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DPCO: A nightmare for Pharma firms?

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In order to make drugs more affordable and accessible to patients, National Pharmaceutical Pricing Authority (NPPA) has capped the price of the (essential) drugs, which has sent pharma sector in a turmoil, most of the pharma companies have witnessed a hit on their profit margins.

DPCO impact on Pharma Sector
The NLEM (National List of Essential Medicines) list has been expanded since DPCO 2013 with amended DPCO in March 2016 taking total notified formulation to 820 from earlier 628. NPPA has fixed ceiling price for 530 of these in March 2016 with overall ~12% of industry coming under price control as on date.

This has resulted in incremental impact for the industry as indicated in slowing growth over last 3 months (accentuated by ban on FDC drugs). The volumes for DPCO covered drugs has been on a declining trend while overall drug volumes in the market has been increasing.

"DPCO 2013 had a considerable impact on domestic business of Indian Pharmaceutical industry with industry growth (in MAT terms) reducing to low single digits in FY2014 from mid double digits earlier. Along with cut in drug prices, it also resulted in trade related issues further impacting overall supply chain. The industry, though, has recovered over last two fiscals with domestic MAT growth at 12-13% in FY2015 and FY2016. The recovery has been driven by volume and price growth in non DPCO portfolio and WPI linked price growth in DPCO portfolio. Pharma companies have launched new products including non DPCO combinations to protect their margins along with increased penetration to support growth," said Mr Subrata Ray, ICRA India, Sr. Group Vice President, ICRA Limited.

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IMS Health report, 'Assessing the Impact of Price Control Measures on Access to Medicines in India' mentions that DPCO has an impact on the tail-end brands than the leading players thereby increasing market concentration and resulting in discontinuation of brands, with average number of brands in DPCO molecules reducing from 36 in 2013 to 32 in 2015. These market forces can move towards strengthening of oligopolistic behaviour, which will result in reduced set of choices for the doctors/patients.

The report further stated that Price control and unstable regulatory environment has increased the margin pressures for companies, thereby impacting their sustainability especially small and midsized players. This further impacts the employment generation potential of the industry. These factors dampen the sentiments across the industry and potential domestic and international investors.
The move have also impacted our export growth, as per the IMS Health report Post 2013, while the volumes grew at 9%, value growth was significantly lesser at 5%. India's pharma exports to other developing countries accounts for ~12% of our total exports of pharmaceuticals. PPP wise price comparison against these countries indicates that average prices of Indian drugs is lower than the prices in these countries. These countries could benchmark their prices against domestic Indian prices and negatively impact our growing exports market.

R&D slump?
DPCO would impact the R&D development for pharma firms, most notably innovation driven biopharmaceutical firms in India. DPCO might inhibit the R&D companies to significantly invest in development of drugs which might come under DPCO scanner in future and affect scale ups, expansions and the international quality.

"This is because curbing the price of a drug which has the market potential to be priced higher, affects the entire business plan for its development and lowers the returns on investments made for that drug, making the entire project financially infeasible, causing rejection," explains Mr N Venkat, co-founder and CEO, Vyome Biosciences.

Decline in R&D resulting in fewer new introductions of generic products; Post DPCO 2013, the average number of new introductions in DPCO molecules has declined, which also indicates increasing concentration and reducing competitive intensity, the IMS Health report stated.

"From last six months hardly new formulations has introduced in domestic market. Even MNCs are not planning to introduce any new therapy in our country due to lack of proper drug and pricing policies," said Dr Sanjay Agarwal, Pharmaceuticals Consultant.

However, Mr Ray feels DPCO may not directly impact R&D. He explains, "The R&D budget of domestic pharma companies are largely export focused and same has actually increased considerable over last few years. While, DPCO does not have a direct impact on R&D/ investments by the industry however significant expansion of the scope of NLEM, may potentially impact the profitability of domestic business - this in turn may limit the ability of Indian Pharma to generate cash surplus for quality/ R&D investments."

It will also have impact on marketing budget of these specific drugs. It is potentially possible that both marketing budget and R&D budget will take hit. The impact varies from company to company based on the allocation of available funds.

Making Drugs affordable
Some reports suggest that many companies have cut down on manufacturing of (essential) drugs, which in turn deflects the purpose of price control.
According to IMS Health report, for low-income households that are reliant on the government system for healthcare, DPCO would not improve the patient's ability to purchase drugs. This is supported by the fact that no significant penetration of price controlled molecules in rural markets is visible, with consumption in rural towns decreasing at ~7% over the last 2 years. The price controlled molecules has also witnessed muted growth in prescriptions outside metros (town class I) as compared to 5% Rx growth in non-DPCO molecules.

What could be the alternative of making drugs affordable and accessible while ensuring pharma firms remain interested in manufacturing these (essential) drugs and profitable?

"Bringing the notional loss due to curb on pricing under CSR programs in addition to the required contributions and asking for companies' commitment to provide pre-defined quantities of drugs per year to patients while simultaneously providing them

benefit of CSR contribution," suggests Mr Venkat.

He further recommends a three-way arrangement between NPPA, Drug Manufacturers and Insurance Companies whereby the drugs under DPCO to be covered under insurance plans reimbursement partially up to a minimum limit before imposing DPCO. This will not only improve profitability of the manufacturers, but will also increase the insurance cover in India. Other benefits like Income tax exemptions on profits made on essential drugs, can be explored.

"With India's enormous population, one of the biggest hurdles that we face is access to quality healthcare for all our citizens. Contrary to popular belief, price control has limited impact on improving patient access to medicines. A good place to begin is to prioritize healthcare and enhance public expenditure towards it. Additionally, there is a need for increased focus on infrastructure and capacity building. A viable public healthcare model requires a combination of financing and non-financing measures," suggests Dr Shailesh Ayyangar, President, OPPI and Managing Director - Sanofi India.

DPCO may not be a nuisance for pharma companies if rolled out with clear provisions and also incorporating some changes and extending some benefits to companies which take into account the profitability of the companies, especially for those companies which are involved in innovation driven work.

"DPCO should improve patients' access to essential medicine, but should also incentivize the pharma companies to invest in innovation, quality and expansion," Mr Venkat concluded.