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Pricing pressure in US generic pharma market to normalise soon: ICRA

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Profitability too not expected to worsen from current levels.

Indian pharma companies with significant presence in the US generic business have been grappling with slow growth as a result of intense US generics pricing pressure and thereby eroding operating profits, are likely to see favourable times in the next 12-15 months. As per an ICRA report, covering a sample of seven large Indian pharma companies, the US generic pricing pressure is expected to normalise, going back to earlier levels of low to mid-single digit. Positive and selective price changes too are not ruled out. This is as against the low teens pricing pressure seen during CY2017 and 10-12% estimated by ICRA during CY2018.

Elaborating further, **Gaurav Jain, Vice President, Corporate Sector ratings, ICRA** says, *"The competitive intensity of US generic business and the pricing pressure thereof was due to the consolidation in distribution supply chain and monopolistic conditions, with three large buying group controlling 90% of the distribution channel. This coupled with the faster pace of ANDA approvals adopted by USFDA too has played its part. Consequently, the US generic business which has been a significant contributor to growth and profitability for Indian pharma players over the last decade faced slowdown registering growth of 4.0%, -13.1%, 1.5% in FY2017, FY2018 & Q1FY2019 respectively."*

The faster pace of ANDA approvals by USFDA impacted generic prices thereby increasing competitive intensity. ANDA approvals rose from 409 in FY2014 (October to September period) to 763 and 781 in FY2017 and FY2018 respectively. The pace increased because in October 2012, the Generic Drug User Fee Act (GDUFA) was implemented in the US leading to increased pricing pressure. Before GDUFA, while the average approval time was 36 months, under GDUFA, action on 90% of the standard ANDAs submitted needs to be taken within 10 months and; for priority ANDAs, the timelines has been reduced to 8 months subject to meeting certain requirements. Priority ANDAs are those drugs that have less than three

approved generics or Para IV filings among others. The USFDA has already issued draft guidelines to promote entry of complex generics such as complex transdermal and topical and is further expected to issue guidelines for injectables, metered dose inhalers, peptides under the Drug Competition Action Plan thereby simplifying the scientific evidence required to show bioequivalence.

The aftermath of this measure is that while higher ANDA approvals leads to high competitive intensity, mid and large size pharma companies will be selective in new launches owing to inadequate profitability, enabling normalisation of prices to some extent. Already between October to September in FY2018, companies have withdrawn 606 approved ANDAs, as compared to 214 and 248 withdrawals in FY2017 and FY2016 respectively.

ICRA note says that, domestic pharma players have exited several products where pricing was unsustainable in the last 12-15 months; the freed capacities have been realigned for manufacturing higher volumes of existing products having strong market, so as to benefit from economies of scale or for new product introductions. The initiatives are likely to reduce competitive pressures and normalise prices.

On the R&D front, companies are rationalising their spending by dropping plain vanilla generics development where there are already several ANDA filers awaiting approval or existing competition is high. They are instead focussing their spends towards complex generics, specialty products including NCEs (New Chemical Entities) & NTEs (New Therapeutic Entities) and bio-similars where less competition is expected. Players are progressively focusing on developing value-added generics (NTEs) by combining drugs, new route of administration or dosage form which allows them certain exclusivity and at the same time the risk reward ratio is more favourable. These drugs are improved or enhanced version of approved drugs. The average R&D cost (as a %age to sales) has reduced from 9.0% in FY2017 to 8.8% in FY2018 and 8.6% in Q1FY2019 for ICRA's sample and is expected to remain at similar levels.

Companies operating profits which fell from 26-28% till Q3FY2017 to current 19.0-21.0% has been cushioned by the cost reduction exercise, undertaken across various expense heads SG&A (selling, general and administrative expenses), R&D as well as employee cost. This has resulted from streamlining of product portfolio and manufacturing facilities.

"Going forward, the profitability will get support from new launches and thereby the impact of on-going pricing pressure will be absorbed. ICRA expects significant reduction in prices will render the US generic business unattractive for many players enabling stabilisation and positive price changes in the medium term. Further, Indian companies having pipeline of complex generics will benefit from faster approval cycle and higher margins before other complex generics entry intensify pricing pressure. All these initiatives combined are likely to reduce competitive pressures enabling normalisation of prices and; will auger well for the Indian pharma players in the medium term," **concludes Jain**.