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Global regulatory agencies bogged down by staff shortage to oversee patent expiry drugs

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With patent expiry drugs expected to reach record levels in the near future, global regulators are expected to vet increased number of applications and their task could only expected to get humongous as these agencies are unable to hire additional manpower to shoulder sudden surge in workload.

"It is unlikely that US and EU regulators will expand their staff to any large extent given the current economic climate where there is a need for governments to control costs of operation unless the industry pays for more people to be employed. This is based on the Prescription Drug User Fee Act that allowed the FDA to recruit more staff in return for quicker assessment times," Dr Mike James, ex UK Regulator (MHRA) and Technical Director, Cambridge Regulatory Services Ltd, UK told Pharmabiz in an email interaction.

For companies, increased number of applications could mean slower assessments and higher fees giving more reason for regulators to reject inadequate or incomplete applications so that these dossiers do not clog up the assessment system, he added.

Pricing and reimbursement are separate issues in drug approvals. It is possible to gain approval to sell (license) but not be able to negotiate a suitable reimbursement price with the health care system in a country. This phenomenon is common for expensive biotechnology drugs where the annual expenditure for each patient can be in excess of $20 000. With limited budgets for all health care funding agencies including insurance, the cost control in budget allocation for drug purchase is the focus. In the wake of this scenario, the regulatory agencies are looking for faster approval of generic medicines and biosimilar products. It will see more companies competing to bring down the prices of drugs.

The markets of EU and US for generics are large in volume, but not in price when compared to costs obtained by the originator products. But demand for generics are bound to grow substantially in the next few years with a rise of an ageing population and with many current blockbuster drugs expected to lose patent and market exclusivity protection. It is estimated that drugs going off patent over the next three years is valued at Rs.320,000 crore (US$ 80 billion).

According to Dr James, there are several barriers to enter the international regulated markets for generics. Cost of doing business in the US and Europe are higher than in India. This is because the modes of pharmaceutical distribution in these developed countries are different from India. The former needs a local partner to ease market entry and a good local firm that understands the rules and culture are critical to the successful launch of a new company and its products into these markets.

Dr. James recommended that pharma and biotech companies should diligently plan and understand the requirements of each market. For instance, data generated for India will not automatically be applicable for other regulated markets. Any development programme should use international standards to maximize product acceptability in multiple markets.

Also he suggested that companies with no prior experience of the USA or EU regulatory framework should take professional advice to ensure that their applications are not rejected for proper compliance of guidelines.