Roadmap for inviting Pharmaceutical Manufacturing Entrepreneurs Big or Small in the State of Jharkhand

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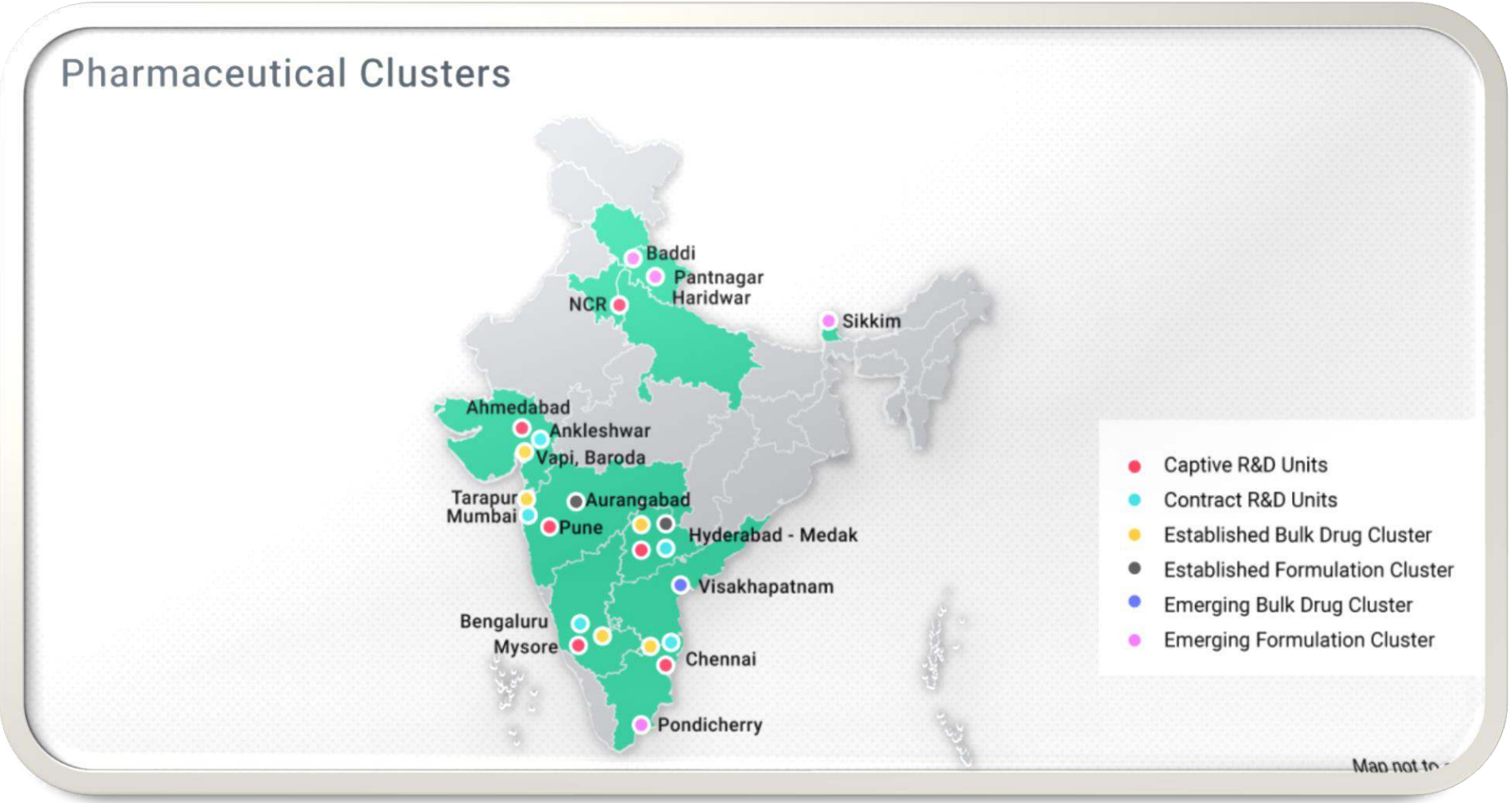
India as pharmacy of World

- India is often referred to as the “Pharmacy of the World”, with a global rank of third in terms of production volume and 10th by value.
- It is the largest producer of generic medicines and vaccines, occupying 20 per cent volume share in generic drugs and 62 per cent in vaccines.

Distribution of different Pharmaceutical Industry in India

- **Traditionally, the pharma industry has been concentrated in a few states.**



Distribution of different Pharmaceutical Industry in India

- **Bulk Drug clusters-** Vapi, Vadodara in Gujarat, Tarapur (Maharashtra), Hyderabad, Mysore, Chennai ,Mohali (Punjab) and Bhiwadi (Rajasthan).
- **Emerging Bulk Drug Clusters** -Dewas, Lalitpur(UP) and Rudrapur(UK).
- **Formulation clusters-** Aurangabad (Maharashtra) , Hyderabad, Pune, Ankleshwar, Mysore, Chennai and Hyderabad.
- **Emerging formulation clusters.** Baddi (Himachal Pradesh), Pantnagar and Haridwar have
- Himachal Pradesh has been a leader in drug manufacturing. More than one-fourth of India's formulation drugs are produced and supplied from Baddi – **Barotiwala -Nalagarh (BBN)** industrial belt bordering Chandigarh. With 800-plus pharmaceutical units, including top brands like Cipla, Dr. Reddy's Lab, Cadila Healthcare, Abbott Laboratories, Ranbaxy, Glenmark, Acme Formulation and Morepen posting a turnover of Rs.5000 Crores, BBN is Asia's biggest pharmaceutical hub.
- Himachal Pradesh is strongly pitching itself as the ideal state for the Rs.1000 Crs bulk drug park, one of three proposed for the country.

Government policy

- The Government of **India's Pharma Vision 2020** is aimed at making India a global leader in end-to-end drug manufacturing.
- The government also plans to set up an **early Rs 1000 billion fund** to provide a boost to companies to manufacture pharmaceutical ingredients domestically. **100 per cent Foreign Direct Investment is allowed under automatic route for green-field pharma and brownfield pharma each, wherein 74** per cent is allowed under the automatic route and thereafter through government approval route.

- The Union Cabinet has cleared the scheme for setting up **three mega "bulk drug parks"** in partnership with states. Each will have an investment of **approx Rs 10,000 Crores.**

- There are **14 states in the running to grab these bulk drug park projects by offering top infrastructure and logistics facilities to the API companies.**

- Availability of railway connectivity, highways, airport, and basic infrastructure are also requirements cited in the bulk drug park proposal. This park will benefit existing companies and will also generate jobs in the state.

Government policy

- **The industry is expected to get a boost with the introduction of the Production Linked Incentive (PLI) Scheme for the domestic pharmaceutical sector for financial years 2020-21 to 2028-29.**

- **Incentives of the order of around Rs.1,50,000 Crores will be provided under the scheme.**

- **The scheme will benefit domestic manufacturers, help generate 30,000 direct and 90,000 indirect jobs, and will likely make available a wider range of affordable medicines to consumers. It is also likely to boost production and export of high-value products.**

Government policy

- **Total incremental sales worth Rs. 2.94 Trillion (One lakh Crore is equal to One Trillion) and incremental exports of Rs. 1.96 trillion are expected during the six years from 2022-23 to 2027-28.**

- **The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods. It is expected to promote development of complex and high-tech products, emerging therapies and in-vitro Diagnostic Devices.**

- **The scheme is expected to bring in investment of Rs. 1,50,000 Crores in the domestic pharmaceutical sector. The manufacturers of pharmaceutical goods registered in India will be grouped based on their Global Manufacturing Revenue (GMR) to ensure wider applicability of the scheme across the industry and at the same time meet objectives of the scheme.**

Additional Regulatory Requirement for Global Pharma

- Classification of Manufacturing Site as per Regulatory Certification.

Sl No	Regulatory Certification	Regulatory Reference Guideline	Issuing Authority	Permitted Market
1.	**C –GMP** Certified	Schedule M & M1 as enacted in Drugs and Cosmetic Act 1945	Local FDA (SLA) of that particular state.	Domestic Market
2.	**WHO-GMP** Certified	WHO –TRS/ICH	CDSCO will issue COPP	Rest of the World/Semi Regulated
3	**PIC's (Pharmaceutical Inspection Certification Scheme)**	PICS /ICH--Guidelines	Participating Authority of member country.	53 Countries.
4	**USFDA, EMA, PMDA(Japan)**	21cfr210/211, EU Guide,Respective Country Guidelines	Respective FDA authorities	Regulated market of European Union and Japan.

Expression of Interest

How to Showcase the “**Expression of Interest**” for inviting Investors in this Pharmaceutical Manufacturing Venture?

i.e What pathway should be paved for this venture….

Salient feature of the “Expression of Interest” to invite Pharma Industry

- Step 1– Policy drafting for Green Field and Brown Field ventures and projects.
- Step 2—Protocol for Expression of Interest.
- Step 3– Showcasing and Promotion/Constitution of core driving team.
- Step 4– Short term and Long term support and engagement.

Here we will be focussing on activities involved in Step 1 and Step 2

Salient feature of the “Expression of Interest” to invite Pharma Industry

- After equipping ourself with promotional and propaganda materials

We can approach following pharmaceutical association

1. **IDMA**—Indian Drug Manufacturing Association.
2. **OPPAI** ---Organisation of Pharmaceutical Producers of India.
3. **BDMA**—Bulk Drug Manufacturer Association.
4. **AISSPMA**---All India Small Scale Pharmaceutical Manufacturing Association.
5. **FICCI -**----Federation of Indian Chambers of Commerce and Industry.

and few more …. ,

We have to keep a watchful eye on these chapters and their sponsership programmes.

Salient feature of the “Expression of Interest” to invite Pharma Industry

- Look out for events organised by
- **IPC** i.e Indian Pharmaceutical Congress ---Annual Events.
- **CPHI**—Convention on Pharmaceutical Ingredients.
- **P-Mec**—Pharmaceutical Machines and Equipment’s Conventions.
- We can approach the office bearer’s and ask for slot in various seminar for allowing our spokesman to give a talk or presentation inviting investments.
- Setting of kiosk’s in their exhibition for showcasing our presentation and discussion.
- Directly approaching principal Industrialists and Entrepreneurs.

Current Business trends in India

- **In business terms Formulations Enterprise can be categorized into Two major groups.**

1- Established Companies,

Noteworthy presence in the market in terms of turnover ,corporate entity ,manufacturing establishment, warehouses and marketing networks ---all are supported by well defined management tools

e.g—Alkem,Dr Reddy,GSK, Pfizer, Sun Pharma, Cipla, Glenmark etc (these companies have considerable turnover are ranked between 1 to 100 in ORG list). Roughly only 30% to 40 % of marketed product list are manufactured in their in house facility rest are out sourced to 3rd Party MSME units.

2-Virtual Companies,

Small to medium MARKETING enterprises having modest turnover and the focus is only on marketing.

e.g –For reference you can buy a current copy Drug Today , almost more than 25000 companies are listed.

“Leeford” is one such company having turnover of Rs 800 crores yet they do not have manufacturing facility of their own.

Current Business trends in India

- Blue chip companies manufacture's only 30 to 40 % of listed products(Ethical or Generics) in their manufacturing facility. Rest 60 to 70 % are outsourced to Contract Manufacturer (or 3rd Party Manufacturer) who delvers their contracted products on Loan License or P2P basis.

- So it can be concluded that if there are more than **10,000** Pharmaceutical Formulations manufacturing sites in India , then only about 8% to 10% of sites are owned by Established Company rest belongs Contract Manufacturers(MSME entity).

- Contract Manufacturer cater (mostly MSME entity) their services to both **Established Enterprise** as well as **Virtual Enterprise.**

Current Business trends in India

- GMP certification are allocated to facility only after stringent Audits conducted by regulatory authorities.

- There are many reasons for conducting Audit of an API /Formulations Manufacturing Site.

- Outcome of Audit assures that the Quality Systems and Manufacturing procedures adopted on manufacturing site reflect actual practice (what we say is what we do); it also uncovers inaccuracies so they can be quickly corrected; Reveals the consistency of a process (from person to person, or on day to day basis).

- **Auditing** is a vital **function** within a **pharmaceutical** company nowadays. Quality **audit** is a review and evaluation of all or part of a quality system with the specific **purpose** of improving it.

Regulatory Respoinsibility

- Once the Ventures starts shaping up ---the Cardinal role of Local Licencing Authority or Local FDA starts.

- All the concerned in Drug Controllers Office have to appraised and upskilled for the occasion as they are the Regulatory Body who will flag off the operations after proper auditing of the plant.