14. Role of Pharmexcil in Facilitating Pharmaceutical Exports

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Pharmexcil at present is assigned the responsibility of facilitating export promotion in the pharmaceutical sector. Due to a variety of constraints pharmexcil is at present only scratching the surface and needs to do a lot. All this will be possible only through concerted efforts of the government and all segments of the industry. The following additional activities are suggested to be taken up by Pharmexcil:

A. Creation of Functional Desks

Functional desks should be created under Pharmexcil to assist industry and regulatory agencies in the following areas:

- **Legal** - Help Indian pharmaceutical organisations to understand intricacies in international contracts for international sale of goods, agency/distributor agreements, JVs, Technical tie-ups, legal environments of various countries, dos and don'ts with respect to obligations etc., Develop standard agreements/templates and keep in export council library, which can be used by members.
- **Marketing** - Help organisations to obtain international marketing knowledge. Develop information base on each country with respect to the structure of the market, environment, SWOT analysis, registration requirements, etc. Collect experiences on countries through active interface with industry and institutionalize the information.
- **Learning and Development (L&D)** - Providing L&D in marketing areas especially distribution, pricing, packaging, promotion, etc., knowledge about market environment in relevant countries to members.

B. Intellectual Property:

The IPR cell should take the following activities:

- **Intellectual Property Rights** - Help organisations in API process development and formulation development.
- Provide Learning & Development in IPR areas. Develop an information base of case laws related to IPR issues. Develop a learning module by experts for members to appreciate the intricacies in developing and defending non-infringing processes and invalidation of patents.
- Confidential evaluation of non-infringing processes and suggestions to build non-infringing processes for medium and small enterprises

Aggressive training programs in IPR with international experts to facilitate L&D are required in:

- Developing innovative process patents
- Drafting intelligent patents
- Training people in international patent laws and regulatory affairs laws

- Analyzing Legal case studies, etc.

C. Regulatory Research Desk

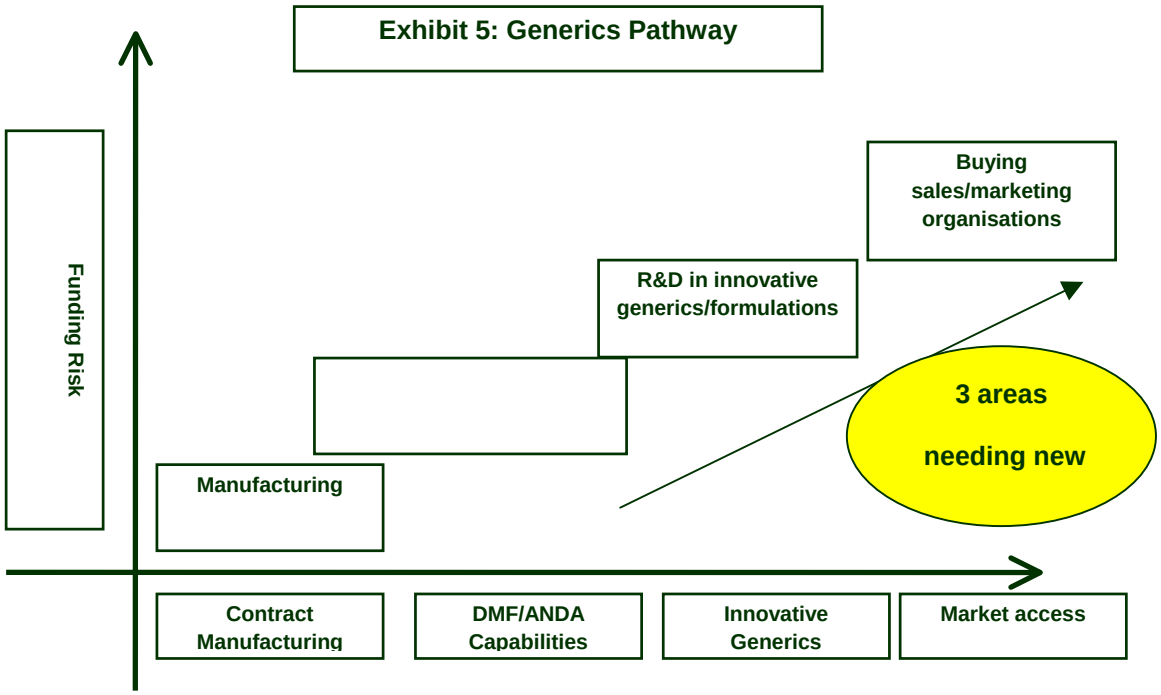
The role of the regulatory research desk should encompass:

a. Helping organisations in understanding regulatory procedures of various countries.
b. Developing useful information base on regulatory requirements, guidelines, and facilitate learning modules to understand the process of registration and understanding intricate issues involved in drug registrations.

E. Advisory Services Centre

- Providing guidance and inputs to financial institutions with respect to R&D. The main function is to encourage venture capital based funding in the areas of DMFs/ANDAs/innovative formulations/NCE building blocks such as contract research hubs; large testing centres, bioequivalence centres, data management centres on a risk and reward-sharing basis and patent filing fund which gives partial funding on profit sharing basis. Exim bank along with export promotion council can work on these strategies. (Exhibit 5 for Key areas requiring a framework).

Exhibit 5: Generics Pathway



The above cells, desks may also develop information databases in the following key areas:

a. Legal information base with standard templates to help members
b. Marketing information base with good information on various countries, market potential, marketing environment, etc.
c. IPR information base

d. Regulatory information base with good collection of all regulatory guidelines for various product classes, facilities in various countries.