

Drugs & Pharma: Export Update

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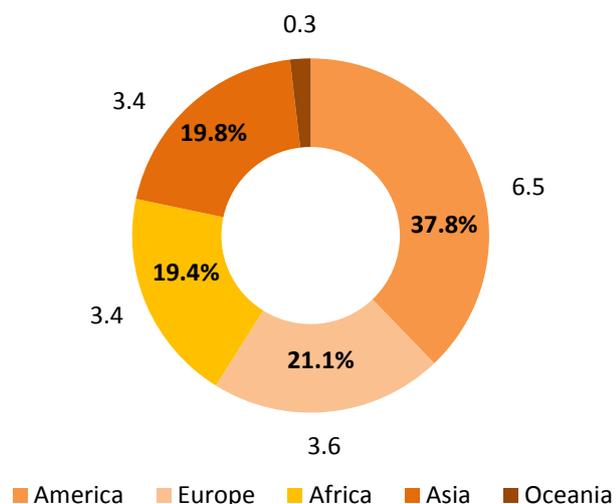
The Indian Pharmaceuticals Industry (IPI) saw a recovery during the first half of FY19 compared to the corresponding period a year ago. During H1FY18, exports and sales of the industry were under pressure on account of price competition in the generics market in USA. Nevertheless, the situation eased in the first half of FY19. A stabilising or decline in price erosion environment of USA and drug launches by pharma companies aided the growth in exports and, in turn, sales of the industry during H1FY19. Besides, exports to other parts of the world except USA also saw acceleration during H1FY19 as it grew by 12.7% compared to 4.1% growth registered by this segment during H1FY18.

We expect the upward momentum in exports to continue in the coming months of FY19 and thus outbound shipments are likely to increase by 8.5%-9.5% during FY19 on a yearly basis.

Pharma exports from India

Exports are a major source of revenue for the Indian pharma industry as it accounts for about 50% of the industry's sales. Outbound shipments from India are to different parts of the world with each continent having a significant share in exports as shown in the chart below.

Chart 1: Continent-wise exports of drugs and pharmaceuticals in FY18 (USD billion)



Source: CMIE

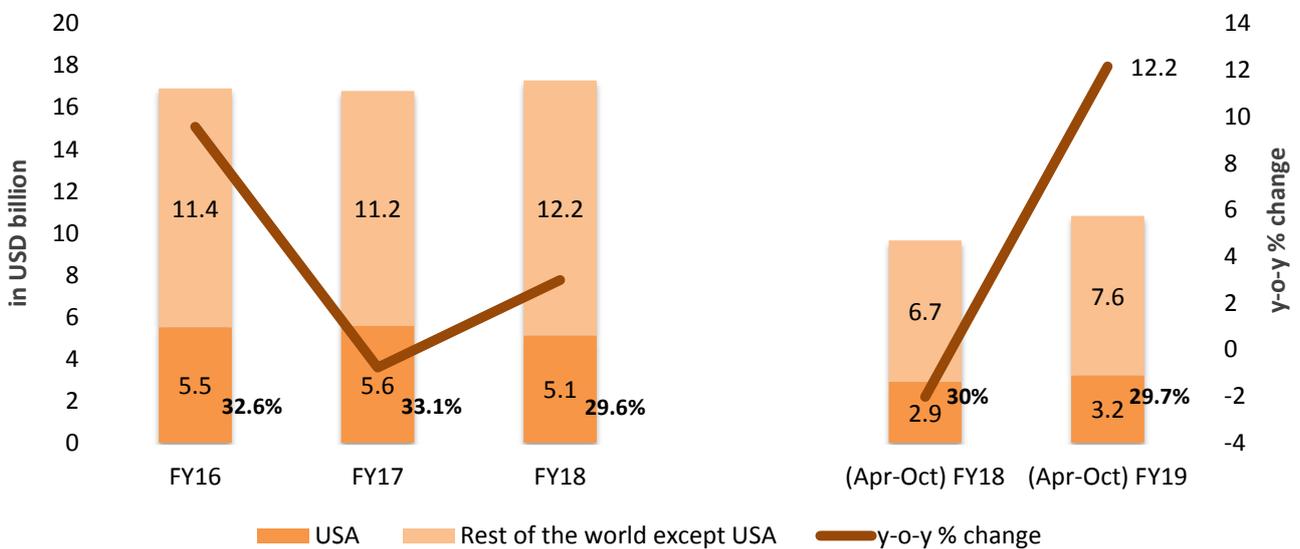
Of the total exports of USD 17.3 billion during the year FY18, majority of the exports accounting for 37.8% were to the American continent followed by 21.1% to Europe, 19.8% to Asia and 19.4% to Africa.

Trend in exports

Among the countries, USA is the primary export destination for India. The share of USA in India’s total pharma exports was 32%-33% during the two years FY16 and FY17. The share however contracted to 29.6% during FY18 as depicted in Chart 2. Also, the shipments to USA declined by 8% y-o-y to USD 5.1 billion during FY18 from USD 5.6 billion in FY17. In the previous year FY17 as well, exports to USA were up by only marginal 1% y-o-y to USD 5.6 billion. Regulatory issues faced by the Indian pharma companies coupled with price erosion in the generic market in USA due to consolidation of distribution channels and increase in competition had impacted exports during these two years.

During FY17, exports to other parts of the world except USA had declined by 1.1% y-o-y to USD 11.2 billion and thus total exports during the year fell by 0.8% to USD 16.8 billion. Nevertheless, pharma exports to other parts of the world except USA grew by 8.4% to USD 12.2 billion during FY18 which, in turn, increased total exports during the year by 3% to USD 17.3 billion.

Chart 2: Drugs & pharmaceuticals exports by India and share of USA in total exports (USD billion)



Source: CMIE

The weak export scenario witnessed by the industry during FY18 changed during the first seven months of FY19. Shipments to USA rose by 10.9% y-o-y to USD 3.2 billion and exports to other parts of the world except USA grew by 12.7% to USD 7.6 billion during April-October 2018. This was backed by a moderation in price erosion environment in USA and introduction of new drugs by Indian pharma companies. Total exports from India increased by 12.2% y-o-y to USD 10.8 billion during the initial seven months of FY19.

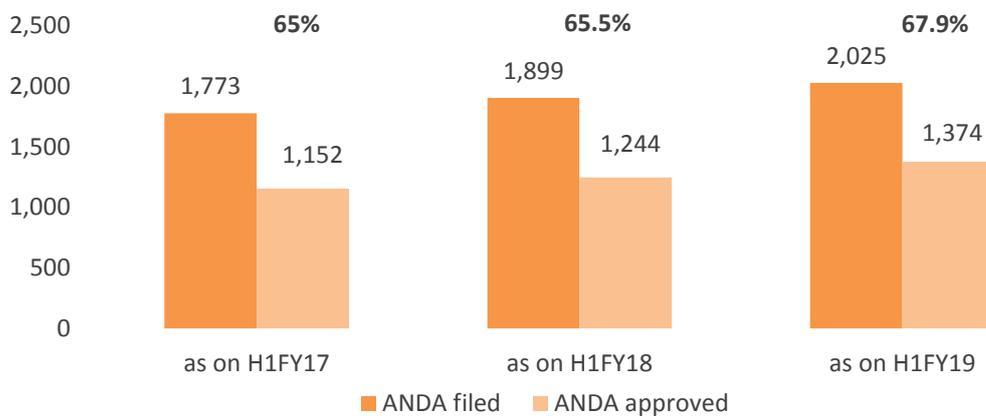
Abbreviated New Drug Application (ANDA) filed and approved

The performance of the industry also depends on the number of approvals received by the pharma companies from the USFDA as USA accounts for the largest share in pharma exports from India. Further, USA remains an attractive market for India because majority of the prescriptions filled in USA are for generic drugs which in turn, provide an opportunity to Indian pharma companies. ANDA approval from USFDA is required to market a generic drug in USA. Thus in order to understand the current scenario with respect to ANDAs filed and approved, here we have considered the number of ANDAs

approved by the USFDA for the top 5 companies of the Indian drugs and pharmaceuticals industry which is shown in Chart 3 below.

From the chart, it can be seen that the approval rate for ANDAs for these companies has improved in the first half of FY19 compared with the corresponding period a year ago. The approval rate has increased to 67.9% for H1FY19 compared with 65.5% for H1FY18 and 65% for H1FY17. In addition to this, the number of approvals received by these top companies during H1FY19 stood at 130 compared to 92 ANDA approvals received during H1FY18. Thus the number of cumulative ANDAs approved for these companies was 1,374 as on September 2018. The number of ANDAs filed for approval however remained same for the period H1FY19 and H1FY18 at 126.

Chart 3: Approval of Abbreviated New Drug Application (ANDA) by USFDA



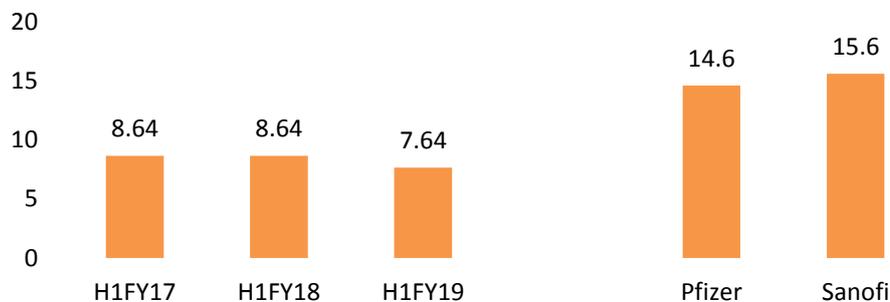
Source: Company reports

Note: The sample includes data of top 5 Indian pharma companies and approvals excludes tentative approvals

Research & Development (R&D) investments

In addition to ANDA approval, another parameter that can be observed to understand the drugs and pharma industry is the investment towards R&D. The expenditure in R&D allows development and innovation in future product pipeline and is one of the important sources of future growth for a pharma company. To examine this parameter, we have plotted below the trend in R&D investments by top 5 Indian pharma companies in the industry.

Chart 4: Trend in R&D investments as % of sales



Source: Ace Equity

Note: H1FY17, H1FY18 and H1FY19 period represents data of 5 top Indian pharma companies

The ratio for Pfizer and Sanofi is for the year 2017

From the chart it can be seen that the aggregate R&D investments as percentage of sales for the top 5 Indian pharma companies remained in the range of 7.6%-8.6% in each of the first half during the period FY17 to FY19. While some companies plan to improve or optimize their efficiencies with respect to R&D spends or expenditure, some aim to increase their spending in the coming quarters. It is to be noted that the Indian companies however have to match their top global counterparts. The R&D investments as percentage of sales for the top global companies was 14%-15% for the year 2017 as exhibited in the above chart.

Correct investments towards R&D leads to better prospects for pharma companies as it results in development of new products and also renders supplementary uses for in-line and alliance products. The R&D investments, in turn, help to achieve a definite pipeline that can support revenues of the companies over a period of time.

Financials of drugs & pharma industry

The movement in drugs and pharma industry’s sales had remained subdued during the first half of FY17 and FY18 on a y-o-y basis. In the first half of FY19, sales of the industry gained momentum and it increased by 16.5%. The pickup in sales can be attributed to the growth in outbound shipments by the industry on account of easing price erosion scenario in USA and drug launches by Indian pharma companies. In addition to this, rupee depreciation also aided sales growth of the industry. The rupee averaged at Rs.68.6 per USD during April-September 2018 as against an average of Rs.64.4 during April-September 2017, this implies a depreciation of 6.5%.

Chart 5: Net sales and growth rate

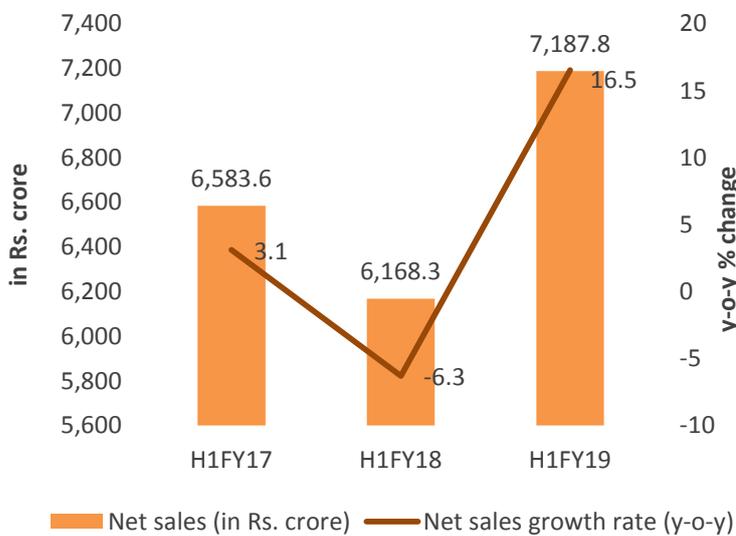
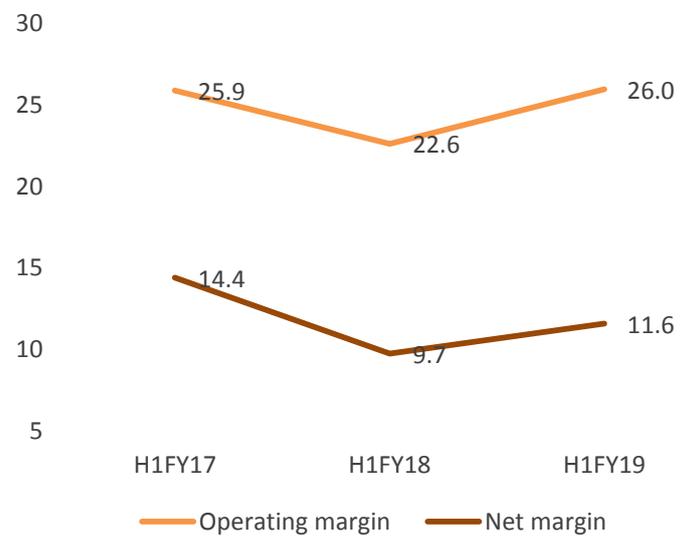


Chart 6: Operating and net margin (in %)



Source: Ace Equity

Note: The financials are based on results of 153 companies

The drugs and pharma industry exhibited an improved performance not only on the sales front but also on the profits front during H1FY19 compared to the corresponding period a year ago. The industry’s operating margin expanded by 334 basis points to 26% and net margin improved by 185 basis points to 11.6% during April-September 2018. The industry’s operating margin and net margin had contracted in the range of 327-467 basis points on a y-o-y basis during H1FY18

primarily due to price erosion in the generic market in USA and increase in scrutiny and regulatory intervention by the USFDA.

Outlook

The Indian pharma export scenario saw a recovery and total exports from India increased by 12.2% y-o-y to USD 10.8 billion during April-October 2018 on account of stabilising or decelerating price erosion environment in USA and drug launches made by domestic pharma companies. We expect the moderation in price erosion environment to continue and the upward trend in outbound shipments to persist in the remaining months of FY19.

Moreover, it is likely that the Indian pharma companies will focus on development of specialty medicines or complex generics to augment their portfolio which will help increase the Indian companies to gain share in world exports. **Thus, we expect pharma outbound shipments to increase by 8.5%-9.5% y-o-y during FY19.**

Concluding remarks

- The ANDA approval rate for the top 5 Indian pharma companies increased to 67.9% for H1FY19 compared to 65.5% for H1FY18 and 65% for H1FY17. In addition to this, the number of approvals received by these top companies during H1FY19 stood at 130 compared to 92 ANDA approvals received during H1FY18.
- The aggregate R&D investments as percentage of sales for the top 5 Indian pharma companies remained in the range of 7.6%-8.6% in each of the first half during the period FY17 to FY19. It is to be noted that the Indian companies however has to match their top global counterparts. The global companies' R&D investments ratio was 14%-15% for the year 2017.
- The Indian pharma export scenario saw a recovery and total exports from India increased by 12.2% y-o-y to USD 10.8 billion during April-October 2018. We expect the deceleration in price erosion environment to continue and the upward trend in outbound shipments to persist in the coming months of FY19. Moreover, it is likely that the Indian pharma companies will focus on development of specialty medicines or complex generics. Thus, we expect pharma outbound shipments to increase by 8.5%-9.5% y-o-y during FY19.