CAPITOL STREET

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Rx in the Crosshairs: Onshoring, MFN, & Tariff Turmoil

New FDA “PreCheck” Program & Sept. 30 FDA Mtg On Domestic Manufacturing

Relevant Companies

Our Take & Next Up

Catalysts abound: Domestic manufacturing, tariffs & MFN are highly interrelated. As the slew of catalysts – social media posts, regulations stemming from Executive Orders, letters to CEOs – engulf the biopharmaceutical industry, we see some clarity as likely in the next 3-4 weeks. Trump’s ‘art of the deal’ continues to play out, as he pounds the table on moving pharmaceutical manufacturing to the US, requests ‘EU pricing’ or DTC programs that benefit all Americans (and eliminates the middleman), and hammers away at country-specific trade deals, noting that (separate sec. 232) punitive pharma tariffs will go into effect after 1.5+ years, should domestic onshoring not take place.

Key Points

DOMESTIC MANUFACTURING

The FDA will host a Sept. 30 public meeting on “Onshoring Manufacturing of Drugs and Biological Products” (here). At this meeting, the FDA will present a draft framework that seeks to facilitate onshoring of pharmaceutical manufacturing, including active pharmaceutical ingredients (APIs) and finished drug and biological products. Recall, several pharma companies (LLY, JNJ, NVS, MRK, AZN, etc.) have already pledged domestic investments.

The meeting stems from a May 5 Executive Order (EO) on pharmaceutical supply chain resiliency in the U.S. (here). The EO was intended to “streamline the regulation of manufacturing pharmaceutical products to facilitate the restoration of a robust domestic pharmaceutical manufacturing base” (our take here). The EO directs the FDA to issue regulations and guidance pertaining to the development of domestic pharmaceutical manufacturing and take steps to:

- Eliminate any duplicative or unnecessary requirements;
- Maximize the timeliness and predictability of agency review;
- Streamline and accelerate the development of domestic pharmaceutical manufacturing.

The FDA will streamline review of domestic manufacturing through FDA PreCheck (2 phase review). The framework requires manufacturers to engage in more frequent FDA communication at critical development stages and allows for pre-application meetings and early feedback. This is a result of President Trump's EO on increasing domestic pharmaceutical manufacturing.

- Facility readiness phase - Companies provide information through a Type V Drug Master File (DMF), such as site operations layout and description, pharmaceutical quality system, and quality management maturity practices. This facility-specific DMF can be incorporated by reference into a drug application as appropriate.
- Application submission phase - Streamlining development of the chemistry, manufacturing, and controls (CMC) section of the application through pre-application meetings and early feedback.

It remains unclear if the communication will result in more frequent (or more likely fewer) inspections as the agency continues to struggle with staffing. In July, HHS finalized several terminations, originally communicated on April 1. Commissioner Makary has also noted an increased vacancy rate for reviewers at the FDA due to early retirement. It is likely that the FDA inspectors are in a similar place post-DOGE cuts.

MFN & DTC

Trump asked 17 manufacturers via CEO letters on July 31 to voluntarily lower prices in multiple ways. The Trump Administration continues to publicly pressure manufacturers asking for an agreement on MFN prices by Sept. 29 (our take here).

Manufacturers continue to engage with the administration on MFN and we expect more direct to consumer (DTC) announcements, since agreeing to EU level pricing is unlikely. Companies are working to forge a deal with the administration (potentially DTC with lower than net prices for a select few drug products).

- LLY noted in their 2Q call yesterday, their experience with the DTC model at scale (“LLY Direct”) and aim to use it to bridge access with Zepbound available at a 50%+ discount.
- In July, the BMS-Pfizer Alliance announced a new direct-to-patient option for purchasing Eliquis via “Eliquis 360 Support,” at a rate of 40%+ lower than the current list price.
- GSK is reviewing DTC options, potentially for products like Trelegy and Blujepa.

A CMS (Center for Innovation) demo is the likely end game if no/few agreements are made. Our thesis is that the administration is engaging in a “carrot and stick” approach with a focus on prodding manufacturers into voluntary agreements first, before implementing the stick, a CMMI mandatory demo. The President is becoming increasingly impatient with the pace of discussions, which does not bode well for manufacturers who are seeking to get on the President’s good side.

PHARMA & COUNTRY-SPECIFIC TARIFFS

A July 27 US-EU trade deal caps tariffs on the industry at 15%, according to an EU fact sheet (here). The fact sheet indicates Sec. 232 pharma tariffs (of up to 250%) will not be added to the 15% (our take here).

Total tariffs on Indian imports would rise to 50% on Aug. 27 following an Aug. 6 Executive Order (here) adding an additional 25% tariff in response to India's continued purchases of Russian oil. In our view, the timing of the new India tariffs - 21 days from the order - may leave some room for continued negotiations.

Our view is that pharma/generics are not currently impacted by the new tariffs on India, though separate Sec. 232 action on biopharma is expected soon. Two carveouts in the Executive Order (EO 14257) are especially important here: products subject to Sec. 232 are excluded from these tariffs and items listed in Annex 2 of the EO - including most pharmaceutical products - are also exempt.

Still, an announcement on Sec. 232 pharma tariffs is expected in the next 2-3 weeks with President Trump saying they will start small, but go up to 150% in 1-1.5 years and then up to 250% (here). We had said 232 tariffs would be announced at a high rate, but ultimately land well below 50% (here). The grace period incentivizes companies to shift supply chains, though building U.S. facilities will take years. Most manufacturers are likely stockpiling for two years, with the hope this administration's rhetoric will blow over (our take here).

We continue to believe generic drugs will likely be excluded from Sec. 232 pharma tariffs. We have previously noted (here) that the Trump Administration is taking into account the potential impact on generics and subsequent drug shortages.

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