Challenges for Indian Pharma Cos – Will they come out stronger??

– By Ankit Gupta

US market

- There are three ways generic companies make money in the US markets:
  - **Base business** – regular off patented drugs post their FTF status (normally more than 8 – 10 companies competing)
  - **FTF opportunities** – Swing hard during limited 3 – 6 month window
  - **Complex generics** – Difficult to manufacture, limited competition molecules – Considered to be the next growth drivers for most of the companies

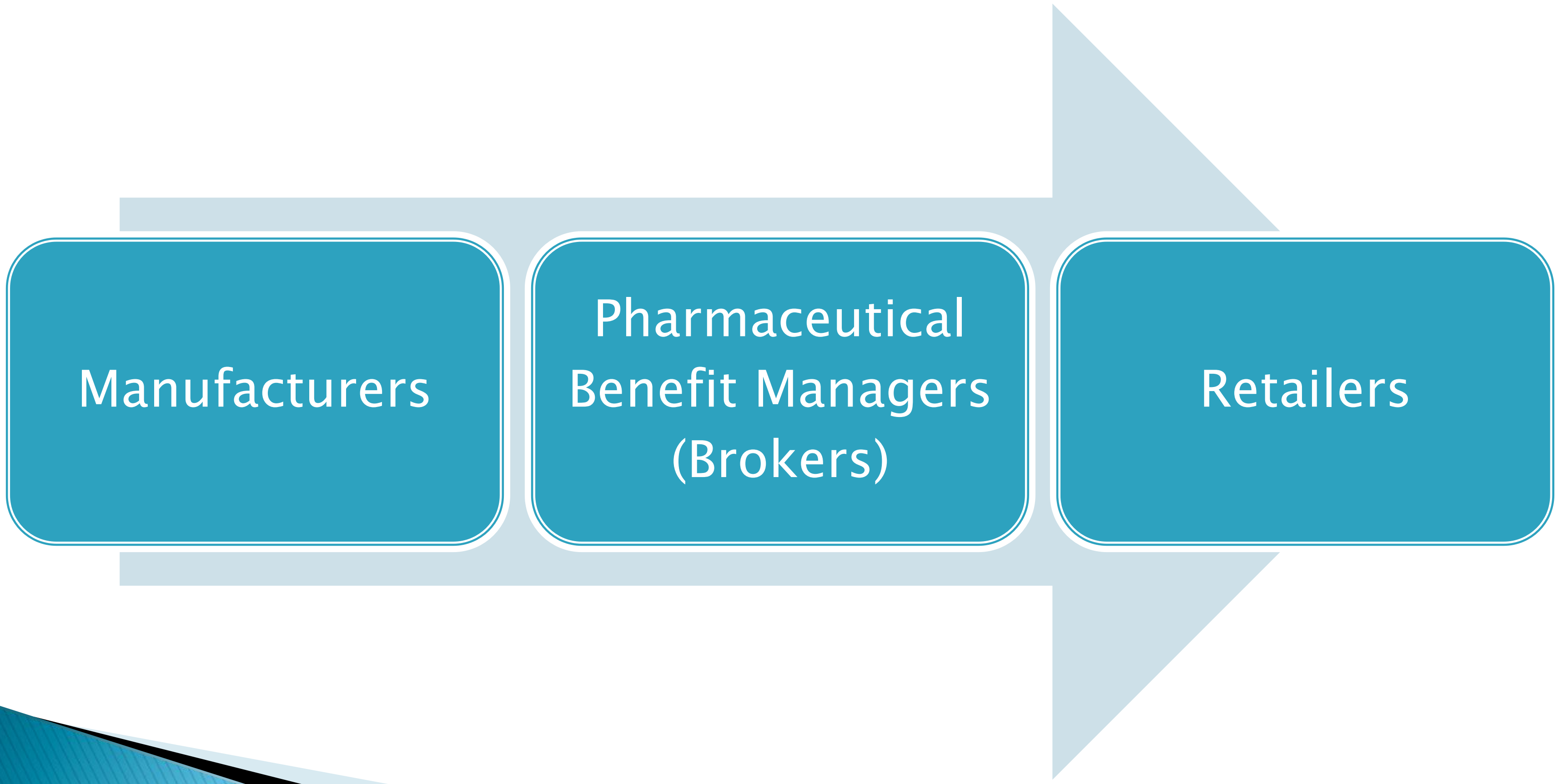
2016 was the first year when US generic industry saw de-growth in sales

Cont…

- Base business eroding due to two major factors:
  - Consolidation of buyers in the US market
  - Increasing competition

Consolidation of buyer's in US market

- Understanding the US market dynamics



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- Key Retailers in USA:
  1. Walgreens Boots Alliance (WBA)
  2. CVS Health Corporation
  3. Walmart Stores
  - WBA and CVS control more than 50% US retail pharma markets.
  - CVS has been horizontally integrating by acquiring PBS cos while WBA has been vertically integrating by acquiring other retailers
  - With its new acquisition, WBA is expected to control 40% of the US pharma retail market

Cont…

- Increasing pressure on these companies to reduce cost

  'Target USD 1.50 billion cost sayings during FY18'

  'Pricing pressures are increasing to address the steady and unrelenting volume growth in the use of medication'

  'One is how do we actually buy better and how do we continue to not just save money'

  – WBA latest concall

  If this was not enough, there are rumors that Amazon might enter into this market

What are the companies saying?

Lupin Q4 concall:

‘And our endeavour is that while we go through this pressure journey from now till about 2019, we build a very strong portfolio of specialty products and of complex generics to go forward from 2019 onwards and pick up our growth trajectory once again’

‘The pricing pressure was more than we anticipated’

Sun Q4 concall:

‘The sales decline in the quarter is a reflection of the pricing pressure that the generic industry is facing in the US’

‘FY18 is likely to be a challenging year for us. The US generics industry is facing rapidly changing market dynamics. Increased competitive intensity and customer consolidation is leading to pressure on pricing’

‘We may see single digit decline in consolidated sales during FY18 over FY17. FY18 is much worse than earlier years’

‘This is a new normal which is getting established. Say like, value of the first-to-file products, even during exclusivity is likely to go down and that's a new normal’.

Cont…

DRL Q4 concall:

‘Unprecedented level of price erosion’

‘This is all about the consolidation of the front end which have happened and the channels got consolidated, impact are showing. Price increase / price adjustments are not there at all. So overall I do not think dynamics specifically have changed’

Cadila Q4 concall:

‘Difficult pricing environment’

‘Base business erosion is high single digit’

‘So price pressure will continue according to my estimates; however, this will be like high single digit. Estimate I cannot say more than that but based on my judgment, I am just saying that it could be high single digit price erosion continuing’

FTF Opportunities

- Three major factors affecting the opportunities:
  1. The amount of drug patent expiry (147 $bn) in next 5 yrs is less than what it was in the last 5 years(214 $ bn)
  2. Higher competition leading to shared exclusivity at the time of launch. 5 – 6 competition at the time of 180 day exclusivity are the new normal
  3. Increased bargaining power of the customers

Cont…

- **Increased competition**

  'The price erosion at the time of launch is so severe that during the Day 1 launch itself the price erosion in 99%. Amneal, Aurobindo and one Chinese player are going cut throat on pricing to gain market share'

  – IR of Alembic in our recent meet in May, 2017

Cont…

- Increased competition at the time of launch:
  - E.g. Gilenya (Fingolimod) – A blockbuster and high growing drug with worldwide sales of USD 3.10 billion. Used for treatment of Multiple Sclerosis. Expected generic launch in 2019.
  - Lets look who all have got tentative approval for it from USFDA:
    - Strides, Biocon, Aurobindo, Par, Glenmark, Accord (Intas), Alkem, Teva, MSN. The list doesn’t include Alembic, Torrent and Shilpa (own or partner’s name) who have also filed ANDA for the drug.

Cont…

- Impact of Authorised Generics (AG):
  - Innovators have become smarter and tie up with some generic company to launch their our AG to compete with generic competition especially during FTF period

Complex generics – Is it the way forward?

- Each and every large and mid sized pharma company is targeting complex generics
- Difficult to manufacture and requires expensive clinical studies to be conducted
- Includes – Injectables, Oncology, Derma products, Topicals, Nasals etc
- Most of the companies have substantially increased their R&D spend and capex to focus on these opportunities
- Is capital the only entry barrier for such opportunities? – Only time will tell and if it is large companies will have stronghold over small and mid sized ones

Cont...

- Large pharma companies realise that generic opportunity is going to get tough in the future. To mitigate these challenges, they have taken few steps
    - Focus on developing their own NDAs
    - Focus on biosimilars
    - Acquiring companies in niche therapeutic areas in US with branded portfolio

Cont...

'If you are in the game, there are chances of survival. If you don't play the game, you are already dead'

'US markets used to be pretty lucrative with high margins. PBILDT Margins have come down substantially in the market at around low to mid teens'

– IR of Alembic

I haven't even spoken about uncertain regulatory environment. In my limited experience, it is like a black swan event which can affect any of the players.

Indian markets

- NPPA, NLM, FDC bans have made the domestic markets also challenging
- GST is expected to have a big impact – Might be temporary
- Uncertainty created by government by advocating use of generics

Europe, LatAm, RoW markets

- Uncertain US markets have forced large generic companies to look at these markets
  - Heard that Sun which hardly had any focus on Europe markets, is planning to make headway in the region and increase its filings substantially
- Many of these markets face forex and political issues
  - Many of the companies were affected by the political situation in Venezuela
- Low hanging fruits in some of the markets like tender business for Africa are no more there

Impact on financials and return ratios

- When one hears pharma cos – We talk about high margins, RoCE, huge cash flows, low/negligible debt etc

- However, the situation might change with high R&D spends and huge capex

- RoCEs and cash flows will come down from the levels we have seen earlier

Way forward for us, the investors?

- Look for small and mid-sized companies operating in niche segments and focused on domestic and developing markets

‘Whatever said and done despite the sector underperforming, we still had a Natco, Shilpa and Cadila doing well over the last one year’

Thank You