

Pharmaceutical Sector

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Sector Update

Evaluating gCopaxone opportunity for potential new entrants – impact of novel drugs, therapeutic substitutes and generic competition

Prior to the approval of first generic copy (Sandoz – Glatopa) in 2015, the Copaxone brand had annual sales of US\$3.5bn in the US. However, we have seen the opportunity erode faster than expectations as we have witnessed an overall decline in the Copaxone prescription volumes in multiple sclerosis markets where it is positioned. Between 2015 and now, the product has lost about 700bps in market share and seen a ~20-25% decline in volumes. Emergence of new treatment options is the primary contributor to the decline in Copaxone's market share. We estimate the current Copaxone market size to be ~US\$1.35bn, which includes both branded and generics drugs. The generic market share is ~40%. Adjusting for the decline in prescription volume, we estimate value erosion on account of generic competition so far to be around 50%. With Dr. Reddy's and Biocon also in the fray for the launch of generic Copaxone, we evaluate how the opportunity would shape up for these potential new entrants.

Broadly we expect the declining trend in Copaxone volume to sustain as there are multiple pressure points.

- 1) Emergence of new therapeutic options
- 2) Growing share of oral therapies
- 3) Cheaper therapeutic substitutes
- 4) Potential launch of once a month gCopaxone is the most relevant threat

New therapeutic options are gaining share from incumbents as they come with better efficacy:

Since the genericisation of Copaxone, we have seen the USFDA approve five new treatment options that directly/indirectly compete with Copaxone. The new treatment options include Ocrevus (Ocrelizumab) from Roche in 2017, Kesimpta (Ofatumumab) from Novartis in August 2020, Zeposia (Ozanimod) in 2020 from Bristol Myers, Mavenclad (Cladribine) from EMD Serono in 2019 and Mayzent (Siponimod) in 2019 from Novartis. The new treatment options that have emerged in the past few years are showing promising efficacy levels along with a very good safety profile, which is leading to a wider usage of these therapies.

With growing number of oral treatment options, use of injectable therapy is declining: Over 2015 to 2020, the share of oral treatments in multiple sclerosis has expanded from 35% to 45%. Recently approved Zeposia (Ozanimod) from Bristol Myers is positioned as the best-in-class oral treatment option and we expect it to be a major threat to Copaxone's market share. Zeposia positioning in the multiple sclerosis market is unique and strong, as it has demonstrated a very robust efficacy profile along with a best-in-class safety profile. The combination of very strong efficacy, best-in-class safety and convenience of oral dosing positions it as a treatment of choice in the first line setting. Apart from Zeposia, other recently approved oral treatment options include EMD serono Mavenclad and Novartis Mayzent.

Genericisation of Tecfidera – widely used treatment option will lead to cannibalization of alternative therapy: Tecfidera, which is currently the most widely used oral treatment option, has seen its patents being invalidated recently and generic versions being launched. Tecfidera has a 23% share in the multiple sclerosis market and with the price of the treatment expected to decline significantly (being a plain vanilla generic) we should expect the drug to cannibalize alternatives including Copaxone

Mylan/Mapi Pharma is developing a long acting Copaxone (once a month glatiramer acetate) which may be launched in 2023: We see this is a very significant threat, as Mylan has initiated Phase 3 trials for once a month dosing of glatiramer acetate. Considering the fact that the active ingredient is same as Copaxone, we believe that there is a high probability of a successful launch. In phase 2 studies, once a month depot produced strong efficacy and safety inline with the thrice weekly version

Sandoz struggling to gain market share: Sandoz, which launched generic copies in 2018, is still struggling with high single digit market share of the Copaxone pie, which implies new entrants might also see a gradual ramp up, since generic players will look to offer very limited discounts.

Conclusion: We estimate the Copaxone pie to contract by about 20% amidst the aforementioned challenges. Assuming that the new entrants would take a 20% discount to existing prices the market size would contract to approximately \$600mn to \$700mn from \$1350mn now. Considering the limited price discounts (20%) that generic players would be willing to pass, low teens market share may be a probable scenario. These assumptions translate to a sales opportunity of \$60mn to \$80mn for the new entrants. The ramp-up should be gradual considering the limited discount that generics would be looking to offer.

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