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Testing, quality norms differ

Dr P V Appaji

The quality issues arise because of various factors. It could be storage conditions in the importing country, approved by local FDA and/or cold storage provided in the supply chain, etc. The methods of testing, adopted by the exporters and the regulatory agency as standard may differ and become a factor. It is also noted that in cases where regulated markets are involved, most of the observations relate to data integrity.

India has over 1300 World Health Organisation GMP (Good Manufacturing Practice) certified manufacturing units. This endorses India's pharmaceutical chemistry skills as of the same order as seen in developed countries and does not give room for any doubt on its capabilities.

India has also been a source of contract manufacturing for many multinationals even for patented drugs. Most of the MNCs were outsourcing only early stages of manufacturing process to India's companies. In the recent past, even the late stages, including complex chemistry manufacturing processes have also been outsourced to Indian companies, which speaks of the increased confidence in Indian manufacturers.

Pharmexcil (Pharmaceuticals Export Promotion Council of India, set up by Government of India), as a part of its knowledge exchange programme, invites officials of regulatory agencies of designated countries and takes them on a visit to India's exporters' manufacturing sites. This showcases India's pharmaceutical chemistry skills, manufacturing discipline employed and builds their confidence. As is the case with any domestic industry, it is possible that India-sourced generics may also face some quality problems.

(Dr Appaji is Director General, Pharmexcil, Hyderabad)

Regulatory.