Current Trends in Pharmaceutical Development

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Any discussion on pharmaceutical manufacturing, research and development, clinical trials, active pharmaceutical ingredients (APIs) will always find India and China being mentioned in the same breath. It has been over three decades since the pharmaceutical industry began the journey of out sourcing non-core competencies to CxOs. This has resulted in excellent up-gradations to infrastructure to meet the sponsors' and regulatory expectations. We have seen many emerging companies gaining highly regulated market approvals specifically USFDA, EMEA and so on for API and finished formulations. The more established generic API manufacturers currently focus on still-under-patent molecules so as to be ready to launch as soon as the patents expire. Many of the API manufacturers are not only working as providers of drug substance to their end users, the formulation companies, but also participating as partners with them as contract developers, to effect both backward and forward integration. CRAMS (Contact Research and Manufacturing Services) is now one of the most preferred modes of partnership, expected to grow to US$65 billion over the next five years recording a year on year growth of over 10% according to several reports. This trend of partnerships is likely to eventually result in mergers and acquisitions across countries and borders. Another major factor promoting consolidation of capabilities and elimination of redundancies is the dwindling number of NCE approvals and hence profitability of innovator companies over the years. First and second tier generic companies have evolved from being domestic players to worldwide suppliers of APIs, finished dosage form companies have moved from being domestic marketing companies to being formidable export houses and yet other companies have become more research-driven elevating from conventional dosage forms to more complex new drug delivery systems. However platform technologies and radically different delivery systems are still coming only from the large based pharmaceutical companies. Generic companies are now attempting to file differentiated generics, 505 (b) (2) types of product applications and some life cycle enhancement formulations. Segment–wise growth in API manufacturing shows that there are many companies moving into biomolecules or biological product type of molecules for growth as opposed to small molecules predominantly produced by chemical synthesis. As strong as the API manufacturing industry in India, the country still imports drugs and intermediates worth $0.5 billion mainly from China and Taiwan but also from countries around the world. API export from India is projected to touch $12 billion by 2012, which is quite likely if the number of DMFs filed is compared country-wise. India has recorded a phenomenal growth in the number of filings going from approximately a 100 in 2005 to over 300 in 2008 as compared to less than 100 by China and USA for the same years. As more formulation companies acquire approval for supplying to regulated markets, it seems logical that most of the DMFs are for primarily captive consumption initially and then make them available for competition. The scenario in China would be slightly different in the sense that the dependence on exports would be more than domestic market. China's strengths in steroids and high potency compounds continue to dominate even though the overall number of filings is lower. The trend in generic market will ultimately be determined by finished dosage form manufacturing company strategies.