

# A Problem of Mindset

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To keep pace with the needs of these changing times, it is absolutely essential that we do not continue to do today's job with yesterday's methods and expect to be in business (or industry or Government) tomorrow. It is needed unfortunate and sad (that is another story) to note that a pragmatic and practical approach is lacking as evident in some of the decisions being arrived at and being communicated by the DGFT/Commerce Ministry. The irrationality of some decisions forces the technical entrepreneur - R&D based manufacturer exporter "to tear his hair to tears" wondering what to do next and which door to knock for help and succour.

The Indian pharma (including bulk drug and intermediate) manufacturer-exporters, especially the research-oriented and technical entrepreneur manufacturers, have tremendous potential to cater to the wide-ranging technology-based products - both bulk drugs and intermediates - needed increasingly by developed countries. Some of these are new drugs (or intermediates for new drugs) which are "first time" enquiries. Being new drugs, they could not have been "enquired" or manufactured before. A few others are proven drugs of yesteryears which have been overtaken by aggressively marketed new drugs. With the advent of NDDS (New Drug Delivery Systems) and related benefits to patients, some of the older drugs which were not recently in demand are also receiving renewed interest.

These developments are leading to enquiries for bulk drugs, hitherto not manufactured in India. Indian Techno-entrepreneurs have no option than to respond promptly as is required in this electronic age. They have to first examine if they have the "in-house" potential and expertise to develop the item. They have to search and review available technologies and choose or alter appropriate process to suit their in-house technological and infrastructure capabilities. After lab trials and developing a lab sample (with matching impurity profile) they get the sample approved by the buyer. An order follows.

In fact one would think that the war is won. Not so. In fact the real war starts now. Being eligible, and being cash-strapped, the entrepreneur-exporter (often an export house) applies for fixation of input-output norms in Form 11-B and applies for a provisional advance licence, which he is issued. He imports the raw material and exports the bulk drug (or intermediates) successfully and to the best satisfaction of the valued customer.

Everyone should feel happy. "CRM" at its best. The Nation benefits export grows, foreign exchange flows in, both skilled and unskilled job opportunities are provided and the viability and healthy future of the Technical Entrepreneur is reassured. Looks like the ideal setting for a comedy.

No, Not so soon. Now, remember the application he made for fixation of input-output norms. Being in Pharma Industry, among the "Trimurtis" of Finance, Commerce and the Parent Industry Ministry of Chemical & Fertilizers, trouble has been brewing for him. A plethora of enquires (about flow-chart, material balance, reaction process report, justification for consumption, yields etc - which is only fair) comes from the C&F Ministry, which are replied to the best of one's ability.

However, often the data sought go beyond the material ratios and yield concerns. After providing all these, he gets a jolt (a bolt from the blue). The letter from the office of the "Foreign Trade Development" (?), representing the DGFT, New Delhi saying "The Committee after deliberation decided to reject the case on the grounds that there is no substantial production of this export product and would be premature to fix the SION (Standard Input-Output Norm)".

Does this make one laugh or cry or tear his hair in despair?

A first-time technology-developed, speciality-export product manufacturer deserves support and encouragement, even deserves award or appreciation. These are not days of Aspirin, Paracetamol or Trimethoprim. The moment an item becomes a bulk commodity we mostly loose out to China or other competitors, because of high domestic costs of fuel, power, infrastructure and other handicaps (that is another story).

Our future is in "first-time developed" new products because they are technology intensive and special CRM (Customer Relation) and CRAM (Contract/Custom Research and Manufacturing) based. How can a manufacturer who after extensive customer-contact and relation-development, lands up an order for a new product, manage to provide details of "substantial production in the country" for input-output norm fixation ?

There has to be a first time for everything. He is called a "Pioneer". He doesn't, he can't follow the oft-beaten track. He has immense challenge of finding his own way. He is no "buffalo" to follow the "pack". A "Pioneer" needs special treatment. The "DGFT" or whoever is the authority on this vexed issue has to solve this "Mind set" problem.

It should also be appreciated by the DGFT and C&F Ministry that when a new process or a new intermediate (route) is developed for first time in the lab and the same is scaled up, there are going to be problems. Only on continued production of many batches will the manufacturer be able to optimize yields, recoveries, recycling etc. Till such time, the enterprising R&D based manufacturer must be given a "handholding" assistance by granting him a Provisional Input-Output Norm (PION) to be confined into a Standard Input-Output Norm (SION) in due course, may be one year. Such pragmatic and practical approach will help the Nation financially by boosting exports and the confidence levels of the entrepreneur-research-manufacturer-exporter.

Many more cases like this are going to come and need be dealt with by DGFT more "positively" and "productively".

A first time grant of a provisional "SION" after preliminary scanning and scrutiny must be issued. The same can be referred to one among a Panel of Technical experts who can be drawn from Universities and Academies and can be "finalized" thereafter in due course for future fine-tuning for a permanent "SION". No rejection should be made summarily. Especially when a genuine exporter has already imported and exported on advance licence and is given a "reject" letter, he has now not only to pay the duty, he has to pay the interest and also the penalty. Oh, God, what a "BOOM" of a "BOON". When will we rise from here ? Will someone do something to save this Nation?

--- The author is Advisor, Bulk Drug Manufacturers' Association