2</sup>. Up to 90% of the population in developing countries meets treatment costs out of their family budget. Further, there are large gaps exist in the availability of medicines in the public and private sectors<sup>1,3</sup>. The prevailing prices in these countries are as much as 6.1 times higher in the private sector and 2.5 times higher in the public sector<sup>4</sup> than international reference prices.

Medicines account for 20–60% of health spending in developing and transitional countries<sup>5</sup>, compared with 18% in countries of the Organization for Economic Co-operation and Development<sup>6</sup> (OECD). High cost of treatment reinforces poverty<sup>7</sup>.

The morbidity rates in Least developed and developing countries are also rapidly increasing in the recent past as a result of urbanization. Increasing exposure to environmental pollution, pesticides, obesity, abandoning of healthy diets, tobacco consumption, alcohol abuse, etc., are leading to cancer, hypertension, diabetes and other life style diseases in these countries<sup>4</sup>.

Malaria claims over a million people every year, most of whom are children and pregnant women. Of these, 86% are in Africa<sup>8</sup>. The rate of cervical cancer among African and Asian women is far higher than in the UK or US<sup>9</sup>. There are 20 million people living with hypertension in Africa and the mortality rate is 10 times higher in

Tanzania than in the UK<sup>10</sup>. An estimated 194 million people have diabetes worldwide of which 120 million in developing countries<sup>11</sup>. Many of the Least developed countries and developing countries due to small population/market size, low GDPs can neither afford high investments required in pharmaceutical industry especially so in case of oncologies, parenterals, biologics, etc. which require dedicated facilities nor have the required knowhow. These countries have huge import dependency.

The pharmaceutical industry is the 5th largest sector in the European Union, accounting for 3.5% of total manufacturing production<sup>12</sup>. The region's pharmaceutical market size is estimated at approx. US\$187.06bn<sup>13</sup> for the year 2007 (data available for 26 countries only) which represents 26.27% of world pharmaceutical market. The total pharmaceutical production of 19 EU countries for which data is available during that year is approx. US\$230bn. As per the data from United Nations commodity trade statistics database 'Comtrade'<sup>14</sup>, the region accounted for approx. 69.56% of global pharmaceutical exports (US\$359.15bn) and 56.46% of the global imports during that year indicating dominance of the region.

EU region therefore, is poised as the driving engine for global pharmaceutical trade and the regulatory & policy changes of the region and actions of the companies are likely to have commanding influence on the availability and affordability of medicine around the world not only impacting the welfare of millions of patients but also health burden of many Least developed and developing countries.

The research therefore tries to analyze the status of EU in world pharmaceutical trade. Towards this, the research attempts to critically examine:

1. Trends in exports & imports of formulations (Pharmaceutical finished products) and Bulk Drugs (APIs) of the countries of the world,
2. Status of European Union in world Formulations and bulk drug trade,
3. Share of European Union in the imports of Least Developed countries & Developing countries,
4. Status of major pharmaceutical companies of EU in world Pharmaceutical market,
5. Revealed Comparative Advantage of pharmaceutical & bulk drugs exports among various regions of the world and
6. Emerging competition in bulk drug registrations in European Union.

#### RESEARCH METHODOLOGY

To analyze the trends in trade in formulations and bulk drugs, export & import statistics from 'Comtrade' were taken for 6 digit Harmonized System of Nomenclature (HSN) codes provided by International Trade Centre (ITC) under the list 'Pharmaceuticals and medicaments cluster'<sup>15</sup> (appearing in members login area).

The list was segregated into APIs & formulations and trends in the pharma trade were studied for all 175 reporter and 244 partner countries/territories presented in the UN database for the 5 year period from 2004 to 08. The countries were also studied by grouping into twelve regions as also based on their degree of economic development and regulation into highly regulated developed countries<sup>4</sup>, other developed countries<sup>16</sup>, highly regulated developing countries, developing countries, Least Developed Countries<sup>17</sup> (LDCs). A further analysis of pharmaceutical sales of top 150 pharmaceutical companies of the world according to region was carried out.

To measure the revealed comparative advantage of different countries 'Balassa Index'<sup>18</sup> was constructed for various countries of the world. The total exports (including re-exports & re-imports) of all countries/territories of the world were also obtained for computation from UN 'Comtrade' for arriving at Revealed Comparative Advantage (Balassa Index) in exports.

To understand emerging competition among EU and non-EU countries in bulk drugs, further analysis of Certificate of European

Pharmacopoeia (CEPs) granted by European Directorate of Quality Medicine (EDQM) was performed. CEPs are granted by EDQM through a centralized procedure and are valid in 37 convention countries<sup>19</sup>. CEPs approval analysis therefore, offers a good approach for analyzing emerging competition for EU countries in APIs. Only valid certificates were taken into consideration. The approval trends were then analyzed region-wise, country-wise, year-wise and also therapeutic category-wise.

During the analysis it was noted that, while Chapter 30 of ITC HS Classification comprehensively covers formulations, the HS codes of bulk drugs being used by international statistical agencies comprise basically HS codes pertaining to plant derived & fermentation products. Many of the chemistry based Active Pharmaceutical Ingredients (APIs) fall under other 6 digit level HS Codes which predominantly consist of chemicals and therefore, they were not included into the list of HS code for bulk drugs. For example, the HS Codes containing Salbutamol, Ethambutol, Paracetamol, Frusemide, Domperidone, entire class of Sulphonamides, etc. were not falling into the list bulk drugs identified by ITC and other agencies. It is therefore found that the trade in bulk drugs, as being reported globally therefore, does not present true picture and is grossly under reported. However, the list was adopted for analysis as data is not available as chemical based APIs fall at 8 digit level.

During the research, several validation and data checking steps were undertaken while collecting and post collection of data to ensure its accuracy. Data were analysed using spreadsheets (excel). Results were then cross-checked and a data validation was performed.

#### RESULTS & DISCUSSION

##### 1. Trends in Exports & Imports of Formulations and APIs of the world

The total pharmaceuticals and bulk drugs exports of the world stood at around US\$404.59bn during 2008 growing at Compounded Annual Growth Rate (CAGR) of 13.94% over the five years 2004-08. Of this formulations exports have a share of 94.52% (CAGR of 14.37%). The top 15 formulation exporting countries of the world and their imports are provided in table 1 below. Germany is the top exporting country of the world with a share of 16.34% in world exports followed by Belgium, Switzerland, USA and France. Out of

the top 15 exporting countries of the world 11 are from European Union and only four are non-European Union. Among these countries formulation exports of India are growing at a very high CAGR followed by Spain, Austria, Canada and Switzerland. USA, Italy, Spain, Netherlands and Canada, however, have higher imports than exports.

Among the major importing countries, imports of Ukraine, Russian Federation, China, Romania, Brazil, Poland, Hungary, Czech Republic, Rep. of Korea and Greece are growing rapidly.

From the analysis of bulk drugs trade statistics it was found that, China is the largest exporter of bulk drugs in the world with a share of 22.61% in the year 2008 growing at a CAGR of 25.38%

from 2004 to 2008 (refer table 2). The dominance of China is perhaps due to the fact that<sup>20</sup> it is the world leader in products like Penicillin (accounting for 60% of world's production), Vitamin C, Cephalosporins, Doxycycline Hydrochloride and Terramycin. Switzerland is the second largest exporter in APIs with a share of over 12% followed by USA (nearly 10%), Ireland (6.86%), and Germany (6.79%).

Among the major API exporters, after China, the countries with highest CAGR for the years from 2004 to 2008 are India, Belgium, Singapore and Ireland. Exports of Netherlands, Sweden and USA are declining for these five years.

**Table 1: Analysis of Top 15 Formulation Exporting Countries of the World (figs. in US\$ m)**

Rank (Exports)	Country	Export			Imports		
		2008	CAGR (2004-08)	% Share in global exports	2008	CAGR (2004-08)	% Share in global imports
1	Germany	62,472.55	18.08%	16.34%	44,097.85	16.35%	11.60%
2	Belgium	48,690.66	12.97%	12.73%	42,102.13	7.99%	11.08%
3	Switzerland	40,089.11	19.36%	10.48%	16,365.09	11.40%	4.31%
4	USA	33,962.73	14.90%	8.88%	52,839.19	13.76%	13.90%
5	France	32,225.45	12.70%	8.43%	22,086.69	13.98%	5.81%
6	United Kingdom	30,446.12	9.01%	7.96%	19,793.18	6.97%	5.21%
7	Ireland	22,546.10	6.14%	5.90%	3,549.27	15.70%	0.93%
8	Italy	15,275.06	10.99%	3.99%	17,187.91	11.54%	4.52%
9	Spain	10,607.27	24.44%	2.77%	14,428.53	16.16%	3.80%
10	Netherlands	9,795.17	1.25%	2.56%	12,029.79	7.95%	3.17%
11	Sweden	8,398.27	5.94%	2.20%	4,096.94	13.75%	1.08%
12	Denmark	7,478.72	11.31%	1.96%	3,117.35	11.14%	0.82%
13	Austria	6,921.11	20.68%	1.81%	5,187.30	15.91%	1.37%
14	Canada	6,065.27	19.68%	1.59%	10,214.99	11.56%	2.69%
15	India	5,003.35	27.24%	1.31%	901.27	32.84%	0.24%

Source: Research based on United Nations commodity trade statistics database 'Comtrade' & ITC

**Table 2: Analysis of Top 15 Bulk Drug Exporting countries of the World (figs. in US\$ m)**

Rank (Exports) (2008)	Country	Export (2008)	CAGR (2004-08)	Import (2008)	CAGR (2004-08)	Rank (Imports) (2008)
1	China	5,013.32	25.38%	604.44	17.06%	12
2	Switzerland	2,674.06	6.58%	754.66	0.66%	9
3	USA	2,179.29	-1.50%	3,345.38	5.93%	1
4	Ireland	1,521.23	12.62%	473.18	5.88%	15
5	Germany	1,506.73	2.80%	2,034.84	0.71%	3
6	Italy	1,201.57	1.94%	2,211.92	9.51%	2
7	Belgium	1,113.82	13.66%	1,599.14	12.72%	4
8	France	783.55	0.19%	1,162.25	4.87%	5
9	India	754.89	23.15%	872.19	25.54%	7
10	Singapore	733.59	13.04%	376.79	8.89%	19
11	Japan	690.81	0.34%	998.97	5.25%	7
12	Spain	668.21	9.87%	779.84	21.98%	8
13	United Kingdom	584.83	4.52%	659.63	6.96%	10
14	Sweden	420.06	-4.94%	66.18	21.13%	41
15	Netherlands	405.60	-13.10%	656.29	-7.32%	11
<b>ROW</b>		<b>1,925.90</b>	<b>4.83%</b>	<b>5,713.15</b>	<b>8.30%</b>	

Source: Research based on United Nations commodity trade statistics database 'Comtrade' & ITC

## 2. Status of European Union in world Formulations and bulk drug trade

As per the analysis of trade statistics from UN Comtrade, the share of EU in world exports is estimated at 68.51% and in imports it is approx. 57.24%. The region occupied a share of 70.13% (CAGR 12.86%) in the world formulation exports and accounted for 57.82% of formulation imports of the world in 2008 valued at US\$219.72bn (CAGR of 12.61%). It accounted for 40.69% of world bulk drug exports and 47.76% of world bulk drug imports. Nearly two thirds of these exports are intra EU and the region exported approx. US\$97.59bn to the rest of the world (refer table 3).

Some plausible explanations for such dominance of European Union (EU 27) in global trade are, trade redistribution effect of the economic union, huge intra-regional market which favors local players due to their proximity, etc., long presence in third world countries, sustained exports to former colonies, highly developed manufacturing expertise, innovation and CGMP compliant capabilities enabling member nations to compete in all other major markets also such as USA,

Japan, etc. While region's trade with USA and intraregional trade appear in international trade, huge domestic business by companies of USA is not reflected. Further, many foreign MNCs also have their subsidiaries in EU.

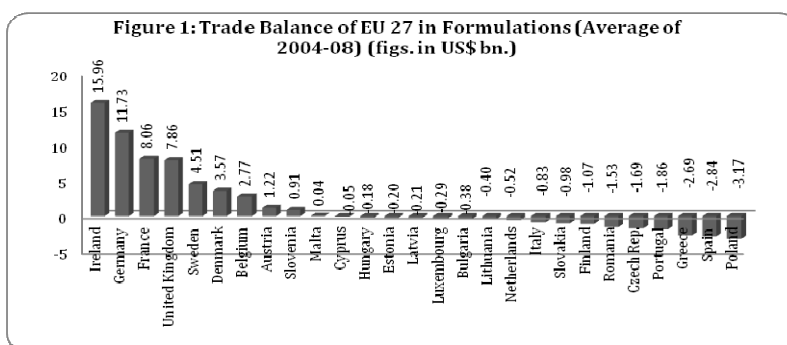
The region imported nearly three quarters of its formulations from within the region and formulations valued at US\$55.80bn were imported from non-EU countries. The major Non-EU exporting countries to EU are USA, Switzerland and Canada.

The average trade balance in formulations of EU countries from 2004 to 2008 reveals that the trade balance of only 10 countries is positive and the trade balance of the remaining 17 EU countries has continuously deteriorated during the 2004 to 2008 among which Spain, Italy and Netherlands are among the of top exporting countries of the world (refer figure 1). Poland has the highest negative trade balance and other countries with sizeable negative trade balance are Greece, Portugal, Romania, Czech Republic, Finland and Slovakia.

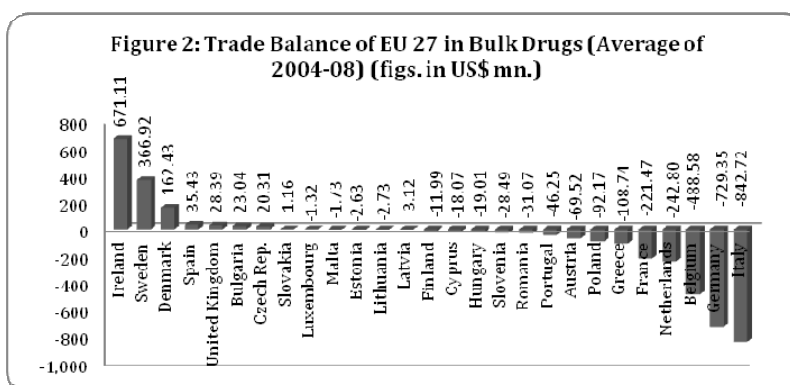
**Table 3: Top Intra & Extra EU Trading Countries of EU in Formulations (figs in US\$ m)**

Rank	Export				Import			
	Country/Area	2008	CAGR (2004-08)	% Share	Country/Area	2008	CAGR (2004-08)	% Share
	<b>Intra EU</b>	<b>170,594.71</b>	<b>13.31%</b>	<b>63.61%</b>	<b>Intra EU</b>	<b>163,918.20</b>	<b>11.94%</b>	<b>74.60%</b>
1	Belgium	33,356.13	8.51%	12.44%	Germany	41,372.11	15.23%	18.83%
2	Germany	31,653.19	13.30%	11.80%	Ireland	29,445.59	5.37%	13.40%
3	France	16,711.25	13.63%	6.23%	France	17,839.68	11.37%	8.12%
4	United Kingdom	13,431.21	7.20%	5.01%	United Kingdom	14,772.37	7.73%	6.72%
5	Netherlands	12,864.97	20.90%	4.80%	Belgium	13,382.43	13.68%	6.09%
6	Italy	11,954.81	13.04%	4.46%	Netherlands	10,309.48	17.01%	4.69%
7	Spain	11,250.50	14.62%	4.19%	Italy	10,066.82	13.62%	4.58%
	<b>Extra EU</b>	<b>97,593.90</b>	<b>12.09%</b>	<b>36.39%</b>	<b>Extra EU</b>	<b>55,804.37</b>	<b>14.71%</b>	<b>25.40%</b>
1	USA	31,105.99	8.12%	11.60%	USA	27,624.58	10.34%	12.57%
2	Switzerland	11,218.40	10.99%	4.18%	Switzerland	18,170.12	19.86%	8.27%
3	Russian Federation	6,789.89	34.16%	2.53%	Canada	1,523.28	21.56%	0.69%
4	Japan	5,061.76	11.07%	1.89%	Japan	1,491.15	3.79%	0.68%
5	Canada	4,823.88	14.82%	1.80%	Singapore	1,402.76	79.26%	0.64%
6	Australia	3,645.17	7.44%	1.36%	Israel	1,014.89	14.00%	0.46%
7	Turkey	3,294.05	17.62%	1.23%	India	831.92	30.85%	0.38%
8	China	2,532.78	40.76%	0.94%	Australia	637.36	11.67%	0.29%

Source: Research based on United Nations commodity trade statistics database 'Comtrade' & ITC



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Rank	Export			Import			
	Country	2008	CAGR (2004-08)	Country	2008	CAGR (2004-08)	
	<b>Extra EU</b>	<b>4,190-73</b>	<b>1-15%</b>	<b>46-44%</b>	<b>Extra EU</b>	<b>6,106-03</b>	<b>10-42%</b>
1	USA	1,124-75	-4-72%	26-84%	Switzerland	1,779-85	10-66%
2	Switzerland	626-40	4-19%	14-95%	China	1,685-92	25-87%
3	Special Categories	275-13	5-43%	6-57%	USA	1,390-55	-0-60%
4	China, Hong Kong SAR	220-85	135-06%	5-27%	Singapore	483-09	33-01%
5	Japan	216-40	-6-53%	5-16%	Japan	352-65	3-00%
6	Brazil	195-98	17-53%	4-68%	India	174-13	16-75%
7	Turkey	142-73	-1-02%	3-41%	Rep. of Korea	59-38	11-58%
	<b>Intra EU</b>	<b>4,833-68</b>	<b>6-60%</b>	<b>53-56%</b>	<b>Intra EU</b>	<b>4,836-00</b>	<b>2-93%</b>
1	Belgium	925-98	28-19%	19-16%	Netherlands	773-77	15-86%
2	Italy	740-04	-3-22%	15-31%	Germany	756-24	-1-68%
3	France	719-01	1-73%	14-87%	United Kingdom	649-38	2-08%
4	Netherlands	543-38	14-89%	11-24%	Belgium	501-20	22-96%
5	United Kingdom	387-06	3-02%	8-01%	Ireland	495-96	-14-91%
6	Germany	346-98	5-49%	7-18%	Spain	484-22	18-88%
7	Austria	277-62	1-75%	5-74%	France	416-87	-0-57%
8	Spain	248-15	11-77%	5-13%	Italy	344-46	2-12%

Source: Research based on United Nations commodity trade statistics database 'Comtrade' & ITC

Exports of Ireland, France, United Kingdom and Denmark are based in their strong domestic industry, while that of Germany is based strong domestic industry as also the country's strength in

trading. Belgium with production deficit of over US\$40bn (25) is a strong trading partner of Germany and Ireland<sup>21</sup>. The exports of Germany, Belgium, France, UK and Spain have grown substantially from 2004 to 2008. Ireland has

production approx. 8 times the countries pharmaceutical market. Among EU countries, France has highest production value which stood at US\$37bn in 2007.

Due to increasing formulation business of EU, their demand for quality API material has also been increasing over the years due to which the region's trade balance in APIs has been deteriorating. The average trade balance between 2004 and 2008 for EU countries reveals that the trade balance of Italy, Germany, Belgium, Netherlands, and France has substantially deteriorated rising their dependency on imports (figure 2).

Switzerland is the largest supplier of Bulk drugs to EU countries followed by China, USA, Singapore and Japan. The top intra & extra EU trading countries of the region are presented in table 4. The analysis reveals that among EU, Italy has the highest dependency on imports for APIs followed by Germany, Belgium, Netherlands and France.

### 3. Share of European Union in the Imports of Least Developed Countries & Developing Countries

There are 49 LDCs, LLDCs & SIDS and 33 developed countries, the rest are developing countries/territories. Drug regulations of 34 countries of the world are considered as highly stringent<sup>4</sup> among which 24 are developed countries while eight are developing countries. Twenty one out of all the highly regulated countries are from EU.

Nearly 94.45% of the world's total formulation imports are by Developed countries. These

countries accounted for 18.06% of the world population in 2009<sup>22</sup>. Developing countries and Least developed countries account for the balance 5.55%. Thirty four Regulated countries account for 93.55% of the total imports. European Union has a share of 58.37% in the imports of Developed countries and 11.46% of imports by developing and underdeveloped countries. The region accounted for 60.39% of formulation imports by Regulated countries.

Most of the EU countries have presence in a large number of countries of the world. UK has presence in 223 countries followed by Germany (221), France (219), Netherlands (213), etc. India, USA, Switzerland, China and Canada are the only other countries exporting to over 200 countries/territories in that order. Among these countries France is the largest supplier of pharmaceutical products to LDCs and has maintained a fairly positive growth over the last 5 years (2004 – 2008). However, during the same period, India has emerged as second largest exporter to LDCs with highest CAGR of 26%.

During the analysis it was noted that in several African countries EU formulation exports are either on the decline or stagnant or growing at a slow pace. EU formulation exports in 8 countries viz., Mozambique, Ivory Coast, Libya, Rwanda, Zambia, Guinea, Chad and Swaziland are falling, while the exports are stagnant in 12 countries among which Nigeria, Ghana and Democratic Republic of Congo are prominent. In another 5 countries including Kenya EU formulation exports are growing at a very slow pace (refer table 5).

**Table 5: Formulation Imports of Select African Countries from European Union (figs. in US\$ m & %)**

Sl. No.	Country	Imports from EU (2008)	CAGR of Exports from EU (2004-08)	Total Imports of the country (2008)	% Imports from EU in total imports
1	Nigeria	174.85	0.15%	517.41	33.79%
2	Kenya	107.04	7.82%	301.39	35.52%
3	Libya	143.90	4.83%	267.83	53.73%
4	Ivory Coast	168.79	5.41%	196.67	85.83%
5	Ghana	97.32	2.83%	196.39	49.56%
6	United Rep. of Tanzania	69.62	10.73%	189.90	36.66%
7	Zambia	6.88	-4.59%	80.30	8.57%
8	Malawi	22.38	1.55%	74.14	30.19%
9	Guinea	30.67	-2.36%	74.04	41.42%
10	Dem. Rep. of the Congo	55.27	4.15%	71.54	77.25%

Source: Research based on United Nations commodity trade statistics database 'Comtrade' & ITC

#### 4. Status of major pharmaceutical companies of EU in world Pharmaceutical market

Analysis of pharmaceutical sales of top 150 pharmaceutical companies<sup>23</sup> of the world was conducted for better understanding the status of EU in world pharmaceutical markets. Top 150 pharmaceutical companies of the world account for 82.74% of global pharmaceutical markets. The average annual sales of these companies are around US\$4.26bn. The analysis reveals that these companies are from 29 countries including 17 EU countries. North America has the highest

share in the total companies among the top 150 followed by EU and Asia (refer table 6). USA has the largest number of companies followed by Japan, India, Germany and South Korea.

The 43 companies from EU appearing among the top 150 Pharmaceutical companies account for 31.66% of world market only next to those from North America which account for 40.82%. The average size of Pharma companies of UK, Germany and Belgium is quite high indicating dominance of the industry among these countries by a few players.

**Table 6: Region-wise analysis of Pharmaceutical Sales of Top 150 pharmaceutical companies of the world**

Region (Country)	Pharma Sales (US\$ m) (2008)	No. of Companies	Average Pharma Sales (US\$ m) (2008)	% Share	Market Size 2008 (US\$ m)
<b>North America</b>	<b>261,097.21</b>	<b>40</b>	<b>6,527.43</b>	<b>40.82%</b>	
USA <sup>c</sup>	260,382.66	39	6,676.48	40.71%	<b>2,91,500</b>
Canada <sup>d</sup>	714.55	1	714.55	0.11%	21,000
<b>EU<sup>a</sup></b>	<b>202,496.51</b>	<b>43</b>	<b>4,709.22</b>	<b>31.66%</b>	
UK	72,165.62	3	24,055.21	11.28%	31,341.01
France	48,726.22	6	8,121.04	7.62%	46,998.49
Germany	44,422.46	7	6,346.07	6.94%	35,950.91
Denmark	12,656.08	4	3,164.02	1.98%	7,592.21
Belgium	8,673.56	3	2,891.19	1.36%	7,160.29
Sweden	1,589.35	1	1,589.35	0.25%	9,170.44
Hungary	1,388.27	1	1,388.27	0.22%	N.A.
Slovenia	1,311.60	1	1,311.60	0.21%	N.A.
Spain	2,512.76	2	1,256.38	0.39%	19,201.97
Czech Republic	941.48	1	941.48	0.15%	N.A.
Finland	883.39	1	883.39	0.14%	1,191.55
Italy	4,452.08	6	742.01	0.70%	30,789.80
Ireland	698.60	1	698.60	0.11%	21,017.41
Greece	1,200.54	3	400.18	0.19%	965.31
Netherlands	332.60	1	332.60	0.05%	7,766.35
Austria	326.64	1	326.64	0.05%	3,083.78
Portugal	215.26	1	215.26	0.03%	2,746.47
<b>Asia<sup>b</sup></b>	<b>95,862.83</b>	<b>56</b>	<b>1,711.84</b>	<b>14.99%</b>	
Japan	72,375.25	33	2,193.19	11.31%	80,100
South Korea	3,113.29	8	389.16	0.49%	10,600
China	250.36	1	250.36	0.04%	24,000
Israel	11,426.94	2	5,713.47	1.79%	
India	8,696.99	12	724.75	1.36%	8,500
<b>Other European Countries</b>	<b>76,365.79</b>	<b>8</b>	<b>9,545.72</b>	<b>11.94%</b>	
Switzerland	76,154.74	7	10,879.25	11.91%	26,998.49
Norway	211.05	1	211.05	0.03%	931.03
<b>Oceania (Australia)</b>	<b>3,033.69</b>	<b>1</b>	<b>3,033.69</b>	<b>0.47%</b>	<b>9600</b>
<b>Africa (South Africa)</b>	<b>466.68</b>	<b>1</b>	<b>466.68</b>	<b>0.07%</b>	
<b>LAC (Chile)</b>	<b>342.53</b>	<b>1</b>	<b>342.53</b>	<b>0.05%</b>	
<b>Grand Total</b>	<b>639,665.24</b>	<b>150</b>	<b>4,264.43</b>	<b>100.00%</b>	

Sources: <sup>a</sup>Analysis based on 'Pharmaceutical Company League Tables 2009',  
<sup>b</sup>Scrip ASIA 100 published in June 2010, Scrip News  
<sup>c</sup>IMS Health  
<sup>d</sup>Canada Pharmaceuticals & Healthcare Report Q3 2010. [www.prlog.org](http://www.prlog.org)

### 5. Analysis of revealed comparative Advantage of Pharmaceuticals & bulk drugs exports among various regions of the world

To identify the extent of advantage EU countries have in pharmaceutical exports Balassa Index<sup>22</sup> (also known as revealed comparative advantage) was constructed (refer panel 1)

World pharmaceutical exports occupy 2.66% in the total world exports. Balassa Index reveals that

most of the EU countries (16 of 27) have high revealed comparative advantage in pharmaceutical industry (refer table 7). Clearly, pharmaceutical industry is the dominant industrial sector for Switzerland, Ireland with around a fifth of their total exports coming from the sector and in case of Belgium and Ireland nearly a tenth of their total exports. The sector is also important for UK and Israel.

#### Panel 1: Balassa Index (Revealed Comparative Advantage)

Balassa Index is a measure of relative export performance by country and industry and is defined as a country's share of world exports of a good divided with its share in total world exports.

The Balassa index for country c in commodity s is given by:

$$BI = \frac{\left( \frac{X_{cs}}{X_{ws}} \right)}{\left( \frac{X_c}{X_w} \right)}$$

Where  $(X_{cs}/X_{ws})$  is share of Country c in the world (w) exports of Commodity s and  $(X_c/X_w)$  is share of country s in world total (t) exports.

**Table 7: Balassa Index of Major Pharmaceutical Exporting Countries of the world and % share of Pharma Exports in their Total Exports**

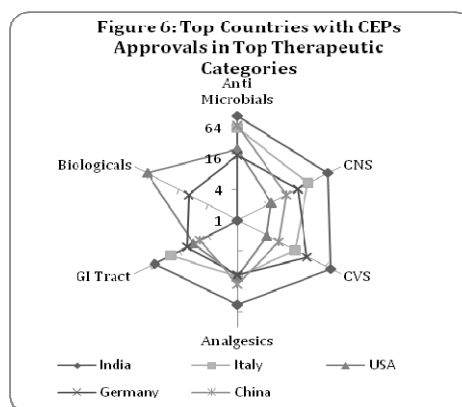
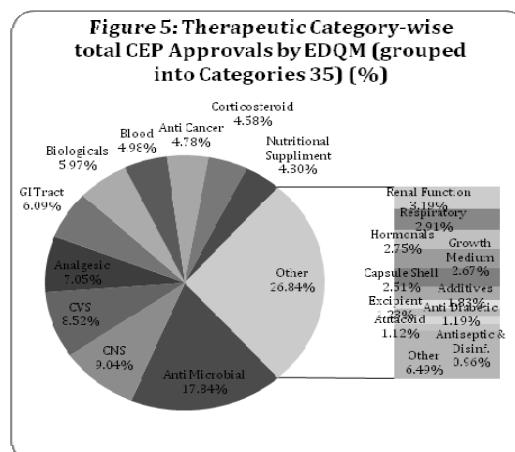
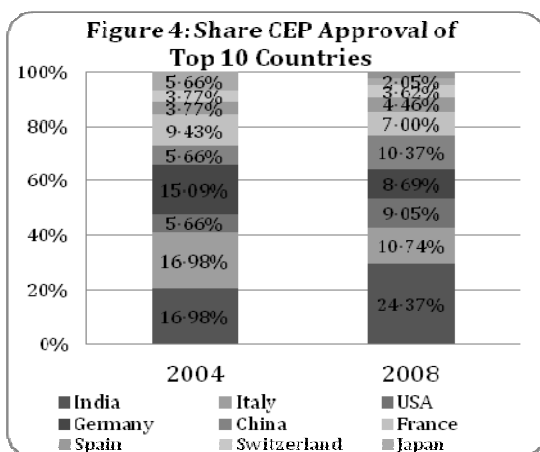
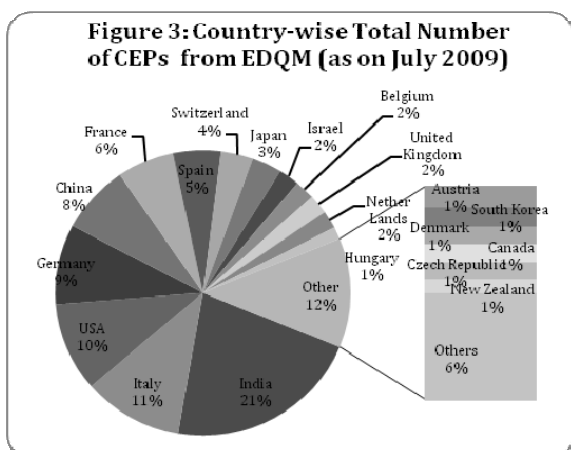
Rank on Index	Country	Balassa Index	Pharma Exports 2008 (US\$ m.)	% of total pharma exports in total exports	Region
1.	Switzerland	8.003	42,763.17	21.32%	Other European Countries
2.	Ireland	7.112	24,067.34	18.94%	EU
3.	Belgium	3.919	49,804.48	10.44%	EU
4.	Israel	2.961	4,836.74	7.89%	Middle East
5.	United Kingdom	2.557	31,030.95	6.81%	EU
6.	Denmark	2.529	7,790.53	6.74%	EU
7.	France	2.085	33,009.00	5.55%	EU
8.	Sweden	1.801	8,818.33	4.80%	EU
9.	Germany	1.638	63,979.28	4.36%	EU
10.	Austria	1.573	7,214.66	4.19%	EU
11.	Spain	1.516	11,275.49	4.04%	EU
12.	India	1.189	5,758.24	3.17%	South Asia
13.	Italy	1.152	16,476.63	3.07%	EU
14.	Hungary	1.074	3,095.32	2.86%	EU
15.	USA	0.971	36,985.91	2.59%	North America

Source: Research based on data from UN database 'Comtrade'



### 6. Status of EU bulk drug Industry – Analysis of CEP approvals by EDQM

To understand emerging status and trends of EU bulk drug industry which would form the basis for sustenance of the ever growing formulation industry and analysis of CEP approvals was performed. Research reveals that, of the total 2,511 CEPs granted by EDQM as on Jul 2009, 45% belongs to European Union countries followed by Asia (37%), North America (11%), Other Europe (4%), Oceania (2%), and LAC (1%). A total of 48 countries have received CEPs from EDQM among which India has the highest number of approvals followed Italy, USA, Germany and China (refer Figure 3). Between 2004 and 2008, China, USA and India have increased rapidly in their year-wise CEP approvals while Italy, Germany, Spain and France have decreased (refer figure 4). It may be noted that India, China and Italy also have highest number of Type II Active DMFs (which pertains to APIs) with U.S. FDA<sup>24</sup>.



Source: Research Based on EDQM online Certification database

Analysis of number of CEP approvals granted by EDQM according to therapeutic categories of molecules reveals that the top five therapeutic categories to be anti-microbials, Central Nervous System (CNS) drugs, Cardio Vascular System (CVS) drugs, Analgesics and Gastro Intestinal (GI) Tract drugs (refer figures 5 & 6). Antimicrobials have the highest share of 17.84% among the CEP approvals by EDQM which is in line with the fact that infectious and parasitic diseases are leading cause of fatalities in EU<sup>11</sup>. India, China and Italy have the highest number of CEPs in this therapeutic category. Among the top countries, India, after Anti-microbials has the largest number of approvals in CVS, CNS, GI Tract and analgesics in that order. In CNS India has gained significantly offering potential competition to Italy & Germany and while in CVS the country is offering competition to the Germany & Spain. Italy has highest number of CEPs in Antimicrobials, CNS, Corticosteroids, GI tract and Anti Cancer molecules. USA has the highest number of approvals in biologicals

followed by Growth Medium, Antimicrobials, expectants and Analgesics.

Out of the 1,177 molecules and their derivatives granted CEPs by EDQM, 62.28% have only one approval and another 15.46% have only two approvals. Only 14.61% of molecules have more than four approvals. Majority of the countries (28) have filed only one CEP per molecule. This indicates that countries and companies are strategically limiting competition by spreading their basket of molecules. The top five countries having highest ratio of number of CEP approvals to molecules are Non-EU countries viz., India (1.97) followed by Japan (1.52), China (1.39), and New Zealand (1.31) and Australia (1.29).

Over 80% of all inspections by EDQM from 2004 to 08 were those of India and China<sup>25</sup> indicating their increasing role as supplier of quality APIs. EDQM is reported to be embarking on another major campaign of inspections in China during the year 2010<sup>26</sup>. The trend of aggressive filing with EDQM by India and China is likely to further strengthen due to recently initiated process between Europe and India to work more closely on drug quality<sup>27</sup>.

## CONCLUSION

European Union occupies a lion's share in world exports of formulations and nearly half of the world bulk drug imports. The region captured large share in intra regional trade. However, the trade balances of many EU countries especially

those of Spain, Italy, Netherlands which are among the top pharmaceutical exporting countries of the world are deteriorating during the 5 year from 2004-2008. Due to increasing formulation business of EU, the region's trade balance in APIs has also been deteriorating.

Majority of the world's total drugs & pharmaceutical trade is among Developed countries. The region also has large number of global pharma giants. Over 1/3<sup>rd</sup> of the top 150 global pharmaceutical companies belong to EU countries. Majority of EU countries also have high Revealed Comparative Advantage in Pharmaceutical exports. The sector as a major export earner is very important for many countries of the region especially to Ireland, Belgium, UK and France.

Between 2004 and 2008, China, USA and India have gained significantly in their share in CEP approvals, while Italy, Germany, Spain, France and Japan have lost. Italy is facing challenge from India and China in Antimicrobials. In CNS India is threatening Italy and Germany and in CVS it is in direct competition with Germany and Spain. India's share in CEP approvals reached over 30% on July 2009 demonstrating quality compliance capabilities. The country has also made significant strides in GI Tract molecules and analgesics. China is emerging as a threat not only in Antimicrobials but also Analgesics, anti-cancer molecules and Nutritional supplements.

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