“International Procurement Forum”
CPhI Japan, April 21st 2016

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Achievements of Indian Pharma Industry

- Self reliant
- Affordable global child care through biologicals/vaccines success
- Affordable healthcare for HIV patients worldwide
- Affordable health care for more than 500 molecules
- width and depth of product portfolio helping health budgets of nations. US alone could have saved $1 Trillion.

India's Pharmaceutical exports

India's Exports of Pharmaceuticals during the last Five years (USD billion)

2010-11	2011-12	2012-13	2013-14	2014-15	CAGR%
10.7	13.3	14.6	14.93	15.4	10

- ~ 5% of India's manufactured exports. 5th largest commodity in exports. Growing ~ 3%
- Over 55% exports of India are to highly regulated markets. India exports around 3.6 bio $ API and 11 bio $ formulations
- Pharmaceuticals are exported to 220 countries. Vaccines to 150 countries. 6 companies in global top 20 are from india in generics
- 615 manufacturing facilities registerd with usfda. Supplies 70% medicines distributed by NGOs. 3000 dmfs and 3000 andas filed. A dominant player

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6 Indian companies are amongst the top 20 globally

Rank	Company	Country	2014 In $ billion	GR%
1	Teva Pharmaceutical	Israel	9.1	-1
2	Novartis	Switzerland	8.6	4
3	Actavis	Ireland / USA	6.6	6
4	Mylan	USA	6.6	10
5	*Sun Pharma india*	India	4.5	68
6	Aspen	South Africa	3	13
7	Hospira	USA	2.6	12
8	Sanofi	France	2.4	11
9	Fresenius	France	2.3	+/-
10	*Lupin india*	India	2	19
11	*Dr.Reddy's india*	India	1.8	10
12	Apotex	Canada	1.7	-2
13	STADA Arzneimittel	Germany	1.6	-1
14	*Aurobindo india*	India	1.6	75
15	*Cipla India*	India	1.4	17
16	Krka Group	Slovenia	1.3	1
17	Valeant Pharmaceuticals	Canada	1.2	-17
18	*Zydus Cadila India*	India	1.2	28
19	Par Pharmaceutical Companies	USA	1.2	20
20	Nichi-Iko Pharmaceutical	Japan	1.2	12
	Total of Top 20		74.2	7

Country	Companies in top 20
India	6
USA	4
France	2
Canada	2
Japan	1
Germany	1
Switzerland	1
Slovenia	1
South Africa	1
Israel	1

Top 20 Companies account for 26% .16 of the above 20 MNCs have manufacturing units in India for catering to India and Global Markets.

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Source :Evaluate

Top 10 Generic Markets & India's Presence

Top Ten Generic market size and India's Exports in $ bn								
	2008		2011		2014		CAGR %	
Country	Mkt Size	India's exports	Mkt size	India's exports	Mkt Size	India's exports	Mkt gr	India's Exports
United States	*50*	*0.95*	*60*	*2.5*	*70*	*4*	*6*	*22*
China	18	0.01	43	0.008	63	0.02	23	12
Germany	10	0.09	11	0.19	13	0.15	4	9
Japan	6	0.01	12	0.03	12	0.03	12	76
UK	*8*	*0.19*	*8*	*0.34*	*11*	*0.37*	*5*	*12*
Russia	*6*	*0.28*	*8*	*0.36*	*9*	*0.42*	*7*	*7*
Brazil	8	0.14	11	0.11	8.5	0.2	1	6
France	6	0.06	6	0.12	8	0.13	5	14
South Korea	6	0.01	7.5	0.009	7	0.01	3	0
Canada	4	0.03	5.5	0.1	5	0.13	4	28

- Significant in USA and non existent in china

Source: IMS/BMI

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Accreditations of Indian pharmaceutical Industry

Authority	Name of Regulatory Agency	Nos.
USA	Number of Companies filed DMFs filed with U.S. FDA (As on Dec 2013)	265
	No: of Sites(Bulk drugs + Formulations) Approved byUS FDA (as on 30th June 2014)	584
	Total No Of DMF's (Type II Active) Filed from India (as on 30thDec 2013)	3411
	ANDAs(As on 31st Dec 2013)	2661
	Formulation companies with USFDA approvals.	32
WHO GMP	WHO GMP Certified Plants (as per Drug Controller General of India)	1400 (approx.)

Accreditations of Indian pharmaceutical Industry

Authority	Name of Regulatory Agency	Nos.
EUROPE	Number of CEPs received (as of 31st Jan 2014)	1105
	Number of companies with CEPs	155
	Number of Molecules for which CEPs have been filed with EDQM	344
	No of Sites approved by EDQM In India(As on 30th April 2013)	353
	UK MHRA (Medicines Healthcare Regulatory Agency), Market authorizations as March 2013	1110
	Number of CEPs with Irish Medicines Board	300
	Number of companies registered in Irish Medicines Board	19
	Number of Authorisations with Sweden MPA (Läkemedelsverket)	209
	Number of companies having MA`s with Sweden MPA (Läkemedelsverket)	14

MEMORANDUM OF COOPERATION
BETWEEN
THE MINISTRY OF HEALTH, LABOUR AND WELFARE OF JAPAN
AND
THE CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
OF
THE MINISTRY OF HEALTH AND FAMILY WELFARE
OF
THE GOVERNMENT OF THE REPUBLIC OF INDIA
ON
MEDICAL PRODUCTS REGULATION DIALOGUE AND
COOPERATION FRAMEWORK

The Ministry of Health, Labour and Welfare of Japan (MHLW) and the Central Drugs Standard Control Organization (CDSCO) of the Republic of India under the Ministry of Health and Family Welfare;

Our Inference and Request

1) The employment of in-country care-taker should be optional;

2) The DMF registration data should be directly applied using the CTD format, if they are written in English with minimum translation into Japanese for the application dossier of the drug products. This will also avoid any errors in translation.

Japanese Master File System

- In the cases where a foreign manufacturer registers an MF in Japan, an in-country caretaker must be appointed as the person who has an address in Japan and who is to perform the clerical registration.

- The MF registrant(foreign manufacturers) must disclose the information contained in the restricted part to in-country caretakers. Foreign manufacturers consider that the system in Japan may lead to violations of business confidentiality.
- Direct MF registration is possible in Europe and the United States but, in Japan, MF registration can only be made through the agency of mediating in-country caretakers.

Japan's Change Control systems/Post-Approval Change Application:

- It is normal for API manufacturers globally to try to change production process for; (1) Reduction of cost (this is beneficial for both supplier and customer) (2)Product improvement (better quality etc.)
- The review time is very long, it generally takes one year; longer than EU or US.
- During this time, foreign manufacturers cannot supply to Japan until review and approval is complete. This causes issues in stable supply (for Japan side). For foreign suppliers, it affects business and production management.

- The criteria to distinguish between what is considered a Major Change and Minor Change can be improved.
- To avoid risk, the reviewer (Japan) tends to judge the change as Major Change rather than Minor Change. In other words, Minor Changes in the US tend to be treated as Major Changes in Japan.
- Minor Changes in the US or EU can be resolved through Annual Reports whereas in Japan, every type of change must be frequently and immediately reported. A minor change must be submitted to PMDA within 30 days of the change being made.

Suggestions

- In Japan, it is either Major or Minor Change. Whereas in US and EU, there are several mid-level classifications and categories, not limited to 2 (Japan) and according to the risks with concrete criteria given so that it is much more clear for everyone to understand and make the right application. Thus the review time could be shorter as views can be discussed between applicant and the reviewer and the appropriate category of change application can be submitted.
- We feel that the review period of Major Change Approval should be reduced to 6 months rather than 1 year.
- If there is more clear classification and criteria, better planning will lead to smoother and faster implementation and approvals.

Other Issues

- Unharmonised regulations PMDA Vs ICH for e.g. for Residual solvents.
- Results in API manufacturers producing two different grades of product for Japan and other markets, for cost reasons.
- Some additional tests in JP does not help companies to offer competitive pricing.

ありがとう