

Pharmaceutical Sector

30 December 2020

Trump's Executive Order witnesses litigation challenges

As a follow up to the [Executive Order](#) issued by US President Donald Trump (Sept'13, 2020), the Center for Medicare & Medicaid Services (CMS) was supposed to roll out a new payment model - "[Most-favored-nation model \(MFN\)](#)" to be effective from January 1, 2021. However, the same has seen a litigation challenge and the District court in Maryland has recently issued an injunction on its implementation.

MFN model will cut prices of Innovator Drugs reimbursed as part of Medicare Part B: In line with the September Executive Order, the proposed MFN payment model is designed to reduce the federal government spending on prescription drugs/biologics. The model will pay for certain designated drugs reimbursed as part of Medicare Part B insurance to the [lowest price](#) that the drug manufacturers receive in other similar countries for the same drug. This model was supposed to be implemented for both Medicare Part B and Medicare Part D drugs, but the latter is a work in progress.

The MFN model will focus on Top 50 Medicare Part B drugs most of which are biologics: Significant majority of the top 50 drugs which are reimbursed under Medicare Part B are biologics. We estimate Medicare's share of the total prescribed volume in the US for these drugs to be in the 25% to 50% range. Some of the biologic drugs which figure in the top 50 names and relevant from an Indian generic companies' point of view and stand to be impacted by the MFN pricing model include Neulasta (pegfilgrastim), Herceptin (Trastuzumab) and Avastin (bevacizumab).

Biocon has stake in Neulasta, Herceptin and Avastin as a biosimilar participant and stands to be impacted if the MFN model sees the light of day: Biocon has launched biosimilar copies of Neulasta and Herceptin in the US and is awaiting approval for Avastin, which has been delayed on account of COVID. We expect the MFN pricing model to translate into an approximately 20%-30% price cut in innovator drugs in the first year and the cut will get steeper every other year. Since innovator drug prices serve as reference prices for generic players, they will also need to match with a pro-rata reduction or otherwise may have to shed some market share.

A few drugs closer to patent expiry, where generics are eyeing an entry will also be impacted: Few other drugs like Velcade, Alimta and Abraxane, which are nearing patent expiry and cumulatively represent ~US\$3.5.bn to US\$4.bn in annual sales, are also part of these top 50 drugs. A number of Indian generic players (Sun Pharma, Dr. Reddy's Labs, Aurobindo Pharma and Cipla), which are eyeing launch generic copies of these drugs will see the opportunity size coming down.

PhRMA (Pharmaceutical Research and Manufacturers of America) has challenged the MFN pricing model: The MFN model will have a significant material impact on the profitability of pharma companies and other stakeholders too. The MFN model has been legally challenged earlier this month and in response to the complaint, the District Court in Maryland has issued a nationwide injunction, which prevents the CMS from implementing the rule for 14 days and allows the court additional time to evaluate the legality of the model. Key concerns raised in the litigation are as follows:

- (1) Procedural defects as the constitution of the MFN model exceeds the statutory authority provided to CMS and fails to follow required rulemaking procedures as set forth in the Administrative Procedure Act
- (2) Harm to citizens – Drug Access and Utilization – the implementation of the MFN model may impact access and utilization of life-saving drugs as innovators may not supply at the prices determined by MFN model
- (3) Adversely impact drug innovation – lower pricing will translate into innovators compromising on R&D investments

The details around Most Favored Nation pricing model: The MFN model will be implemented in a phased manner beginning 2021. In the first four years, drug pricing would be a blend of the MFN price and the current pricing model, which is based on ASP (Average Selling Price). ASP is determined by prices that innovators sell to other insurers in the country.

Calculation of MFN price – Blend of ASP and MFN price

Calendar Year 2021	25% MFN Price + 75% ASP
Calendar Year 2022	50% MFN Price + 50% ASP
Calendar Year 2023	75% MFN Price + 25% ASP
Calendar Years 2024-2027	100% MFN Price

Biden administration will have a short window to suspend/modify the MFN rule: The proposed MFN model is currently open for comment until January 26, 2021 – 60 days following its November 27th publication date. The new Biden administration will be in place prior to the closure of the comment period, which will give them a short window of opportunity to quickly modify or suspend the Final Rule before the comment period closes.

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