Restricted pharmaceutical exports from India: Are you ready to mitigate risk of drug shortages?

On March 3rd, concerns over supply chain shortages led the Indian government to place limits on the export of a significant number of API's and finished formulations to ensure drug availability in India for domestic consumption.

Several antiviral and antibiotic drug substances and drug products are included in the restricted list. If restricted over a prolonged period, there is a risk of possible drug shortages globally.

It is likely that global drug manufacturers will plan to take proactive steps to deal with possible drug shortages. Manufacturers may be considering:

- Addition of manufacturing capacity in other regions (e.g. US or EU) either at sites within their own network or through use of contract manufacturing facilities.
- Addition of new sites to approved ANDA, NDA, MAH
- Consideration of expedited regulatory review processes

Parexel's regulatory consulting group can help!

Drawing expertise from our 1000+ strong global consulting team, we are ready to assist pharmaceutical companies in several ways including:

- Due diligence
- CGMP compliance
- PAI audits
- Inspection preparedness of sites

Our regulatory consulting group includes 80+ former regulators who have experienced these situations on the agency side, and know how to help manufacturers rapidly navigate the process of submitting a supplemental application or variation to add a site; and utilizing the drug shortage processes at FDA, EMA, etc.

Manufacturers may be concerned that an inspection will delay a quick approval of a supplement. Our compliance team can help ensure that the site is ready, strategize about possible inspection waivers, and help you pick the right site to accelerate time to manufacturing.

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